Sunday, April 26 presentations:

The Virtues and Pitfalls of Implementing a New Test

What is the CV or Coefficient of Variation?
- A – SD/Mean x 100
- B – Mean/SD
- C – σ² = Σ (Xi - X)² / N
- D – Σ (X) / N

What is the definition of verification?
- A – Establishing the performance specifications of a new diagnostic tool such as a new test created by a laboratory
- B – Identifying the factors that will affect the performance of a laboratory test, such as hemolysis.
- C – A one-time process to determine performance characteristics of a test before use in patient testing
- D – Identifying the accuracy and precision of a new methodology or test

Who regulates laboratory quality in the United States?
- A – CDC
- B – CMS
- C – FDA
- D – OSHA

What is the analytical reference range?
- A – The range of test results obtained from 100 healthy individuals.
- B – A target or threshold concentration defined by an expert panel consensus
- C – The spread of results from at least 40 inpatients without disease.
- D – All of the above

So You Want to Develop a Test? Navigating the Regulatory Waters of Laboratory Developed Testing

What is an LDT?
- A – New method or test
- B – Modified FDA approved test
- C – Laboratory developed test
- D – All of the above

What agency currently oversees the quality of LDTs?
- A – CDC
- B – CMS through CLIA
- C – NIDA
What agency could levy a fine against you (personally) and your institution for improperly mailing a specimen?

A – FDA  
B – CMS through CLIA  
C – FAA and IATA  
D – OSHA

What change is proposed by the FDA that will most impact clinical labs performing LDTs?

A – Inspect for quality control of LDTs  
B – Require analytical validation of test performance  
C – Audit billing of LDTs  
D – No longer offer enforcement discretion for LDTs

Endocrinology of the Female Reproductive Axis

Which hormone is capable of negative and positive feedback effects on the pituitary gland during the normal menstrual cycle?

A) estradiol  
B) progesterone  
C) inhibin A  
D) Inhibin B

Which hormone is NOT secreted by the corpus luteum.

A) estradiol  
B) progesterone  
C) inhibin A  
D) Inhibin B

Human chorionic gonadotropin levels should increase by about ______every 24-48 hours in a healthy, first-trimester pregnancy.

A) 25%  
B) 50%  
C) 75%  
D) 100%

Prenatal Screening: Serum or DNA?
A common cut-off used to determine women at high risk for a fetal open neural tube defect is an AFP MoM greater than______.

A) 0.5  
B) 1.0  
C) 1.5  
D) 2.0

The serum test with the best performance for Down syndrome screening is______________.

A) Integrated  
B) First trimester  
C) Quad  
D) AFP

Which of the following is NOT an appropriate next step to follow a screen positive cfDNA test?

A) Termination  
B) Amniocentesis  
C) CVS  
D) Genetic counseling

In which ethnic group is prenatal screening for cystic fibrosis LEAST effective?

A) Caucasian  
B) Hispanic  
C) African American  
D) Asian

Neonatal Anemia: Recognizing Thalassemia and Hemoglobin Variants
No self-assessment questions

Complications of Pregnancy
When hCG exceeds the discriminatory zone and no IUP is visualized by TVUS

A. An ectopic pregnancy is present  
B. A molar pregnancy is present
C. **hCG testing should be repeated in 48 hours**
D. Urine hCG testing should be performed to confirm pregnancy

Use of the 75g-2h OGTT increases the prevalence of GDM because

- **A. It requires a single glucose result above a cutoff for the test to be considered an abnormal**
- B. The oral carbohydrate is maltose which was 2x the glucose content of the 100g-3h OGTT
- C. More women undergo testing by that protocol
- D. The glucose cutoffs for identifying GDM are low

Which lab result would not support the diagnostic criteria for preeclampsia?

