

Clinical Pathology Chemistry Curriculum

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I. Introduction

The Chemistry rotation covers chemistry testing completed in the Core Lab, the Special Chemistry Lab, the Point of Care Testing Lab, the CTSA Lab, and the Biochemical Genetics Lab. The resident hours in the rotation are from 8 am to 5pm during which the Clinical Chemistry pager 8-7055 is expected to be covered (the CP resident on-call is expected to cover the pager from 5pm-8am).

During the rotation, the residents will play an active role in providing medical oversight for the laboratory. The resident is expected to attend the weekly standing meetings that occur in the lab which are detailed on the Calendar. The residents are responsible for completing consults regarding referral laboratory testing and completing the necessary paperwork for test approval. Residents are also expected to investigate questions/complaints from hospital staff regarding laboratory results and/or process related issues. The interpretation of SPEP/UPEP cases will be completed daily by the resident and reviewed with the attending twice a week or more if resident needs more help. For 2 weeks, the resident will round in the Pediatric Emergency Lab and spend time observing the satellite lab workflow. The residents will attend and participate in rounds within the Special Chemistry Lab. Residents will also sign out together with the supervisors of Special Chemistry and Serology on a daily basis when in Special Chemistry.

Didactic lectures will be given throughout the rotation in addition to the lectures given at the CP didactic lectures on Fridays. Access to the standard operating procedures (SOPs) will be given and residents are expected to familiarize themselves with these SOPs. The residents are expected to give one 30-45 minute CME lecture to the lab technologists during each 4-week block, delivered at 3 different times so that technologists from all shifts have the opportunity to attend. Opportunities to perform mock CAP inspections or to conduct a tracer audit of the laboratory as well as to review proficiency testing results will be provided. Small rotation projects are available to interested residents. A written examination will be performed at the end of each 4-week block to assess knowledge of chemistry.

The residents will assume gradually increasing responsibilities and decreasing supervision as the rotation progresses. If a resident is interested and their knowledge, skills and clinical judgment are deemed outstanding, they may complete a laboratory director elective rotation at the Allen Hospital, or a more specialized elective rotation in one of the Specialty Labs serving as the lab director for 4 weeks.

III. Goals and Objectives

ACGME competencies fulfilled by these objectives are labeled as:

PR: Professionalism

PC: patient care

MK: medical knowledge

PL: practice-based learning and improvement

IC: interpersonal and communication skills

SP: systems-based practice

Skill level 1

1. Summarize the basic principles of laboratory testing, including spectrophotometry, nephelometry, osmometry, flow cytometry, and conductance. [MK]
2. Summarize the stages of laboratory testing with regard to pre-analytical, analytical, and post analytical factors. [MK]
3. Demonstrate knowledge of governmental laboratory regulations. [MK, PC]
4. Demonstrate knowledge of quality control methods including proficiency testing. [MK, PC]
5. Summarize the required steps for method validation for an FDA approved and a non-FDA approved laboratory assay. [MK, PL]
6. Communicate effectively with clinicians regarding referral laboratory testing. [IC, SP, PR, MK]
7. Demonstrate knowledge of protein electrophoresis and proficiency in interpreting cases. [MK, PC, IC, SP]

Skill level 2

8. Discuss laboratory statistics used for quality control and method validation. [PC, MK]
9. Understand diagnostic sensitivity and specificity of a test, positive and negative predictive value. [PC, MK]
10. Demonstrate proficiency in interpreting Proficiency Testing Reports. [MK, PC, PL]
11. Demonstrate proficiency in evaluating method validation studies. [MK, PL]
12. Demonstrate ability to evaluate unusual laboratory results and conduct a root cause analysis. [PC, MK, IC, PL]
13. Understand the differences between Point of Care and Central Laboratory Testing. [MK]

Skill level 3

14. Summarize more complex principles of laboratory testing, including mass spectrometry and Chromatography. [MK]
15. Demonstrate knowledge of clinical laboratory informatics including the Laboratory Information System(s) and the Electronic Medical Record System(s). [MK, SP]
16. Summarize a Quality Management System for a laboratory and summarize Quality Indicators used to monitor performance. [PR, MK, SP]

IV. Books

Henry's Clinical Diagnosis and Management by Laboratory Methods edited by McPherson and Pincus, current edition.

Tietz Textbook of Clinical Chemistry and Molecular Diagnostics by Carl Burtis, Edward Ashwood and David Bruns, current edition.

Protein Electrophoresis in Clinical Diagnosis, by David Keren.

V. Papers/Readings:

In Henry's: Analysis: Principles of Instrumentation (chapter 4 in the 21st edition).

