COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 90

Grossing in the Pathology Laboratory

• Overview •

Grossing of specimens in the pathology laboratory is the evaluation and dissection of surgical tissue specimens removed for examination by a pathologist or by non-pathologist grossing personnel. Preparation of sections from tissues requiring processing is the initial step towards an accurate diagnostic report.

Tissue specimens may be submitted fresh for immediate evaluation, including intraprocedural consultation and/or frozen section. They may also be submitted fresh when culture is required, or when they must be placed in specialty fixatives (e.g. RPMI, Michel's solution, glutaraldehyde) for additional specialized testing. For routine tissue processing, specimens are often placed in a 10% neutral buffered formalin solution. The laboratory, depending on testing requested, may use additional fixatives for routine processing.

The purpose of this COLA Primer is to assist you in ensuring your grossing personnel and practices are compliant with regulatory requirements and ensure a safe working environment for the staff.

• Personnel •

Grossing of surgical tissue specimens requires qualified individuals who meet high-complexity testing requirements as defined by CMS.

Many laboratories delegate grossing to non-pathologists. This may include histotechnicians or histotechnologists, grossing technicians, and Pathologist's Assistants (PAs).

If delegation of grossing to a non-pathologist is permitted according to national, federal, state, and local guidelines, the individuals performing grossing must meet the qualifications as high-complexity testing personnel as defined below. It is the Laboratory Director's responsibility to define the extent of delegated responsibilities associated with grossing of tissue specimens. The laboratory must assess and verify the qualifications, training, and competency of each individual performing gross tissue processing. The extent of supervision must be defined and may vary from indirect to consultative to direct depending on the complexity level of the tissue specimen.

High complexity testing personnel must meet one of the following criteria:

1. MD/DO/DPM licensed in the state in which the laboratory is located
2. Doctoral, master's, bachelor's, or associate's degree in a chemical, physical, biological, or laboratory science
3. Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or have education equivalent to an associate's degree[1] AND graduated from a clinical laboratory training program AND have 3 months experience in each specialty of high complexity testing performed.

See 42 CFR 493.1489 (b) for details and additional information on personnel qualifications for high complexity testing

● Training for Non-Pathologist Grossing Personnel ●

Pathologist's Assistant

A certified PA is a highly trained professional who provides a variety of services under the direction and supervision of the pathologist. PAs interact with pathologists carrying out their duties under the direction of the pathologist. They are academically and practically trained to provide accurate and timely processing of the majority of pathology specimens received in the laboratory.

Grossing Technicians

Any personnel who are delegated grossing responsibilities must meet the educational and experience requirements for high complexity testing personnel, and are generally trained "on the job" under the direct supervision of a pathologist. The training requirement defined by CMS for high complexity testing is "*at least three months documented laboratory training in each specialty in which the individual performs high complexity testing*".

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[1] *(ii) Have education and training equivalent to that specified in paragraph 42 CFR 493.1489 (b)(2)(i) of this section that includes -*
(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either -
(1) 24 semester hours of medical laboratory technology courses; or
(2) 24 semester hours of science courses that include -
(i) Six semester hours of chemistry;
(ii) Six semester hours of biology; and
(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and
(B) Have laboratory training that includes either of the following:
(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)
(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

● Personnel Competency ●

ALL personnel who perform grossing responsibilities must be deemed competent to perform all aspects of their assigned responsibilities. Competency assessments should occur every six months for the first year and annually thereafter. Competency assessments must be reviewed and signed by the Laboratory Director or designated qualified pathologist.

For more detailed information on the personnel requirements for training and competency, please refer to the PER and HIS sections of the COLA Laboratory Accreditation Manual.

● Criteria for Grossing ●

Grossing of Tissue Specimens (HIS 52 – HIS 55)

Written procedures must include who can perform gross examinations; what parameters are included in the examination; guidelines for submission by tissue type; and how to document the gross examination. A grossing manual must be easily accessible to grossing personnel at the grossing stations.

If non-pathologists perform gross tissue examinations, the procedures must define the type of specimens that can be examined; the nature and extent of the examination to be performed; and the nature and extent of the pathologist's oversight.

● Grossing ●

Patient information on the requisition and specimen container MUST be reviewed prior to grossing to include patient demographics and specimen source/site. If there are any discrepancies, the process must halt until these are resolved.

Each individual specimen received is documented in the pathology report as a "gross description". This provides essential information for the pathologist to make an accurate diagnosis.

● Gross Description ●

The gross description must be clear and include the following pertinent findings when applicable:

- Description of what is received
- Type of fixation – if specimen is not received in a fixative, this must be noted

- Color
- Laterality
- Measurements to include dimensions and/or weight
- Biopsy specimens – number of pieces or cores
- Orientation of specimen – lumens, inked margins
- Key if applicable – inked margins, designation of o'clock positions
- Description of sections submitted for processing
- Cassette key with number of pieces in each cassette

Tissue should be sectioned according to the laboratory's written and approved procedures. Grossing protocols must be standardized for all grossing personnel to ensure consistent results and quality.

● Safety●

The pathology laboratory can be a hazardous place to work. Hazards to staff in the pathology laboratory include physical, environmental, biological, chemical, radioactive and ergonomic hazards, just to name a few. It is imperative that the laboratory have knowledge and understanding of all local, state, and federal requirements for laboratory safety to ensure a successful safety program and to keep laboratory staff safe on the job.

Grossing work stations/work spaces must be well ventilated to minimize inhalation of formaldehyde fumes by grossing staff. Personal protective equipment (PPE) is provided to employees to include disposable gloves, lab coats, eye and face protection and respirators as designated by the facility's exposure control plan and designation for the task performed.

You can find more detailed guidance about safe practices in COLA Primer 80, Safety in the Pathology Laboratory.

● References ●

COLA Laboratory Accreditation Manual
COLA Histopathology Criteria
COLA Primer 80 Safety in the Pathology Laboratory
American Association of Pathologists' Assistants