- A. Protein/creatinine ratio of 0.40
- B. Platelet count of 90,000/μL
- **C. Serum creatinine of 1.0 mg/dL**
- D. Blood pressure of 150/95 mmHg

**Complications of Childbirth**

Preterm premature rupture of membranes is defined as a rupture of membranes:

- A. Prior to 24 weeks of gestation
- **B. Between 24 and 37 weeks of gestation**
- C. Beyond 37 weeks of gestation
- D. At the onset of labor

Fetal fibronectin testing is potentially useful to identify women:

- A. With symptoms of preterm labor who are likely to deliver preterm infants
- B. Without symptoms of preterm labor who are likely to deliver preterm infants
- **C. With symptoms of preterm labor who are unlikely to deliver preterm infants**
- D. Without symptoms of preterm labor who are unlikely to deliver preterm infants

The clinical benefit of fetal lung maturity tests is:

- A. Their ability to predict which infants will develop RDS
- B. Their high positive predictive value
- C. They are easy to perform and readily available
- **D. Minimal**

Which laboratory test should be used to identify HIV infection in infants born to HIV+ mothers?

- A. 3rd generation HIV-1/2 antibody test
- B. 4th generation HIV-1/2 combination test
- **C. HIV DNA test**
- D. HIV Western blot

**Newborn Screening and Methods for Diagnosing Inborn Errors of Metabolism**

Which of the following is a reason to include an IEM in NBS programs?

- A. Disorder has no effective treatment
- B. Disorder can be detected a week after birth
- C. Cost of testing and treatment is more than the cost of the untreated disorder
D. Disorder has an appropriately sensitive and specific screening test

The first newborn screening test:
   a) Was instituted in Maine and was for tyrosinemia
   b) **Was a bacterial growth inhibition assay**
   c) Was developed on the tandem mass spectrometer
   d) Screened for 5 disorders

Common laboratory findings in IEM presentations do NOT include:
   a) Hyperammonemia
   b) Low concentrations of transaminases
   c) Metabolic acidosis with elevated anion gap
   d) Hypoglycemia

Propionic and methylmalonic acidemias are commonly differentiated by which of the following tests:
   a) **Organic acids by GC/MS**
   b) Acylcarnitines by tandem mass spectrometry
   c) Amino acids by MS/MS
   d) PCR for specific genetic defects

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**Neonatal Hyperbilirubinemia: The Basics, Testing, and Interpretation of Results**

Which of the following chemistry results would you be likely to see in hemolytic anemia?

- A. Normal lactate dehydrogenase
- B. Elevated total serum bilirubin with increased conjugated (direct) bilirubin
- C. **Elevated total serum bilirubin with normal conjugated bilirubin**
- D. Normal total and conjugated serum bilirubins

What is the most likely cause of an unconjugated bilirubin of 11 mg/dL (188 µmol/L) on day of life 2 in a newborn?

- A. bacteria have not yet colonized the intestines
- B. **hepatic enzymes are not fully functional**
- C. mother's bilirubin is increased
- D. hemolytic disease of the newborn

A baby with biliary atresia is most likely to have markedly elevated serum level of:

- A. **conjugated bilirubin**
- B. unconjugated bilirubin
- C. delta bilirubin
- D. urine urobilinogen

Unconjugated bilirubin is directly measured by which of the following methods?

- A. methods using diazotized sulfanilic acids
- B. Jendrassik-Grof method
- C. **HPLC methods**
- D. Ortho dry-slides with reflectance spectrometry

Of the following bilirubin species, which one would be most likely to give you close to the same results no matter which method you used to measure it?
A. Conjugated bilirubin
B. Unconjugated bilirubin
C. Albumin bound bilirubin
D. Total bilirubin

Who Drugged the Baby? Managing Neonatal Abstinence Syndrome

What is NAS?
A. Network Attached Storage
B. National Achievement Strategies
C. Nashville Academy of Songwriters
D. Neonatal Abstinence Syndrome

What laws regulate neonatal abstinence syndrome?
A. Federal CLIA law
B. Local State regulations
C. College of American Pathologists
D. FDA Federal Food, Drug and Cosmetic Act

Why is umbilical cord becoming a preferred sample for neonatal drug testing?
A. Homogeneous
B. Can be collected over several days
C. Available in sufficient quantities to prevent QNS errors
D. Can be rapidly analyzed in most hospital laboratories

