COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 92

Immunohistochemistry - IHC

• Overview •

Immunohistochemistry (IHC) is a common application of staining utilizing either chromogenic or fluorescent detection system. It involves the process of selectively identifying antigens (proteins) in cells using the principle of antibodies binding specifically to antigens in tissue sections. IHC may be used in Histology and Cytology laboratories by the pathologists to aid in diagnosing a multitude of processes including the identification of infectious organisms, the detection of metabolic defects, and the evaluation of neoplastic processes such as tumor classification/differentiation/origin, prognosis, and therapeutic responses. Manual and/or automated staining methods and platforms may be used in the laboratory.

The preferred specimen for immunohistochemistry is formalin fixed paraffin embedded tissue. Specimens fixed in specialty fixatives, cytology preparations, frozen sections, and tissue that has been decalcified, require separate validation and optimization of antibodies and control material.

The purpose of this COLA Primer is to provide assistance in assuring that your laboratory testing practices are compliant with regulatory requirements and ensure a safe working environment for the staff.

See the HIS section of the COLA Laboratory Accreditation Manual for complete COLA Histopathology requirements to include immunohistochemistry.

• Personnel•

See the Personnel Requirements for Anatomic Pathology Laboratories table included in the HIS section of the COLA Accreditation manual, following HIS 9. It is important to recognize that all staff must have competency assessed and documented semi-annually the first year and annually thereafter. Competency assessment requirements for all Histopathology personnel are the same as general laboratory competency assessment requirements. See PER 5-5.6 in the COLA Laboratory Accreditation Manual.

• Immunohistochemistry Procedures•

Laboratory procedures must include criteria for validation, verification, and calibration of all testing procedures. If the platform utilizes heated staining pads, stations, or drawers, temperature verification must be included.

Procedures must include monitoring and quality control of pH of buffers, reagent management including new lots and/or new shipments, requirements for revalidation, and control management. The procedure must include the documentation of reactivity (negative and positive) performed for each patient specimen, by the pathologist.

Procedures must include instructions for specimens submitted for staining that are NOT formalin fixed or paraffin embedded tissue specimens. These could include cytologic smears or preparations, or specimens processed for decalcification and specimen fixatives other than 10% formalin.

• Validation and Optimization •

Immunohistochemistry validation requirements must be defined in the laboratory's procedures. Procedures should include the number of established positive and negative cases to be utilized in the validation, the types of tissue required for validation, that staining and review be performed by the pathologist, and evaluation criteria. The laboratory should follow published guidelines and recommended industry standards, when possible, however, the Laboratory Director has the discretion to determine the scope of the validation, which most fits the need of the laboratory and can vary from antibody to antibody.

Laboratories performing predictive marker staining, quantitative image analysis, must meet current published guidelines and industry standards for validation. (See HIS 65)

Validation and optimization of each antibody/marker and the protocol for each staining method must be reviewed, approved, and signed by the Laboratory Director prior to use by the laboratory.

• Storage •

All reagents to include antibodies, detection kits, buffers, wash reagents, purchased controls, control blocks and laboratory prepared reagents must be stored according to manufacturer recommendations and defined laboratory procedures.

• Proficiency Testing •

Proficiency tests have a wide range of quality assurance applications. While proficiency testing can be used to evaluate individual proficiency, the main intent is to verify that a laboratory's analytical operations platforms, manual or automated, are effective and the quality of work is consistent and being maintained. Laboratories should include immunohistochemistry in their Proficiency Testing plan. Markers considered to be predictive such as ER/PR, Her2, are required, however, many other markers could be included such as Ki67, CD117, PD-L1, enhancing the laboratory's ongoing quality assessment.

• Biohazard and Hazardous Waste •

The bloodborne pathogens standard defines regulated waste as liquid or semi-liquid blood or other potentially infectious material (OPIM). Blood, body fluids, pathology tissues and contaminated items are considered biohazardous waste and must be disposed of accordingly. Biohazardous waste is disposed of in appropriately labeled biohazard bags or bins.

All sharps to include glass slides must be disposed of in a biohazard sharps waste container.

Regulations of what can and cannot be dumped down the drain vary from city to city and state to state. If you are unsure whether or not you can dispose of a chemical used in your laboratory (such as formalin, DAB chromogen, buffers and other reagents used in immunohistochemistry) down the drain, review the SDS sheet and consult your Chemical Hygiene Officer.

Both biomedical and hazardous waste management may be controlled by the facility rather than the pathology department and must be disposed of in compliance with all local, state, and federal regulations.

• Personal Protective Equipment •

Personal protective equipment (PPE) includes protection for eyes, face, head, extremities, protective clothing, and respiratory protection. Common PPE includes goggles, face shields, chest rest shields, gloves, lab coats, surgical and/or N95 masks, and respirators. Appropriate PPE is based on the task and workplace assessment performed at and by your facility.

One of the most common chemicals laboratory workers are exposed to is latex. Some healthcare workers may be latex sensitive. Although many laboratories have eliminated latex in the workplace, staff sensitive to latex must be provided alternative PPE and special precautions may be needed to protect these workers from exposure to latex gloves and other products containing latex.

This Primer includes highlights of the safety standards covering the major hazards that staff may encounter in the pathology laboratory. Please reference OSHA's Laboratory Safety Guidance for additional details and full requirements.

See the FAC and HIS sections of the COLA Laboratory Accreditation Manual for laboratory safety criteria.

• Documentation •

All documentation, including validation and optimization of antibodies, controls, quality control, new lot and shipment verification records, temperatures, maintenance of instrumentation, pipettes, pH meters, ovens, other equipment and hoods, exposure control monitoring and training documents are maintained and current as specified by your facility, COLA accreditation requirements, and all local, state, and federal regulations.

• Definitions •

IHC – Immunohistochemistry
OSHA – Occupational Safety and Health Administration
PPE – Person Protective Equipment

SDS – Safety Data Sheets

• References •

COLA Laboratory Accreditation Manual
COLA Primer 80 Safety in the Pathology Laboratory
CLIA Laboratory Interpretive Guidelines

OSHA Fact Sheets for quick reference:

Bloodborne pathogens
https://www.osha.gov/sites/default/files/publications/bbfact04.pdf

Chemical Hygiene Plan (CHP)
https://www.osha.gov/sites/default/files/publications/OSHAfactsheet-laboratory-safety-chemical-hygiene-plan.pdf

Chemical Fume Hoods
https://www.osha.gov/sites/default/files/publications/OSHAquickfacts-lab-safety-chemical-fume-hoods.pdf

Latex Allergy
https://www.osha.gov/sites/default/files/publications/OSHAquickfacts-lab-safety-latex-allergy.pdf

Personal Protective Equipment (PPE)
https://www.osha.gov/sites/default/files/publications/bbfact03.pdf