BAP.05366 Slide Quality **Phase II**

The immunohistochemical stains produced are of acceptable technical quality.

NOTE: The biorepository director or designee reviews slides and determines if they are of acceptable technical quality. The inspector must examine examples of the immunohistochemical preparations offered by the biorepository. A reasonable sample might include 5-10 diagnostic antibody panels.

REFERENCES
1) Shellhorn N. IHC troubleshooting tips. *Advance/Lab*. 2000;9(1):33-37

BAP.05367 QC - Immunofluorescence **Phase II**

For immunofluorescence microscopy, appropriate positive and negative controls are performed.

NOTE: Internal antigens serve as positive controls (eg, IgA in tubular casts, IgG in protein droplets and C3 in blood vessels). When internal positive controls are absent, daily external positive controls are required. Non-reactive elements in the patient specimen may serve as a negative tissue control. A negative reagent control in which the patient tissue is processed in an identical manner to the test specimen, but with the primary antibody omitted, should be performed for each patient test specimen at the discretion of the biorepository director.

Evidence of Compliance:
- ✓ Records of immunofluorescence QC

REFERENCES
1) Walker PD, *et al.* Practice guidelines for the renal biopsy. *Mod. Pathol.* 2004;17:1555-1563
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1273(a)]

BAP.05369 Special Handling of Creutzfeldt-Jakob Disease (CJD) **Phase II**

The biorepository handles tissues from cases of suspected transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease (CJD), using procedures that minimize the risk of transmission.

NOTE: Specialized handling instructions and an appropriate process for intra-laboratory communication must be addressed in the written procedure.

Neuropathology tissues from suspected cases of Creutzfeldt-Jakob disease should be treated with formic acid. Paraffin blocks and slides prepared from formic-acid-treated tissue may be handled routinely.

If tissue has not been treated with formic acid, it must be hand-processed and treated as containing potentially transmissible prions. Double gloves must be worn at all times when handling such tissue. All solutions, including water washes, must be collected and treated with equal volumes of fresh undiluted household bleach for 60 minutes before disposal. All scraps of paraffin and unused sections should be collected on a disposable sheet. The microtome may be wiped with bleach or NaOH solution. No special precautions are needed in handling intact glass slides once they have been coverslipped. Broken slides should be decontaminated and discarded. Paraffin blocks should be stored in a bag or box and labeled as infectious. Alternatively, the biorepository may reseal the cut surface of the blocks with paraffin.

REFERENCES
1) Brown W, et al. A simple and effective method for inactivating virus activity in formalin-fixed tissue samples from patients with Creutzfeldt-Jakob disease. *Neurology.* 1990; 40:887-890.
2) Brown P. Guidelines for high risk autopsy cases: special precautions for Creutzfeldt-Jakob disease. In: Hutchins G, ed. Autopsy performance and reporting. Northfield, IL: College of American Pathologists. 1990:68-74.
3) Greenblatt M. Q&A. Northfield, IL: College of American Pathologists. *CAP Today.* 1993(March): 7(3):69-70.
4) Crain BJ. Safety tips for anatomic studies of possible CJD. Northfield, IL: College of American Pathologists. *CAP Today.* 1996(Jan); 10(1):56.

5) Rank JP. How can histotechnologists protect themselves from Creutzfeldt-Jakob disease. *Lab Med.* 1999; 30:305.
6) Nixon RR. Prions and prion diseases. *Lab Med.* 1999; 30:335-338.
7) Collins KA, ed. *Autopsy Performance & Reporting.* 3rd ed. Northfield, IL: CAP Press; 2017.

SPECIALIZED TECHNIQUES

WHOLE SLIDE IMAGING

Inspector Instructions:

READ	• *Sampling of training records* • *System validation records*
ASK	• *How are the images generated used?*

BAP.05375 Whole Slide Imaging User Training **Phase I**

There are records showing that all users of the whole slide imaging system have been trained.

NOTE: Users of the whole slide imaging system include individuals responsible for slide scanning and digital slide quality assessment, as well as pathologists. The training procedure should include role-specific training, as defined in the approved laboratory procedures. Retraining may be required when significant system changes are made.

Evidence of Compliance:
✓ Records for whole slide image training in personnel files

BAP.05400 System Qualification - Whole Slide Imaging **Phase II**

If digital whole slide imaging is used as an integral part of the biorepository operation, there are records that the system has been qualified for the intended use.

DIGITAL IMAGE ANALYSIS (DIA)

This section applies to laboratories using digital image analysis to evaluate specific features in a tissue section image following enhancement and processing of that image, including but not limited to, IHC, morphometric analysis, and ISH. This checklist section does not apply to laboratories that are imaging slides for manual scoring or review by an individual.