Why might a baby’s cord drug testing results disagree with meconium or urine collected at the same time?
A. Different sample types
B. Analyzed by different laboratories
C. Tested by different methodologies
D. Urine presents with more labeling errors than umbilical cord samples

Acute Coronary Syndrome: Key Test for Diagnosis

Which disease is NOT considered part of the acute coronary syndrome continuum?
A. Stable angina
B. Unstable angina
C. NSTEMI
D. STEMI

What is the 2014 AHA/ACC recommended troponin cutoff for considering myocardial necrosis?
A. Value at assay’s 10% CV
B. Value at assay’s 20% CV
C. 99th percentile URL with CV ≤ 10%
D. 99th percentile URL with CV ≤ 20%

Which of the following statements best describes high-sensitivity cTn assay performance?
A. Improved clinical sensitivity for unstable angina
B. Improved clinical sensitivity for myocardial ischemia  
C. Improved analytical sensitivity with equimolar detection of both cTnT and cTnI  
D. Improved analytical sensitivity with detection of cTn in ≥ 50% healthy patient population

**Two Great Tests for Shortness of Breath**

Why should higher thresholds be used for BNP (and NTproBNP) in ER patients with shortness of breath than for diagnosing CHF?  
A. COPD causes shortness of breath  
B. ER patients are older  
C. CHF can exist without shortness of breath  
D. Anxiety can raise BNP (and NTproBNP) levels

Which of the following patients can be screened with D-Dimer levels as a means of ruling out DVT or PE?  
A. A hospitalized patient  
B. A patient with history of DVT and heart rate > 100  
C. A patient with a swollen, tender leg  
D. A patient on chemotherapy for breast cancer

Which of the following is an advantage of offering D-Dimer testing in the Emergency Room?  
A. Increased numbers of patients admitted to hospitals for thorough examinations  
B. Decreased numbers of patients exposed to radiation  
C. Increased revenue to radiologists for performing CTAs  
D. No need for physicians to carefully evaluate patients

**Is My Patient Drugged? Identifying Drugs of Abuse in the Emergency Room**

What is the difference between heterogeneous and homogeneous immunoassays?  
A. Heterogeneous requires extended incubation steps  
B. With heterogeneous IA there is no mixing of reagents  
C. Heterogeneous requires separation of bound and free antibody before detection  
D. Heterogeneous runs on the same analyzer as chemistry tests

What is the advantage of confirmation testing?  
A. Lower cost  
B. Specificity  
C. Using high tech equipment  
D. Greater efficiency

A patient is positive for 6-monoacetyl morphine. This indicates ingestion of which drug?  
A. Heroin  
B. Methamphetamine  
C. Cocaine  
D. Marijuana

How would the laboratory director find the potential for a drug to cross-react in an immunoassay?  
A. Defer to the clinician
B. Run an interference study on their assay
C. Ask the patient what medications they ingested
D. Look in the package insert

“All Things Are Poison”: So What Should We Test For?
Which toxidrome is characterized by Salivation, Lacrimation, Urination, Diarrhea, GI upset, Emesis –
A. “SLUDGE”?
B. Anticholinergic
C. Cholinergic
D. Sympatomemetic
E. Sedative-hypnotic

A blood ethanol concentration of 130 mg/dL will contribute how much to a serum osmolality?
A. 2.8 mOsm/kg
B. 3.5 mOsm/kg
C. 28 mOsm/kg
D. 35 mOsm/kg
E. 280 mOsm/kg

By what mechanism does N-acetylcystine help prevent hepatic damage in acetaminophen overdose?
A. Blocks absorption of acetaminophen
B. Provides a source of glutathione
C. Prevents hepatic conjugation of acetaminophen
D. Blocks acetaminophen receptors on hepatocytes
E. Forms an inactive complex with acetaminophen

Drug Testing: The Moving Target
Which of the following is not a class of amphetamine/cathinone like novel psychoactive substances?
A. Piperazines
B. Phenethylamines
C. Naphthoylindoles
D. Typtamines

