University of Delaware

Department of Medical and Molecular Sciences Medical Laboratory Science Program

2025

Clinical Practicum Student Handbook

INTRODUCTION

The clinical practicum is the culmination of several years of study. It is an exciting time for students and offers unique experiences in the clinical laboratory setting. Students will achieve from this experience benefits comparable to the effort they put forth.

This handbook has been prepared to guide you for the Medical Laboratory Science Clinical Practicums. It is designed to assist both the MLS students and the clinical instructors with the policies and regulations governing participation in these practicums. The students are responsible for all information and policies included in this handbook and the Student Guide to University Policies which can be accessed at https://www.udel.edu/students/community-standards/student-guide.

Medical and Molecular Sciences Department Chair:
Esther Biswas-Fiss, Ph.D., MB(ASCP)^{CM}
(302) 831-2912
ebiswas@udel.edu

Medical Laboratory Science Program Director:
Andrew Hollinger, M.S., MLS(ASCP)^{CM}, SM(ASCP)^{CM}
(302) 831-8595
ahollin@udel.edu

Medical Laboratory Science Manager of Clinical Operations/External Relations:
Joselin Abraham, M.S.,MLS (ASCP)^{CM}
abrahamj@udel.edu

STUDENT LEARNING GOALS

Student learning goals for the clinical practicums focus on active participation in daily laboratory operations and personal performance as a laboratory professional. Thus, the learning goals for the technical portion of the clinical practicums are to facilitate and enhance the student's application of clinical laboratory theory, laboratory experience, and test data interpretation learned in campus courses to an active clinical laboratory setting. To accomplish this goal, students will apply principles of pre-analytical, analytical, and post-analytical components of laboratory practice in clinical to the performance of laboratory operations in a contemporary clinical setting. The learning goal for the professional component is for students to attain high level interpersonal performance so as to interact professionally with fellow staff and all consumers of laboratory testing. The ultimate outcome of a successfully completed practicum experience is the ability to perform testing of the highest quality to support the laboratory's role in quality patient care and safety. Student achievement during this practicum course will lay the foundation for success as an entry-level medical laboratory scientist.

GENERAL COURSE OBJECTIVES

Upon the completion of these courses, based upon the objectives detailed in this document, the student must achieve a final minimum average of 70% on the assessment tools utilized in this course.

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC didactic and laboratory courses, the student will:

1. Demonstrate correctly proper procedures for the collection, safe handling, and analysis of biological specimens to the satisfaction of the instructor

2. Utilize correctly scientific principles, principles of methods for quantifying, clinical correlations, and clinical decision making for analytes of interest in clinical urinalysis

3. Perform correctly laboratory testing according to established laboratory protocol

4. Apply correctly appropriate problem-solving steps for determining instrument/methodology problems, utilizing instrument manuals, laboratory procedure manuals, and information contained in package inserts

5. Operate equipment properly, troubleshoot, and perform preventive and corrective maintenance according to the manufacturer's directions to the satisfaction of the instructor

6. Utilize proper techniques in the performance of all laboratory testing to the satisfaction of the instructor

7. Evaluate correctly laboratory test results to determine disease diagnosis

8. Evaluate correctly acceptability of quality control and test result data

9. Discuss the impact and apply principles of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process

10. Comply with established safety regulations and regulations governing regulatory compliance related to laboratory practice to the satisfaction of the instructor

11. Assess correctly critical pathways to facilitate diagnosis and to determine additional testing as warranted

12. Communicate effectively and professionally as a member of the healthcare team to enable consultative and educational interactions with other healthcare personnel, the public, and patients to the satisfaction of the instructor.

13. Demonstrate ethical behavior and professionalism, including maintaining the confidentiality of patient information to the satisfaction of the instructor

14. Participate in continuing education as opportunities arise for one's own professional career development to the satisfaction of the instructor

Table of Contents

Course Details

The clinical practicum courses will meet at a clinical affiliate to be determined by the University instructor. Students will be notified of this location prior to the commencement of the clinical practicum. Attendance at all clinical practicums is MANDATORY, and missed time must be rescheduled with the date/time at the discretion of the clinical instructor and the University instructor.

Instructor: Joselin Abraham, M.S.,MLS (ASCP)^{CM}
305D Willard Hall Education Building
Phone: 302-831-3662
Email: abrahamj@udel.edu

Additional Requirements

Journals are one of the most frequently prescribed methods of reflecting on lifetime experiences. Each student is required to maintain a journal for each clinical practicum period. The student may record the sequence of daily events, as well as unusual or memorable situations or events that transpired and how he/she reacted to them. Think about what happened. How would you react the next time you encounter a similar situation? Or perhaps provide a commentary about a particular laboratory employee or environment that you encounter. Think about how your day impacted you professionally. Write regularly and record the date of each entry. Adhere to HIPAA and confidentiality guidelines; do not disclose any identifying facts or information. For more information and guidelines for the journal, students will consult with the education coordinator.

Site evaluations are a tool used by the Clinical and University instructors to assess the achievement of the clinical practicum experience and the academic preparation for it. Students are required to submit a completed Site Evaluation for each clinical practicum to the University instructor. These will be collated by affiliate institutions and disciplines and will be provided in an anonymous format to the Clinical instructors during the summer following completion of the clinical practicums. Comments regarding academic preparation will be shared and discussed with the University instructors and used to enhance the curriculum as indicated.

Textbooks and Other Resources

One of the following review books is required for all clinical practicums senior year and should be taken daily to your clinical practicum sites for review during slower periods:

> ASCP Editorial Board. *BOC Study Guide: Clinical Laboratory Certification Examinations*. 7th ed. Chicago, Ill.: American Society For Clinical Pathology, 2022. ISBN: 978-089189-684
>
> Harr, RR, *Medical Laboratory Science Review*. 5th ed., F. A. Davis Co., 2019, ISBN: 978-0-8036-6827-0
>
> Lehman DL, Chiasera JM. *Success! In Clinical Laboratory Sciences*. 5th ed. Upper Saddle River, NJ: Pearson Education, Inc.; 2019. ISBN: 978-0-13-4989181

Students should refer to the textbook and lecture and laboratory course materials from the corresponding MMSC on campus courses. Students are expected to review these materials in preparation for this clinical practicum experience. In addition, students are expected to use these materials as resources during this practicum, as well as in preparation for the written final examination.

We strongly encourage students to use the ASCP BOC review materials on a regular basis throughout the

practicum period, and to consider subscribing to and using MediaLab's exam simulator for MLS as well.

Students also have access to the medical/reference library at the affiliate institution. This library provides students access to journals and medical-related books.

Through the University of Delaware, students have online access to DELCAT – UD's library online catalog https://library.udel.edu.

Dress Code

All University of Delaware Medical Laboratory Science majors assume responsibility for their own attire while in the clinical setting. Each site has established guidelines for employees/students. In addition to abiding by the guidelines of the site at which the rotation occurs, each student must adhere to the following minimum guidelines of the University of Delaware Medical Laboratory Science Program described below.

- Navy blue medical scrub uniforms are required. Clothing must be neatly pressed, and colors must match. Hose or socks are required when wearing pants.
- White shoes are recommended; flat shoes are required. Shoes must be made of a non- porous material. Cloth or open-toed shoes, jeans, and sweatshirts are not acceptable.
- A clean, white lab coat is required unless otherwise specified by the clinical site. A University of Delaware pin with your name, denoting status as a University of Delaware student must be worn at all times while at the clinical affiliate sites.
- Safety glasses must be worn while in the clinical laboratory as per University of Delaware requirements.
- Hair styles which extend below the shoulder must be tied back.
- For safety reasons, most jewelry is limited. Small post earrings that do not extend below the ears are acceptable, long necklaces or dangling bracelets are not. Facial, ear cartilage and tongue piercings must be removed while at the affiliate institution. Tattoos that are visible must be covered.
- The various clinical sites may have additional dress code requirements. The student must adhere to any additional requirements at that site.
- Each student is expected to present a professional appearance and attitude at all times. NO EXCEPTIONS!!

Clinical Practicum Attendance Policy

Students should report to their clinical rotations eight hours a day, five days a week. Exact times will be arranged by individual laboratories. If time is missed, it will be made up at the convenience and discretion of the affiliate instructor (i.e., weekdays, Saturdays, evenings, etc.). A **minimum of fifteen full days** must be completed for each rotation. Any time missed which is not made up by the end of rotations may result in completion of the rotation during summer session and postponement of graduation.

In the event of a clinical absence the student must:

- Contact the clinical instructor at the scheduled report time. If necessary, leave a message with the previous shift and then call back to the clinical instructor to make sure the message was received.

- Contact the UD clinical education coordinator using the method outlined during the practicum orientation meeting.

- Absences or tardiness from clinical rotations for reasons other than health or emergencies will not be tolerated and the student will be subject to possible removal from the clinical rotation.

- No scheduled appointments are to be made for times during clinical hours unless arrangements are discussed with the clinical education coordinator in advance.

- All students must log in and out using the Trajecsys reporting system.

NOTE: Scheduling any trips, appointments, etc. which extend over the regularly scheduled UD spring break *will not* be considered excused absences and will result in an Incomplete for the practicum grade. Graduation will be delayed and completion of the clinical practicum will occur in the summer.

NOTE: Dorms will be closed during the regularly scheduled spring break, which begins the Friday before spring break at 7:00 pm and ends the Sunday at the end of spring break at noon. *Alternate housing arrangements must be made by students residing in the dorms during this period*. This is the responsibility of the student.

At least 2 days prior to the start of a new rotation the student should make a courtesy call to the clinical site. The student will verify the hours and dates of the rotation, whom to report to, location of the laboratory, where to park and any other dress code requirements. As a reminder, if your clinical site does not have a dress code policy, you are to abide by the University of DE Medical Laboratory Science Program requirements of navy blue scrubs.

Social Media and Electronic Device Use Policy

Do not share, post, or otherwise disseminate any information, including images, about a patient or information gained as a result of your presence in a clinical/practicum setting to as a result of a student-patient/client relationship. Do not identify patients/clients by name or post or publish information that may lead to the identification of a patient/client (examples include but are not limited to: date of care, facility name, diagnosis, and treatment/surgery). Limiting access to postings through privacy settings is not sufficient to ensure privacy. During clinical/practicums, any use of electronic devices (cell phones, laptops, etc.,) must be with faculty approval within the guidelines of facility/program policies. Do not take photos or videos of patients on personal devices, including cell phones.

Maintain professional boundaries in the use of electronic media. Online contact with patients/clients or former patients/clients blurs the distinction between a professional and personal relationship. Personal phone conversations or texting are NOT allowed at any time while in patient/client areas or in the laboratory setting. If the student needs to respond to an emergency text or call during the day, the student will ask to step away from the laboratory setting to address the issue.

Transportation

Transportation to clinical facilities is the sole responsibility of the student. Students are encouraged to carpool and use public transportation when this is a viable option.

Academic Honesty

Honesty is essential in the profession of Medical Laboratory Science. You are encouraged to become familiar with the UD Student Guide to University Policies https://www.udel.edu/students/community-standards/student-guide. The content of the handbook applies to this course. If you have any questions about this policy, please consult with the instructor.

Harassment, Discrimination, and Sexual Misconduct

The University of Delaware works to promote an academic and work environment that is free from all forms of discrimination, including harassment and sexual misconduct. As a member of the community, your rights, resources and responsibilities are reflected in the Non-Discrimination, Sexual Misconduct, and Title IX policy. Please familiarize yourself with this policy at the University's Office of Equity & Inclusion's website. You can report any concerns to the University's Office of Equity & Inclusion (302) 831-8063 or at titleixcoordinator@udel.edu. you can report anonymously through UD Police (302) 831-2222 or the EthicsPoint Compliance Hotline.

- Read the full policy
- File a report

Faculty Statement on Disclosures of Instances of Sexual Misconduct

If, at any time during this course, I happen to be made aware that a student may have been the victim of sexual misconduct (including sexual harassment, sexual violence, domestic/dating violence, or stalking), I am a responsible employee, which means I am directed to report any incident of sexual harassment or misconduct to the University's Title IX Coordinator. The Title IX Coordinator will then meet with the student to discuss how the University will respond to the report and the student's rights and options, to offer resources, and to ensure that the student and the campus community are safe. If such a situation is disclosed to me in class, in a paper assignment, or in office hours, I promise to protect your privacy--I will not disclose the incident to anyone but the Title IX Coordinator in a confidential manner.

For more information on Sexual Misconduct policies, where to get help, and reporting information, please refer to www.udel.edu/sexualmisconduct. You can also send an email to the Title IX Coordinator at titleixcoordinator@udel.edu. At UD, we provide 24/7/365 crisis assistance and victim advocacy and counseling. Contact 302-831-1001 to get in touch with a sexual offense support advocate, as well as confidential and anonymous counseling services for other concerns.

Accommodations for Students with Disabilities

Any student who may need disability-related accommodations should contact the Office of Disability Support Services (DSS) office as soon as possible. For more information, please visit Getting Registered at DSS. Contact DSS by phone: 302-831-4643; fax: 302-831-3261; website: www.udel.edu/dss; email: dssoffice@udel.edu; or visit 240 Academy Street, Alison Hall Suite 130 during business hours (8-5 M-F).

Non-Discrimination

The University of Delaware does not discriminate against any person on the basis of race, color, national origin, sex, gender identity or expression, sexual orientation, genetic information, marital status, disability, religion, age, veteran status or any other characteristic protected by applicable law in its employment, educational programs and activities, admissions policies, and scholarship and loan programs as required by Title IX of the Educational Amendments of 1972, the Americans with Disabilities Act of 1990, Section 504 of the Rehabilitation Act of 1973, Title VII of the Civil Rights Act of 1964, and other applicable statutes and University policies. The University of Delaware also prohibits unlawful

harassment including sexual harassment and sexual violence.

For inquiries or complaints related to non-discrimination policies, please contact: Office of Equity & Inclusion- oei@udel.edu, (302) 831-8063

For complaints related to Section 504 of the Rehabilitation Act of 1973 and/or the Americans with Disabilities Act, please contact: Office of Disability Support Services, dssoffice@udel.edu, Alison Hall, Suite 130, Newark, DE 19716 (302) 831-4643 OR contact the U.S. Department of Education - Office for Civil Rights

Trajecsys Reporting System

Trajecsys is a Cloud-based clinical recordkeeping system for Health Education Programs. Trajecsys allows us to:

1. Monitor student location, arrival and departure time

2. Digitally record technical performance evaluations, practical examinations, evaluations of student professional performance, and general summary evaluations

Trajecsys enables the UD MLS program to record attendance, orientation/safety checklists, student health policies, evaluations, and examinations online for easier access and ease of use.

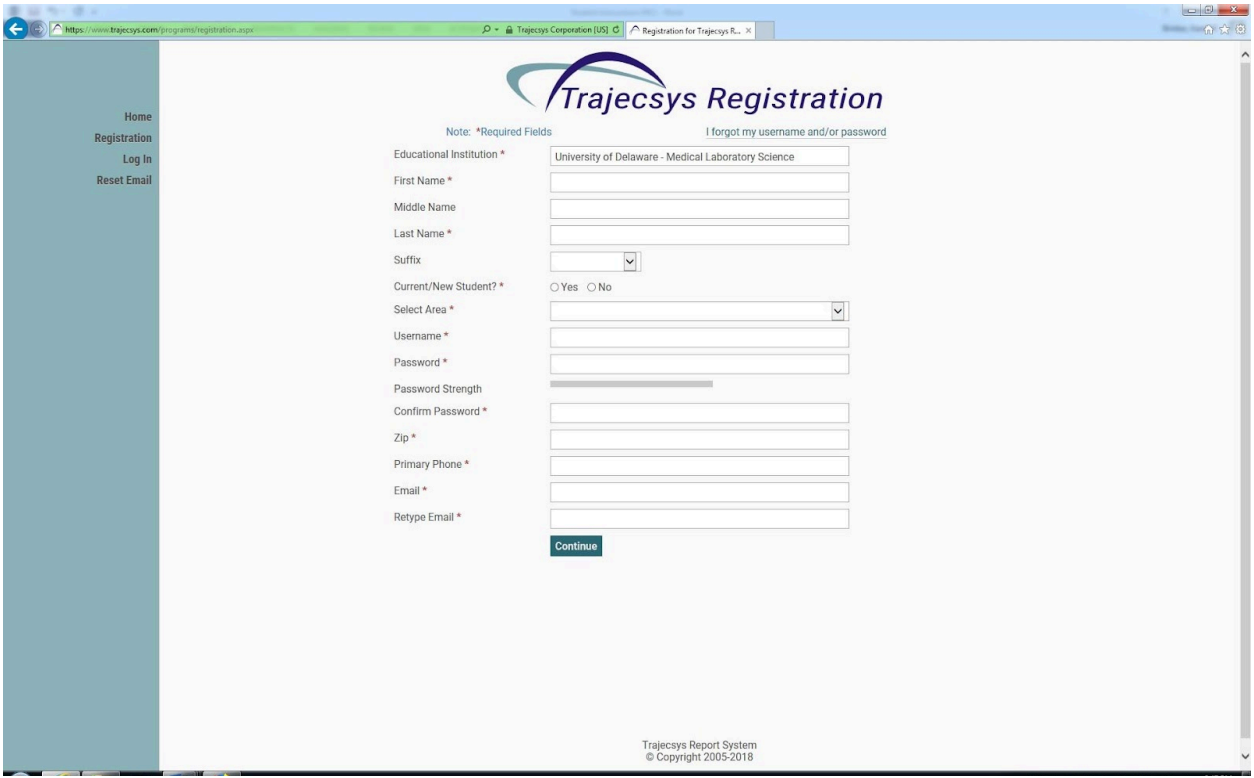
In this system, the clinical instructor (in this system called the clinical supervisor) on many reports is asked to do several things including: approving student time records, reviewing student log sheets, and completing student performance evaluations.

The Trajecsys Student Menu was designed to be as user friendly as possible. This “cheat sheet” highlights the primary functions that most students will utilize on a daily basis.

Registration

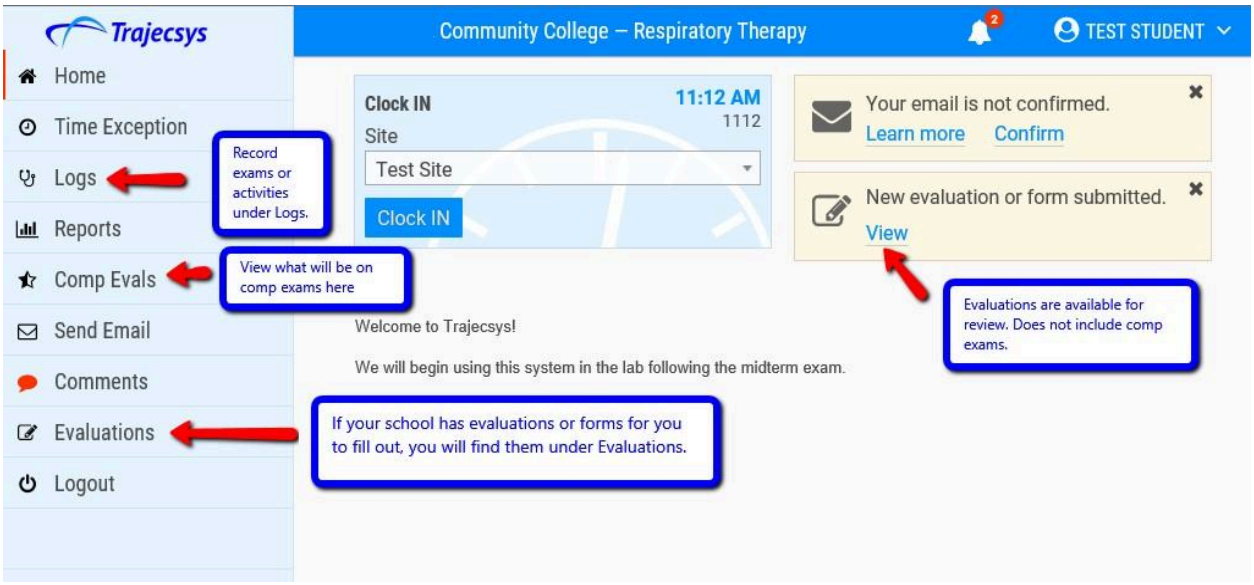
Registration link: https://www.trajecsys.com/programs/registration.aspx

Institution Name: University of Delaware Medical Laboratory Science



Students may register up to 45 days prior to the start date of the payment arrangement. Students who pay directly can go to www.trajecsys.com and click Payments in the upper right corner.

Student Home Page



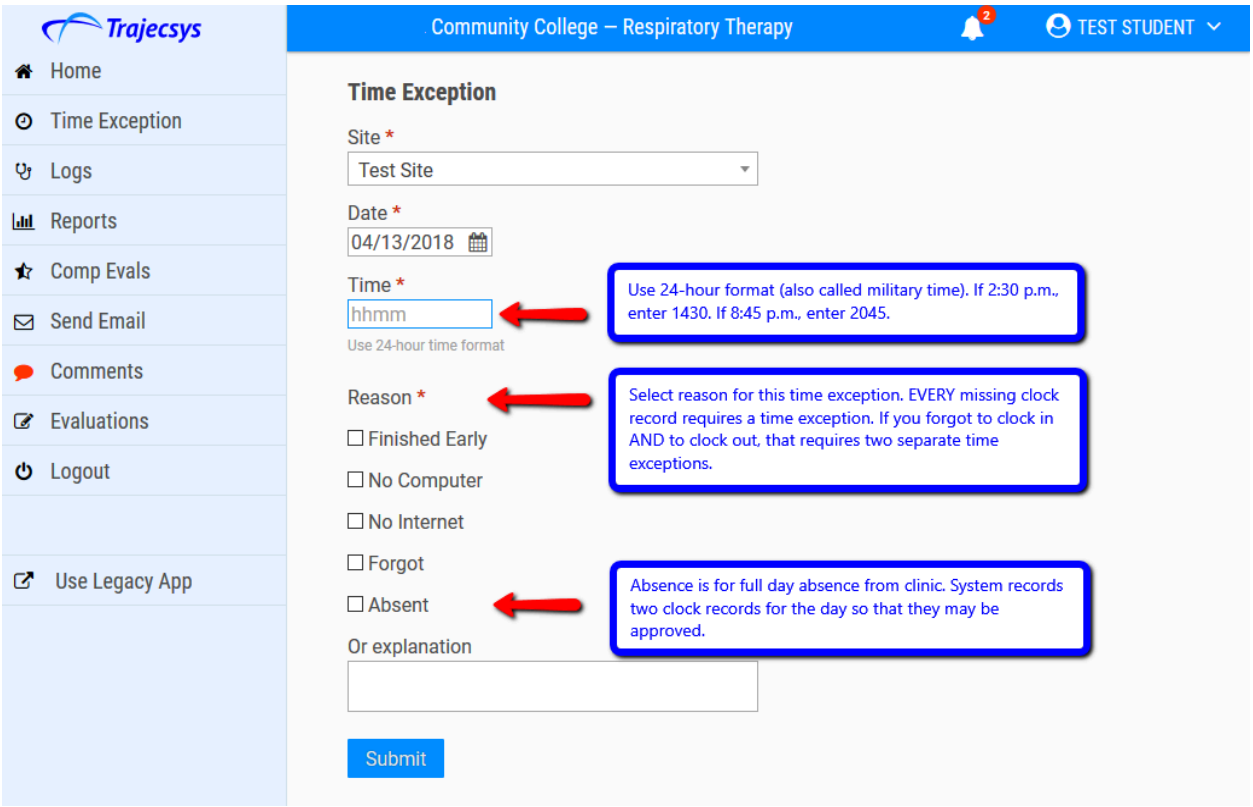
Clock In/Out: Students will clock in each day at their clinical site and clock out at the end of their shift. This also may be done on the student's smartphone; use phone browser to go to Trajecsys.com, log in, agree to share location (on phone); select site and click Clock In/Out button.

