# CLIA Corner

**State Hygienic Laboratory at The University of Iowa**

**First Quarter 2016**

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## In This Issue of the CLIA Corner we adress:



## Frozen Section Requirements

Many hospital laboratories have a cryostat used to perform an occasional frozen section. Do you know what the CLIA regulations and interpretive guidelines require when performing frozen sections? You can find the CLIA regulations and interpretive guidelines referenced in this article at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/App-C_Survey-Procedures-IGs-for-Labs-Labs-Svcs-Final.pdf.

### PRE-ANALYTIC

Test Request: The laboratory must have a written or electronic request for patient testing from an authorized person. Refer to §493.1242 (D5304) for specific test requisition requirements.

Specimen processing procedures: The laboratory must have a written procedure that includes the following, when applicable: patient preparation; specimen collection; specimen labeling, patient name or unique patient identifier; specimen source (when appropriate); specimen storage and preservation; conditions for specimen transport; specimen processing; specimen acceptability and rejection; and specimen referral.

- The interpretive guidelines list specific procedural requirements for histopathology/frozen section testing related to specimen processing. **Specimen processing for histopathology may include: specimen accessioning with or without fixation, embedding the paraffin block, cutting the paraffin block, mounting the embedded cut tissue to a slide, preparing the slide for staining, staining and cover slipping the slide, or any other slide preparation procedures that do not involve examination resulting in diagnostic interpretation.**

### ANALYTIC

Testing procedures: The laboratory must have a written procedure manual for all tests, assays and examinations performed by the laboratory, and these procedures must be available to, and followed by, laboratory personnel. Refer to §493.1251 (D5403) for specific test procedure requirements.

- Procedures for performing frozen sections must include, but are not limited to: microscopic examination of frozen section slides, including the detection of inadequately prepared slides; preparation of frozen section slides, solutions and stains; control procedures; corrective action to take when control results fail to meet the laboratory's criteria for acceptability; laboratory's system for entering results into the patient's record; and description of the course of action to take if the cryostat becomes inoperable.

Temperature records: The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: water quality, ***temperature***, humidity, and protection of equipment

and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

- The laboratory must document the cryostat temperature each day of patient testing.

Reagents and stains: Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate the following: identity and, when significant, titer, strength or concentration; storage requirements; preparation and expiration dates; and other pertinent information required for proper use.

- The laboratory must ensure that the staining containers themselves (not the lids) are labeled with the correct staining reagent.
- The laboratory must document lot numbers and expiration dates for the stains used to perform frozen sections and ensure the stains are not used past the expiration date.

Maintenance and function checks: The laboratory must perform and document maintenance and function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer.

- The laboratory must perform and document microscope and cryostat maintenance including, but not limited to, cleaning; defrosting; changing of the blade; etc.
- If the manufacturer does not specify the frequency for maintenance and functions checks, then it is the laboratory's responsibility to define them.

Quality Control: Each day of use, the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

- Each day of patient testing, the laboratory must document that the hematoxylin and eosin (H & E) stain quality is acceptable for the frozen section.

Retention requirements: The laboratory must retain stained slides, specimen blocks and tissue remnants as specified in §493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made.

- For retention requirements, including those for frozen sections, see the attached chart on p. 4.

## POST ANALYTIC

Test report: The test report must indicate the following: for positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number; the name and address of the laboratory location where the test was performed; the test report date; the test performed; specimen source, when appropriate; the test result and, if applicable, the units of measurement or interpretation, or both; and any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

- For frozen sections, the test report must state the location (name and address) where the frozen section was performed and the date the frozen section slides were read and reported. It should be made clear if the biopsy and frozen section were not performed at the same location. For example, if the frozen section was performed at Hospital ABC and the remainder of the biopsy was read at Hospital DEF, the test report should clearly indicate that the frozen section was performed at Hospital ABC.

**Quality Assessment**

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the pre analytic, analytic and post analytic systems.

**IQCP Reminder**

The Individualized Quality Control Plan (IQCP) education and transition period ends 12/31/2015. After this date, Equivalent Quality Control (EQC) will no longer be an acceptable option for CLIA quality control (QC) compliance.

Beginning 01/01/2016, there are two acceptable QC options:

1. Follow the CLIA “default” regulations of performing at least two levels of controls each day of patient testing; or

2. If the test system is eligible, develop and implement a complete IQCP.

After 01/01/2016, laboratories will receive deficiency citations if they are not in compliance with one of these options.

For more information in regards to IQCP, use the following links:

- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf
- www.whitehatcom.com/alere.
- http://clinmicro.asm.org/iqcp.

## CLIA RECORD RETENTION REQUIREMENTS

(As of August 2007)

| Type of Record | Specialty/Subspecialty | Retention Time |
|---|---|---|
| **Test Requisitions & Authorizations**<br>• Including patient's chart or medical record | **All** | **2 years** |
| **Test Procedures**<br>• Include dates of initial use and discontinuance | **All** | **2 years after procedure has been discontinued** |
| **Analytic Systems Records**<br>• Quality control, including instrument printouts, if applicable<br>• Patient test records, including instrument printouts, if applicable<br>• Analytic systems activities (maintenance, temperatures, functions checks), including instrument printouts, if applicable.<br>• Test performance specifications | **Immunohematology (Transfusion-related Only)** | As specified in FDA 21 CFR 606.160(b)(3)(ii), (b)(3)(v), & (d): ***Currently 10 years*** (After processing records have been completed, or six months after the latest expiration date whichever is the later date.) |
| | **All Others** | **2 years** |
| **Proficiency Testing**<br>• All records, including reporting forms, test records, signed attestation statement, program test reports | **All** | **2 years** |
| **Laboratory Quality Systems Assessment** | **All** | **2 years** |
| **Test Reports**<br>• Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) | **Immunohematology (Transfusion-related Only)** | As specified in FDA 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), & (d): ***Currently 10 years*** (After processing records have been completed, or six months after the latest expiration date whichever is the later date.) |
| | **Pathology Cytology & Histopathology** | **10 years** |
| | **All Others** | **2 years** |
| **Slides** | **Cytology** | **5 years** |
| | **Histopathology Oral Pathology Dermatopathology** | **10 Years** |
| | **All Others** | **No requirements** |
| **Specimen Blocks** | **Pathology** | **2 years** |
| **Tissue Remnants** | **Pathology** | **Completion of diagnosis** |

*NOTE: If the laboratory ceases operation, the laboratory must make provisions for record retention for the specified requirements.*