Which of the following is not a characteristic of a high resolution mass spectrometry method?
A. Provides accurate mass, retention time, isotope pattern and fragmentation information for drugs and metabolites in a biological sample
B. Acquires data in an untargeted manner
C. Method develop is complex due to the need to establish multiple method parameters
D. Data can be analyzed using targeted, suspect or untargeted data analysis

Which of the following compounds is not detected by most opiate immunoassays?
A. Morphine
B. Codeine
C. Hydrocodone
D. Oxycodone
E. Fentanyl
F. Both d and e

Blood Gases 1: Why Oxygen Concentration can be Confusing
Which is the best indicator of oxygen concentration in blood?
A. PO2
B. Hematocrit
C. O2 content
D. O2 saturation
Which of the following is true?
A. A normal alveolar PO2 is higher in Denver than in Boston because the air is cleaner
B. A normal fractional oxyhemoglobin is higher in Denver than Boston because it has less air pollution
C. Typical pulse oximeters provide reliable measurements of “oxygen saturation” for use in patients with smoke inhalation
D. One must use arterial blood to get an accurate assessment of methemoglobin concentrations
What method principle is involved in measuring oxyhemoglobin percentages?
A. Gas chromatography
B. Ion selective electrodes
C. Beer’s Law
D. O2 electrode, followed by interpolation from oxyhemoglobin dissociation curve

Blood Gases 2: Acid-Base and Electrolytes Made Simple
Which of the following represents the typical findings in a respiratory alkalosis?
A. increased PCO2, decreased HCO3
B. increased PCO2, increased HCO3
C. decreased PCO2, decreased HCO3
D. decreases PCO2, increased HCO3
Which of the following is a cause for a normal anion gap metabolic acidosis?
A. diarrhea
B. diabetic ketoacidosis
C. vomiting
D. lactic acidosis
Pseudohyponatremia can be caused by which of the following:
A. high glucose concentrations
B. low platelet counts
C. high concentrations of serum proteins (e.g. multiple myeloma)
D. high concentrations of ADH

Principles and Practices of Therapeutic Drug Monitoring
Ethanol distributes in total body water (approx 40 L), if the legal limit for intoxication is 1 mg/mL in plasma, how much pure ethanol must be consumed to reach intoxication levels?
A. 400 mg  
B. 40 g  
C. 4g  
D. 40 ml  

Warfarin (anticoagulant) is about 98% protein bound. For a 5 mg dose, only 0.1 mg of warfarin is free. If a patient takes a normal dose of aspirin at the same time as warfarin (occupies 50% of binding sites), what is the new level of free warfarin in the body?  
A. 0.1 mg  
B. 0.2 mg  
C. 0.4 mg  
D. 2.5 mg  

A 55 kg woman has a plasma theophylline (Vd = 0.5 L/kg) concentration of 15 µg/L. How much theophylline does she have in her body?  
A. 200 µg  
B. 300 µg  
C. 400 µg  
D. 500 µg  

A patient has a potentially toxic digoxin level of 4.5 µg/L. Given that the half-life of digoxin in this patient is 60 hr, and assuming that renal function is stable, how long should the drug be stopped to allow the level to fall to 1.5 µg/L?  
A. 1 day  
B. 2 days  
C. 3 days  
D. 4 days  

A doctor orders 200 mg of Rocephin to be taken by a 7 Kg infant every 8 hrs. The medication label shows that 75 – 150 mg/Kg per day is the appropriate dosage range. What is the most appropriate answer?  
A. The dose is lower than the minimum desired dosage  
B. **The dose is within the appropriate dosage range**  
C. The dose is higher than the minimum desired dosage  
D. The range cannot be calculated from the supplied information  

Phenobarbital 180 mg/m2/24 hrs is ordered to be given every 8 hours for a child whose BSA (body surface area is 0.29 m2). If this formulation of phenobarbital is only 50% bioavailable, how much should be given at each dose?  
A. 15 mg  
B. 17 mg  
C. **35 mg**  
D. 50 mg  

**Immunosuppressants in Clinical Practice**  
No questions provided  

**Cancer Diagnosis and Management**  
No questions provided
**Chemotherapy and the Infusion Clinic**

A heparinized-syringe whole blood sample is received in the laboratory for blood-gas and electrolyte testing. Upon careful examination, the medical technologist notices frothy air bubbles in the sample. What impact, if any, may air bubbles have on pH and free $\text{iCa}^{2+}$ results using ISE methodology?