Reports: Students may access these items on the Reports menu page:

- Time summary
- Skill summary (compilation of log sheet entries and linked comp exam results; click comp date hyperlink to view item-by-item results)
- Evaluation results other than comps (use either the Evaluation Summaries or Completed Evals/Forms for evaluation results; same info in different formats)

Time Exception

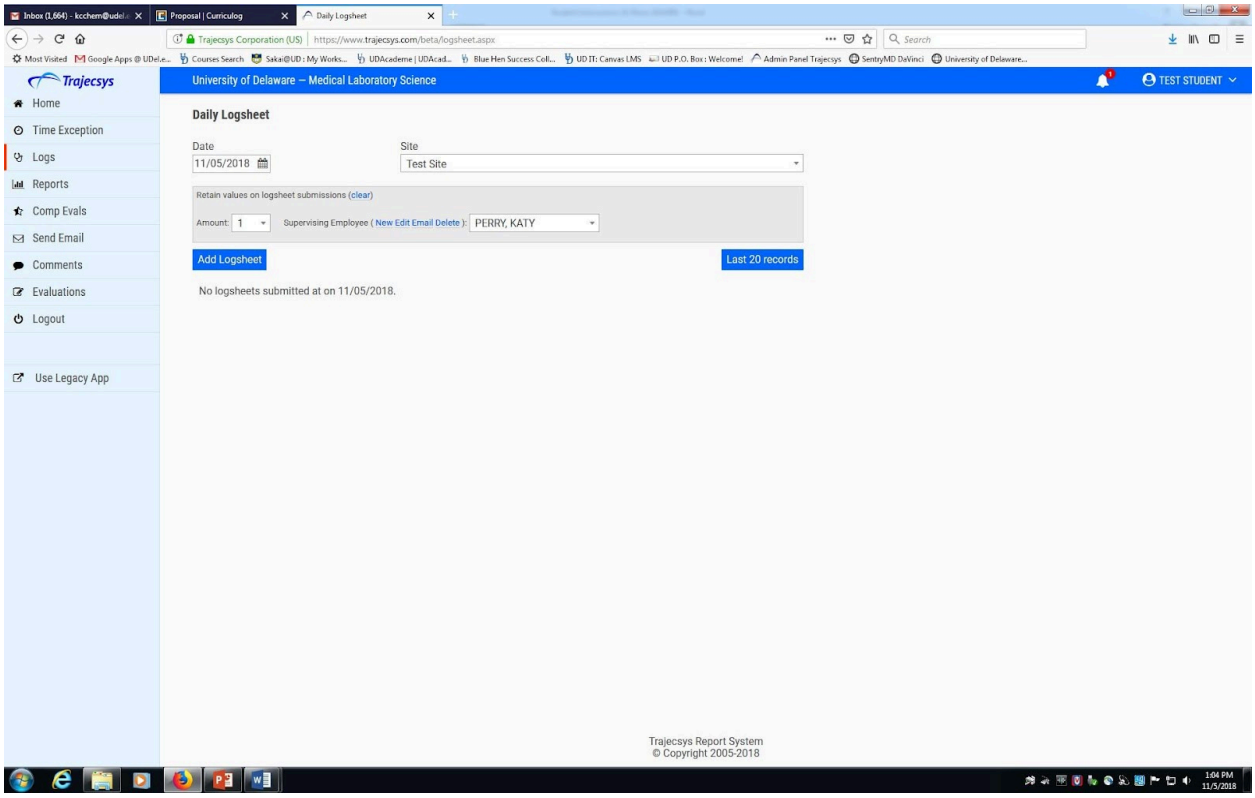
Students will file a time exception if they did not clock in or out for some reason. Typically, students should use the clock in/out feature on the home page. However, if they forget, they must file a time exception for each missing clock record. If a student forgot to clock in AND out on the same day, the student must file two-time exceptions – one for each missing clock record. If filing a time exception on a day that the student was absent, only one-time exception is needed if "Absent" is selected as the reason.



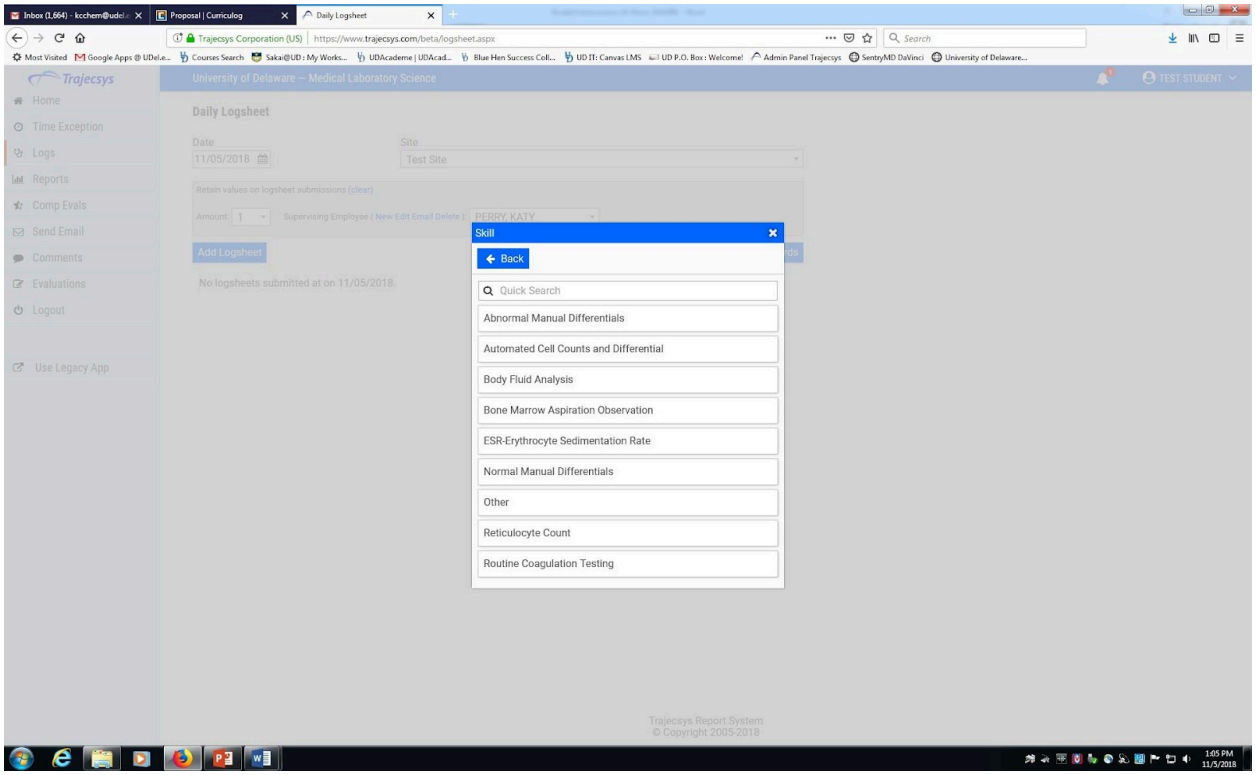
Daily Log Sheets

Students will complete the items on the Logs menu page. Selections may include:

- Date of exam or activity practiced
- Clinical site
- Name of supervising employee (if not in list, click New and add full first and last names, then click Add)
- Click Add Log sheet; then select:
    - Major study
    - Procedure
    - Time
    - Comments



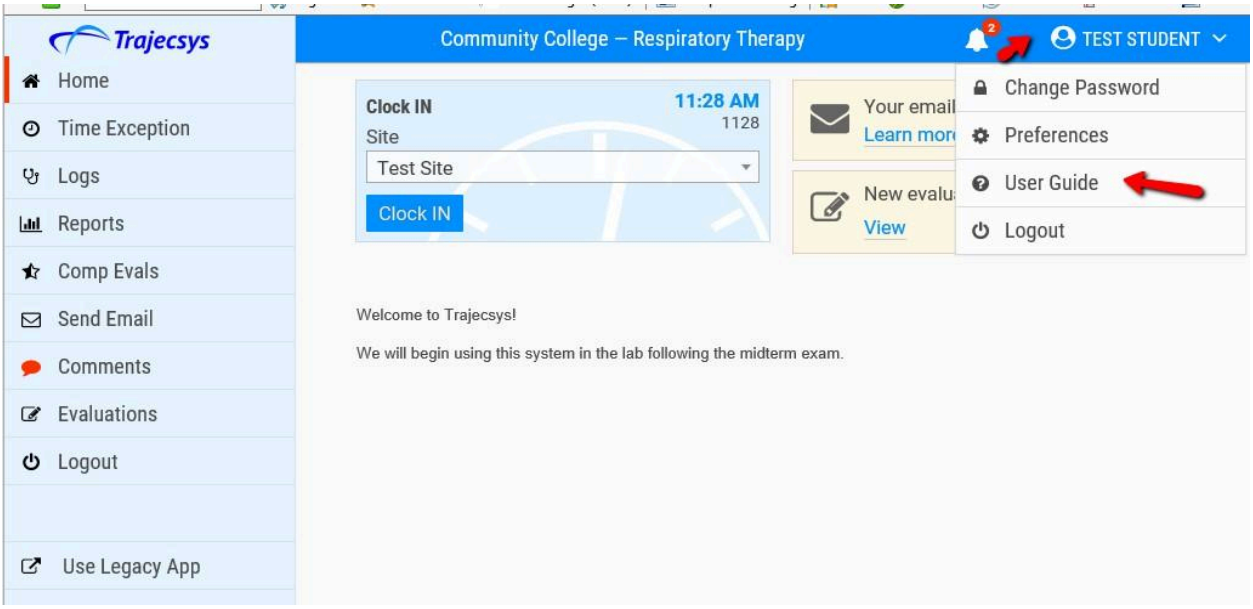
Evaluations



This menu item is used for evaluations or other forms that students will complete. Prior to the beginning of the practicum period (before the end of the fall semester), you will need to read and sign off on the student health policies for the 4 sites that you will be going to plus the Blood Bank of Delmarva, the Delaware Public Health Laboratory, and the Lasher Lab (if you are going to these 2 sites as well).

Troubleshooting

The User Guide can be accessed by clicking your name which will be located in the upper righthand corner.



Affective Objectives

The following objectives have been listed as general affective objectives, since they apply to the overall performance and participation by the student during clinical rotations at the affiliate institutions. Among other qualities, the student is expected to demonstrate dependability, organizational skills, time efficiency and the ability to work with others in accordance with a professional program of study. As a member of the health care team, it is expected that the student will maintain an appropriate professional demeanor at all times.

During the clinical rotations and upon completion of the program of study in Medical Laboratory Science, the student will:

1. Comply with the established dress code policy as outlined in the clinical practicum manual
2. Report to the laboratory at the scheduled time
3. Notify the Clinical Coordinator and the University Education Coordinator when unable to report to the clinical practicum
4. Comply with the attendance policy as outlined in the clinical practicum manual
5. Comply with instructions given either orally or written
6. Demonstrate the ability to ask pertinent questions or for assistance if needed
7. Demonstrate the ability to work independently within student guidelines
8. Communicate courteously, effectively and professionally with instructors, laboratory staff, other

health care personnel, patients and visitors

9. Demonstrate interest and enthusiasm for the clinical laboratory science profession

10. Accept evaluation of performance as constructive when offered by instructors and other laboratory personnel and follow through with suggestions made

11. Adhere to laboratory safety regulations in each clinical area

12. Maintain a clean, organized work area

13. Utilize reagents and supplies judiciously

14. Replenish supplies required in the laboratory work area

15. Demonstrate self-confidence in the operation of equipment and in the performance of laboratory procedures

16. Report patient laboratory results only to authorized personnel

17. Maintain the confidentiality of all privileged information

18. Cooperate with other laboratory personnel to create a pleasant and efficient work environment

19. Demonstrate the ability to concentrate on the laboratory test procedure being performed and the need to avoid distractions

20. Demonstrate organizational skills through ability to coordinate the quantity of work needed to be done with the time available for its completion

21. Practice acceptable quality assurance as established for each clinical area

22. Defend the policy of running quality control samples according to laboratory protocol

23. Coordinate theory with laboratory analysis to appropriately judge patient data

24. Offer assistance to other laboratory personnel when scheduled assignment is complete

25. Recognize technical problems and plan possible corrective action

26. Maintain composure and work quality under stressful conditions

27. Demonstrate concern for professional self-image and that of the medical laboratory science profession by practicing ethical behavior, participating in professional activities and attending professional seminars to maintain knowledge base

Professionalism

The student is expected to conduct himself/herself in a professional manner at all times. The ability to communicate in a respectful manner under all circumstances is an expectation of a professional. The student must remember that all patient information is privileged and as such strict confidentiality must be maintained. The student should realize that in some ways his/her education is just beginning, and to

remain current during the work years ahead, it is important to participate in continuing education activities on a routine basis. If continuing education activities are available at the affiliate institution during the practicum, it is expected that the student will avail himself/herself of the opportunity. Professional performance is guided by the affective objectives previously listed, and professional behavior is evaluated using the form located at the end of this syllabus.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from the prerequisite MMSC courses, the student will:

1. Communicate effectively and professionally as a member of the healthcare team to enable consultative and educational interactions with other healthcare personnel, the public, and patients to the satisfaction of the instructor

2. Demonstrate ethical behavior and professionalism to the satisfaction of the instructor

3. Maintain confidentiality of patient information to the satisfaction of the instructor

4. Participate in continuing education as opportunities arise for one's own professional career development to the satisfaction of the instructor

Note: Review affective objectives and affective evaluation form.

MMSC 473/673 Clinical Chemistry and Body Fluid Analysis Practicum

COURSE SYLLABUS

STUDENT LEARNING GOALS

Student learning goals for the clinical chemistry practicum focus on active participation in daily laboratory operations and personal performance as a laboratory professional. Thus, the learning goal for the technical portion of the clinical chemistry practicum is to facilitate and enhance the student's application of clinical chemistry theory, laboratory experience, and test data interpretation learned in campus courses to an active clinical laboratory setting. To accomplish this goal, students will apply principles of pre- analytical, analytical, and post-analytical components of laboratory practice in clinical chemistry to the performance of laboratory operations in a contemporary clinical setting. The learning goal for the professional component is for students to attain high level interpersonal performance so as to interact professionally with fellow staff and all consumers of laboratory testing. The ultimate outcome of a successfully completed practicum experience is the ability to perform testing of the highest quality to support the laboratory's role in quality patient care and safety. Student achievement during this practicum course will lay the foundation for success as an entry-level medical laboratory scientist.

Student learning goals for the clinical urinalysis portion of the practicum focus on active participation in daily laboratory operations and personal performance as a laboratory professional. Thus, the learning goal for the technical portion of the clinical urinalysis portion of the practicum is to facilitate and enhance the student's application of clinical urinalysis theory, laboratory experience, and test data interpretation learned in campus courses to an active clinical laboratory setting. To accomplish this goal, students will apply principles of pre- analytical, analytical, and post-analytical components of laboratory practice in clinical urinalysis to the performance of laboratory operations in a contemporary clinical setting. The learning goal for the professional component is for students to attain high level interpersonal performance to interact professionally with fellow staff and all consumers of laboratory testing. The ultimate outcome of a successfully completed practicum experience is the ability to perform testing of the highest quality to support the laboratory's role in quality patient care and safety. Student achievement during this practicum course will lay the foundation for success as an entry-level medical laboratory scientist.

COURSE DETAILS

This is a clinical practicum course, and it will meet at a clinical affiliate to be determined by the University instructor. Students will be notified of this location prior to the commencement of the clinical practicum.

MODES OF INSTRUCTION

Clinical faculty will utilize various methods of instruction, including but not limited to a combination of:

1. Clinical specimens
2. Quality control materials
3. Chemistry and urinalysis automated analyzers

4. Assay of proficiency samples previously analyzed and stock samples

5. Case studies

Students will receive instruction about proper operation of equipment, specimen processing, quality control, use of the LIS, and result interpretation and reporting mechanisms specific to the clinical facility where they are assigned.

METHODS OF ASSESSMENT

Upon the completion of this course, based upon affective, cognitive, and psychomotor objectives, the student must achieve a final minimum average of 70% (C-) on the assessment tools utilized in this course.

The clinical instructor will administer written quizzes. In addition, the clinical instructor will assign papers or projects that are relevant to the practicum. This component of the Evaluation comprises **40%** of the practicum grade.

A practical examination is another means of assessment employed by the clinical instructor. The instructions and rubric for the practical examination will be provided to the student prior to commencing the practical examination. The clinical instructor will complete the practical grading rubric and will return it to the University instructor. This component of the Evaluation comprises **40%** of the practicum grade.

Affective assessment is incorporated into the mid- and final-evaluation process. A mid- evaluation will be completed by the clinical instructor and will be discussed with the student. If there are any issues to be addressed, this will also be shared with the University instructor. The final MMSC 473 Clinical Chemistry Practicum Evaluation will be completed by the clinical instructor and discussed with/reviewed by the student. The affective component on the final Evaluation comprises **20%** of the practicum grade.

A written final examination will be administered by the University instructor at the conclusion of the practicum. The University-administered written final examination component of the Evaluation does not affect the practicum grade but is included on the form.

A sample MMSC 473 Clinical Chemistry Practical Evaluation Tool can be found at the end of this syllabus.

COURSE PREREQUISITES

MMSC 436/437 or MMSC 636/637 RESTRICTIONS: Open to medical laboratory science students only.

MMSC 402/412 or MMSC 602/612 RESTRICTIONS: Open to medical laboratory science students only.

CLINICAL CHEMISTRY COURSE OBJECTIVES RELATED TO SPECIFIC CONTENT AREAS

Upon the completion of this course, based upon the objectives detailed in this document, the student must achieve a final minimum average of 70% on the assessment tools utilized in this course.

I. Specimen Management/Safety

II. Quality Control / Quality Assessment / Total Quality Management

III. Automated Chemistry

IV. Arterial Blood Gases*

V. Iontophoresis*

VI. Osmometry

VII. Proteins and Electrophoresis*

VIII. Therapeutic Drug Monitoring and Drugs of Abuse

IX. Urine and Other Body Fluid Chemistries

X. Glycated Hemoglobin

*Psychomotor performance in these areas is considered an enhancement or an elective to the basic clinical practicum educational experience. However, students are responsible for the corresponding theoretical content.

SPECIMEN MANAGEMENT/SAFETY

Introduction

Thorough knowledge of safety procedures is essential before performing any duties in the clinical laboratory which might be hazardous to personnel. The chemistry department is responsible for monitoring departmental criteria for specimen acceptance, processing of various testing, evaluating, and reporting laboratory results. These pre-analytical, analytical, and post-analytical factors are essential for quality assessment in the laboratory. In the chemistry department, a considerable amount of effort is placed on specimen handling and collection, since the final results for any analyte are dependent on these two factors. The following precautions or conditions are essential for quality specimens:

- correct identification of patient
- correct labeling of specimen
- correct identification of the state of the patient – fasting, non-fasting, etc.
- correct time for specimen collection – drug levels, hormones, etc.
- correct specimen type – anticoagulants, preservatives
- correct identification of special handling – ice, prechilled tubes, spin immediately, etc.
- correct storage conditions

Prerequisite

The student will familiarize herself/himself with the overall management of the Chemistry Department.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Discuss the specimen management system used by the chemistry laboratory
2. Distribute specimens to workstations appropriately to the satisfaction of the instructor

3. State the tests performed at each station or instrument in the chemistry laboratory (e.g., Automated Chemistry Instruments, Manual Methods, Special Chemistry, TDM, etc.)

4. Evaluate correctly specimens for acceptance or rejection using laboratory guidelines

5. Document correctly specimen rejection according to laboratory guidelines

6. Report correctly all test results according to laboratory protocol

7. Call test results according to laboratory protocol to the satisfaction of the instructor

8. Maintain correctly patient records according to laboratory protocol

9. File correctly patient records according to laboratory protocol

10. Utilize correctly safe techniques in handling and disposal of infectious materials according to laboratory protocol

11. Comply with established safety regulations and regulations governing regulatory compliance related to laboratory practice to the satisfaction of the instructor

QUALITY CONTROL / QUALITY ASSESSMENT / TOTAL QUALITY MANAGEMENT

Introduction

Quality is of utmost importance in every laboratory. Today's laboratories have a variety of programs in place to control, assess, and improve their quality.

Prerequisite

The student should read the department's quality control (QC), quality assessment (QA), total quality management (TQM) and/or continuous quality improvement (CQI) policies.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Compare and contrast quality control, quality assessment, and total quality management

2. Evaluate correctly laboratory QC data according to laboratory protocol

3. Demonstrate the ability to identify appropriate corrective action when data falls out of control range to the satisfaction of the instructor

4. Discuss how QC is monitored and recorded for each procedure in the chemistry laboratory

5. Record correctly QC data according to laboratory guidelines

6. Identify QC shifts and trends when given laboratory data to analyze, suggesting corrective action

7. Discuss the need for departmental quality assessment and/or total quality management programs

8. Explain the purpose of proficiency testing

9. Discuss the impact of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process

10. Apply correctly principles of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process

11. Discuss the role of the medical laboratory scientist in maintaining laboratory quality

AUTOMATED CHEMISTRY

Introduction

Automated chemistry analyzers are the workhorse of the chemistry laboratory. While instruments vary by manufacturer and type, the following basic objectives remain the same for each analyzer.

Prerequisites

The student should review the Automated Chemistry Analyzer Instrument Manuals for those instruments that will be employed during the practicum period.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, student will:

1. Examine correctly specimen acceptability for analysis based on proper labeling, specimen characteristics (e.g., serum, plasma, hemolysis, lipemia, etc.), sufficiency of volume, and appropriateness of storage method

2. Identify different types of analyzers, i.e., batch, random access, etc.

3. Identify the basic operating components of the analyzer(s)

4. Explain the function of each component of the analyzer(s)

5. Describe the chemical principles for each test performed on the analyzer(s)

6. List the assays that utilize immunologic techniques

7. Identify the analytes that utilize immunologic techniques

8. Perform correctly routine daily maintenance on the analyzer(s) according to the manufacturer’s directions

9. Identify correctly periodic (weekly, monthly, etc.) maintenance requirements according to the manufacturer’s directions

10. Prepare correctly reagents for use on the analyzer(s) according to the manufacturer’s directions

11. State how reagents are stored when not in use on the analyzer

12. Operate the automated chemistry analyzer(s) to quantify controls and specimens according to

the manufacturer's directions to the satisfaction of the instructor

13. Record correctly quality control data according to laboratory protocol
14. Evaluate correctly quality control data according to laboratory protocol
15. State the calibration schedule (frequency) for calibrating the analyzer(s)
16. Describe the procedure(s) for calibration of the automated analyzer(s)
17. Perform correctly calibration(s) as required according to the manufacturer's directions
18. Explain where to find basic troubleshooting information about the analyzer
19. Participate in troubleshooting the analyzer as appropriate to the satisfaction of the instructor
20. Apply appropriate problem-solving steps for determining instrument/methodology problems, utilizing instrument manuals, laboratory procedure manuals, and information contained in package inserts to the satisfaction of the instructor
21. Justify the importance of documenting maintenance, quality control, and troubleshooting
22. Correlate correctly patient results with clinical significance (e.g., impact on diagnosis or treatment of associated disease) and clinical decision making
23. Assess critical pathways to facilitate diagnosis and to determine additional testing as warranted to the satisfaction of the instructor
24. Evaluate inaccurate analyzer results to the satisfaction of the instructor
25. Report correctly all test results according to laboratory protocol
26. Calculate new reference ranges when needed according to manufacturer protocol

ARTERIAL BLOOD GASES*

Introduction

Arterial blood gases are used to assess acid-base balance and blood oxygen levels. The parameters generally measured are pH, pCO2, and pO2. Depending upon the protocol established by a particular hospital, these analyses may be performed either by the laboratory or the respiratory therapy department.

