

## **CLINICAL PATHOLOGY CONTENT SPECIFICATIONS LABORATORY ADMINISTRATION AND OPERATIONS**

Unannounced inspections by CAP

Automation in the laboratory

Regulatory agencies, accreditation requirements, quality assurance

- new method validation

- method comparisons

- laboratory quality management plan

- specimen collection and handling

- reference ranges and critical value determinations

- publicly reported laboratory measures

Updates to CLIA, and other federal regulations

HIPPA

Laboratory Safety

Patient Safety

Critical values; Joint Commission recommendations for reporting

Informatics

IT issues - patient armbands, sample barcoding, laboratory automation

Consultations

Coding and Billing

Basic statistics used in internal QC, PT evaluation, reference range development, etc.

Bayesian statistics-sensitivity, specificity, PPV, NPV

The influence of prevalence on the positive and negative predictive values of assays

- Example 1: The impact of molecular diagnostics that are not 100% specific for the detection of *Neisseria gonorrhoeae* in low prevalence scenarios (i.e. the likelihood that a positive result will be false positive result).

- Example 2: As above, the impact of using the rapid respiratory virus EIA when the prevalence of disease is low (e.g., summertime in Ohio).

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