Laboratory Statistics (chapter 9 in the 21st edition).

Quality Control (chapter 10 in the 21st edition).

Immunoassay and Immunochemistry (chapter 43 in the 21st edition).

Clinical and Laboratory Evaluation of Systemic Rheumatic Diseases (chapter 50 in the 21st edition).

In Tietz's: Immunochemistry Techniques Chapter

Good Laboratory Practices for Waived Testing Sites. MMWR November 11, 2005 / Vol. 54 / No. RR-13.
<http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>

NY State Guidance for Developing a Quality Management System:
http://www.wadsworth.org/labcert/clep/ProgramGuide/NYS_QMS_Guidance_0810.pdf

Reading folder Protein Electrophoresis on the encrypted Boxcryptor folder for Gel analyses on dropbox.
(Each resident gets access to this the first time they meet with attending)

VI. Exercises/Cases:

Core Lab Cases:

Girindra Raval, Joel E. Straughen, Gwendolyn A. McMillin, and Joshua A. Bornhorst. Unexplained Hemolytic Anemia with Multiorgan Failure. Clinical Chemistry 57:11. 1485–1489 (2011).

R. Brian Sommerville and Robert H. Baloh. Anemia, Paresthesias, and Gait Ataxia in a 57-Year-Old Denture Wearer. Clinical Chemistry 57:8. 1103–1107 (2011).

Toxicology/TDM Cases:

The resident will be asked to identify and work out at least one clinical toxicology case or a Therapeutic Drug Monitoring case during the 8 week rotation. For this they will meet with Dr. Cremers at the beginning and the end of the rotation in his office (PH10-105b, 212-305-9287, sc2752@columbia.edu).

Several cases from the past and the literature will be provided and discussed.

Protein electrophoresis Exercise:

The specialty laboratory on the 2nd floor at Babies Hospital Central generates serum protein electrophoresis (SPEP) on Mondays, Wednesdays and Fridays, and immunofixation electrophoresis (IFE) gels on Tuesdays, Thursdays, Saturdays and Sundays. Evaluation for the presence of cryoglobulinemia is carried out whenever samples reach the lab. Approximate volumes are ~10,000 SPEP/ IFE/ year and 800 cryoglobulin evaluations / year.

Overall goal: Resident can interpret SPEP, IFE and cryoglobulins and make the correct diagnosis.

To achieve this goal, resident needs to be familiar with technical aspects of protein electrophoresis including the challenges and pitfalls, needs to understand the biology of immunoglobulins, and needs to be familiar with terminology and state of the art diagnosis and treatment options, including but not limited to multiple myeloma, monoclonal gammopathy of unknown significance (MGUS), and cryoglobulinemia.

Approach: Resident meets with the attending when starting the rotation at BB 457 (212-305-3961). Residents can set up a date via e-mail (tpw7@columbia.edu). An introduction and tour of the specialty lab where gels are generated will be given. Will understand how gels are stored on the special chemistry folder and a boxcryptor encrypted Dropbox that is managed by Evelyn Thompson.

The Resident can download the boxcryptor program (free) to their work computer (can ask Pathology IT for help). Through the boxcryptor, the resident can access the link to the encrypted Dropbox folder, forwarded by the attending.

Each day, resident will review and annotate gels using Adobe Professional –typewriter. The goal is to preview gels before the attending sees the case. The attending will review the case after the resident and annotate the resident's performance. For example: there are 9 IFE's per gel. Maximum score per gel is 9. Resident can monitor score to assess progress.

Resident will start out sitting with attending, then preview alone and meet with attending twice a week or on as needed to discuss cases.

Practical exercises:

ELISA: run an ELISA in Special Chemistry

Conduct sample pre-treatment Tacrolimus

Biochemical Genetics/CTSA Labs: Run LC-MS and GC-MS samples

Blood Lead: Participate in sample pretreatment and data-analysis

VII. Faculty Contact Information

Attending	Office ext.	Beeper #	LongRange#	Home#	Cell#
Brie Stotler, MD	305-0849	85946	917-899-7231		215-817-0829
Alexander Kratz, MD, Ph.D.	305-6487	83518	917-899-3060	201-244-5515	646-320-9246
Tilla S. Worgall, MD, PhD	305-3961			212-759-1935	
Steven Spitalnik, MD	305-2204	85038	917-899-0835	212-247-5622	646-287-3800
Serge Cremers, PharmD, PhD	305-9287		646-262-2272	646-262-2272	646-262-2272
Alex Rai, PhD	305-6569				201-841-8000
Jorge Sepulveda, MD	305-6360				917- 862-6050