Prerequisites

The student should:

1. Read the Instrument Manual for the Blood-Gas Analyzer
2. Review acid-base balance

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Examine correctly specimen acceptability for analysis based on proper labeling, specimen

characteristics (e.g., anticoagulant, etc.), sufficiency of volume, and appropriateness of transport/handling method

2. Operate correctly the blood-gas analyzer according to the manufacturer's directions
3. Perform correctly instrument calibration
4. Assay correctly controls and specimens
5. Evaluate correctly quality control results according to laboratory protocol
6. Record correctly the gas calibration values, quality control values, patient results, and maintenance for each operation according to laboratory protocol
7. Describe the procedure for changing electrodes
8. Explain the one- and two-point calibration procedures
9. Explain the function of the buffers and flush solutions
10. Explain the principles of operation for the PO2, PCO2, and pH electrodes
11. Compare and contrast the following acid-base/blood-gas imbalances:
    a. Metabolic acidosis
    b. Metabolic alkalosis
    c. Respiratory acidosis
    d. Respiratory alkalosis
12. Correlate patient results with the clinical significance of test noting any abnormal result
13. Maintain correctly patient records according to established laboratory protocol

IONTOPHORESIS*

Introduction

The technique of iontophoresis aids in the diagnosis of cystic fibrosis. After the iontophoretic procedure, the chloride concentration of the sweat is measured using an acceptable method. One clinical feature of cystic fibrosis individuals is an increased chloride concentration in the sweat.

Prerequisites

The student should read the Instrument Manual for the Iontophoresis system.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Explain the principles of iontophoresis and coulometry
2. Weigh correctly pre- and post-sweat test vials on the analytical balance

3. Perform correctly iontophoresis following established laboratory protocol (Under no circumstances should the student perform analysis without the guidance of an instructor and adherence to established protocol as explained in procedure manual.)
4. Perform correctly chloride analysis on obtained sweat according to laboratory protocol
5. Calculate correctly the chloride level in obtained sweat
6. Correlate chloride levels in sweat with clinical significance of testing procedure
7. List possible sources of chloride contamination in the collection and in analysis of the sweat
8. Describe the effects of incorrect specimen collection/handling on test results
9. Explain the significance of sweat testing in children and adults
10. Explain the diagnostic value of the following laboratory tests and clinical features in relation to cystic fibrosis:
    a. d-Xylose absorption
    b. patient history
    c. physical symptoms

OSMOMETRY

Introduction

Osmolality is a measure of the total number of dissolved particles in solution and is independent of the molecular weight of the particles. Osmolality measurements are made in the clinical laboratory using either a freezing-point depression or vapor-pressure osmometer.

Prerequisite

The student should read the Instrument Manual for the Osmometer.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Examine correctly specimen acceptability for analysis based on proper labeling, specimen characteristics (e.g., urine, serum, plasma, etc.), sufficiency of volume, and appropriateness of storage method
2. Explain the principles of osmometry and osmolality measurement by freezing-point depression or vapor pressure
3. Operate correctly the osmometer according to the manufacturer's directions:
    a. perform correctly instrument calibration
    b. assay correctly controls and specimens
4. Evaluate correctly quality control results according to laboratory protocol

5. Correlate patient results with clinical significance of test

6. Report correctly osmolality test results according to laboratory protocol

7. Perform correctly required maintenance according to the manufacturer's directions

8. Record correctly patient results, quality control and maintenance according to laboratory protocol

9. List the major serum osmotic constituents that affect osmolality

10. Calculate correctly the serum osmolality from the measured concentrations of osmotic constituents using a recommended formula

11. List the significance of the Urine/Serum osmolality ratio as an important tool in evaluating H2O balance and renal function

12. Explain the relationship between urine specific gravity and osmolality as an indication of renal concentration ability and how they might be used to establish criteria for hemodialysis

PROTEINS AND ELECTROPHORESIS*

Introduction

Proteins are composed of amino acids linked by peptide bonds in a sequence and configuration characteristic for each specific protein. There are over one hundred proteins present in plasma serving numerous physiological functions. The ability to vary the charge on a protein molecule by changing the pH of its matrix can be used to purify and characterize proteins by electrophoresis and ion exchange chromatography.

Electrophoresis is the movement of charged particles through an electrical field. In order for electrophoresis to occur, there must be an electrical field, a medium for absorbing and holding the analyte and charged particles. The electrical field is supplied by providing a tank through which current may pass. The charged particles are supplied by using an appropriate buffer for ionizing the molecule. After migration, the proteins are stained, and protein bands are identified and quantified. Electrophoresis is useful as a diagnostic technique for the separation of proteins in serum, urine, and CSF, for the separation of hemoglobins, and for the separation of serum isoenzymes.

Prerequisites

The student should read the Instrumentation Manual for the Electrophoresis system.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Examine correctly specimen acceptability for analysis based on proper labeling, specimen characteristics (e.g., serum, plasma, whole blood, hemolysis, etc.), sufficiency of volume, and appropriateness of storage method

2. Explain the basic principle of electrophoresis

3. Describe factors influencing the mobility and resolution of proteins

4. Perform correctly the following procedures according to the manufacturer's directions:
    a. serum and urine protein electrophoresis
    b. hemoglobin electrophoresis
5. Explain the principles for the specific electrophoretic tests in objective 4
6. Use correctly sample concentrators for electrophoresis specimen preparation
7. Describe the principle of operation of the sample concentrators
8. Identify the protein fractions visualized on cellulose acetate/agarose electrophoresis for:
    a. serum and urine protein
    b. hemoglobin
9. Interpret protein electrophoresis data in relation to pathological conditions
10. Perform correctly quality control checks on the densitometer according to laboratory protocol
11. Record correctly quality control checks on the densitometer according to laboratory protocol
12. Operate correctly the densitometer according to manufacturer's directions
13. Prepare correctly patient report forms according to laboratory protocol
14. Record correctly patient results according to laboratory protocol
15. Perform troubleshooting when necessary according to the manufacturer's directions to the satisfaction of the instructor
16. Discuss the following conditions in relation to structural changes in the hemoglobin molecule:
    a. thalassemia
    b. sickle cell disease
    c. sickle/thalassemia
    d. lepore
17. Evaluate the percent of hemoglobins A1, S, A2 and F of the total hemoglobin as they relate to the conditions listed in objective 16
18. Discuss the quantitative methods for differentiating and determining hemoglobins A2, S and C
19. List a confirmatory test for Hgb C
20. Explain the structures of the following hemoglobins:
    a. A1
    b. A2
    c. S

d. F

THERAPEUTIC DRUG MONITORING AND DRUGS OF ABUSE

Introduction

Therapeutic drug monitoring (TDM) is a process by which the quantity of a drug is determined to assist the physician in determining whether a drug dosage should be maintained or altered. Methods used to quantify drugs include sophisticated instrumentation that is capable of performing such assays as Enzyme Immunoassay (EIA), Fluorescence Polarization Immunoassay (FPIA), etc.

Prerequisite

The student should review the Instrument Manual for the Therapeutic Drug Monitoring Analyzer.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Examine correctly specimen acceptability for analysis based on proper labeling, time of collection, specimen characteristics (e.g., serum, plasma, hemolysis, lipemia, etc.), sufficiency of volume, and appropriateness of storage method
2. Explain the significance of the following selected classes of therapeutic drugs:
    a. cardioactive
    b. antiepileptic
    c. bronchodilator
    d. antibiotic
    e. antipsychotic
    f. antineoplastic
3. For each class of drugs noted in objective 2, list the generic name of drugs that are commonly ordered
4. Explain the significance of performing therapeutic drug monitoring
5. Define the following terminology:
    a. therapeutic level
    b. toxic level
    c. steady-state, peak, and trough concentrations
    d. half-life
6. Discuss the significance of peak and trough levels in therapeutic drug monitoring
7. Differentiate between half-life and steady-state

8. Explain the principle of enzyme immunoassay

9. Explain the principle of fluorescence polarization immunoassay

10. Perform correctly TDM and drugs of abuse assays employing proper analytical techniques according to the manufacturer's directions

11. Perform correctly all functions related to automated analyzers as stated in the "Automated Chemistry" objectives, including but not limited to daily maintenance, calibration, operation, QC, etc.

12. Assess correctly drug test results for therapeutic management

13. Discuss the applications of urine drug screens and the importance of confirming positive drug screens

14. List the type of analytical systems that may be employed for confirmation purposes

15. Explain the principle of the confirmatory analytical systems

16. Classify the most common drugs of abuse into the following categories noting the drug groups and the generic names: depressant (sedative-hypnotic), depressant (tranquilizer), narcotic, hallucinogen, stimulant, analgesic, and antidepressant

17. Identify correctly abnormal and/or erroneous results according to laboratory protocol

18. Troubleshoot correctly erroneous drug results according to laboratory protocol

19. Correlate patient results with clinical significance (e.g., impact on treatment of associated disease or impact on drug abuse assessment) and clinical decision making

20. Assess critical pathways to facilitate diagnosis and to determine additional testing as warranted to the satisfaction of the instructor

21. Report correctly all drug results according to laboratory protocol

22. Record correctly patient drug results, quality control and maintenance according to laboratory protocol

URINE AND OTHER BODY FLUID CHEMISTRIES

Introduction

This section deals with urine chemistries and those body fluid chemistries that require manual manipulation or testing.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Correctly prepare 24-hour urine containers according to laboratory protocol

2. Correctly explain 24-hour urine collection procedures according to laboratory protocol

3. Correctly perform 24-hour urine collection assay according to laboratory protocol
4. Correctly calculate 24-hour urine results according to laboratory protocol for:
    a. protein
    b. creatinine
    c. creatinine clearance
    d. electrolytes
    e. calcium
    f. phosphorus
    g. urea
5. Perform correctly the 2 hour urine amylase assay according to laboratory protocol
6. Calculate correctly a 2-hout urine amylase result according to laboratory protocol
7. Calculate correctly the micro-albumin-to-creatinine ratio performing the urine albumin and creatinine assays according to laboratory protocol
8. Interpret the mico-albumin-to-creatinine ration correctly for being normal pathological
9. Discuss procedures to evaluate other body fluids (CSF, Pleural, amniotic, etc.)
10. Perform correctly chemical testing, protein, glucose, etc.) on such body fluids as CSF Pleural, etc. according to laboratory protocol
11. Perform correctly urine and serum pregnancy tests according to laboratory protocol
12. Correlate patient results with clinical significance
13. Report correctly all test results according to laboratory protocol
14. Record correctly patient results and quality control according to laboratory protocol

GLYCATED HEMOGLOBIN

Introduction

Glycated hemoglobins, HbA1a, HbA1b, and HbA1c, are modifications of Hb A and are formed by the condensation between glucose and the *N*-terminal valine amino acid of each beta-chain. The level of glycated hemoglobin depends on the time-averaged glucose concentration during the preceding 6 to 8 weeks before measurement.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 407/417/607/617 and 436/437/636/637, the student will:

1. Examine correctly specimen acceptability for analysis based on proper labeling, specimen characteristics, sufficiency of volume, and appropriateness of storage method

2. Explain the principle of the glycated hemoglobin method
3. Describe why glycated hemoglobin is a better indicator than a random or a fasting blood glucose for evaluating long-term glucose control
4. Perform correctly the glycated hemoglobin assay using specimens, controls and standards according to laboratory protocol
5. Evaluate correctly quality control results according to laboratory protocol
6. Correlate patient results with clinical significance
7. Record correctly patient results and quality control according to laboratory protocol
8. Report correctly all test results according to laboratory protocol

ASSESSMENT TOOLS

See below for:

Clinical Practicum Student Affective Evaluation Grading Scale
Clinical Practicum Practical Evaluation Instructions
Clinical Practicum Practical Evaluation Grading Rubric

All students must complete the Urinalysis Tally included as part of the Clinical Practicum.

Student Evaluation (see below) to obtain a passing grade in MMSC473/673 - completed on Trajecsys
Clinical Practicum Student Evaluation – Revised, 2020

Clinical Practicum Student Affective Evaluation Grading Scale

For items #1 through #15: Rate on 1-5 point scale below. Record rating in the column provided. Space is provided with each evaluation item for narrative appraisal. Any unsatisfactory evaluation **must** be documented. Please indicate strong points exhibited. The completed evaluation form must be discussed with the student at mid-point and end of the clinical practicum.

Performance Level	**Rating Value**	**Performance Indicators**
Outstanding	5	Contribution **far exceeds** what is normally expected of a student. Personal commitment to a high level of performance and professionalism is clear.
Exceeds Expectations	4	Seizes initiative in development and implementation of challenging projects. Accomplishments **exceed** requirements. Requires minimal direction.
Fully Satisfactory	**3**	**Performance is what is expected in senior clinical practicum. Does not require significant improvement. Errors are minimal and seldom repeated. Requires only normal supervision and follow-up.**
Less Than Satisfactory	2	Performance generally does not meet minimum requirements for senior clinical practicum. Errors are significant and frequently repeated. Requires close surveillance and guidance.
Unacceptable Performance	1	Has had sufficient exposure to have shown better performance. Does not grasp basic concepts no matter how many times they have been explained. Does not demonstrate commitment to this aspect of professional development.

Practical Evaluation Instructions **Student:**

Eval by: **Date:**

Clinical Chemistry Instrumentation Practical

As detailed in the practical evaluation rubric, perform the following functions:

1. Perform daily maintenance procedures according to protocol.
2. Calibrate instrument as needed or required.
3. Run controls as needed or required and evaluate their acceptability before running patient samples.
4. Run patient samples.
5. Interpret patient results.
6. The following conditions apply to this practical (all that are marked with a √):

Time limit =

Use of instrument operating manuals is permitted

Use of course manuals is permitted

Other:

Clinical Chemistry Practical Evaluation Grading **Student:**

Eval by: **Date:**

	POINTS POSSIBLE	POINTS EARNED	COMMENTS
Instrument startup completed accurately and efficiently, all necessary documentation recorded accurately and legibly	10		
Reagents and supplies utilized efficiently, no unnecessary waste of materials	5		
Temperatures of reagent refrigerators, incubators, etc. documented accurately and legibly	5		
Calibrations performed as needed, accurately evaluated, and documentation recorded accurately and legibly	15		
Appropriate QC processed, accurately evaluated, and documentation recorded accurately and legibly on instrument or LIS	15		
Troubleshooting error messages, delta checks, or other instrument "needs" as applicable	5		
Unknown samples processed and accurately evaluated and reported	25		
Critical results noted and reported appropriately, all necessary documentation recorded accurately and legibly	15		
If applicable, verify calculations	5		
Other			
TOTALS:			
PRACTICAL GRADE:			

FINAL CLINICAL PRACTICUM GRADE WILL BE CALCULATED AS DETAILED BELOW:	
Student Affective Evaluation 20% The same numbers apply here as those on the final evaluation for the rotation discipline with which Urinalysis was included.	UA Tally Score _____X .40 = _____ Practical Score _____X .40 = _____ Affective Score _____X .20 = _____ Grade for Practicum = _____ **PASS or FAIL**
A grade of INCOMPLETE will be recorded unless ALL practicum documentation is completed by the end of the semester. This includes attendance sheets, orientation checklists, and the completion of the online site evaluation for each clinical practicum.	

NOTE: Student must PASS both the chemistry and body fluid analysis components of this practicum to earn a grade of PASS for MMSC 473/673.

CLINICAL URINALYSIS COURSE OBJECTIVES RELATED TO SPECIFIC CONTENT AREAS

Upon the completion of this course, based upon the objectives detailed in this document, the student must achieve a final minimum average of 70% on the assessment tools utilized in this course.

UNIT I Specimen Management/Safety

UNIT II Quality Control/Quality Assessment/Total Quality Management

UNIT III Clinical Urinalysis

UNIT I: SPECIMEN MANAGEMENT/SAFETY

Introduction

Thorough knowledge of safety procedures is essential before performing any duties in the clinical laboratory which might be hazardous to personnel. The urinalysis department is responsible for monitoring departmental criteria for specimen acceptance, processing of various testing, evaluating, and reporting laboratory results. These pre-analytical, analytical, and post-analytical factors are essential for quality assessment in the laboratory. In the urinalysis department, a considerable amount of effort is placed on specimen handling and collection, since the final results for any analyte are dependent on these two factors. The following precautions or conditions are essential for quality specimens:

- correct identification of patient
- correct labeling of specimen
- correct identification of the state of the patient – fasting, non-fasting, etc.
- correct time for specimen collection
- correct storage conditions

Prerequisite

The student will familiarize herself/himself with the overall management of the Urinalysis Department.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375 and MMSC 402/412/602/612, the student will:

1. Discuss the specimen management system used by the urinalysis laboratory
2. Distribute specimens to workstations appropriately to the satisfaction of the instructor
3. State the tests performed at each station or instrument in the urinalysis laboratory
4. Correctly evaluate specimens for acceptance or rejection using laboratory guidelines
5. Correctly document specimen rejection according to laboratory guidelines
6. Report and/or call test results according to laboratory protocol to the satisfaction of the instructor

7. Correctly maintain patient records according to laboratory protocol
8. Correctly file patient records according to laboratory protocol
9. Correctly utilize safe techniques in handling and disposal of infectious materials according to laboratory protocol
10. Comply with established safety regulations and regulations governing compliance related to laboratory practice to the instructor's satisfaction

UNIT II: QUALITY CONTROL / QUALITY ASSESSMENT / TOTAL QUALITY MANAGEMENT

Introduction

Quality is of utmost importance in every laboratory. Today's laboratories have a variety of programs in place to control, assess, and improve their quality.

Prerequisite

The student should read the department's quality control (QC), quality assessment (QA), total quality management (TQM) and/or continuous quality improvement (CQI) policies.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375 and MMSC 402/412/602/612, the student will:

1. Compare and contrast quality control, quality assessment, and total quality management
2. Correctly evaluate laboratory QC data according to laboratory protocol
3. Demonstrate the ability to identify appropriate corrective action when data falls out of control range to the satisfaction of the instructor
4. Discuss how QC is monitored and recorded for each procedure in the urinalysis laboratory
5. Accurately record QC data according to departmental guidelines
6. Identify QC shifts and trends when given laboratory data to analyze
7. Suggest appropriate corrective action when QC shifts and trends are identified
8. Discuss the need for departmental quality assessment and/or total quality management programs
9. Explain the purpose of proficiency testing
10. Discuss the impact of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process
11. Correctly apply principles of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process
12. Discuss the role of the medical laboratory scientist in maintaining laboratory quality

13. Apply Westgard Rules to determine appropriate action when evaluating quality control

UNIT III: CLINICAL URINALYSIS

Introduction

The knowledge of the principles and clinical significance of routine urinalysis are essential to the entry level bench technologist. Proper performance and understanding of the macroscopic and microscopic procedures, quality assurance, and clinical correlation should be observed and practiced during this phase of the student's medical laboratory science instruction.

Prerequisites

The student should review the Automated Urinalysis Analyzer Instrument Manuals for those instruments that will be employed during the practicum period.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375 and MMSC 402/412/602/612, the student will:

1. Correctly evaluate urine specimens for acceptability using laboratory guidelines
2. Take necessary action when the specimen is unsuitable for analysis to the satisfaction of the instructor
3. Evaluate urine specimens correctly for their proper handling and timely examination according to established laboratory procedures
4. Correctly perform the macroscopic and microscopic urinalysis tests according to established laboratory procedures
5. Evaluate if confirmatory tests are needed
6. Correctly perform the confirmatory tests when appropriate to complete a routine urinalysis according to established laboratory procedures
7. Demonstrate proper use of the refractometer according to manufacturer’s guidelines
8. Correctly perform the quality control procedures for routine urinalysis according to laboratory protocol
9. Record correctly quality control results according to laboratory protocol
10. Evaluate correctly quality control results according to established laboratory procedures, taking corrective action when necessary
11. Correctly calibrate the reagent strip analyzer according to operator’s guide
12. Perform preventive maintenance of the reagent strip analyzer according to operator’s guide to the satisfaction of the instructor
13. Correctly operate the reagent strip analyzer according to operator’s manual
14. Record correctly patient results according to laboratory protocol, rechecking results as needed

15. Evaluate correctly patient results, rechecking results as needed

16. Correctly interpret a patient's urine macroscopic results to determine whether a microscopic analysis should be performed, according to laboratory protocol

17. Differentiate among the following types of specimens: 2-hour, 24-hour, postprandial, clean catch, midstream and random

18. Categorize patient physical urinalysis results correctly as being "normal" or "abnormal":

    a. volume

    b. specific gravity

    c. clarity

    d. color

19. Differentiate among specific gravity, osmolality and osmolarity

20. Illustrate the principles of refractometry and osmolality

21. Correctly evaluate instances of normal versus abnormal results for the following chemical tests:

    a. pH

    b. protein

    c. glucose

    d. ketone bodies

    e. occult blood

    f. bilirubin

    g. urobilinogen

    h. nitrite

    i. leukocytes

    j. creatinine

22. Demonstrate the proper follow-up for abnormal or unexpected patient urinalysis results, according to laboratory protocol

23. Differentiate between diabetes insipidus and diabetes mellitus

24. Correctly correlate urinalysis result patterns with normal and pathological conditions to the satisfaction of the instructor

25. Correctly interpret the results of reducing substance testing with pediatric urine samples according to laboratory protocol

26. Differentiate between conjugated and unconjugated bilirubin

27. Discern the use of stains to aid in the identification of urine elements

28. Identify the following urinary sediment/components in bright field, phase, or polarized microscopy:

    a. cell types

    b. types of casts

    c. crystals found in acid pH

    d. crystals found in alkaline pH

29. Correctly evaluate instances of significant versus insignificant results for the following crystals:

    a. bilirubin

    b. cysteine

    c. leucine

    d. tyrosine

    e. cholesterol

ASSESSMENT TOOLS (Evaluations and Logs will be done in Trajecsys)

See below for:

Clinical Practicum Student Affective Evaluation Grading Scale
Clinical Practicum Practical Evaluation Instructions
Clinical Practicum Practical Evaluation Grading Rubric

All students must complete the Urinalysis Tally included as part of the Clinical Practicum.

Student Evaluation (see below) to obtain a passing grade in MMSC472 - completed on Trajecsys
Clinical Practicum Student Evaluation – Revised, 2020

Clinical Practicum Student Affective Evaluation Grading Scale

For items #1 through #15: Rate on 1-5 point scale below. Record rating in the column provided. Space is provided with each evaluation item for narrative appraisal. Any unsatisfactory evaluation **must** be documented. Please indicate strong points exhibited. The completed evaluation form must be discussed with the student at mid-point and end of the clinical practicum.

Performance Level	Rating Value	Performance Indicators
Outstanding	5	Contribution **far exceeds** what is normally expected of a student. Personal commitment to a high level of performance and professionalism is clear.
Exceeds Expectations	4	Seizes initiative in development and implementation of challenging projects. Accomplishments **exceed** requirements. Requires minimal direction.
Fully Satisfactory	**3**	**Performance is what is expected in senior clinical practicum. Does not require significant improvement. Errors are minimal and seldom repeated. Requires only normal supervision and follow-up.**
Less Than Satisfactory	2	Performance generally does not meet minimum requirements for senior clinical practicum. Errors are significant and frequently repeated. Requires close surveillance and guidance.
Unacceptable Performance	1	Has had sufficient exposure to have shown better performance. Does not grasp basic concepts no matter how many times they have been explained. Does not demonstrate commitment to this aspect of professional development.

