COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 93

Mohs Surgery

• Overview •

The purpose of this COLA Primer is to provide you with assistance in maintaining Mohs laboratory services that are both compliant with regulatory requirements and provide an accurate and reliable service to surgeons and patients.

Mohs surgery, aka Mohs micrographic surgery, is an outpatient procedure that is used to treat skin cancers in anatomic areas where tissue preservation is of utmost importance, such as the face, neck, hands and feet.

Typically, the procedure is done in stages and involves excising the tumor in layers along with a margin of non-cancerous skin around the tumor. The excised tissue is frozen and the margins are microscopically examined on-site immediately for the presence of any tumor. If cancer cells are found, an additional thin layer of tissue from the specific area of concern is removed, frozen and microscopically examined for the presence of any tumor. The process repeats until the tumor is completely removed.

The benefits of Mohs surgery include an exceptionally high cure rate and minimal cosmetic impact by preserving as much surrounding healthy tissue as possible. Because the success of Mohs surgery depends on the microscopic examination of surgical margins at the time of surgery, accurate and precise preparation of high-quality frozen sections in the Mohs laboratory is critical.

See the HIS section of the COLA Laboratory Accreditation Manual for complete COLA histopathology requirements.

• Cleanliness and Safety •

The space where frozen sections are performed must be adequate for processing and be kept clean and tidy. Ideally, it should be located close to the surgical suites to allow timely transport of tissue from the operating room to the laboratory and allow easy communication regarding the specimen, special considerations with specimen processing and other needs.

To protect laboratory staff, provide an easily accessible and working eyewash station, appropriate cabinets to store hazardous and/or flammable chemicals and a suitable fire extinguisher if flammable and combustible liquids are stored or handled. Supply staff with proper personal protective equipment (PPE) and ensure that all staff have been trained on the laboratory's chemical hygiene plan and hazard communication plan.

Clean, defrost and decontaminate the cryostat at regular intervals as defined in the laboratory's procedure. Document all maintenance activities and corrective actions.

If xylene or formaldehyde are used, levels must be monitored when the laboratory begins operation. Levels must be reassessed any time changes are made in personnel, equipment, procedures, testing volume or facility engineering that could affect exposure and/or exposure limits. Periodic repeat monitoring of formaldehyde may be required based on results. Xylene must be monitored initially, but there is no requirement for periodic monitoring.

Monitor and document the room temperature and humidity of the frozen section area daily to ensure proper performance of the cryostat. In addition, define acceptable ranges for the cryostat internal temperature, and check and record this temperature each day of use. Perform and document corrective actions when room temperature, humidity or the cryostat temperature are out of range, and include the name or initials of the person performing the monitoring and corrective actions.

● Labeling and Storage ●

Clearly label stain containers with the identity and concentration of the stain, open date and expiration date. Manufacturer instructions for use and storage of stains must always be followed, and no reagents may be used after their expiration date. Hazardous chemicals must be stored in appropriate cabinetry such as flammable, acid or base cabinets. Please refer to Primer 80 regarding Safety in the Pathology Laboratory. Frozen tissue specimens, chucks and slides must be properly labeled during processing and for storage immediately after completion of the intraoperative consultation.

Since the frozen section chuck often needs to be removed from the cutting stage of the cryostat in the course of sectioning, a method of temporary labeling of frozen section chucks is highly recommended to avoid mix-ups when working on cases with multiple chucks and slides.

Retain residual gross specimens after completion of the frozen section for at least the minimum required length of time. Store tissue specimens in an organized manner so that they are easily retrievable upon request.

• The Preanalytic Phase •

The preanalytic phase includes specimen collection, transportation and handling, patient and specimen identification and specimen orientation. Errors within the preanalytic phase can have significant impact to the subsequent phases of frozen section.

Communication between the surgeons and Mohs technicians in regards to specimen orientation is important. Common methods to designate specimen orientation include the use of sutures of differing number or length, clips of differing number and inks of differing color. A specimen may also be accompanied by a diagram or Mohs map indicating the location, orientation and Mohs layer of the specimen.

Specimens for frozen section should be delivered fresh without added preservative and as quickly as possible to best preserve the tissue. If there is any delay in delivery or processing, small tissue fragments should be placed on saline-moistened gauze to prevent the tissue from drying. Immersing the tissue in saline is not recommended because the tissue can absorb excess water, resulting in increased ice artifacts in the frozen tissue sections.