A. No effect  
B. Falsely $\downarrow$ pH and $\uparrow$ $\text{iCa}^{2+}$  
C. Falsely $\downarrow$ pH and $\downarrow$ $\text{iCa}^{2+}$  
D. Falsely $\uparrow$ pH and $\uparrow$ $\text{iCa}^{2+}$  
E. Falsely $\uparrow$ pH and $\downarrow$ $\text{iCa}^{2+}$

Patients exhibiting tumor lysis syndrome have electrolyte imbalances characterized by:

A. $\uparrow$ K$^+$, $\uparrow$ Ca$^{2+}$, $\uparrow$ PO$_4^{3-}$, $\uparrow$ uric acid  
B. $\downarrow$ K$^+$, $\uparrow$ Ca$^{2+}$, $\uparrow$ PO$_4^{3-}$, $\uparrow$ uric acid  
C. $\uparrow$ K$^+$, $\downarrow$ Ca$^{2+}$, $\uparrow$ PO$_4^{3-}$, $\uparrow$ uric acid  
D. $\uparrow$ K$^+$, $\uparrow$ Ca$^{2+}$, $\downarrow$ PO$_4^{3-}$, $\uparrow$ uric acid

$\uparrow$ = above reference range  
$\downarrow$ = below reference range

Reverse pseudohyperkalemia is characterized by:

A. Elevated serum K$^+$ artifact  
B. Elevated plasma K$^+$ artifact  
C. Elevated K$^+$ artifact in both serum and plasma  
D. Physiologically elevated K$^+$ concentration

**What Clinical Chemist Should Know about M-Proteins**

The best combination of tests to screen for monoclonal proteins is:

A. Serum immunoglobulin concentrations (IgG, IgA, IgM)  
B. Serum protein electrophoresis and immunofixation electrophoresis  
C. Serum and urine protein electrophoresis  
D. Urine protein electrophoresis and immunofixation electrophoresis

Typical findings in Light Chain Myeloma include all of the following EXCEPT:

A. **A discrete band in the serum protein electrophoresis**  
B. (Serum) hypogammaglobulinemia  
C. A discrete band in the urine protein electrophoresis  
D. A negative urine dipstick for protein

What is the most common diagnosis associated with monoclonal proteins?

A. Amyloidosis  
B. Multiple Myeloma  
C. **Monoclonal Gammopathy of Undetermined Significance**  
D. Waldenstrom's Macroglobulinemia
Cooking Meth and Doctor Shopping: The Challenges of Managing Prescription Therapeutics
A patient with Hx of illicit drug use on adderall for ADHD is positive for methamp (3500 ng/mL) and amphetamine (5500 ng/mL), what is the most appropriate interpretation of these results?
   A. Adderall can cause both methamphetamine and amphetamine to be positive
   B. Adderall will cause positive methamphetamine but not amphetamine
   C. Adderall will cause positive amphetamine but not methamphetamine
   D. Adderall will not cause either methamphetamine or amphetamine to be positive

A patient is being prescribed morphine and OxyIR with a positive drug test for morphine (48,000 ng/mL), hydrocodone (5,000 ng/mL), hydromorphone (6,500 ng/mL), oxycodone (6,900 ng/mL), and oxymorphone (6,400 ng/mL). What is the most appropriate interpretation of these results?
   A. Consistent with ingestion of morphine and OxyIR.
   B. Consistent with ingestion of morphine and Oxy IR, but also shows presence of hydrocodone
   C. Consistent with ingestion of OxyIR, but also indicates heroin use
   D. Consistent with ingestion of morphine, but not OxyIR

A patient is being prescribed morphine and OxyIR with a positive drug test for morphine (127,000 ng/mL), oxycodone (760 ng/mL) and oxymorphone (1,170 ng/mL). What is the most appropriate interpretation of these results?
   A. Consistent with ingestion of morphine and OxyIR
   B. Consistent with ingestion of morphine, but not OxyIR
   C. Consistent with ingestion of OxyIR, but not morphine
   D. Consistent with ingestion of morphine and OxyIR, but also numorphan (oxymorphone)