Practical Evaluation Instructions **Student:**

Eval by: **Date:**

Clinical Urinalysis Practical

As detailed in the practical evaluation rubric, perform the following functions:

1. Perform daily maintenance procedures according to protocol.
2. Identify microscopic, formed elements accurately.
3. Run controls as needed or required and evaluate their acceptability before running patient samples.
4. Run patient samples.
5. Handle instrumentation correctly.
6. Interpret patient results.
7. The following conditions apply to this practical (all that are marked with a √):

Time limit =

Use of instrument operating manuals is permitted

Use of course manuals is permitted

Other:

Clinical Urinalysis Practical Evaluation Grading **Student:**

Eval by: **Date:**

	POINTS POSSIBLE	POINTS EARNED	COMMENTS
Instrument startup completed accurately and efficiently, troubleshooting done as necessary, all necessary documentation recorded accurately and legibly	10		
Reagents and supplies utilized efficiently, no unnecessary waste of materials	10		
Calibrations performed as needed, accurately evaluated, and documentation recorded accurately and legibly	10		
Appropriate QC processed, accurately evaluated, and documentation recorded accurately and legibly on instrument or LIS	20		
Unknown samples processed by *instrumentation* and accurately evaluated and reported	20		
Unknown samples analyzed for formed elements *manually* and accurately evaluated and reported	20		
Correlations or discrepancies noted between instrumentation results and manually performed tests	10		
Other			
TOTALS:			
PRACTICAL GRADE:			

University of Delaware
Medical Laboratory Science Program

Urinalysis Clinical Practicum Sample Tally Sheet (Students will log this in Trajecsys)

Student's Name: Affiliate Site:

Day (date)	Biochem Only	Micro Only	Complete UA	Other
1				
2				
3				
Total				

Comments:

Student's Signature:

UA Tally Objective: A minimum of 30 complete urinalyses should be performed (physical, chemical, microscopic). The emphasis should be placed on evaluating high quality urines to ensure that all major formed elements are observed. When a facility uses fully automated urinalysis, the student must still experience sufficient manual microscopics to observe all major formed elements. Student is responsible for returning the Urinalysis Tally to the UD Education Coordinator.

FINAL CLINICAL PRACTICUM GRADE
WILL BE CALCULATED AS DETAILED BELOW:

Student Affective Evaluation 20% The same numbers apply here as those on the final evaluation for the rotation discipline with which Urinalysis was included.	UA Tally Score X .40 = Practical Score X .40 = Affective Score X .20 = Grade for Practicum = **PASS or FAIL**
A grade of INCOMPLETE will be recorded unless ALL practicum documentation is completed by the end of the semester. This includes attendance sheets, orientation checklists, and the completion of the online site evaluation for each clinical practicum.	

NOTE: Student must PASS both the chemistry and body fluid analysis components of this practicum to earn a grade of PASS for MMSC 473/673.

MMSC 475/675 Clinical Hematology Practicum

COURSE SYLLABUS

STUDENT LEARNING GOALS

Student learning goals for the clinical hematology practicum focus on active participation in daily laboratory operations and personal performance as a laboratory professional. Thus, the learning goal for the technical portion of the clinical hematology practicum is to facilitate and enhance the student's application of clinical hematology theory, laboratory experience, and test data interpretation learned in campus courses to an active clinical laboratory setting. To accomplish this goal, students will apply principles of pre- analytical, analytical, and post-analytical components of laboratory practice in clinical hematology to the performance of laboratory operations in a contemporary clinical setting. The learning goal for the professional component is for students to attain high level interpersonal performance so as to interact professionally with fellow staff and all consumers of laboratory testing. The ultimate outcome of a successfully completed practicum experience is the ability to perform testing of the highest quality to support the laboratory's role in quality patient care and safety. Student achievement during this practicum course will lay the foundation for success as an entry-level medical laboratory scientist.

COURSE DETAILS

This is a clinical practicum course, and it will meet at a clinical affiliate to be determined by the University instructor. Students will be notified of this location prior to the commencement of the clinical practicum.

MODES OF INSTRUCTION

Clinical faculty will utilize various methods of instruction, including but not limited to a combination of:

1. Clinical specimens
2. Quality control materials
3. Hematology and coagulation automated analyzers
4. Preserved normal and abnormal peripheral blood and bone marrow slides with histograms and case histories
5. CAP disease state/case study kodachromes
6. Case studies

Students will receive instruction about proper operation of equipment, specimen processing, quality control, use of the LIS, and result interpretation and reporting mechanisms specific to the clinical facility where they are assigned.

METHODS OF ASSESSMENT

Upon the completion of this course, based upon affective, cognitive and psychomotor objectives, the student must achieve a final minimum average of 70% (C-) on the assessment tools utilized in this course.

The clinical instructor will administer written quizzes. In addition, the clinical instructor will assign papers or projects that are relevant to the practicum. This component of the Evaluation comprises 40% of the practicum grade.

A practical examination is another means of assessment employed by the clinical instructor. The instructions and rubric for the practical examination will be provided to the student prior to commencing the practical examination. The clinical instructor will complete the practical grading rubric and will return it to the University instructor. This component of the Evaluation comprises 40% of the practicum grade.

Affective assessment is incorporated into the mid- and final-evaluation process. A mid- evaluation will be completed by the clinical instructor and will be discussed with the student. If there are any issues to be addressed, this will also be shared with the University instructor. The final MMSC 475 Clinical Hematology Practicum Evaluation will be completed by the clinical instructor and discussed with/reviewed by the student. The affective component on the final Evaluation comprises 20% of the practicum grade.

A written final examination will be administered by the University instructor at the conclusion of the practicum. The University-administered written final examination component of the Evaluation does not affect the practicum grade but is included on the form.

A sample MMSC 475 Clinical Hematology Practical Evaluation can be found at the end of this syllabus.

COURSE PREREQUISITES

MMSC 433/434 or MMSC 633/634 RESTRICTIONS: Open to medical laboratory science students only.

COURSE OBJECTIVES RELATED TO SPECIFIC CONTENT AREAS

Upon the completion of this course, based upon the objectives detailed in this document, the student must achieve a final minimum average of 70% on the assessment tools utilized in this course.

I. Specimen Management/Safety

II. Quality Control / Quality Assessment / Total Quality Management

III. Automated Hematology/Coagulation Instrumentation

IV. Differentials, RBC Morphology and RBC & WBC Disorders

V. Body Fluids

VI. Routine and Miscellaneous Hematology Procedures

VII. Coagulation

VIII. Molecular Diagnostic and Immunologic Assays

SPECIMEN MANAGEMENT/SAFETY

Introduction

Thorough knowledge of safety procedures is essential before performing any duties in the clinical rotation. The hematology department is responsible for monitoring departmental criteria for specimen acceptance, processing of various testing, evaluating, and reporting laboratory results. Specimen handling

involves the following steps: proper specimen collection, appropriate specimen containers, accurate labeling of forms and specimens, timeliness of transport, and proper storage upon completion of analysis. These pre-analytical, analytical, and post-analytical factors are essential for quality assessment in the laboratory. The following precautions or conditions are essential for quality specimens:

- correct identification of patient
- correct labeling of specimen
- correct identification of the state of the patient – fasting, non-fasting, etc.
- correct time for specimen collection as applicable
- correct specimen type – anticoagulants, preservatives
- correct special handling – specimen rocker, etc.
- correct storage conditions

Prerequisite

The student will familiarize herself/himself with the overall management of the Hematology Department.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Discuss the specimen management system used by the hematology laboratory
2. Distribute specimens to workstations appropriately to the satisfaction of the instructor
3. State the tests performed at each station or instrument in the hematology laboratory (e.g., Automated Hematology Instruments, Manual Methods, Automated Coagulation Instruments, Differentials, etc.)
4. Correctly evaluate specimens for acceptance or rejection using laboratory guidelines
5. Correctly document specimen rejection according to laboratory guidelines
6. Report and/or call test results according to laboratory protocol to the satisfaction of the instructor
7. Correctly maintain patient records according to laboratory protocol
8. Correctly file patient records according to laboratory protocol
9. Correctly utilize safe techniques in handling and disposal of infectious materials according to laboratory protocol
10. Comply with established safety regulations and regulations governing regulatory compliance related to laboratory practice to the satisfaction of the instructor

QUALITY CONTROL / QUALITY ASSESSMENT / TOTAL QUALITY MANAGEMENT

Introduction

Quality is of utmost importance in every laboratory. Today's laboratories have a variety of programs in place to control, assess, and improve their quality.

Prerequisite

The student should read the department's quality control (QC), quality assessment (QA), total quality management (TQM) and/or continuous quality improvement (CQI) policies.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Explain the rationale for departmental quality assessment and/or total quality management programs
2. List specific areas which require surveillance
3. Demonstrate correctly how the performance of specific reagents are evaluated and how often
4. Discuss the necessity of keeping written records of all surveillance
5. Discuss the importance of periodic review of surveillance of records and documentation corrective actions taken
6. Compare and contrast quality control, quality assessment, and total quality management
7. Correctly evaluate laboratory QC data according to laboratory protocol
8. Demonstrate the ability to identify appropriate corrective action when data falls out of control range to the satisfaction of the instructor
9. Discuss how QC is monitored and recorded for each procedure in the hematology laboratory
10. Correctly record QC data according to laboratory guidelines
11. Identify QC shifts and trends when given laboratory data to analyze, suggesting corrective action
12. Explain the purpose of proficiency testing
13. Discuss the impact of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process
14. Apply correctly principles of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process
15. Discuss the role of the medical laboratory scientist in maintaining laboratory quality

AUTOMATED HEMATOLOGY/COAGULATION INSTRUMENTATION

Introduction

Automated hematology/coagulation analyzers are the workhorse of the hematology/coagulation laboratory. While instruments vary by manufacturer and type, the following basic objectives remain the same for each analyzer.

Prerequisites

The student should review the Automated Hematology Analyzer Instrument Manuals, Coagulation Analyzer Instrument Manuals, Slide Stainer Instrument Manuals, and Flow Cytometry Instrument Manuals for those instruments that will be employed during the practicum period.

Automated Cell Counters and Coagulation Instrumentation

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Correctly operate the automated cell counter(s) according to the manufacturer's directions to produce accurate quality control and patient results
2. Correctly operate the coagulation instrument(s) according to the manufacturer's directions to produce accurate quality control and patient results
3. Correctly record quality control data according to laboratory protocol
4. Correctly evaluate quality control data according to laboratory protocol
5. Correctly evaluate inaccurate instrument results, including a discussion of steps to correct the problem
6. Correctly correlate patient results with clinical significance (e.g., impact on diagnosis or treatment of associated disease) and clinical decision making
7. Assess critical pathways to facilitate diagnosis and to determine additional testing as warranted to the satisfaction of the instructor
8. Identify the basic operating components of the analyzer(s)
9. Locate the basic operating components of the analyzer(s) to the satisfaction of the instructor
10. Explain the function of each component of the analyzer(s)
11. Perform routine daily maintenance on the analyzer(s) according to the manufacturer's directions to the satisfaction of the instructor
12. Identify periodic (weekly, monthly, etc.) maintenance requirements according to the manufacturer's directions to the satisfaction of the instructor
13. Explain the function of each reagent used on the automated cell counter(s) and coagulation instrument(s)

14. State how reagents are stored when not in use on the analyzer
15. State the calibration schedule (frequency) for calibrating the analyzer(s)
16. Describe the procedure(s) for calibration of the analyzer(s) according to the manufacturer's directions
17. Correctly perform calibration(s) as required according to the manufacturer's directions
18. Explain where to find basic troubleshooting information about the analyzer
19. Participate in troubleshooting the analyzer(s) as appropriate to the satisfaction of the instructor
20. Discuss appropriate problem-solving steps for determining instrument/methodology problems, utilizing instrument manuals, laboratory procedure manuals, and information contained in package inserts
21. Justify the importance of documenting maintenance, quality control, and troubleshooting
22. Discuss the significance of clumped platelets
23. Correct an elevated MCHC due to an interfering substance (lipemia, icteric, and hemolysis)
24. Evaluate delta checks on white blood cells, hemoglobin and hematocrits, MCV, and platelets

Slide Stainer

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Correctly perform an adjustment of the stain, buffer, and rinse on the laboratory stainer as indicated according to the manufacturer's directions
2. Produce a quality-stained blood smear to the satisfaction of the instructor
3. Explain the function of each reagent used on the automated slide stainer
4. Correctly prepare reagents for use on the slide stainer according to the manufacturer's directions
5. State how reagents are stored when not in use on the slide stainer

Flow Cytometry Instrumentation

(When a Flow Cytometer is not available at the clinical site, students should refer to their text for review.)

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624, 433/434/633/634, and 627, the student will:

1. Discuss the basic principle of flow cytometry, including information obtained from forward and side scattered light
2. List common fluorescent dyes used in flow cytometry
3. Discuss hematological applications of flow cytometry
4. Discuss cellular applications of flow cytometry
5. Discuss flow cytometry markers used in the differentiation of various leukocytic disorders
6. Correctly operate the flow cytometer according to the manufacturer's directions, producing accurate quality control and patient results

DIFFERENTIALS, RBC MORPHOLOGY AND RBC & WBC DISORDERS

Introduction

The differential measures the percentage of each type of white blood cell in the peripheral blood.

Evaluation and interpretation of red blood cell morphology is an important component that accompanies the performance of a differential.

Prerequisite

The student should review the laboratory procedure manual for determination of when automated differentials need to be reviewed and the grading system used for evaluating red blood cell morphology.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Identify all the cells in the myelocytic, monocytic, and lymphocytic series
2. Discuss the major characteristics pertinent to each of the cells in the myelocytic, monocytic, and lymphocytic series
3. Compare and contrast all of the cells in the erythroid series
4. Differentiate among the following: eosinophils, basophils, lymphocytes, monocytes
5. Differentiate among the following: reactive lymphocytes, plasma cells, lymphoblasts
6. Differentiate platelets from other cells on a Wright's Stained blood smear
7. Correctly perform a successful platelet estimate from the Wright's Stained blood smear
8. Prepare good wedge smears to the satisfaction of the instructor
9. Prepare a good manual stained slide to the satisfaction of the instructor
10. Perform a white cell estimate and correlate with white count
11. Distinguish abnormal platelet shapes and large platelets

12. Explain the significance of abnormal platelet shapes and large platelets
13. Correctly calculate a corrected white count, based on the number of NRBC seen on the smear
14. Correctly differentiate the following on a Wright Stain smear:
    a. sickle cells
    b. acanthocytes
    c. echinocytes
    d. ovalocytes
    e. elliptocytes
    f. schistocytes
    g. target cells
    h. spherocytes
    i. macrocytes
    j. microcytes
    k. teardrop cells
    l. stomatocytes
15. Correctly grade the items in objective #14 on a Wright Stain smear
16. Correctly examine a blood smear for RBC morphology, assessing and grading the following:
    a. polychromasia
    b. basophilic stippling
    c. Howell-Jolly bodies
    d. Pappenheimer bodies
    e. hypochromia
17. Correctly identify malarial and babesian parasites
18. Correctly assess a blood smear for rouleaux
19. Correctly differentiate between normal and hypersegmented PMNs on a blood smear
20. Explain the significance of normal and hypersegmented PMNs on a blood smear
21. Correctly examine a stained smear to determine if the RDW (Red Cell Distribution Width) is correct
22. Correctly examine a Wright's stained blood smear for toxic granulation, toxic vacuoles, and Dohle bodies
23. Explain the significance of toxic granulation and Dohle bodies on a Wright’s stained blood

smear

24. Differentiate vacuolation in PMNs from other intra cellular structures.
25. Explain the significance of vacuolation in PMNs from other intra cellular structures
26. Distinguish between normal and pyknotic PMNs
27. Explain the significance of normal and pyknotic PMNs
28. Correctly identify smudge cells on a Wright's stained blood smear
29. Evaluate RBC and WBC abnormalities in relation to pathological conditions
30. Correctly perform differentials and grading of red cell morphology according to laboratory protocol
31. Compare and contrast three pathways of RBC metabolism identifying key intermediates as well as the relationship of each to RBC survival and function of hemoglobin
32. Discuss the function of ATP production as it relates to the RBC
33. Discuss Auer rods in terms of their appearance, composition, staining properties, and type of leukemia they are found in
34. Calculate RBC indices predicting what is expected on the peripheral blood smear
35. Explain the metabolic link that B^{12} and folic acid share indicating why a deficiency in either would result in megaloblastic maturation

BODY FLUIDS

Introduction

Enumeration and identification of cellular components of body fluids are needed for characterization of inflammatory, infectious, neoplastic, and immune alterations.

Prerequisite

The student should review the laboratory procedure manual for reporting of body fluid results.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 402/412/602/612, 423/424/623/624 and 433/434/633/634, the student will:

1. Determine the body source of each of the following fluids:
    - CSF
    - synovial
    - pleural
    - peritoneal

- pericardial
- thoracentesis

2. Determine color and clarity of each body fluid specimen and explain their significance
3. Determine:
    - the number of tubes normally taken for CSF (3-4).
    - which tubes go to which department and why.
4. Correctly perform a cell count on the following CSF specimens:
    - clear & colorless
    - slightly hazy and colorless
    - cloudy and white
    - cloudy and red
    - grossly bloody
    - amber and clear
5. Explain how to determine if a specimen was a bloody tap
6. Explain the significance of a 500:1 RBC to WBC ratio
7. Determine when a dilution is necessary
8. Determine what dilution to make
9. Correctly multiply the number of cells counted by the dilution factor to get an accurate result
10. Correctly make a cytospin preparation from body fluids, staining smears to the satisfaction of the instructor
11. Correctly examine a prepared smear of a body fluid, identifying the cells present
12. Correctly examine cytospin preparations
13. Correctly identify the cell types present
14. State the common characteristics (e.g., cell type) of:
    - viral meningitis
    - bacterial meningitis.
15. Explain why it is important to differentiate between viral meningitis and bacterial meningitis
16. Discuss the reasons why CSF from leukemic patients should always have a cell count and differential (or cytospin if available)
17. Explain the significance of crenated RBCs in CSF

18. Explain why body fluid cell counts should be performed immediately upon arrival in the laboratory

19. Distinguish a CSF that is contaminated with bone marrow from a non-contaminated CSF

20. Explain "xanthochromia" in body fluids, including the clinical significance of its presence

21. Explain the general characteristics of malignant cells

22. Correctly perform a cell count on various body fluids (e.g., synovial, pleural, peritoneal, pericardial)

ROUTINE AND MISC. HEMATOLOGY PROCEDURES

Introduction

Various hematology procedures can provide additional information regarding erythroid, leukocytic and platelet pathophysiology.

Prerequisite

The student should review the laboratory procedure manual for performance and reporting of test results.

Erythrocyte Sedimentation Rate

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. State the normal erythrocyte sedimentation rate (ESR) reference ranges for an adult male, adult female, and children

2. Discuss the procedure involved in setting up an ESR

3. Discuss anemia and its relationship to the ESR

4. Explain how coldness of the blood, polycythemia, rouleaux, and agglutination will affect the ESR

5. Explain how certain RBC shapes cause a decreased ESR

6. Examine correctly whether a specimen is acceptable for an ESR determination

7. Evaluate the ESR as a diagnostic tool

8. Perform correctly an ESR according to laboratory protocol

Reticulocyte Counts

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Explain the procedure used in staining reticulocytes
2. Describe the method for counting the reticulocytes
3. Describe how to calculate the percent of reticulocytes
4. Discuss the implications of considering only the % reticulocytes rather than the absolute number of reticulocytes
5. Clarify the type of stain that is used to visualize reticulocytes
6. Describe the significance of this type of stain in objective #5
7. Discuss the role of reticulocytes; include shift macrocytosis, response to stress, and normal reference range
8. Compare polychromasia on a smear to the reticulocyte count
9. Explain the importance of proper mixing of the specimen immediately before the smears are made
10. Discuss the clinical implications of the immature reticulocyte fraction (IRF)
11. Correctly perform a reticulocyte count according to laboratory protocol

Sickle Cell

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Explain the principle involved in solubility tests that analyze for the presence of sickling hemoglobin
2. Describe the technique and method used to set up a sample for a Sickle Solubility Test
3. Describe a quality control procedure that is acceptable for the above procedures
4. Discuss the importance of the Hemoglobin-S concentration in the solubility tests and the need to adjust for a low hemoglobin
5. Correctly perform a solubility test that will analyze for the presence of sickling hemoglobin following the procedure according to the manufacturer's directions

Glucose-6-Phosphate Dehydrogenase Screen

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Discuss the principle of the glucose-6-phosphate dehydrogenase (G6PD) screening test, including the clinical significance of a positive screening test

2. Discuss the problems involved with the test when using blood from a patient that has been transfused

3. Evaluate problems involved with the test when using blood from a patient that has a high percentage of reticulocytes, e.g., after a hemolytic episode

4. Discuss the function and importance of G6PD in the Hexose Monophosphate Shunt

Bone Marrows

Objectives 5 6

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. State the site from which bone marrow is most commonly aspirated

2. Review the general procedure of bone marrow aspiration

3. Explain the technique used by the Hematology technologists in preparing bone marrow smears and staining procedures

4. Define hypoplasia and hyperplasia of the bone marrow

5. State the normal myeloid: erythroid ratio of the bone marrow

6. Participate in as many bone marrow aspirations as possible to the satisfaction of the instructor

7. Examine at least one bone marrow sample under the microscope to the satisfaction of the instructor

Cytochemical Stains

Objectives 5 6

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Discuss the purpose for performing cytochemical stains

2. Discuss the principles of the following cytochemical stains:

    a. Periodic Acid Schiff

    b. Peroxidase

    c. Sudan Black

    d. NASDA/NASDA-F

    e. Non-specific esterase

    f. Chloracetate esterase

    g. Acid Phosphatase and Tartrate-resistant Acid Phosphatase (TRAP)

3. Interpret correctly the results from each of the stains listed in objective #2
4. Evaluate the expected results for each of the stains listed in objective #2 for the following disease states:
    a. Acute Lymphoblastic Leukemia
    b. Acute Myeloid Leukemia (M0, M1, M2, M3)
    c. Acute Myelomonocytic Leukemia
    d. Acute Monocytic Leukemia
    e. Erythroleukemia
    f. Acute Megakaryoblastic Leukemia
5. Compare and contrast the expected staining reactions for the stains listed in objective #2 for the following:
    a. Normal myeloid cell series
    b. Normal lymphocytes
    c. Normal monocytes
    d. Normal platelets, megakaryocytes
    e. Normal nucleated RBC's

Leukocyte Alkaline Phosphatase Stain

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Explain the principle in the Leukocyte Alkaline Phosphatase (LAP) staining procedure
2. Explain the procedure involved in the LAP stain
3. Explain the necessity of staining a normal control slide with each set of patient slides
4. Explain the necessity for establishing a normal range for each laboratory
5. Discuss the importance of the LAP test in distinguishing a leukemic myeloid process from a non- leukemic myeloid reaction
6. Evaluate the disease (condition) based on the LAP score
7. Correctly perform the LAP staining procedure according to laboratory protocol
8. Correctly report a Kaplow score according to laboratory protocol

Manual Platelet Count

Objectives 5
6

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. State the normal reference range for a platelet count
2. Explain the method for diluting a specimen for a manual platelet count
3. Correctly perform a dilution of a specimen for a manual platelet count according to laboratory protocol
4. State the reason for using ammonium oxalate as the reservoir diluent
5. Clarify the method employed in counting the platelet count
6. State the type of hemocytometer used, type of microscope used, area of hemocytometer counted, and the factor for performing a manual platelet count
7. Discuss the dimensions of the hemocytometer and the area used for platelet counts
8. Describe the method employed in doing a platelet estimate
9. Compare the platelet count and estimate, to determine if they correlate
10. Discuss the principle of the phase microscope
11. Discuss disease states that may have abnormal platelet counts or morphology
12. Explain how the patient's hematocrit and the thickness of the smear can affect the platelet estimate
13. Correctly perform manual platelet counts according to laboratory protocol

*Objectives are considered electives or enhancements to the basic clinical practicum educational experience.