• Prevention of Cross-contamination •

Cross-contamination refers to the presence of tissue fragments from a different specimen or patient than the one being examined. A malignant cross-contaminant poses major implications for diagnostic interpretations and subsequent patient management. Therefore, it is critical for the laboratory to develop procedures that reduce the risk of cross-contamination at each step of the process where it may occur.

Cross-contamination may occur during grossing and staining, if the cutting board is not properly cleaned between specimens; this introduces risk of carryover from a malignant specimen to a benign one or vice versa. Each specimen should be grossed on a clean surface and all tools and other instruments in direct contact with the specimen must be changed or thoroughly cleaned before handling another specimen.

Staining lines can also be a source of cross-contamination. Frozen tissue sections can fragment and small pieces can break free and fall off from the slide as they are moved between stains. Free-floating tissue fragments in the staining baths could adhere to a different slide; filtering and/or changing the staining reagents frequently is recommended as a means to reduce this risk.

• Documentation •

Quality Control for frozen section includes the maintenance of all equipment, including the cryostat and the microscope; monitoring daily room temperature and humidity; and evaluation of stain quality each day of use. Maintain documentation of these activities, along with any unexpected events or problems and corrective action taken.

The frozen section laboratory must have detailed procedures approved by the laboratory director. These should include reagent management, specimen labeling requirements, staining procedure, specimen retention, quality control activities and reporting, to name a few.

Written procedures for cryomicrotomy must include the use of appropriate PPE while grossing and handling tissue, operating the cryostat, temperature settings of the cryostat, thickness of tissue sections for frozen section and marking of tissues to maintain patient identification at all times.

• Personnel •

See the Personnel Requirements for Anatomic Pathology Laboratories table included in the HIS section of the COLA Accreditation Manual.

All technical staff involved in frozen section examination and processing must undergo training initially and when changes or additions are made to the procedures. In addition, all technical staff must have their competency assessed and documented semi-annually the first year and annually thereafter. Competency assessment requirements for frozen sections are the same as general laboratory competency assessment requirements.

The requirement for competency assessment also applies to all physicians that provide diagnostic evaluation of the frozen section. If the Laboratory Director is the only physician providing diagnostic evaluation, they must document evidence of peer review, which could include case reviews and review of records, consultation documentation and reporting.

• Result Reporting •

The results of Mohs frozen section examination must be rendered, documented and signed by a dermatologist or dermatopathologist. The signature can be handwritten or electronic.

The written report must include required elements such as a gross description with a cassette/block designation key and diagnosis on each specimen submitted during the surgery. If available, pertinent prior histologic material and/or reports should be reviewed with current material being examined. Documentation of such review should be included in the current patient report.

The laboratory must have a written procedure to issue corrected or amended reports when required; for example, if discrepancies are noted upon review of previously reported results. All corrected or amended reports issued by the laboratory should indicate the reason for the changes made. Additionally, the procedure must include instructions to notify any other physician(s) who could be impacted by the changes.

● Handling of Frozen Section Slides and Residual Tissue ●

After frozen section evaluation, all frozen section slides should be permanently stained, mounted, properly labeled and retained along with the permanent section slides, if any, of the same case.

According to the American Academy of Dermatology (AAD), residual frozen tissue from Mohs surgical procedure is not required to submit for routine processing to permanent section except for rare occasions. Please refer to the 2014 American Academy of Dermatology Position Statement: Appropriate Uses of Paraffin Sections in Association with Mohs Micrographic Surgery.[1]

● Quality Assessment Plan ●

Like any clinical laboratory, Mohs surgery laboratories must establish and follow a written quality assessment (QA) plan to allow the detection of errors and ensure the quality of diagnoses. The QA plan must include preanalytic, analytic and postanalytic phases of testing. Examples of elements that should be included in a QA plan specific for Mohs surgery laboratories include test volumes, turnaround times, gross

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1 https://server.aad.org/Forms/Policies/Uploads/PS/PS%20Appropriate%20Uses%20of%20Paraffin%20Sections%20in%20Association%20with%20Mohs%20Mircographic%20Surgery.pdf?

examination, processing, staining, diagnostic accuracy, amended reports and incidents and errors.