ANP.24300 Special Handling of Transmissible Spongiform Encephalopathies (TSE) Phase II

The laboratory 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. Disposables, glassware, tools, etc. must be handled according to the procedures employed in the autopsy room described elsewhere in this checklist. 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 laboratory may reseal the cut surface of the blocks with paraffin. Additional information may be found in the Autopsy section of this checklist.

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 and Reporting.* 3rd ed. Northfield, IL: CAP Press: 2017.

ANP.27150 Glass Slide/Block Disposal Phase I

The laboratory safely disposes of used glass slides and paraffin blocks.

NOTE: The laboratory must follow CAP retention requirements for slides and blocks (refer to checklist requirement in the Surgical Pathology Reports section of this checklist).

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). Clinical Laboratory Waste Management; Approved Guideline—Third Edition. CLSI document GP05-A3 (ISBN 1-56238-744-8). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2011.
2) Title 45, CFR; parts 160, 162, And 164, Health Insurance Reform: Security Standards; Final Rule, Federal Register, Published Feb. 20, 2003. Health Insurance Reform].

NOTE: The following four requirements apply to microwave devices used in the histology laboratory.

ANP.27170 Microwave Usage Phase I

Microwave devices are used in accordance with manufacturer's instructions.

ANP.28290 Microwave Monitoring Phase I

Microwave devices are monitored for reproducibility at least annually.

NOTE: "Reproducibility" is defined as consistency in diagnostic quality obtained from microwave equipment and procedures. For some devices, reproducibility may be evaluated by monitoring

the temperatures of identical samples after microwave processing. For those microwave devices (particularly those incorporated into histology processing equipment) that use temperature-independent methods to evaluate reproducibility, the reproducibility must be assessed following instrument manufacturer's instructions.

The microwave device must be tested for radiation leakage if there is visible damage to the device. A description of the specific damage along with the result of the test must be recorded.

Evidence of Compliance:

- ✓ Records of monitoring the diagnostic quality of specimens processed using microwaves

ANP.28860 Microwave Container Venting **Phase I**

All containers used in microwave devices are vented or are used in compliance with manufacturer's instructions for the microwave instrumentation used.

NOTE: Venting of containers is necessary so that processing occurs at atmospheric pressure, to prevent explosion. For procedures using pressure above that of the atmosphere, specialized containers must be used, with strict adherence to manufacturer's instructions.

ANP.29430 Microwave Venting **Phase I**

Microwave devices are properly vented and the effectiveness of ventilation is monitored at least annually.

NOTE: Some types of microwave devices need to be operated in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents. Before operation of the microwave device, flammable and corrosive reagents must be removed from the hood to prevent fire or chemical damage to the electronic components of the device. Microwave devices used outside a fume hood must have an integral fume extractor certified by the manufacturer for use in a clinical laboratory.

This checklist item does not apply to microwave devices that are designed by the manufacturer to operate without venting. It also does not apply if only non-hazardous reagents (as defined in the safety data sheets) and non-infectious specimens (eg, paraffin specimens) are used in the device.

Evidence of Compliance:

- ✓ Records of annual evaluation of ventilation effectiveness

CIRCULATING TUMOR CELL ANALYSIS (CTC)

This section applies to laboratories using a test system to prepare, analyze, and quantify circulating tumor cells in whole blood, including immunomagnetic separation and labeling using antibodies and fluorescent stain.

VALIDATION AND CALIBRATION

Inspector Instructions:

READ

- Sampling of validation and calibration policies and procedures
- Sampling of validation/calibration records