

CLIA GUIDANCE for DIGITAL PATHOLOGY

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CLIA

- Intent is to ensure accurate, reliable, timely testing
- Requirements minimal
- Based on test complexity, not lab location

CLIA QUALITY ASSURANCE

- Develop overall plan to monitor quality of test systems & processes
- Includes all CLIA regulations
- Includes all phases of testing: general, pre-analytic, analytic, post analytic systems
- Correct problems/complaints effectively to prevent reoccurrence
- Communicate with staff, clients

ADDITIONAL REQUIREMENTS

- Certificate rules w/ multi-site exceptions for hospitals, limited public health testing, mobile labs, temporary testing sites; otherwise, one (1) certificate per site
- Pre-analytical: test requisition information, specimen handling, test referral, test orders
- Analytical: evaluation with diagnostic interpretation
- Post analytical: result reporting;
- General: specimen integrity, confidentiality, complaints, personnel and proficiency

CLIA PERSONNEL

Required positions w/education, experience, training & **quality** responsibilities

- *Laboratory Director (LD) — overall quality responsibility*
- *Clinical Consultant (CC)*
- *Technical Supervisor (TS)/Consultant (TC)*
- *General Supervisor (GS)*
- *Testing Personnel (TP)*

High complexity tests have more stringent personnel standards than moderate

- **Competency**- annual check of personnel capability on all tests performed

Subpart K 493-1230

General Laboratory Systems

- Confidentiality
- Specimen Identification and Integrity
- Complaint Investigations
- Communications
- Personnel Competencies
- Evaluation of PT performance

CLIA NONWAIVED QUALITY STANDARDS

High complexity testing requirements:

- Certificates & Fees
- Quality Control
- Personnel qualifications & Responsibilities
- Recordkeeping and Retention
- Proficiency testing
- Quality Assessments for all Systems
- Inspections
- Enforcement