Weeding Through the Information: Interpreting Laboratory Test to Determine Second-hand Recreational, or Medical Use of Marijuana
Questions not provided

The Lab’s Responsibilities Concerning the 2013 ACC/AHA Lipid Guidelines
No questions provided

The Role of the Laboratory in Managing Osteoporosis
No questions provided

Congenital Adrenal Hyperplasia in Women
No questions provided

Male Menopause: Disease or Pseudoscience?
No questions provided
Chronic Kidney Disease: The Role of the Clinical Chemist
Which of the following lab tests is used in making a diagnosis of CKD?
A. Serum cystatin C
B. FE(Na)
C. Urine glucose
D. Urine albumin/creatinine

Which of the following variables is not part of the MDRD equation for estimated GFR?
A. serum creatinine
B. age
C. gender
D. serum cystatin C

Which statement about urine dipstick protein is true?
A. It will reliably detect Bence-Jones protein
B. It can be used to screen for antigen excess for immunoassays for urine albumin.
C. By itself, it can be used to give a good estimate of the severity of proteinuria
D. It is adequately sensitive to detect microalbuminuria

Autoimmune Disease: So Many Tests, but Not So Complicated
Which of the following combinations of autoantibody and disease is incorrect?
A. ANA: Systemic Lupus Erythematosus
B. ANCA: Wegner’s Granulomatosis
C. ANA: Primary Biliary Cirrhosis
D. anti-TTG: Celiac Disease

Which of the following methods is not typically used for autoantibody measurement?
A. Indirect Immunofluorescence
B. ELISA
C. Multiplex ELISA
D. Mass Spectrometry

All of the following are “weird but true” except:
A. You shouldn’t measure Tg unless you’ve proved that anti-Tg is not present
B. Rheumatoid Factor is an autoantibody directed against normal IgM molecules
C. IgA deficiency complicates screening for celiac disease
D. A large minority of healthy people positive ANAs

Coumadin Clinic: How the Lab Results are Used for Management and Treatment
No questions provided

Laboratory Management in a Health System
No questions provided

Take that Health System Laboratory to a New Level
No questions provided
Quality Control of the Future: Risk Management and Individualized Quality Control Plans (IQCPs)

Which device would best benefit from an individualized quality control plan?
A. A glucose meter where manufacturer recommends daily QC
B. A high volume chemistry analyzer requiring QC 3 times daily
C. A molecular test with 500 reactions occurring on a single use cartridge
D. A batch analyzer for infrequent therapeutic drug testing

Which errors would most likely be detected by traditional liquid QC?
A. A mistake where the assay pipette is set to the incorrect volume
B. Drug interference in a patient’s sample
C. Hemolysis in a neonatal specimen
D. A clot in a dialysis patient sample

Staff approach the medical laboratory director with a problem. During maintenance on Monday morning, a brown precipitate was found in the acid wash buffer which cleans all the cuvettes. It appears sometime over the weekend, staff poured an assay reagent into the wash buffer. What is the best course of action?
A. Fire the weekend staff
B. Call the manufacturer to determine how to flush the analyzer
C. Verify the validity of the weekend quality controls and reanalyze all the samples, correcting results as necessary
D. Contact risk management

CMS and CLIA Regulations: What to Know Now and Looking Ahead

What is the major CLIA regulatory change as a result of the Patient Access regulation?
A. Allows providers to send test results to patients
B. Allows patients to request test results directly from laboratory
C. Clarifies the HIPAA requirements for data security

The TEST Act allows the Secretary discretion for?
A. Revocation of the CLIA certificate for PT Referral
B. Imposition of the 2 year owner/operator ban when sanctioned for PT referral
C. Both a and b

What are the definitions included under Burden II that clarify intentional PT referral?
A. Reflex Testing
B. Confirmatory Testing
C. Distributive Testing
D. All of the above

IVD: What You wish You Learned in Training But Never Did

No questions provided