*Urine Hemosiderin**

Objectives 5
6

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, 402/412 the student will:

1. Define urine hemosiderin
2. Discuss the significance of urine hemosiderin, including how it is formed
3. Clarify the procedure involved in the smear preparation
4. Explain the principle of the Prussian Blue stain
5. Correctly examine any specimens received for urine hemosiderin

6. Explain the procedure for performing a Prussian Blue stain
7. Correctly perform the procedure for a Prussian Blue stain
8. Discuss the importance of filtering reagents for a Prussian Blue stain
9. State the procedure for specimen collection

Nasal Smears*

Objectives 5
6

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Discuss the importance of nasal smears
2. Explain the procedure used to collect the specimens
3. Clarify the procedure used to prepare and stain the smears
4. Summarize the smear examination procedure
5. Correctly examine any nasal smears that are available

COAGULATION

Introduction

Laboratory tests performed in the coagulation laboratory evaluate hemostatic balance of the patient. Hemostatic imbalance can increase the risk of hemorrhage or thrombosis formation.

Prerequisite

The student should review the laboratory procedure manual for the performance and reporting of coagulation results.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624 and 433/434/633/634, the student will:

1. Explain platelet function following subendothelial exposure, including the steps involved in adhesion, release, and aggregation
2. State site of production of the proteins involved in coagulation, including factor VIII:C and factor VIII: VWF
3. Discuss the coagulation factors dependent on vitamin K for their complete synthesis
4. Discuss the role of vitamin K in the hepatic synthesis of these factors indicated in objective #3
5. List the coagulation factors that are components of the intrinsic pathway

6. Describe the coagulation factors that are components of the extrinsic pathway

7. Describe how the extrinsic pathway is initiated *in vivo*

8. Explain the action and function of antithrombin and its relationship to heparin

9. Clarify the function of protein C including site of production and the clinical significance of a protein C deficiency

10. Name components of hemostatic function that are measured by the bleeding time

11. Explain the principle of platelet aggregometry including the most common substances that either aggregate platelets directly or induce the release of platelet ADP

12. Discuss the principle of the prothrombin time (PT) test including reagents used and their major components, methodology, coagulation factors measured, and normal reference range

13. Compare prolonged prothrombin times with clinical conditions and/or disease states

14. Discuss the purpose of the International Normalized Ratio (INR) for reporting prothrombin time test results for patients who are undergoing oral anticoagulant therapy

15. Given the patient's prothrombin time, normal control value, and the International Sensitivity Index (ISI), correctly calculate the INR

16. Discuss the principle of the activated partial thromboplastin time (APTT) test including reagents used and their major components, methodology, coagulation factors measured, and normal reference range

17. Compare prolonged activated partial thromboplastin times with clinical conditions and/or disease states

18. Discuss the principle of "mixing studies" performed on patients with prolonged PT and/or APTT results

19. Discuss what is indicated when a prolonged patient APTT is "corrected" by the addition of normal plasma and what is indicated when a prolonged patient APTT is not "corrected" by the addition of normal plasma

20. Compare and contrast the principle of specific coagulation factor assay tests

21. Discuss the principle of the thrombin time test, including reagents used and methodology

22. Explain the principle of quantitative fibrinogen determinations using a modification of the thrombin time test, including reagents used and normal reference range

23. Correlate abnormal quantitative fibrinogen results with clinical conditions and/or disease states

24. Discuss the effect of the lupus-like anticoagulants on the PT, APTT, factor assay, and mixing studies

25. Indicate the action of lupus-like anticoagulants on both in vivo and in vitro coagulation systems

26. Compare the principles of the laboratory tests used most frequently to diagnose von

Willebrand's Disease for bleeding time, PT, APTT, factor VIII:C assay, factor VII, ristocetin cofactor activity, factor VIII: VWF antigen, and platelet aggregation studies

27. Compare patterns of inheritance for hemophilia A and hemophilia B

28. State the specific factor deficiency for each disorder: hemophilia A and hemophilia B

29. Explain the effect of circulating factor VIII:C antibodies on hemophilic patients

30. Explain the effect of vitamin K deficiency on PT and APTT results

31. Clarify the effect of coumarin compounds on the synthesis and activation of the vitamin K-dependent coagulation factors

32. Discuss the rationale for coumarin therapy, including the mode of administration

33. State optimal therapeutic range of the PT for patients on coumarin therapy

34. Describe the effect of coumarin therapy on the APTT

35. Explain the uses of therapeutic heparin and the effect this anticoagulant has on coagulation tests

36. Discuss the process of disseminated intravascular coagulation, including differentiating laboratory tests

37. List common clinical problems associated with excessive activation on the extrinsic pathway

38. Explain the effect of DIC on antithrombin, protein C, coagulation factor and platelet levels

39. Explain why examination of a peripheral blood smear is important when DIC is suspected

40. Compare and contrast the type of expected coagulation results (D-dimers, PT, APTT, thrombin time, platelet count, fibrinogen) in patients with DIC and associated fibrinolysis who are bleeding

41. Discuss different endpoint detection methodologies used to detect clot formation by coagulation analyzers

42. Explain the significance of improperly filled sodium citrate (blue top) tubes

43. Describe the proper steps to be taken when the situation in objective #42 arises

44. Explain the principle of the D-dimers test, the significance of elevated levels of D-dimers, and the importance of a negative D-dimers in terms of deep venous thrombosis

45. Discuss the laboratory procedures used in the determination of Factor V Lieden, APC resistance, Prothrombin mutation and hyperhomocysteinemia

46. Evaluate coagulation results in relation to pathological conditions

47. Discuss the clinical and laboratory implications of aspirin resistance

48. Discuss the clinical and laboratory implications of clopidogrel resistance

49. Explain the significance of reticulated platelets

50. Discuss the components of thromboelastography (TEG®) (e.g., R time, K time, alpha angle,

maximum amplitude, clot lysis at 30 minutes)

51. Correctly perform coagulation procedures (e.g., PT, APTT, fibrinogen, factor assays) according to laboratory protocol

52. Evaluate delta checks on PT, APTT, TT, and fibrinogen

MOLECULAR DIAGNOSTIC and IMMUNOLOGIC ASSAYS

Introduction

Molecular diagnostic testing is used for the diagnosis, prognosis, and monitoring of various hematopoietic and coagulation disorders.

Prerequisite

The student should review the laboratory procedure manual for the performance and reporting of various molecular diagnostic assays.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 375, 423/424/623/624, 433/434/633/634 and 493/693, the student will:

1. Identify each molecular diagnostic assay utilized in the affiliate hematology laboratory

2. Explain the principle of each assay listed in objective #1

3. Discuss the clinical significance for each assay listed in objective #1, (e.g., impact on diagnosis or treatment of associated disease)

4. Correctly perform molecular diagnostic assays according to manufacturer’s directions

5. List the assays and corresponding analytes in the affiliate's hematology laboratory that utilize diagnostic immunologic techniques

6. Explain the principle of each assay listed in objective #5

7. Discuss the clinical significance for each assay listed in objective #5, (e.g., impact on diagnosis)

8. Correctly perform immunological assays according to manufacturer’s directions

ASSESSMENT TOOLS

See below for:

Clinical Practicum Student Affective Evaluation Grading Scale
Clinical Practicum Practical Evaluation Instructions
Clinical Practicum Practical Evaluation Grading Rubric

All students must complete the Urinalysis Tally included as part of the Clinical Practicum.

Student Evaluation (see below) to obtain a passing grade in MMSC475/675 - completed on Trajecsys
Clinical Practicum Student Evaluation – Revised, 2020

Clinical Practicum Student Affective Evaluation Grading Scale

For items #1 through #15: Rate on 1-5 point scale below. Record rating in the column provided. Space is provided with each evaluation item for narrative appraisal. Any unsatisfactory evaluation **must** be documented. Please indicate strong points exhibited. The completed evaluation form must be discussed with the student at mid-point and end of the clinical practicum.

Performance Level	**Rating Value**	**Performance Indicators**
Outstanding	5	Contribution **far exceeds** what is normally expected of a student. Personal commitment to a high level of performance and professionalism is clear.
Exceeds Expectations	4	Seizes initiative in development and implementation of challenging projects. Accomplishments **exceed** requirements. Requires minimal direction.
Fully Satisfactory	**3**	**Performance is what is expected in senior clinical practicum. Does not require significant improvement. Errors are minimal and seldom repeated. Requires only normal supervision and follow-up.**
Less Than Satisfactory	2	Performance generally does not meet minimum requirements for senior clinical practicum. Errors are significant and frequently repeated. Requires close surveillance and guidance.
Unacceptable Performance	1	Has had sufficient exposure to have shown better performance. Does not grasp basic concepts no matter how many times they have been explained. Does not demonstrate commitment to this aspect of professional development.

Practical Evaluation Instructions **Student:**

Eval by: **Date:**

Clinical Hematology Practical

INSTRUMENT:

As detailed in the practical evaluation rubric, perform the following functions:

1. Perform daily maintenance procedures according to protocol.
2. Run controls and patient samples.
3. Evaluate acceptability of controls.
4. Interpret patient results.
5. Perform accurate differential analysis on assigned blood smear slides.
6. Perform accurate manual testing as assigned.
7. The following conditions apply to this practical (all that are marked with a √):

Time limit =

Use of instrument operating manuals is permitted

Use of course manuals is permitted

Other:

Clinical Hematology Practical Evaluation Grading **Student:**

Eval by: **Date:**

Separate into pre-analytical, analytical, post analytical.	**POINTS POSSIBLE**	**POINTS EARNED**	**COMMENTS**
Instrument startup completed accurately and efficiently, all necessary documentation accurately and legibly recorded	10		
Reagents and supplies utilized efficiently, no unnecessary waste of materials; proper documentation of reagent handling (i.e., expiration dates, etc.)	5		
Proper performance and documentation of preventative maintenance and troubleshooting procedures	5		
Temperatures of reagent refrigerators, incubators, etc. documented accurately and legibly	5		
Evaluate specimen integrity (i.e., specimen clotted, hemolyzed, QNS, etc.) by lab policy	10		
Appropriate QC processed, accurately evaluated, and documentation recorded accurately and legibly on instrument or LIS (i.e., identification of trends, shifts, etc.)	15		
Troubleshooting error messages, delta checks, or other instrument “needs” as applicable	5		
Unknown samples processed and accurately evaluated and reported	25		
Critical results noted and reported appropriately, all necessary documentation recorded accurately and legibly	15		
If applicable, verify calculations	5		
Other			
TOTALS:			
PRACTICAL GRADE:			

Final Clinical Practicum Grade will be calculated as detailed below:

Student Affective Evaluation 20% Average Points: total points / 15 = Look up grade below: X 20% = Example: 52/15 = 3.47 = B- (80 x 20%) = 16 5.00 – 4.50 = A = 95 4.49 – 4.00 = A- = 90 3.99 – 3.50 = B = 85 3.49 – 3.00 = B- = 80 2.99 – 2.50 = C = 75 2.49 – 2.00 = C- = 70 1.99 – 1.50 = D = 65 1.49 – 1.00 = D- = 60 <1.00 = F = 55	Written Assessment Ave. Score X .40 = Practical Score X .40 = Affective Score X .20 = Grade for Practicum = **PASS or FAIL**

A grade of INCOMPLETE will be recorded unless ALL practicum documentation is completed by the end of the semester. This includes attendance sheets, orientation checklists, and the completion of the online site evaluation for each clinical practicum.

MMSC 477/677 Clinical Microbiology & Immunology Practicum

COURSE SYLLABUS

STUDENT LEARNING GOALS

Student learning goals for the clinical microbiology & immunology practicum focus on active participation in daily laboratory operations and personal performance as a laboratory professional. Thus, the learning goal for the technical portion of the clinical microbiology & immunology practicum is to facilitate and enhance the student's application of clinical microbiology & immunology theory, laboratory experience, and test data interpretation learned in campus courses to an active clinical laboratory setting. To accomplish this goal, students will apply principles of pre-analytical, analytical, and post-analytical components of laboratory practice in clinical microbiology & immunology to the performance of laboratory operations in a contemporary clinical setting. The learning goal for the professional component is for students to attain high level interpersonal performance so as to interact professionally with fellow staff and all consumers of laboratory testing. The ultimate outcome of a successfully completed practicum experience is the ability to perform testing of the highest quality to support the laboratory's role in quality patient care and safety. Student achievement during this practicum course will lay the foundation for success as an entry-level medical laboratory scientist.

COURSE DETAILS

This is a clinical practicum course, and it will meet at a clinical affiliate to be determined by the University instructor. Students will be notified of this location prior to the commencement of the clinical practicum.

MODES OF INSTRUCTION

Clinical faculty will utilize various methods of instruction, including but not limited to a combination of:

1. Clinical specimens
2. Quality control materials
3. Microbiology automated analyzers
4. Proficiency samples previously analyzed and stock cultures
5. Gram stain slides, acid-fast smears, fungal smears, and thick and thin blood smears
6. Positive O&P specimens
7. Case studies

Students will receive instruction about proper operation and maintenance of equipment, specimen processing, quality control, use of the laboratory information system, and result interpretation and reporting mechanisms specific to the clinical facility where they are assigned.

METHODS OF ASSESSMENT

Upon the completion of this course, based upon affective, cognitive, and psychomotor objectives, the student must achieve a final minimum average of 70% (C-) on the assessment tools utilized in this course. The clinical instructor will administer written quizzes. In addition, the clinical instructor will assign papers or projects that are relevant to the practicum. This component of the Evaluation comprises 40% of the practicum grade.

A practical examination is another means of assessment employed by the clinical instructor. The instructions and rubric for the practical examination will be provided to the student prior to commencing the practical examination. The clinical instructor will complete the practical grading rubric and will return it to the University instructor. This component of the Evaluation comprises 40% of the practicum grade.

Affective assessment is incorporated into the mid- and final-evaluation process. A mid-evaluation will be completed by the clinical instructor and will be discussed with the student. If there are any issues to be addressed, this will also be shared with the University instructor. The final MMSC 477/677 Clinical Microbiology & Immunology Practicum Evaluation will be completed by the clinical instructor and discussed with/reviewed by the student. The affective component on the final Evaluation comprises 20% of the practicum grade.

A written final examination will be administered by the University instructor at the conclusion of the practicum. The University-administered written final examination component of the Evaluation does not affect the practicum grade but is included on the form.

A sample MMSC 477/677 Clinical Microbiology & Immunology Practicum Evaluation can be found at the end of this syllabus.

COURSE PREREQUISITES

MMSC 438/439 or MMSC 638/639

RESTRICTIONS: Open to medical laboratory science students only.

COURSE OBJECTIVES RELATED TO SPECIFIC CONTENT AREAS

Upon the completion of this course, based upon the objectives detailed in this document, the student must achieve a final minimum average of 70% on the assessment tools utilized in this course.

I. Specimen Management/Safety

II. Quality Control / Quality Assessment / Total Quality Management

III. Blood Cultures

IV. Respiratory Cultures

V. Stool Cultures

VI. Urine Cultures

VII. Anaerobic Cultures

VIII. Miscellaneous Cultures

IX. Susceptibility Testing

X. Mycology

XI. Mycobacteriology

XII. Parasitology

XIII. Virology

XIV. Molecular Diagnostic and Immunologic Assays

SPECIMEN MANAGEMENT/SAFETY

Introduction

Thorough knowledge of safety procedures is essential before performing any duties in the clinical laboratory which may be hazardous to personnel. The microbiology department is responsible for monitoring departmental criteria for specimen acceptance, processing of various testing, evaluating, and reporting laboratory results. The first step in the accurate diagnosis of infectious diseases is the proper collection and handling of specimens. These pre-analytical, analytical, and post-analytical factors are essential for quality assessment in the laboratory. Proper specimen handling involves the following steps:

- correct identification of patients
- collecting the appropriate specimen
- correct time for specimen collection – blood cultures, etc.
- correct identification of special handling – ice, prechilled tubes, spin immediately, etc.
- collect the specimen correctly
- correct use of appropriate specimen containers
- correct labeling of forms and containers
- timeliness of transport
- correctly logging the specimen in the laboratory
- correct identification of special procedures based on suspected pathogens
- correct handling in the laboratory with respect to selection of growth media, stains, incubation times and temperatures
- correct reporting of results

Prerequisite

The student will familiarize herself/himself with the overall management of the microbiology department.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 415/416, 493/693, 428/429/628/629 and 438/439/638/639, the student will:

1. Explain the importance of safe and proper specimen collection and transport

2. Evaluate the criteria for determining specimen quality
3. State corrective actions to be taken to resolve specimen quality problems
4. Discuss the specimen management system used by the microbiology laboratory
5. Demonstrate accurately the ability to accession specimens according to laboratory protocol
6. Demonstrate accurately the ability to label specimens according to laboratory protocol
7. Distribute appropriately specimens to workstations to the satisfaction of the instructor
8. Complete correctly daily worksheets according to laboratory protocol
9. Report and/or call results according to laboratory protocol to the satisfaction of the instructor
10. Identify correctly which specimen is appropriate for the culture requested, e.g., anaerobic cultures are not performed on stool specimens
11. Examine correctly specimens for acceptance or rejection using laboratory guidelines
12. Document correctly specimen rejection according to laboratory guidelines
13. Demonstrate correctly the ability to enter patient information and culture results into a laboratory information system (LIS) if applicable
14. Demonstrate proper technique in preparing smears for direct microscopic examination according to laboratory protocol to the satisfaction of the clinical instructor
15. For each patient specimen, choose correctly appropriate media, proper atmospheric conditions, and incubation temperatures and times according to laboratory protocol
16. Select potentially clinically significant isolates grown on laboratory media for identification
17. Perform appropriate biochemical and molecular biology tests for the identification of microorganisms, according to laboratory protocol, to the satisfaction of the laboratory instructor
18. Evaluate the results of biochemical and molecular biology tests to determine the most likely identification of microorganisms
19. Explain the rationale for use of the biological safety cabinet
20. Utilize correctly safe techniques, and personal protective equipment, in handling and disposal of infectious materials according to laboratory protocol
21. Explain the function of an autoclave
22. State the pressure (p.s.i.), temperature, and time most commonly used for sterilization of media and contaminated laboratory waste
23. Comply with established safety regulations and regulations governing regulatory compliance related to laboratory practice to the satisfaction of the instructor

QUALITY CONTROL / QUALITY ASSESSMENT / TOTAL QUALITY MANAGEMENT

Introduction

Quality is of utmost importance in every laboratory. Today's laboratories have a variety of programs in place to control, assess, and improve their quality. The purpose of quality control in the microbiology department is to ensure that the final product has an acceptable degree of conformity within previously established tolerance limits. It is only by constant self-evaluation of the laboratory's performance by thorough monitoring of reagents, equipment, culture media, and proficiency that a high level of expertise and accuracy can be attained.

Prerequisite

The student should read the department's quality control (QC), quality assessment (QA), total quality management (TQM), individualized quality control plan (IQCP) and/or continuous quality improvement (CQI) policies.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 415/416, 493/693, 428/429/628/629 and 438/439/638/639, the student will:

1. Compare and contrast QC, QA, and TQM
2. Evaluate laboratory QC data according to laboratory protocol
3. Demonstrate the ability to identify appropriate corrective action when data fall outside of the control range to the satisfaction of the instructor
4. Justify the rationale for the QC program in the clinical microbiology laboratory
5. List specific areas involving testing in the clinical microbiology laboratory which require surveillance
6. Discuss the criteria and frequency of media performance evaluations
7. List each media component that allows for the selection and differentiation of organisms
8. Explain the mechanism of each media component that allows for the selection and differentiation of organisms
9. Evaluate reactivity of media, pertaining to microbial growth, using proper quality control procedures
10. Discuss the necessity of written record keeping for: 1) all quality control results, 2) periodic review of surveillance records, and 3) corrective action documentation
11. Discuss accreditation requirements with regard to thermometers, CO^2 incubators, and sterilization procedures (i.e., autoclaving)
12. Discuss the use of proficiency testing
13. Discuss the impact of TQM on laboratory operations, including relevance to the

pre-analytical, analytical, and post-analytical stages of the testing process

14. Apply correctly principles of TQM on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process

15. Discuss the role of the medical laboratory scientist in maintaining laboratory quality

BLOOD CULTURES

Introduction

Blood is one of the most important specimens received in the microbiology laboratory. Quick and accurate reporting of preliminary and final results can have lifesaving effects for the patient. The blood specimen must be handled correctly from collection to subculturing for the results to be valid.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. Explain proper blood culture collection procedures, including the recommended number of cultures to be collected and total blood volume relating to patient age

2. Identify the proper incubation temperatures, times, and growth requirements for microorganisms typically isolated from blood cultures

3. List the major components of blood culture media

4. Justify the inclusion of the major components of blood culture media

5. Identify correctly visual signs of a positive blood culture

6. Select correctly, procedures for the handling of positive cultures

7. Perform correctly procedures for the handling of positive cultures according to laboratory protocol

8. Explain the procedure and principle of automated continuous monitoring blood culture detection systems used in the affiliate's laboratory

9. Name the most frequently detected organisms isolated from blood cultures

10. Differentiate correctly, possible blood culture contaminants from pathogens

11. Discuss the significance of a positive blood culture

12. Perform correctly blood culture Gram stains according to laboratory protocol

13. Interpret correctly blood culture Gram stains read microscopically according to laboratory protocol

14. Explain the principle of the acridine orange stain and the reason for using it

15. Perform blood culture acridine orange stain according to laboratory protocol to the satisfaction of the instructor

16. Interpret correctly blood culture acridine orange stain read microscopically according to laboratory protocol

17. Demonstrate to the satisfaction of the clinical instructor positive blood culture work-up to include:

    a. proper subculturing

    b. biochemical identification

    c. susceptibility testing

    d. molecular testing methods

18. Identify colony morphology and growth characteristics of pathogenic organisms commonly isolated from blood culture specimens to the satisfaction of the laboratory instructor

19. Explain the affiliate's procedure for reporting positive blood cultures

20. Correlate positive blood cultures with positive cultures from other sites for the same patient

21. Correlate culture results with patient history and presentation

RESPIRATORY CULTURES

Introduction

Respiratory cultures include all routine cultures of throat, nose, nasopharynx, ear, sputum, endotracheal tube aspirates, transtracheal aspirates and bronchial washings/lavages. These cultures are difficult to interpret, but with the help of a Gram stain, potential pathogens and contaminants may be recognized and differentiated from those organisms representing "normal respiratory flora."