HISTOPATHOLOGY

- GROSS EXAMINATION

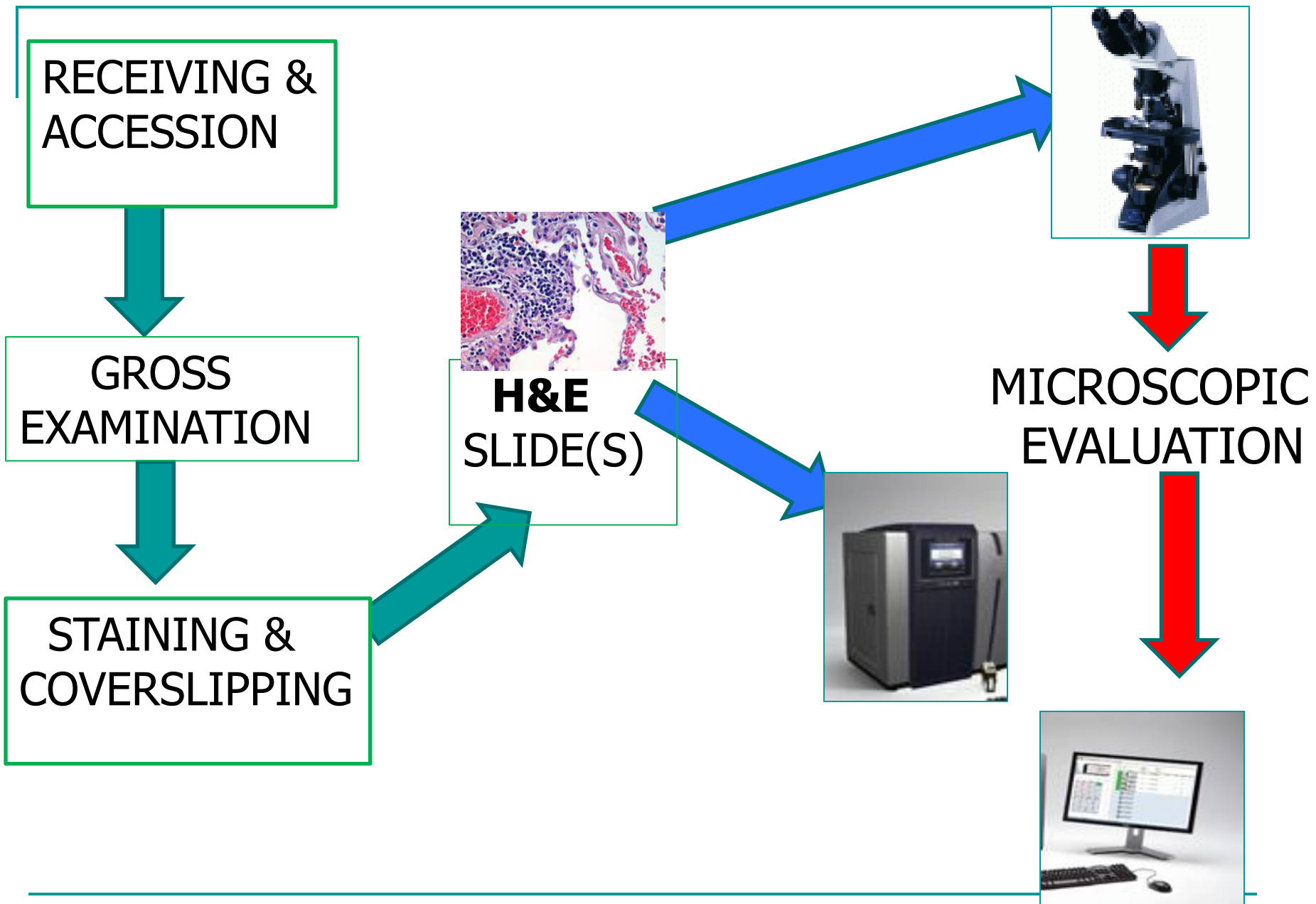


- MICROSCOPIC EVALUATION WITH DIAGNOSTIC INTERPRETATION

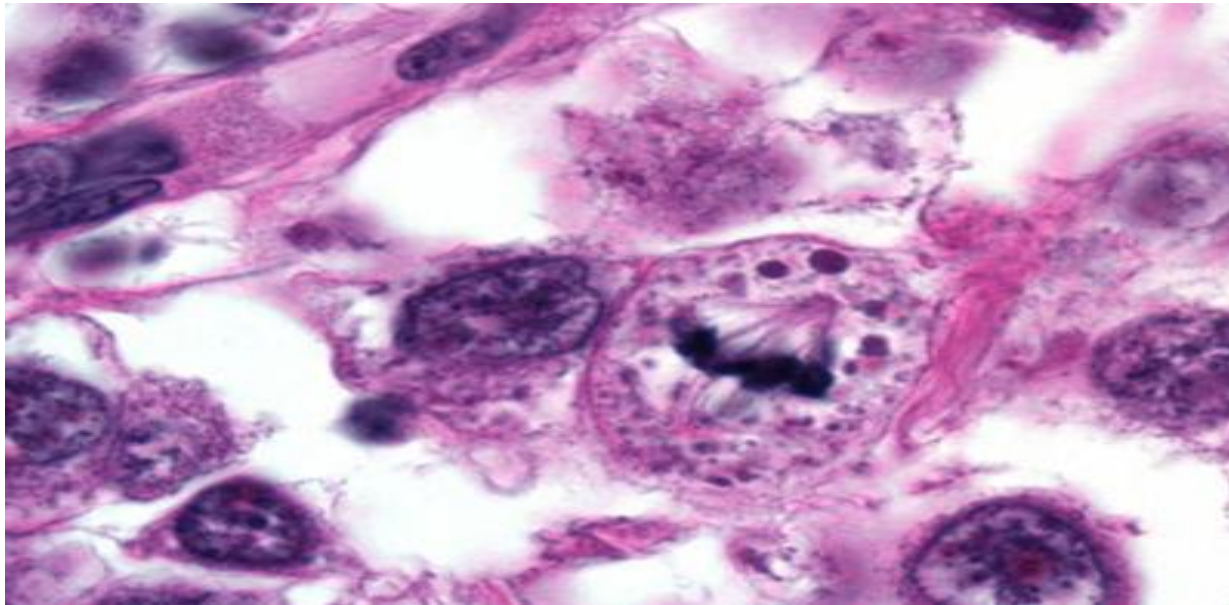


Preanalytic Systems

- Test Request
- Specimen submission, handling, and referral
- Preanalytic Systems Quality Assessment



Preparation of Tests



GLASS SLIDE OR DIGITAL IMAGE?

Analytic Systems

- Procedure manual
- Test Systems, equipment, etc.
- Establishment and verification of performance specifications
- Maintenance and Function Checks
- Calibration and Calibration verification
- Control Procedures

Analytic Systems (Cont.)

- Comparison of Test Results
- Corrective Actions
- Test Records

HISTOPATHOLOGY – SUBSPECIALTY REQUIREMENTS 493.1273

Analytic Systems quality Assessment

PATHOLOGY OFFICE

NEW



SURGI-CENTER



Surgery

Subpart J 493.1100

FACILITY

- FACILITIES - Location of imager - equipment

Location test performed - equipment

- RECORDS - test reports/specimen retention including slides/images

CLIA QUALITY CONTROL (QC) ANALYTIC SYSTEMS

- Monitors the quality of the performer, test, & lab's environment
 - Daily QC
 - Calibration/calibration check
 - Establish or verification of manufacturer's specifications
 - Instruments, reagents, supplies, maintenance
 - Procedure manual
 - Test results comparison
 - Corrective actions

WHOLE SLIDE IMAGING WITH H & E STAINED SLIDES

IMAGES SELECTED FOR DIAGNOSTIC INTERPRETATION

VALIDATION OF EQUIPMENT

- **FDA APPROVED / CLEARED**
Verify manufacturers specifications
- **NOT FDA APPROVED / CLEARED**
Established specification including analytic sensitivity/specificity

Validation of the test results*

Quality includes correlation studies

- STRONG AGREEMENT AND VALIDATION OF GLASS SLIDES WITH THOSE REVIEWED USING THE IMAGER
- CONDUCT CHECKS TO VERIFY THAT THE IMAGE TRANSMITTED, IS WHAT THE REVIEWER RECEIVED AT THE OTHER END

BACK UP PLAN IF COMPUTER FAILS

Post Analytic Systems

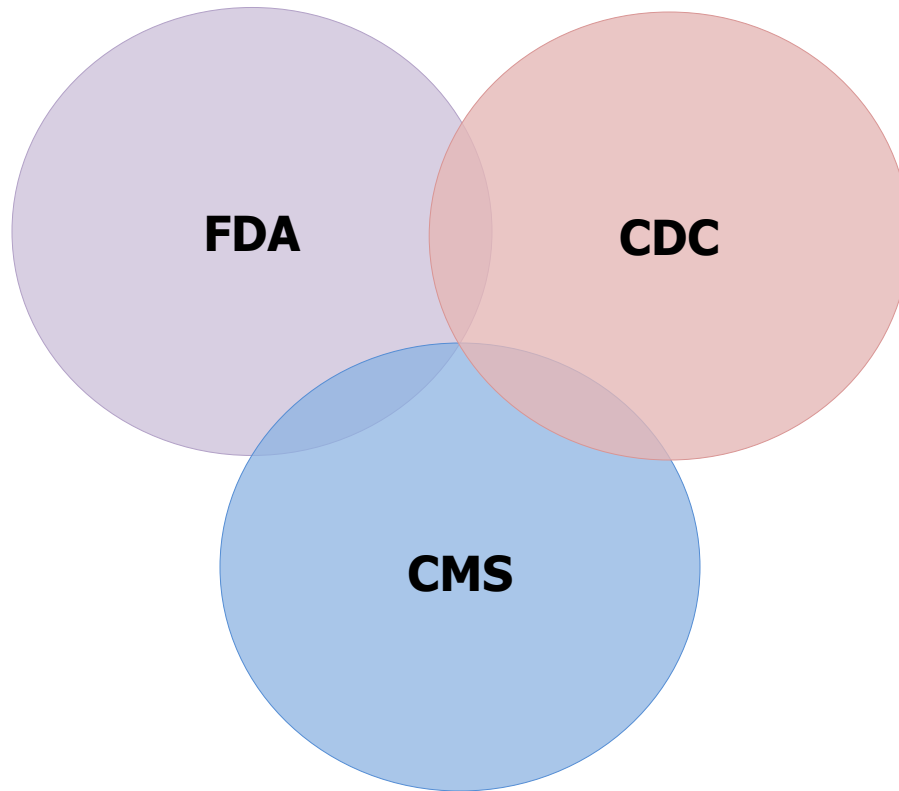
TEST REPORTS

- 493.1291 (c) (2) the location of the test performed???
- Interpretation at imaging location?
- Evaluated from Hotel? Home? Lab?

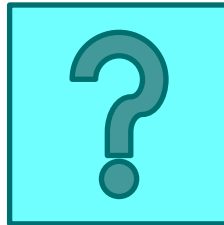
DIGITAL GROSSING



FEDERAL Tri-Agency CLIA ROLES



QUESTIONS



Thank You