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. List examples of all respiratory specimens possibly encountered in the clinical microbiology laboratory

2. Perform correctly direct Gram stains of respiratory specimens according to laboratory protocol

3. Evaluate expectorated sputum culture rejection criteria by Gram stain review

4. Interpret correctly direct Gram stains of respiratory specimens read microscopically according to laboratory protocol

5. List organisms considered normal respiratory flora
6. List organisms commonly considered pathogenic from different respiratory sites
7. Explain the rationale for selecting primary plating media for each respiratory specimen
8. Select correctly primary plating media for each respiratory specimen
9. Plate correctly all respiratory specimens to appropriate media
10. Identify the proper collection, incubation temperatures, times, and growth requirements for respiratory pathogens
11. Describe colony morphology and growth characteristics of normal flora and pathogens
12. Differentiate correctly pathogens from normal flora in respiratory cultures
13. Correlate colony morphology and growth characteristics of pathogenic organisms commonly isolated from respiratory specimens to the satisfaction of the laboratory instructor
14. Quantify correctly potential pathogens in respiratory cultures
15. Correlate direct specimen Gram stains with culture results
16. Determine appropriate biochemical tests or supplementary procedures required for the identification of significant isolates, e.g., X and V factor requirements for *Haemophilus* spp.
17. Perform correctly antimicrobial susceptibility testing as required, evaluating their appropriateness with regard to organism isolation
18. Justify the rationale for use of transtracheal aspiration for collection of respiratory specimens
19. Explain the principle of the agglutination test for the identification of *Streptococcus pyogenes* and other beta-hemolytic streptococci
20. Correlate culture results with clinical history and presentation
21. Evaluate respiratory cultures for epidemiologic patterns and problems
22. Evaluate the special procedures required for the isolation of species from the following genera: *Mycobacterium, Nocardia, Actinomyces*, *Bordetella*, *Mycoplasma*, *Legionella*, as well as fungi and viruses from the respiratory tract

STOOL CULTURES

Introduction

In most clinical laboratories, a stool specimen submitted for routine culture is examined for *Salmonella*, *Shigella*, enterohemorrhagic *E. coli*, and *Campylobacter*. Proper media selection and rapid identification procedures are important tools for the microbiologist. The primary care provider must alert the laboratory to look for other suspected pathogens that might include *Yersinia*, *Vibrio*, *Aeromonas*, *Pleisiomonas shigelloides*, *Staphylococcus aureus*, *Clostridioides difficile*, and yeast.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. List the major bacterial pathogens found in stool specimens and bacterial constituting normal microbiota
2. List each media component that allow for the selection and differentiation of all bacterial pathogens encountered in stool specimens
3. Explain the mechanism of each media component that allows for the selection and differentiation of all bacterial pathogens encountered in stool specimens
4. Explain the growth requirements and selective and differential media necessary for the isolation of:
    a. *Campylobacter*
    b. *Salmonella* and *Shigella*
    c. *Vibrio, Aeromonas* and *Plesiomonas*
    d. *Yersinia*
    e. *Staphylococcus aureus*
    f. enterohemorrhagic *E. coli*
    g. yeast
5. Identify the proper collection, transport media, incubation temperatures, times, and growth requirements for pathogens typically encountered in stool cultures
6. Examine specimens for leukocytes utilizing direct stool smears to the satisfaction of the laboratory instructor
7. Identify correctly colonies of normal fecal microbiota on all types of media
8. Identify correctly suspicious colonies of possible enteric pathogens on all differential and selective media
9. Select correctly the proper biochemicals, molecular biology methods, and serotyping to identify all pathogens
10. Inoculate correctly the proper biochemicals, and serotyping, to identify all pathogens
11. Perform antimicrobial susceptibility testing on appropriate stool pathogens to the satisfaction of the laboratory instructor
12. Perform correctly slide agglutination tests for serogrouping *Salmonella* and *Shigella*
13. Explain what should be done if an organism does not serotype because of the presence of Vi antigen
14. Identify risk factors for *Clostridioides difficile* infection

15. Compare and contrast the different methods of *Clostridioides difficile* detection including: 1) bacterial cultures, 2) ELISA toxin assay, 3) glutamate dehydrogenase assay and 4) PCR

16. Justify the rationale for screening stools for non-lactose fermenters

17. Justify the rationale for screening stools for oxidase positive, gram-negative rods

18. Correlate culture results with patient history and presentation

URINE CULTURES

Introduction

Urinary tract infection is one of the most common bacterial diseases. The urine specimen is easy to obtain and can be collected in several different ways. A quantitative culture result can help diagnose significant bacteriuria and is performed by most laboratories.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. Compare the different methods employed to obtain urine specimens suitable for microbiologic analysis

2. Plate urine specimens on the appropriate media to the satisfaction of the laboratory instructor

3. Justify the use of each primary plating medium

4. Identify the proper incubation temperatures, times, and growth requirements for urine cultures

5. Quantify colonies of urine cultures plated with calibrated loops (e.g., 0.01 and 0.001 mL) to the satisfaction of the laboratory instructor

6. Evaluate colony counts that do not correspond on both plates from the same urine and explain possible discrepancies

7. Discuss the significance of colony counts as related to the methods of urine collection

8. List organisms that are often urine contaminants

9. Differentiate correctly grossly contaminated specimens from those which should be considered likely to contain pathogens

10. Identify colony morphology and growth characteristics of pathogenic organisms commonly isolated from urine specimens to the satisfaction of the laboratory instructor

11. Select correctly media to isolate overgrown organisms on subculture

12. Select correctly appropriate biochemical tests for the identification of isolates

13. Perform antimicrobial susceptibility testing as required to the satisfaction of the instructor
14. Compare available urine screening methods
15. List transport media available for urine specimens to decrease overgrowth of contaminants
16. Correlate culture results with patient history and presentation

ANAEROBE CULTURES

Introduction

Anaerobic bacteria are found in a variety of clinical specimens and often are involved in clinically significant infections. Because antimicrobial therapy may depend on the species involved, it is important for the laboratory to isolate and identify these etiologic agents.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. Compare the following groups of bacteria in relation to their oxygen requirements:
    a. obligate aerobes
    b. obligate anaerobes
    c. microaerophiles
    d. facultative anaerobes
    e. aerotolerant anaerobes
2. Identify correctly anaerobes found as normal microbiota in:
    a. skin
    b. upper respiratory tract
    c. gastrointestinal tract
    d. genitourinary tract
3. Discuss the types of infectious diseases commonly caused by anaerobes or their toxins
4. Evaluate the types of specimens that are appropriate for the diagnosis of specific anaerobic infections
5. List specimens that are typically unacceptable for anaerobic culture
6. Explain the techniques and importance of proper collection and handling of anaerobic specimens

7. Justify the rationale for the use of:

    a. primary anaerobic plating media

    b. enrichment broth media

    c. primary aerobic plating media

8. List the key components of primary plating media used for the isolation of anaerobic bacteria

9. Justify the use of the key components of primary plating media in culturing for anaerobic bacteria

10. Justify the rationale for the aerotolerance test on all anaerobic isolates

11. Select incubation temperature and time for anaerobic culture for each clinical specimen to the satisfaction of the laboratory instructor

12. Compare the anaerobic incubation systems in use at the affiliate microbiology laboratory (as applicable):

    a. Gas-Pak

    b. evacuation-replacement jar

    c. glove box (anaerobic hood)

    d. Bio-Bag

    e. oxyrase® plates

    f. Anoxomat system

13. Describe the microscopic, colony and biochemical characteristics of selected anaerobes including:

    a. Clostridium perfringens

    b. Fusobacterium nucleatum

    c. *Bacteroides fragilis* group

    d. Prevotella melaninogenica

    e. *Porphyromonas* spp.

    f. *Actinomyces* spp.

    g. *Peptococcus/Peptostreptococcus/Peptoniphilus* spp.

    h. Propionibacterium acnes

    i. *Veillonella* spp.

14. Correlate Gram stains of direct smears or enrichment broths with culture results

15. Identify medically important anaerobic genera of:

    a. gram-negative rods

b. gram-negative cocci

c. gram-positive cocci

d. gram-positive spore-forming rods

e. gram-positive non spore-forming rods

16. Justify the rationale for differentiating the *Bacteroides fragilis* group from other anaerobic gram- negative rods

17. Identify anaerobic isolates with one or more of the following systems to the satisfaction of the laboratory instructor:

    a. conventional biochemicals

    b. micro methods dependent on growth of viable cells

    c. rapid enzyme systems not dependent on bacterial growth

    d. molecular biology methods

18. Describe the methods of performing anaerobic antimicrobial susceptibility testing

19. Discuss the problems encountered in performing anaerobic antimicrobial susceptibility testing

20. Correlate culture results with patient history and presentation

MISCELLANEOUS CULTURES

Introduction

Miscellaneous cultures include all routine cultures of tissue, bone, CSF and other body fluids, wounds, genital tract, catheter tips, etc. Miscellaneous cultures are all routine cultures other than respiratory specimens, stools, anaerobic cultures, urines, and blood cultures, which have individual unit objectives.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. List examples of miscellaneous specimens acceptable for culture

2. List commonly detected normal microbiota and pathogenic isolates recovered from each miscellaneous source

3. Differentiate sterile from non-sterile sites that might have normal microbiota

4. Discuss the predisposing factors allowing normal microbiota to cause infection

5. Justify the use of each of the primary plating media for each miscellaneous specimen

6. Demonstrate specimen plating to appropriate media to the satisfaction of the laboratory instructor

7. Identify the proper incubation temperatures, times, and growth requirements for each miscellaneous culture

8. Perform correctly direct Gram stains of miscellaneous specimens according to laboratory protocol

9. Interpret correctly direct Gram stains of miscellaneous specimens read microscopically according to laboratory protocol

10. Interpret correctly Gram stains of bacterial culture growth read microscopically according to laboratory protocol

11. Identify colony morphology and growth characteristics of pathogenic organisms commonly isolated from miscellaneous specimens to the satisfaction of the laboratory instructor

12. Explain the growth requirements and selective and differential media necessary for the isolation of pathogens from miscellaneous specimens

13. Differentiate correctly commensals from potential pathogens

14. Select correctly proper media for subculture of potential pathogens

15. Select correctly the proper biochemical and molecular biology methods to identify all pathogens

16. Evaluate culture results with respect to type of specimen submitted

17. Correlate direct specimen Gram stains with culture growth

18. Correlate culture results with clinical history and presentation

19. Perform antimicrobial susceptibility tests as required to the satisfaction of the laboratory instructor

20. Evaluate appropriate sensitivity patterns specific for each microorganism tested

21. Perform correctly a wet preparation for trichomonads

22. Interpret correctly a wet preparation for trichomonads

23. If available, observe molecular testing methods used for the detection/identification of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

24. Explain the theory for each molecular testing methods used for the detection/identification of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

25. Correlate culture results with patient history and presentation

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Introduction

One of the most important services offered by the microbiology laboratory to the attending physician is

the determination of the antimicrobial susceptibility pattern of bacterial pathogens by standardized methods.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. Compare and contrast the methods available in antimicrobial susceptibility testing (e.g., minimal inhibitory concentration vs. minimal bactericidal concentration)
2. For the Kirby-Bauer (K-B) method:
    a. describe the principle and procedure
    b. choose correctly the appropriate test medium and incubation conditions for fastidious organisms such as *Haemophilus influenzae*, *Streptococcus pneumoniae,* and *Neisseria gonorrhoeae.*
    c. describe the appropriate culture conditions for detecting methicillin-resistant *Staphylococcus aureus* (MRSA)
3. Discuss the effects the following factors have on the K-B method:
    a. blood
    b. cations
    c. pH
    d. inoculum size
    e. temperature
    f. agar depth
    g. thymidine
    h. length of incubation
    i. atmospheric conditions
4. Select correctly appropriate antimicrobial agents for testing:
    a. gram-positive organisms
    b. gram-negative organisms
    c. anaerobic organisms
    d. mycobacteria/actinomycetes
    e. yeast

5. If appropriate, perform a K-B antimicrobial susceptibility test according to laboratory protocol to the satisfaction of the laboratory instructor

6. Interpret correctly a K-B antimicrobial susceptibility test

7. Describe the storage requirements for antimicrobial disks and Etest strips

8. Identify the major antimicrobial families

9. List agents found in each major antimicrobial family and the mechanism of microbial inhibition employed by each commonly used family

10. Define "beta-lactam" and "penicillinase-resistant" antibiotics

11. Give an example of “beta-lactam” and “penicillinase-resistant” antibiotics

12. Perform correctly an assay to detect beta-lactamase production

13. Identify antimicrobial agents which are effective against *Mycobacterium* spp.

14. Identify antimicrobial agents which penetrate the blood brain barrier

15. Identify antimicrobial agents used primarily for urinary tract infections

16. List the attributes of an ideal antimicrobial agent

17. Justify performing direct susceptibility tests on clinical materials

18. For the agar dilution minimal inhibitory concentration (MIC) method:

    a. describe the principle and procedure

    b. discuss the preparation of the antimicrobial agents and their dilution

    c. discuss the preparation of the inoculum

19. For the broth microdilution MIC method:

    a. discuss the principle and procedure

    b. discuss the significance of cation supplemented medium

    c. discuss the storage conditions for MIC trays

    d. discuss the alternative methods of inoculum preparation

    e. discuss the rationale for purity checks on inocula

20. If appropriate, perform a broth microdilution antimicrobial susceptibility test according to laboratory protocol to the satisfaction of the laboratory instructor

21. Interpret correctly a broth microdilution antimicrobial susceptibility test

22. For quality control (QC) of susceptibility testing:

    a. discuss the rationale for QC testing

    b. discuss the required frequency of testing for different systems

c. list the QC organisms required for the K-B and MIC procedures

d. discuss acceptable methods for the acquisition and propagation of QC strains

e. discuss corrective measures for out of control results

23. Correlate MICs to blood levels of antimicrobial agents

24. Explain therapeutic considerations in the selection of appropriate antimicrobial therapy

25. Explain the principle and rationale of the following special screening tests:

a. beta-lactamase

b. extended-spectrum beta-lactamase (ESBL)

c. carbapenemase testing (e.g., Carba NP, mCIM, or molecular testing)

d. vancomycin-intermediate and resistant *Staphylococcus aureus* (VISA/VRSA)

e. vancomycin-resistant *Enterococci* (VRE)

f. methicillin-resistant *Staphylococcus aureus* (MRSA)

g. inducible-clindamycin resistance (D-test)

h. penicillin-resistant *Streptococcus pneumoniae* (PRSP)

MYCOLOGY

Introduction

Since symptoms of fungal infection are often nonspecific and appear similar to other infections, it is especially important for the physician to gather all pertinent information regarding the patient's medical history, background, and travel. This information must be communicated to the microbiology laboratory so that proper specimens will be collected and the correct media inoculated. Complete identification of yeasts and fungi is especially important today due to the increased number of immunocompromised patients. It has become harder for the physician and microbiologist to distinguish between pathogen and nonpathogen as many organisms formerly termed nonpathogens have now been shown to be opportunistic pathogens.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 438/439/638/639, the student will:

1. Describe safety precautions, including the use of biological safety cabinets, for handling fungal cultures

2. List each fungal medium component that allows for the selection of fungal isolates and inhibition of contaminating bacteria

3. Explain the mechanism of each fungal medium component that allows for the selection of

fungal isolates and inhibition of contaminating bacteria

4. Identify the proper incubation temperatures, times, and growth requirements for fungal cultures

5. Inoculate fungus specimens onto appropriate media to the satisfaction of the laboratory instructor

6. Describe the principles of the procedures for direct microscopic detection of fungi in specimens and the identification of fungi in cultures

7. Perform correctly the procedures for direct microscopic detection of fungi in specimens and the identification of fungi in cultures

8. Interpret correctly the direct methods of detecting fungi in clinical specimens read microscopically according to laboratory protocol

9. Interpret correctly the methods of detecting fungi in cultures read microscopically according to laboratory protocol

10. Differentiate correctly fungi isolated as nonpathogens or contaminants versus those considered pathogenic

11. Identify the important dimorphic fungi, growth requirements for mold and yeast phase, endemic areas, and associated diseases to the satisfaction of the laboratory instructor

12. Explain the rationale for complete identification of yeasts and fung.

13. Compare and contrast the different methods for identifying yeasts, including commercial methods

14. Describe the pathogenic *Actinomycetes*, including related organisms and the diseases that they cause

15. Describe methods for identifying molds

MYCOBACTERIOLOGY

Introduction

Mycobacteria are acid-fast aerobic bacilli which typically grow very slowly compared to other aerobic bacteria. For this reason, specimens that might contain normal microbiota (e.g., respiratory specimens) must be "decontaminated" prior to plating so that overgrowth does not occur. Direct and concentrated smears for acid fast bacilli, therefore, may provide for a rapid presumptive diagnosis of *Mycobacterium tuberculosis*. Colonies of *Mycobacterium tuberculosis* may take 6 to 8 weeks for growth and identification.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629 and 438/439/638/639, the student will:

1. List safety measures that must be employed in processing cultures for acid-fast bacilli (AFB)
2. Justify the use of safety measures when processing specimens and cultures for mycobacteria
3. Discuss the appropriate digestion/decontamination procedure as outlined in the procedure manual for contaminated specimens
4. Select correctly the appropriate digestion/decontamination procedure as outlined in the procedure manual for contaminated specimens
5. Perform the appropriate digestion/decontamination procedure as outlined in the procedure manual for contaminated specimens to the satisfaction of the laboratory instructor
6. Justify the use of each component in the digestion/decontamination procedure
7. Identify specimens which do not require decontamination
8. Perform correctly direct plating of cultures, utilizing appropriate media, incubation times and temperatures
9. Compare the media, incubation times, incubation temperatures, and growth conditions for the growth of the most commonly isolated mycobacteria
10. Discuss the necessity for a gastric lavage
11. Explain the procedure for processing a bronchial lavage for AFB
12. Perform correctly both the Ziehl-Neelsen (or Kinyoun's) and fluorochrome stains for mycobacteria, on direct and concentrated smears according to laboratory protocol
13. Describe DNA probe technology and mass spectrometry for identification of mycobacteria
14. Describe colony morphology and growth characteristics of pathogenic mycobacteria commonly isolated from clinical specimens
15. Identify colony morphology and growth characteristics of pathogenic mycobacteria commonly isolated from clinical specimens to the satisfaction of the laboratory instructor
16. Select correctly appropriate biochemical tests for the identification of pathogenic organisms
17. Identify correctly *M. tuberculosis* by accurately interpreting the following test results:
    a. rate of growth
    b. pigment production
    c. catalase (room temperature and 68◦C)
    d. niacin
    e. nitrate
    f. molecular biology methods
18. Correlate culture results with patient history and presentation

PARASITOLOGY

Introduction

The accurate identification of ova and parasites requires expertise. It is important for the clinical scientists and the primary care provider to communicate a patient's history (i.e., immunosuppression) or travel to areas of the world where parasites are endemic.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 428/429/628/629, the student will:

1. Describe appropriate collection techniques for stool specimens including timing, number of specimens and special procedures
2. List specimens other than stool which may be submitted for detection of parasites
3. List parasites which might be present in the specimens identified in objective #2
4. List substances which would interfere with a fecal exam for parasites
5. Compare and contrast several stool preservatives, including advantages and disadvantages of each
6. Explain the formalin-ethyl acetate sedimentation procedures for examining stool specimens
7. Perform the formalin-ethyl acetate concentration procedure on stool specimens following the laboratory protocol to the satisfaction of the laboratory instructor
8. Interpret correctly direct saline wet mounts of watery stools for parasites read microscopically according to laboratory protocol
9. Interpret correctly iodine wet mounts of stool concentrates for parasites read microscopically according to laboratory protocol
10. Justify the need of the ocular micrometer for parasitology
11. Calibrate correctly the ocular micrometer
12. Use correctly the ocular micrometer when measuring the size of microscopic objects
13. Describe common methods of staining parasites
14. Based on morphology, differentiate among the intestinal protozoa
15. Based on morphology, differentiate among the intestinal helminths
16. Based on morphology, differentiate each stage of the life cycle of *Plasmodium vivax, P. falciparum, P. malariae*, and *P. ovale* to the satisfaction of the instructor
17. Explain methods of examining specimens for *Cryptosporidium*, including the modified acid-fast stain and fluorescent stains

18. Perform correctly a modified acid-fast stain for *Cryptosporidium* following the laboratory protocol

19. Interpret correctly a modified acid-fast stain for *Cryptosporidium* to the satisfaction of the laboratory instructor

20. Prepare stool smears using the trichrome stain according to laboratory protocol to the satisfaction of the laboratory instructor

21. Interpret correctly stool smears using the trichrome stain

22. If available, correctly perform an antigen detection assay for *Giardia* and/or *Cryptosporidium*

23. Compare the methods used to prepare and examine blood smears for parasites

24. Describe the morphology of *Babesia* spp.

VIROLOGY

Introduction

The commercial availability of rapid detection systems for the diagnosis of viral infections makes this aspect of microbiology increasingly accessible to most clinical laboratories. A laboratory may elect to limit its services to the isolation of only herpes simplex viruses, cytomegalovirus, and/or respiratory viruses by utilizing one of the several available rapid systems (e.g., shell vial cultures). With the improved accuracy of molecular assays for the detection of viruses, few laboratories today still attempt viral isolation in cell lines. *Chlamydia trachomatis*, an obligate intracellular bacterium requiring cell culture for growth, is therefore included in this unit. This infectious agent is also generally detected by molecular assays. The objectives can only be completed at affiliate locations that offer virology services.

Prerequisite

The student will complete assigned readings in procedure manuals, handouts, and reference books.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 415/416 and 428/429/628/629, the student will:

1. List the types of specimens suitable for viral cultures

2. Describe the collection methods of clinical specimens for the detection of viruses

3. Explain the procedures for the proper handling, transport, and storage of viral specimens

4. Compare and contrast primary, semi-continuous (finite), and continuous cell lines

5. List cell cultures and appropriate specimens used for the rapid isolation of herpes simplex virus

6. Describe the media and key supplements used to propagate cell cultures

7. If appropriate, prepare correctly clinical specimens for inoculation onto cell monolayers for the recovery of viruses

8. Describe the cytopathic effects produced by clinically significant viruses
9. If appropriate, perform correctly a molecular biology assay on a clinical specimen for the detection of viruses
10. Compare molecular diagnostic methods currently used in the affiliate's laboratory for the detection of viruses
11. Compare methods used for the diagnosis of *Chlamydia trachomatis* infection
12. List the cell culture line most commonly used for the isolation of *Chlamydia trachomatis*
13. Describe the appearance of *Chlamydia trachomatis* in direct specimen smears
14. Correlate serologic test results with patient history and diagnosis

MOLECULAR DIAGNOSTIC and IMMUNOLOGIC ASSAYS

Introduction

Molecular diagnostic testing is used for the identification of various pathogenic microorganisms. These methods have become widely used in clinical microbiology laboratories and offer rapid and accurate results. Immunologic assays are based on the in vitro detection of antibody-antigen reactions. These assays are used to diagnose infectious diseases and immunologic disorders, prevent blood transfusion reactions, and to detect analytes in clinical chemistry.

Prerequisite

The student should review the laboratory procedure manual for the performance and reporting of various molecular diagnostic assays.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 415/416, 493/693, 428/429/628/629 and 438/439/638/639, the student will:

1. Identify each molecular diagnostic assay utilized in the affiliate microbiology laboratory
2. Explain the principle and clinical significance of each molecular based assay
3. Perform correctly each molecular diagnostic assay offered by the affiliate laboratory according to laboratory protocol
4. Interpret correctly molecular diagnostic assay results offered by the affiliate laboratory
5. Illustrate the humoral-mediated and cell-mediated immune responses identifying key cells involved
6. Evaluate the factors involved in the binding of antibody to an epitope on an antigen
7. Evaluate the assays used to diagnose immunologic disorders (e.g., immunodeficiencies, rheumatoid arthritis, systemic lupus erythematosus, etc.)
8. Explain the causes of immunologic disorders

9. Explain the principle and clinical significance of each immunologic assay used in the affiliate laboratory
10. Perform correctly immunologic assays offered by the affiliate laboratory according to laboratory protocol
11. Define the following: sensitivity, specificity, positive predictive value, and negative predictive value
12. Explain how to determine an antibody titer
13. Compare the significance of a high IgM titer to a high IgG titer when diagnosing an infectious disease
14. Justify the use of acute vs. convalescent serum sample antibody titers when diagnosing infectious diseases
15. Evaluate the serologic markers for the diagnosis of hepatitis A, B, C, D, and E
16. Evaluate the serologic markers for the diagnosis of Epstein-Barr virus infection
17. Compare treponemal antigen serologic assays to non-treponemal assays

ASSESSMENT TOOLS

See below for:

Clinical Practicum Student Affective Evaluation Grading Scale
Clinical Practicum Practical Evaluation Instructions
Clinical Practicum Practical Evaluation Grading Rubric

All students must complete the Urinalysis Tally included as part of the Clinical Practicum.

Student Evaluation (see below) to obtain a passing grade in MMSC477/677 - completed on Trajecsys
Clinical Practicum Student Evaluation – Revised, 2020

Clinical Practicum Student Affective Evaluation Grading Scale

For items #1 through #15: Rate on 1-5 point scale below. Record rating in the column provided. Space is provided with each evaluation item for narrative appraisal. Any unsatisfactory evaluation **must** be documented. Please indicate strong points exhibited. The completed evaluation form must be discussed with the student at mid-point and end of the clinical practicum.

Performance Level	**Rating Value**	**Performance Indicators**
Outstanding	5	Contribution **far exceeds** what is normally expected of a student. Personal commitment to a high level of performance and professionalism is clear.
Exceeds Expectations	4	Seizes initiative in development and implementation of challenging projects. Accomplishments **exceed** requirements. Requires minimal direction.
Fully Satisfactory	**3**	**Performance is what is expected in senior clinical practicum. Does not require significant improvement. Errors are minimal and seldom repeated. Requires only normal supervision and follow-up.**
Less Than Satisfactory	2	Performance generally does not meet minimum requirements for senior clinical practicum. Errors are significant and frequently repeated. Requires close surveillance and guidance.
Unacceptable Performance	1	Has had sufficient exposure to have shown better performance. Does not grasp basic concepts no matter how many times they have been explained. Does not demonstrate commitment to this aspect of professional development.

Practical Evaluation Instructions **Student:**

Eval by: **Date:**

Clinical Microbiology Practical

For the Clinical Microbiology Practical, you will be given:

As detailed in the practical evaluation rubric, perform the following on each specimen:

1. Plate the assigned unknown specimens to appropriate media.
2. Perform direct gram stain on each specimen (if required).
3. Incubate each media.
4. Interpret each direct gram stain and report according to format appropriate for the source.
5. Examine growth and perform appropriate biochemical tests for identification of all isolates if required.
6. Perform and interpret antimicrobial testing on appropriate isolates.
7. Generate preliminary and final reports according to format appropriate for the source.
8. Perform and record quality control for all testing performed if required.
9. Record all results on the following Laboratory report sheets.

Clinical Microbiology Practical Evaluation Grading **Student:**

Eval by: **Date:**

	POINTS POSSIBLE	POINTS EARNED	COMMENTS
Unknown samples processed, plated, labeled, and incubated following appropriate procedures for specific source	20		
Direct gram stain, preliminary and final reports recorded accurately and using source appropriate format	20		
Organisms identified and reported correctly according to source specific procedures	20		
Appropriate QC processed, accurately evaluated, and documentation recorded accurately and legibly	10		
Reagents and supplies utilized efficiently, no unnecessary waste of materials	10		
Critical results noted and reported appropriately, all necessary documentation recorded accurately and legibly	20		
Other			
TOTALS:			
PRACTICAL GRADE:			

Laboratory Report

Name: Specimen#:
Source: Received Date:

Direct Gram Stain Report

Result:

Date: Time:

Preliminary Report:

Result:

Date: Time:

Preliminary Report #2 (If needed)

Result:

Date: Time:

Final Report:

Result:

Date: Time:

Organism Workup Information

Attach Automated or manual identification/ sensitivity printouts.

.

Isolate #

Media/ colony description:

Date	Tests set up/ Performed	Results	QC

Isolate #

Media/ colony description:

Date	Tests set up/ Performed	Results	QC

.

Final Clinical Practicum Grade will be calculated as detailed below:

Student Affective Evaluation 20% Average Points: total points / 15 = Look up grade below: X 20% = Example: 52/15 = 3.47 = B- (80 x 20%) = 16 5.00 – 4.50 = A = 95 4.49 – 4.00 = A- = 90 3.99 – 3.50 = B = 85 3.49 – 3.00 = B- = 80 2.99 – 2.50 = C = 75 2.49 – 2.00 = C- = 70 1.99 – 1.50 = D = 65 1.49 – 1.00 = D- = 60 <1.00 = F = 55	Written Assessment Ave. Score X .40 = Practical Score X .40 = Affective Score = Grade for Practicum = **PASS or FAIL**
A grade of INCOMPLETE will be recorded unless ALL practicum documentation is completed by the end of the semester. This includes attendance sheets, orientation checklists, and the completion of the online site evaluation for each clinical practicum.	

MMSC 479/679 Clinical Immunohematology Practicum

COURSE SYLLABUS

The clinical practicum is the culmination of several years of study. It is an exciting time for students and offers unique experiences in the clinical laboratory setting. Students will achieve from this experience benefits comparable to the effort they put forth.

COURSE DETAILS

This is a clinical practicum course, and it will meet at a clinical affiliate to be determined by the University instructor. Students will be notified of this location prior to the commencement of the clinical practicum.

MODES OF INSTRUCTION

Clinical faculty will utilize various methods of instruction, including but not limited to a combination of:

1. Clinical specimens
2. Quality control materials
3. Immunohematology automated analyzers
4. Assay of proficiency samples previously analyzed and stock samples
5. Case studies

Students will receive instruction about proper operation of equipment, specimen processing, quality control, use of the LIS, and result interpretation and reporting mechanisms specific to the clinical facility where they are assigned.

METHODS OF ASSESSMENT

Upon the completion of this course, based upon affective, cognitive and psychomotor objectives, the student must achieve a final minimum average of 70% (C-) on the assessment tools utilized in this course.

The clinical instructor will administer written quizzes. In addition, the clinical instructor will assign papers or projects that are relevant to the practicum. This component of the Evaluation comprises 40% of the practicum grade.

A practical examination is another means of assessment employed by the clinical instructor. The instructions and rubric for the practical examination will be provided to the student prior to commencing the practical examination. The clinical instructor will complete the practical grading rubric and will return it to the University instructor. This component of the Evaluation comprises 40% of the practicum grade.

Affective assessment is incorporated into the mid- and final-evaluation process. A mid-evaluation will be completed by the clinical instructor and will be discussed with the student. If there are any issues to be addressed, this will also be shared with the University instructor. The final MMSC 479 Clinical Immunohematology Practicum Evaluation will be completed by the clinical instructor and discussed with/reviewed by the student. The affective component on the final Evaluation comprises 20% of the practicum grade.

A written final examination will be administered by the University instructor at the conclusion of the practicum. The University-administered written final examination component of the Evaluation does not affect the practicum grade but is included on the form.

A sample MMSC 479 Clinical Immunohematology Practicum Evaluation can be found at the end of this syllabus.

COURSE PREREQUISITES

MMSC 420/421 or 620/621

RESTRICTIONS: Open to medical laboratory science students only.

COURSE OBJECTIVES RELATED TO SPECIFIC CONTENT AREAS

Upon the completion of this course, based upon the objectives detailed in this document, the student must achieve a final minimum average of 70% on the assessment tools utilized in this course.

I. Specimen Management/Safety

II. Quality Control / Quality Assessment / Total Quality Management

III. Inventory and Processing

IV. Issuing and Proper Usage of Blood and Components

V. Storage and Transportation of Blood/Components

VI. Specimen Acceptability/Pretransfusion Testing

VII. Automated Immunohematology Instrumentation

VIII. Obstetrical Considerations

IX. Neonatal Transfusion Practices

X. Transfusion Complications

XI. Molecular Diagnostic and Immunologic Assays

SPECIMEN MANAGEMENT/SAFETY

Introduction

Thorough knowledge of safety procedures is essential before performing any duties in the clinical laboratory which might be hazardous to personnel. The immunohematology department is responsible for monitoring departmental criteria for specimen acceptance, processing of various testing, evaluating and reporting laboratory results. These pre-analytical, analytical, and post-analytical factors are essential for quality assessment in the laboratory. In the immunohematology department, a considerable amount of effort is placed on specimen handling and collection since the final results for any analysis and potential transfusion of the patient are dependent on these two factors. The following precautions or conditions are essential for quality specimens:

- correct identification of patient
- correct labeling of specimen
- correct specimen type – anticoagulants, preservatives
- correct special handling – 37°C, etc.
- correct storage conditions

Prerequisite

The student will familiarize herself/himself with the overall management of the Immunohematology Department.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 409/419/609/619, and 420/421/620/621, the student will:

1. Discuss the specimen management system used by the immunohematology laboratory
2. Distribute specimens to workstations appropriately to the satisfaction of the instructor
3. State the tests performed at each station or instrument in the immunohematology laboratory (e.g., Type and Screen, Antibody Identification, Type Rechecks, etc.)
4. Evaluate correctly specimens for acceptance or rejection using laboratory guidelines
5. Document correctly specimen rejection according to laboratory guidelines
6. Report and/or call test results according to laboratory protocol to the satisfaction of the instructor
7. Maintain correctly patient records according to laboratory protocol
8. File correctly patient records according to laboratory protocol
9. Utilize correctly safe techniques in handling and disposal of infectious materials according to laboratory protocol
10. Comply with established safety regulations and regulations governing regulatory compliance related to laboratory practice to the satisfaction of the instructor

QUALITY CONTROL / QUALITY ASSESSMENT / TOTAL QUALITY MANAGEMENT

Introduction

Quality is of utmost importance in every laboratory. Today's laboratories have a variety of programs in place to control, assess, and improve their quality.

Prerequisite

The student should read the department's quality control (QC), quality assessment (QA), total quality management (TQM) and/or continuous quality improvement (CQI) policies.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 409/419/609/619, and 420/421/620/621, the student will:

1. Compare and contrast quality control, quality assessment, and total quality management
2. Evaluate correctly laboratory QC data according to laboratory protocol
3. Demonstrate the ability to identify appropriate corrective action when data falls out of control range to the satisfaction of the instructor
4. Explain how quality is verified and documented for critical equipment used in the blood bank laboratory
5. Discuss how QC is monitored and recorded for each procedure in the immunohematology laboratory
6. Perform correctly daily reagent Quality Control including checking reagent expiration dates
7. Record correctly QC data according to departmental guidelines
8. Discuss the need for departmental quality assessment and/or total quality management programs
9. Identify the key components of the Blood Bank's Quality Plan
10. Explain the purpose of proficiency testing
11. Discuss the impact of total quality management on laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process
12. Apply correctly principles of total quality management to laboratory operations, including relevance to the pre-analytical, analytical, and post-analytical stages of the testing process
13. Discuss the role of the medical laboratory scientist in maintaining laboratory quality
14. State the AABB standards for the appropriate time interval related to maintaining the following records:

a. patient blood types

b. compatibility test record

c. units dispositions

d. patient antibody identifications

15. List factors that can minimize human errors and assure Personnel Quality Control

16. Differentiate between the terms "Preventative Action" and "Corrective Action" as they relate to error management

INVENTORY AND PROCESSING

Introduction

For an immunohematology laboratory to function efficiently, it is important to maintain an appropriate inventory of blood and components. The student will gain experience in serologic testing, record keeping and component storage.

Prerequisite

The student should read the department's Standard Operating Procedures relating to product inventory and processing.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 409/419/609/619, and 420/421/620/621, the student will:

1. Document correctly inventory levels according to laboratory protocol

2. Report correctly inventory levels to the blood supplier

3. Place orders for and/or coordinate return of products based on established target inventory levels, anticipated usage, product availability, and product expirations to the satisfaction of the instructor

4. Inspect correctly donor units as received into inventory and prior to issue according to defined criteria

5. Initiate correctly quarantine and appropriate documentation for any nonconforming product

6. Perform correctly unit log-in/accessioning of donor units according to laboratory protocol

7. Perform correctly confirmatory ABO and Rh typing, as appropriate

8. Perform correctly the labeling of donor units according to laboratory protocol

ISSUING AND PROPER USAGE OF BLOOD AND COMPONENTS

Introduction

Providing blood components efficiently to the appropriate patient is the major objective of immunohematology laboratories. Ensuring safe inspection of the blood products and accurate labeling/dispensing of the blood products is essential for the safety of the intended recipient. The student will learn and assist in the proper issuance of blood and components. She/he will learn to evaluate proper blood utilization based on criteria established by the clinical facility.

Prerequisite

The student should read the department's Standard Operating Procedures relating to issuing and proper usage of blood and components.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 409/419/609/619, and 420/421/620/621, the student will:

1. Perform correctly all record keeping procedures related to the issuance of blood and components for patient transfusion
2. Review correctly all patient and donor unit identification names and numbers:
    a. visual inspection of units
    b. documentation of unit disposition
3. Discuss the return of products following dispense regarding acceptance criteria for reissue
4. State the procedures for the emergency release of uncross matched blood and massive transfusion protocols
5. Select correctly platelet products for transfusion according to laboratory protocol
6. Pool correctly platelet products (as indicated) for transfusion according to laboratory protocol
7. Compare and contrast the storage conditions and expiration time of the products prior to and after preparation for transfusion
8. Select correctly fresh frozen plasma or other plasma products for transfusion according to laboratory protocol
9. Prepare correctly fresh frozen plasma or other plasma products for transfusion according to laboratory protocol
10. Compare and contrast the storage conditions and expiration time of the products prior to and after preparation for transfusion
11. Select correctly cryoprecipitate for transfusion according to laboratory protocol
12. Prepare correctly cryoprecipitate for transfusion according to laboratory protocol
13. Compare and contrast the storage conditions and expiration time of the products prior to and after preparation for transfusion

14. Select correctly appropriate red blood cell products (RBC) for transfusion according to laboratory protocol

15. Discuss how special requirements listed below impact RBC product selection:

    a. Leukoreduced

    b. Irradiated

    c. CMV Negative

    d. Hgb S Negative

    e. Antigen Negative

16. Explain why blood is irradiated for selected patients

17. Identify which patient groups should receive CMV Negative products

18. Recognize ISBT compliant labels for modified blood components when required

19. Prepare correctly ISBT compliant labels for modified blood components when required

20. Describe the circumstances and policies associated when compatible products cannot be obtained for a patient

21. Manage and prepare whole blood units for distribution to the ED for emergency use as appropriate

22. Return and modify whole blood units to inventory following established protocols, to include expressing off the plasma and making/labeling the red blood cell unit for inclusion in inventory as needed

STORAGE AND TRANSPORTATION OF BLOOD/COMPONENTS

Introduction

It is important to remember that for the blood and/or components to provide maximum benefit to the recipient, the products must be maintained at the required temperature on the shelf or during transport.

Prerequisite

The student should read the department's Standard Operating Procedures relating to storage and transportation of blood/components.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 409/419/609/619, and 420/421/620/621, the student will:

1. Identify the different components that can be prepared from a single whole blood donation

2. State the purpose and advantages of collecting and transfusing platelets prepared from an apheresis instrument

3. List the storage/transport conditions required for each component following manufacturing

4. Identify the various packing materials designed to maintain appropriate temperature during transportation of each product type
5. Explain how transportation temperatures are periodically quality controlled
6. Discuss how continuous monitoring of blood storage devices is conducted and documented
7. State the acceptable storage temperature ranges for the following storage devices:
    a. red cell refrigerators
    b. plasma/cryo freezers
    c. platelet incubators
    d. reagent refrigerators
    e. Room temperature storage (e.g. for reagents and/or coagulation factor storage)
8. Discuss how required periodic preventative maintenance is performed on each type of blood storage device

SPECIMEN ACCEPTABILITY/PRETRANSFUSION TESTING

Introduction

Pretransfusion testing lays the groundwork for a successful transfusion. Specimens must be evaluated carefully for acceptability prior to commencing pretransfusion testing. The student will learn and perform the various tests involved in compatibility testing. He/she will also learn the follow-up procedures used when blood is incompatible.

Prerequisite

The student should read the department's Standard Operating Procedures relating to specimen acceptability and pretransfusion testing.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 409/419/609/619, and 420/421/620/621, the student will:

1. Examine specimens submitted for pretransfusion testing with respect to defined labeling criteria, age of specimen, and appearance of specimen to the satisfaction of the instructor
2. Perform correctly all serologic testing procedures required to provide compatible blood for transfusion, including:
    a. ABO and Rh typing of patient
    b. antibody screening
    c. antibody identification
    d. selection of appropriate donor units for compatibility testing
    e. compatibility testing

3. Interpret correctly all serologic testing procedures required to provide compatible blood for transfusion listed in objective #2

4. Recognize test reactions characteristic of the following situations:

    a. ABO cell-serum grouping discrepancies

    b. rouleaux

    c. cold reactive auto and/or alloantibodies

    d. single/multiple blood group alloantibodies

    e. warm autoantibodies

5. Suggest or perform correctly follow-up procedures and appropriate crossmatch methods for the situations listed in objective #4

6. Identify when weak D testing must be performed as part of Rh typing (i.e., donor units, neonates)

7. Given a patient sample with one or more clinically significant antibody(ies):

    a. accurately identify antibody specificity(ies) with statistical confidence

    b. confirm correct identification by antigen typing patient red cells

    c. determine correctly the number of units to select for antigen screening

    d. perform correctly antigen typing of selected donor units using appropriate controls

    e. document correctly antigen typing of selected donor units and appropriate controls

    f. accurately label donor units as antigen negative following laboratory protocol.

8. Given a specimen with a positive DAT:

    a. perform correctly Direct Antiglobulin Test using appropriate polyspecific and monospecific reagents

    b. evaluate correctly DAT results relative to patient diagnosis, medication, transfusion history

    c. perform correctly an RBC elution when indicated

    d. identify correctly antibody(ies) contained in an eluate

9. Discuss results of special procedures for antibody testing/identification and resolution of incompatibility, such as:

    a. R.E.S.t.® absorption technique

    b. enzyme treatment of RBCs

    c. W.A.R.M.™ autoabsorption

    d. homologous adsorption

e. neutralization techniques for Lewis, P1, Sda, Chido, Rogers antibodies

f. antibody titration procedures

g. other procedures available at your institution

10. Interpret results of special procedures listed in objective #9 for antibody testing/identification and resolution of incompatibility

AUTOMATED IMMUNOHEMATOLOGY INSTRUMENTATION

Introduction

Automated immunohematology analyzers may be the workhorse of the immunohematology laboratory. While instruments vary by manufacturer and type, the following basic objectives remain the same for each analyzer.

Prerequisites

The student should review the automated immunohematology analyzer operator manuals for those instruments that will be employed during the practicum period.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing the automated immunohematology analyzer operator manuals, the student will:

1. Operate correctly the automated immunohematology instrument(s) according to the manufacturer's directions, producing accurate quality control and patient results
2. Evaluate correctly quality control data according to laboratory protocol
3. Record correctly quality control data according to laboratory protocol
4. Identify inaccurate/indeterminate instrument results
5. Troubleshoot inaccurate/indeterminate instrument results according to laboratory protocol to the satisfaction of the instructor
6. Correlate correctly patient results with clinical significance (e.g., impact on ability to safely transfuse the patient) and clinical decision making
7. Assess critical pathways to facilitate diagnosis and to determine additional testing as warranted to the satisfaction of the instructor
8. Identify the basic operating components of the analyzer(s)
9. Locate the basic operating components of the analyzer(s) to the satisfaction of the instructor
10. Explain the function of each component of the analyzer(s)
11. Perform routine daily maintenance on the analyzer(s) according to the manufacturer's directions to the satisfaction of the instructor
12. Identify periodic (weekly, monthly, etc.) maintenance requirements according to the manufacturer's directions

13. Explain the function of each reagent used on the automated instrument(s)

14. Prepare correctly reagents for use on the analyzer(s) according to the manufacturer's directions

15. State how reagents are stored when not in use on the analyzer

16. Explain where to find basic troubleshooting information about the analyzer

17. Participate in troubleshooting the analyzer(s) as appropriate to the satisfaction of the instructor

18. Apply correctly appropriate problem-solving steps for determining instrument/methodology problems, utilizing instrument manuals, laboratory procedure manuals, and information contained in package inserts

19. Justify the importance of documenting maintenance, quality control, and troubleshooting

OBSTETRICAL CONSIDERATIONS

Introduction

Hemolytic Disease of the Newborn can have critical implications for the baby. The student will perform and interpret tests on maternal blood samples as related to the issue of RhIG products and recognition of potential HDFN.

Prerequisite

The student should read the department's Standard Operating Procedures relating to prenatal, postpartum, and newborn testing.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 415, 409/419/609/619, and 420/421/620/621, the student will:

1. Determine correctly the ABO blood group and Rh type of maternal blood samples

2. Interpret the results of ABO blood group and Rh type testing of maternal blood samples

3. Identify correctly a mixed field weak D test due to a feto-maternal hemorrhage

4. Examine correctly patient history and test results to determine the need for:

    a. antepartum RhIG

    b. postpartum RhIG

5. State the dose of RhIG in available RhIG products

6. Perform correctly a screening test for a feto-maternal hemorrhage

7. Evaluate results of a screening test for a feto-maternal hemorrhage

8. Explain the principle of a quantitative test for feto-maternal hemorrhage

9. Perform correctly a quantitative test for feto-maternal hemorrhage

10. From case histories, determine correctly the volume of the fetal bleed

11. From case histories, calculate correctly the required dose of RhIG

12. Evaluate the antibody screen and antibody identification as to possible cause of Hemolytic Disease of the Fetus and Newborn (HDFN)

13. Demonstrate correctly proper technique in performing an antibody titration:

    a. interpret result as to titer and score

    b. recognize a significant change in titer given a series of results on the same patient

14. Explain the transfusion requirements for Rh negative females

NEONATAL TRANSFUSION PRACTICES

Introduction

Transfusion therapy for neonates is uniquely different from adult transfusion therapy. The student will receive blood samples from neonates and perform tests as requested. He/she will evaluate results and perform additional tests as indicated or directed by physician or instructor. The student will assist in the selection and preparation of blood and components requested for transfusion therapy of neonates.

Prerequisite

The student should read the department's Standard Operating Procedures relating to neonatal pretransfusion testing and selection and manipulation of blood and components for neonates.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 409/419/609/619, and 420/421/620/621, the student will:

1. Define the neonatal period

2. Demonstrate proper technique when determining the ABO Blood Group, the Rh type, the Direct Antiglobulin Test (DAT) on either cord blood, venous and/or capillary samples to the satisfaction of the instructor

3. Distinguish ABO Hemolytic Disease of the Fetus and Newborn (HDFN) from HDFN caused by maternal alloantibody(ies)

    a. evaluation to be based on actual serologic findings or known case histories

4. Select correctly the most appropriate elution technique when evaluating a positive direct antiglobulin test

5. Demonstrate correctly the elution of an antibody (if applicable) using either the Lui-Freeze/Thaw or Acid Elution technique

6. Discuss policies related to blood selection and compatibility testing requirements for neonates in need of:

a. routine transfusion

b. exchange transfusion

7. Describe the preparation of blood products for aliquot or exchange transfusion including:

   a. packed red blood cells

   b. modified whole blood

   c. platelets

   d. fresh frozen plasma

   e. cryoprecipitate

8. If possible at the clinical affiliate, prepare correctly blood products for aliquot transfusion for neonates including the products listed in objective #7

TRANSFUSION COMPLICATIONS

Introduction

Transfusion complications create the potential for injury or death. The suspected transfusion reaction work-up must be completed in a timely fashion with accuracy and care. The student will perform all necessary tests and clerical work necessary to work up a transfusion reaction.

Prerequisite

The student should read the department's Standard Operating Procedures relating to suspected transfusion reactions, including but not limited to stat, acute hemolytic, delayed hemolytic, TRALI, TACO, NAIT, anaphylactic, bacterial, and urticarial transfusion reactions.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing materials associated with the course objectives from MMSC 415, 409/419/609/619, and 420/421/620/621, the student will:

1. Define the term "transfusion reaction”

2. Identify correctly the signs and symptoms that may accompany hemolytic transfusion reactions

3. Describe the protocol for the investigation of a transfusion reaction including initial and extended testing according to AABB Standards

4. Arrange the steps in a post-transfusion work-up in the appropriate sequence

5. State the most frequent cause of an acute hemolytic transfusion reaction

6. List the characteristics of a delayed hemolytic transfusion reaction, including the etiology and the usual clinical consequences of such a reaction

7. Name the most frequent cause of febrile transfusion reactions

8. Name other types of immunologic transfusion reactions (not including acute hemolytic and

febrile non- hemolytic)

9. Name the nonimmunologic cause or causes of immediate and delayed transfusion reactions
10. Describe the signs and symptoms of a urticarial reaction
11. Differentiate the testing required among the various types of suspected transfusion reactions
12. Describe the signs, symptoms and causes of anaphylactic transfusion reactions
13. Discuss the treatment options for the various types of transfusion reactions
14. Given a pretransfusion specimen and post transfusion specimen, perform correctly serologic techniques required in a suspected transfusion workup
15. Interpret the test results of a suspected transfusion workup in an acceptable amount of time to assist the physician to initiate appropriate therapy
16. Discuss the features of graft-versus-host disease including etiology and prevention
17. Name the diseases that can be transmitted through blood or blood components
18. List the screening tests currently performed on donor blood to detect and prevent transfusion transmitted diseases
19. Identify the limitations of infectious disease testing in relation to the "window period" of infection
20. Explain how new technologies are impacting the "window period" of particular infectious diseases
21. Explain the fundamental differences between infectious disease screening tests and confirmatory tests
22. Define the current risk of disease transmission for HBV, HCV, and HIV through blood transfusion
23. Define the term "Look-back"

MOLECULAR DIAGNOSTIC and IMMUNOLOGIC ASSAYS

Introduction

Molecular diagnostic techniques are being integrated in all aspects of laboratory testing. Some affiliate institutions are utilizing molecular techniques in pretransfusion testing, antigen typing, etc. Many transfusion service laboratories also perform immunologic assays. Students will be given the opportunity to observe and possibly perform these assays as available.

Prerequisite

The student should read the department's Standard Operating Procedures relating to molecular diagnostic and immunologic assays.

Objectives

Upon successful completion of the clinical practicum, studying assigned materials, and reviewing

materials associated with the course objectives from MMSC 415, 493/693, 409/419/609/619, and 420/421/620/621, the student will:

1. Identify each molecular diagnostic assay utilized in the affiliate immunohematology laboratory

    a. explain the principle of each molecular based assay, discussing its clinical significance

    b. perform correctly molecular diagnostic assays offered by the affiliate laboratory according to laboratory protocol

2. Identify each immunologic assay utilized in the affiliate immunohematology laboratory

    a. explain the principle of each immunologic assay, discussing its clinical significance

    b. perform correctly immunologic assays offered by the affiliate laboratory according to laboratory protocol

ASSESSMENT TOOLS

See below for:

Clinical Practicum Student Affective Evaluation Grading Scale
Clinical Practicum Practical Evaluation Instructions
Clinical Practicum Practical Evaluation Grading Rubric

All students must complete the Urinalysis Tally included as part of the Clinical Practicum.

Student Evaluation (see below) to obtain a passing grade in MMSC479/679 - completed on Trajecsys
Clinical Practicum Student Evaluation – Revised, 2020

Clinical Practicum Student Affective Evaluation Grading Scale

For items #1 through #15: Rate on 1-5 point scale below. Record rating in the column provided. Space is provided with each evaluation item for narrative appraisal. Any unsatisfactory evaluation **must** be documented. Please indicate strong points exhibited. The completed evaluation form must be discussed with the student at mid-point and end of the clinical practicum.

Performance Level	**Rating Value**	**Performance Indicators**
Outstanding	5	Contribution **far exceeds** what is normally expected of a student. Personal commitment to a high level of performance and professionalism is clear.
Exceeds Expectations	4	Seizes initiative in development and implementation of challenging projects. Accomplishments **exceed** requirements. Requires minimal direction.
Fully Satisfactory	**3**	**Performance is what is expected in senior clinical practicum. Does not require significant improvement. Errors are minimal and seldom repeated. Requires only normal supervision and follow-up.**
Less Than Satisfactory	2	Performance generally does not meet minimum requirements for senior clinical practicum. Errors are significant and frequently repeated. Requires close surveillance and guidance.
Unacceptable Performance	1	Has had sufficient exposure to have shown better performance. Does not grasp basic concepts no matter how many times they have been explained. Does not demonstrate commitment to this aspect of professional development.

Practical Evaluation Instructions **Student:**

Eval by: **Date:**

Clinical Immunohematology Practical

INSTRUMENT:

As detailed in the practical evaluation rubric, perform the following functions:

1. Perform daily maintenance procedures according to protocol.
2. Perform weekly maintenance and quality assurance procedures assigned according to protocol.
3. Process appropriate controls and patient samples.
4. Evaluate acceptability of controls.
5. Interpret patient results.
6. Perform appropriate follow-up testing as indicated.
7. The following conditions apply to this practical (all that are marked with a √):

Time limit =

Use of instrument operating manuals is permitted

Use of course manuals is permitted

Other:

UNIVERSITY OF DELAWARE/CHRISTIANA CARE HEALTH SERVICES MEDICAL LABORATORY SCIENCE PROGRAM MMSC 479 IMMUNOHEMATOLOGY PRACTICAL EXAM GRADING SCHEME

Student _____ Grade _____

T.S.L. _____ Pre-Natal-Neonatal _____ Instructor _____

The instructor will design a practical exam suitable to the laboratory service. She/he will assign a point value based on the grading scheme presented below. The student must obtain a passing grade of 70 unless otherwise noted by the instructor.

GRADING SCHEME

ITEM		VALUE	SAMPLE		SAMPLE		SAMPLE		SAMPLE		SAMPLE	
			Possible	Earned	Possible	Earned	Possible	Earned	Possible	Earned	Possible	Earned
ABO	Anti-A;B	2										
	Cell A;B	2										
	Interp	5										
Rh	Anti-D	2										
	D Ct.	1										
	Interp	5										
Serum	ABSC	10										
Tests	Interp	20										
	Panel	30										
	Interp	50										
Donor	Comp Test (pr unit)	5										
	Comp Test (pr unit)	5										
	Comp Test (pr unit)	5										
	Comp Test (pr unit)	5										
Misc	Titer	10										
	Titer Interp	20										
	Prewarm - ABSC	10										
	Panel	20										
Fetal Screen Technique		10										
	Interp	15										
DAT	P.S.	10										
	IgG	10										
	C3bC3d	3										
	Interp	3										
Antigen	Patient	3										
Typing	Units	10										
Daily Temperatures		10										
Daily Reagent QC		10										
Product Selection	AG Frequency	10										

Calculation of grade: $\frac{\text{Student numerical score}}{\text{Exam numerical score}}$ = exam grade

Page Score _____ = _____

Overall Score _____ = _____

FINAL CLINICAL PRACTICUM GRADE REPORT

Please provide scores and a description for the written assessments and practical. The UD Clinical Education Coordinator will calculate the final grade based upon these scores and the affective score.

Written Assessment(s) – please include brief description below	**QUIZ grades**	**TEST grades**	**PROJECT grades**
Practical – please include brief description of practical below	**Practical**	**Score achieved** _____	

Description of Written Assessment Tools and Practical:

Additional Instructor Comments: _____

_____

Mid Evaluation

Signature of student _____ Date _____

Final Evaluation

Signature of student _____ Date _____

Student comments: _____

_____

STOP – Grade will be calculated by the UD Education Coordinator. Thank you ☺

Student Affective Evaluation 20%

Average Points: total points / 15 =

Look up grade below: X 20% =

Example: 52/15 = 3.47 = B- (80 x 20%) = 16

5.00 – 4.50 = A = 95
4.49 – 4.00 = A- = 90
3.99 – 3.50 = B = 85
3.49 – 3.00 = B- = 80
2.99 – 2.50 = C = 75
2.49 – 2.00 = C- = 70
1.99 – 1.50 = D = 65
1.49 – 1.00 = D- = 60
<1.00 = F = 55

Written Assessment Ave. Score X .40 =

Practical Score X .40 =

Affective Score =

Grade for Practicum =

PASS or FAIL

A grade of INCOMPLETE will be recorded unless ALL practicum documentation is completed by the end of the semester. This includes attendance sheets, orientation checklists, and the completion of the online site evaluation for each clinical practicum.

2025 MLS Clinical Practicum Calendar

2025		January			2025	
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1 **New Year's Day**	**2** **Winter Session** MMSC470	**3**	**4**
5	**6 Begin Winter Rotation**	**7**	**8**	**9**	**10**	**11**
12	**13**	**14**	**15**	**16**	**17**	**18**
19	**20** **MLK Holiday/** Day off	**21**	**22**	**23**	**24**	**25**
26	**27 End Winter Rotation**	**28 Makeup Day**	**29 Makeup Day** **Zoom Mtg w/ Mrs. Abraham at 9 am**	**30** **Virtual Meeting**	**31** **End of Winter Session** MMSC470	

2025		February			2025	
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	**3** **Spring Semester Begin Rotation #1**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12** **DPHL DAY** **12, 14, 17, 18**	**13**	**14**	**15**
16	**17**	**18**	**19**	**20**	**21** **BBD DAY** **5, 9, 13, 15, 20** **End Rotation #1**	**22**
23	**24 Makeup Day**	**25 Makeup Day**	**26** **Zoom Mtg w/ Mrs. Abraham at 9 am**	**27**	**28**	

2025		March			2025	
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	**3** **Begin Rotation #2**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12** **DPHL DAY 3, 9, 13, 15, 19, 20**	**13**	**14**	**15**
16	**17**	**18**	**19**	**20**	**21** **BBD DAY 2, 4, 12, 17** **End Rotation #2**	**22**
23	**24** **UD Spring Break** **Makeup Day**	**25** **UD Spring Break** **Makeup Day**	**26** **UD Spring Break**	**27** **UD Spring Break**	**28** **UD Spring Break**	**29**

2025		April			2025	
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	**2**	**3**	**4**	**5**
6	**7**	**8**	**9** **DPHL DAY** **11**	**10**	**11** **BBD DAY** **7, 8, 16, 18, 19**	**12**
13	**14**	**15**	**16**	**17**	**18** **End Rotation #3**	**19**
20	**21 Makeup Day**	**22 Makeup Day**	**23** **COMP EXAM (Time & Location TBD)**	**24**	**25** **Zoom Mtg w/ Mrs. Abraham at 9 am**	**26**
27	**28** **Begin Rotation #4**	**29**	**30**			

2025		May			2025	
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	**2** **BBD DAY** **3, 11, 14**	**3** **COMP RETAKE** **9am -1pm** **WHL 327**
4	**5**	**6**	**7** **DPHL DAY** **2, 4, 5, 7, 8, 16**	**8**	**9**	**10**
11	**12**	**13**	**14**	**15**	**16** **End Rotation #4**	**17**
18	**19 Makeup Day**	**20 Makeup Day**	**21** **Zoom Mtg w/ Mrs. Abraham at 9 am**	**22**	**23** **CONVOCATION**	**24** **COMMENCEMENT**
25	**26**	**27**	**28**	**29**	**30**	**31**

Clinical Practicums Schedule

University of Delaware/Christiana Care Health Services Medical Laboratory Science Program 2025 MLS Clinical Practicum by Site					
	Winter 1/6/25 - 1/27/25	Rotation #1 2/3/25-2/21/25	Rotation #2 3/3/25-3/21/25	Rotation #3 3/31/25-4/18/25	Rotation #4 4/28/25-5/16/25
AtlantiCare Regional Medical Center, Atlantic City, NJ					
Microbiology		**17**			
Atlantic General Hospital, Berlin, MD					
Chemistry				**9**	**19**
Bayhealth Medical Center-Kent, Dover, DE					
Chemistry		**8**			**18**
Hematology		**3**			
Immunohematology		**9**		**19**	
Microbiology			**9**		
Bayhealth Medical Center-Sussex, Milford, DE					
Hematology			**5**		
Beebe Medical Center, Lewes DE					
Hematology		**19**			
Microbiology			**19**		
Chester County Hospital-Penn Medicine, West Chester PA					
Chemistry				**17**	
The Children's Hospital of Philadelphia, Philadelphia, PA					
Chemistry		**2**		**13**	
Hematology			**16**	**15**	
Immunohematology		**20**			
Microbiology					**4**
ChristianaCare-Christiana Hospital, Newark, DE					
Hematology		**7**			**17**
Immunohematology		**13**	**4, 12**	**8, 16**	**3**
Microbiology		**14, 18**	**20**	**11**	**2**
Crozer Health, PA					
Chemistry	**10**	**4**			**20**
Hematology	**6**		**14**	**2**	
Immunohematology		**5**			
Microbiology			**13**		
Department of Veteran Affairs, Wilmington Veterans Administration Center					
Chemistry				**14**	
Hematology			**18**		

Hunterdon Medical Center, Flemington, NJ					
Immunohematology			**17**		
Microbiology			**15**		
Inspira					
Hematology				**4**	
Immunohematology					**11**
Johns Hopkins Hospital, Baltimore, MD (End of Sept)					
Chemistry					**15**
Hematology				**12**	
Immunohematology					**14**
Microbiology					**8, 16**
Main Line					
Chemistry			**7**	**3**	
Hematology				**20**	
Microbiology		**12**			
St. Francis, Wilmington, DE					
Chemistry				**5**	
Hematology					**13**
Immunohematology				**18**	
Microbiology					**7**
University of Pennsylvania Health System, Philadelphia, PA					
Chemistry		**11**			
Immunohematology			**2**		
University of Maryland Shore Medical Center, Chestertown, MD					
Hematology			**8**		**9**
Virtua Health, Mt. Holly, OLOL, and Voorhees, NJ					
Chemistry		**16**			**12**
Hematology			**11**		
Immunohematology		**15**		**7**	
Microbiology					**5**

Four 15-day rotations - 15 days needed

Missed time is made up by student; dates for make-up days are built into the rotation schedule.

Joint Affiliate/UD Instructor & Senior Student Meeting: December 6, 2024
Joint Affiliate/UD Instructor Meeting: May 16, 2025
Commencement: May 24, 2025

#	Student Name
1	Hajar Al-Mashrafi
2	Bettina Bauman
3	Xavier Benston
4	Hien Bui
5	Alexandra Ceballos
6	Herbie Cintron
7	Alexandra Clarke
8	Kelly Cooperman
9	Rhett Davis
10	Eric Dombrower
11	Kari Fahy
12	Yessenia Lagunas
13	Hera Lee
14	Shane McGarry
15	India McKay
16	Anika Mundalmani
17	Maddie Share
18	Maryam Soumahoro
19	Francesca Tantillo
20	Lainey Wriggins

Joint Affiliate/UD Instructor & Senior Student Meeting: December 6, 2024
Joint Affiliate/UD Instructor Meeting: May 16, 2025
Commencement: May 24, 2025

UD MLS Questions to Ask Affiliates

Institution						
Questions to ask:						
Arrival Time Day one/every day						
Where to park						
Parking costs						
Do I need my UD lab coat with me?						
Do I need my UD ID in a badge holder to wear?						
Do I need to check in with anyone when I arrive? Who?						
Will I be met in the lobby, or do I come to the lab?						
Lunch: cafeteria/costs vs. if I want to pack, is there a refrigerator to use?						
How long is lunch? When do I need to be back?						
When do I come back from break?						
What is my departure time at the end of the day?						
Any restrictions on jewelry/tattoos/piercings/ cartilage jewelry/tongue jewelry etc.?						
What instrumentation do you have in Chem/Heme/ Micro/BB/UA as applicable?						
OTHER:						

What Every Student Should Know about Compliance and HIPAA Regulations

MMSC461-010

Vipul Shah, MBA, MLS(ASCP), DLM(ASCP)

Fall 2024

1

HIPAA History

- **Health Insurance Portability and Accountability Act**
- Also known as:
  - Public Law 104-191
  - The Kennedy/Kassebaum Bill
- Enacted August 21, 1996
  - Efforts of the Clinton Administration and health care reform proponents

2

HIPAA Purpose

- Allow individuals to keep the insurance while changing jobs
- Improve the efficiency and effectiveness of the health care industry
- Prevent fraud and abuse
- Guarantee the privacy and confidentiality of patient medical records
- Enhance patient care
- Advance medical research and health status of the population
- Improve the quality assurance mechanisms
- Reduce paperwork - savings of $3 - $5 Billion

3

HIPAA

Two parts

- Title I- Health insurance reform
  - Assures continuation of health insurance coverage when individuals change or lose jobs
- Title II- Administrative Simplification
  - Protects individuals' private health information

4

Title II- HIPAA Administrative Simplification

- Standards governing the electronic transmission containing **Protected Health Information (PHI),** a.k.a. individually **Identifiable Healthcare Information (IHI).**
  - Compliance date October 16, 2002
- Privacy standards that set boundaries for the use of PHI
  - Compliance date April 14, 2003
- Security and confidentiality standards
  - Compliance date April 20, 2005

5

What is PHI?

- Individually identifiable health information that is transmitted or maintained by electronic media or maintained in any other form. Includes:
  - Name
  - Address
  - Relatives'/employers' names
  - Birth date
  - Telephone/fax number
  - Email address
  - Social Security number
  - Medical Record number
  - Health Plan number
  - License number/serial number of vehicles
  - Other assorted specific information

6

HIPAA Applicability

- Privacy and Security measures apply to all organizations that maintain patient identifiable information (any form). This includes hospitals, physician offices, pharmacies, health plans, insurance companies, etc.

7

HIPAA Impact

- It requires considerable involvement from all areas in a health care facility
- It requires on-going compliance; this is not just a "one time" event.
- It focuses to ensure that patient records are kept secure and confidential
- It is enforced by the Office for Civil Rights (OCR)

8

HIPAA Penalties

	For violations occurring prior to 2/18/2009	For violations occurring on or after 2/1/2009
Penalty Amount	Up to $100 per violation	$100 to $50,000 or more per violation
Calendar Year Cap	$25,000	$1,500,000

9

HIPAA Penalties

- Penalties for "knowingly" disclosing PHI from $50K to $250K AND 1 to 10 years in prison or both

10

HIPAA Implementation/Maintenance Focus

- Technology (20%)
  - Fax
  - Telephone
  - Computers
  - Radio Frequency transmission
- People (80%)
  - Policies
  - Procedures
  - Cultural change

11

HIPAA Privacy Standards

- All patient information is covered, whether on paper or electronic, on film or oral, clinical or financial.
- Access to information (PHI) based on employee's role and the "need to know".
- A program to actively preclude inappropriate or illegal disclosure of PHI is required of organizations.
- Extensive employee training initiatives and documentation of the training.

12

Privacy Standards - Continued

- PHI should not be disclosed without patient's authorization.
- Patients must be given a detailed explanation in writing (the "Notice of Privacy Practices") how the PHI will be used.
- Patients have the right to object to how their information will be used.
- Patients have the right to inspect the medical record and request corrections.
- Patients have the right to know when PHI has been improperly disclosed and to whom.

13

Privacy Implementation Cost

$22 Billion over five years

14

HIPAA Security Standards

- Physical Safeguards (equipment & security)
  - Work area security (persons without ID badges)
  - Facility security
- Technical Safeguards
  - System access (passwords, screen timeouts)
- Administrative Safeguards (policies, procedures, staff training)
- Security incident resolution process

15

HIPAA Outcomes

- Improve the effectiveness of health care systems by standardizing the electronic exchange of administrative and financial information.
- Protect the security and privacy of health care information held by organizations subject to HIPAA.

16

HIPAA Business Associate

Definition:

- Any entity, or individual, which, on behalf of the organization, performs or assists in the performance of a function or activity that involves the use or disclosure of individually Identifiable Health Information.
- Includes legal, accounting, auditing, consulting, administrative services, utilization review, quality assurance, transcription, benefits management, nursing agencies, …

17

HIPAA Business Associate Agreement

HIPAA Business Associate (BA) provision obligates organizations to have a Business Associate Agreement (BAA) with vendors who have access to Patient Protected Health Information (PHI). The intent of the Business Associate Agreement is to protect the confidentiality of PHI.

18

HITECH Act

- **Health Information Technology for Economic and Clinical Health Act of 2009**
  - Changes to HIPAA including the Business Associates Agreement
  - Effective 2/17/2010 new HIPAA requirement that the Business Associate must notify the other member in the event of a breach of the privacy or security of unsecured PHI.

19

Red Flag Rules

- Obligations under the Federal Trade Commission (FTC)
  - To detect, prevent and mitigate identity theft from occurring.
  - Requires companies to implement identity theft prevention programs.
  - Requires service providers have policies and procedures in place to detect, prevent, and mitigate the risk of identity theft.

20

HIPAA Impact on Laboratory

- Physical security within the lab
- Communications with physicians and physician office staff (55% of EMR access is for lab results)
- Conversations – oral communications
- Patient consent – is it needed?

21

Impact on Laboratory - cont'd

- Training of staff/documentation of training
- Training of outside resources
- Relationships with Business Associates
- Devices --variety and quantity needs to be monitored

22

Impact on Laboratory - cont'd

- Containers (e.g., tubes, slides) with PHI must be destroyed appropriately
- Requests for patient test results by phone, dedicated printer, fax, or LIS
- Location of personal health info needs to be monitored

23

Summary of HIPAA

Five main themes that make up HIPAA Title II

Enforcement Rule	Hefty fines, corrective actions, civil penalties
Privacy Rule	The "need to know" is the rule
Security Rule	Lock it, password protect it, conceal it, encrypt it, get permission before you share it
Transactions Rule	Standard code must be used, i.e. MRN#, unique id
Unique Identifiers Rule	Employees, patients, and all entities must have unique id

24

Self-assessment Scenarios

25

Scenario 1
A DIAGNOSIS PLEASE...

You receive a call from the nurse in the local nursing home. A patient needs a chest x-ray. You arrive at the facility and get the requisition from the head nurse. It is scantily completed. There is a physician order that says chest x-ray stat. There is no diagnosis. You take the x-ray and ask the nurse who is down the hall for the diagnosis. She said she wasn't sure but thinks it is abdominal pain. You are not sure the nurse was talking about the right patient. But instead of researching the issue further, you just use the diagnosis pneumonia because you know that Medicare will pay for a chest x-ray provided with that diagnosis. After all, the doctor would not have ordered the x-ray unless it were necessary. Later that day, you wonder if you should have checked the diagnosis a little further.

26

Scenario 2

True or False

In doing your routine work, you discover that someone you know is in the hospital and you go and visit the person. You have not violated the patient's confidentiality.

27

Scenario 3

True or False

Your sister with whom your family has not had contact in 5 years is in the hospital. You go into the LIS to check her lab results because your mother is very worried about her. You have violated your sister's confidentiality.

28