Q&A column

Editor: Frederick L. Kiechle, MD, PhD

Submit your pathology-related question for reply by appropriate medical consultants. CAP TODAY will make every effort to answer all relevant questions. However, those questions that are not of general interest may not receive a reply. For your question to be considered, you must include your name and address; this information will be omitted if your question is published in CAP TODAY.

Q. The laboratory at which I work uses two proficiency testing programs—from the CAP and an alternate provider—for dermatologists who perform fungal smears. Our laboratory administers challenges for both programs every six months. The dermatologists have variably passed and failed challenges from both programs such that the record of satisfactory challenges alternates between the CAP and the alternate provider's programs. Is our approach allowed? Do we need to stick with a single PT provider for one year before switching?

A.September 2022—A laboratory may enroll in a proficiency testing program for a particular test with more than one PT provider. However, the laboratory needs to designate one of the two as the primary PT provider for that test for at least one year to comply with CLIA regulations. This ensures that performance can be monitored continuously for an extended period to detect trends and/or performance issues. A different PT provider may be designated after one year.

The laboratory must review and evaluate PT results from the designated PT provider and take corrective action for each unacceptable result. If a laboratory enrolls in a secondary PT program to ensure proficiency or competency in additional areas performing the same test or to evaluate multiple personnel who perform the same test, then the laboratory must review the results from the secondary PT provider and address them per its policy.

In lieu of using two PT providers, the laboratory may want to use one PT provider and reuse the PT challenges *after* the PT result due date to evaluate the proficiency or competency of additional dermatologists. You cannot share the PT materials prior to the PT result due date.

Clinical and Laboratory Standards Institute. QMS24: Using proficiency testing and alternative assessment to improve medical laboratory quality. 3rd ed. 2016.

Condition: Enrollment and Testing of Samples. 42 CFR §493.801(a) (1992).

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Q. Should flow cytometry be used to test a cerebrospinal fluid specimen with known or suspected Creutzfeldt-Jakob disease? Our hospital administration is pushing to run such samples. I think the testing should not be done because it would contaminate the instrument and potentially endanger the flow techs.

A.*Biosafety in Microbiological and Biomedical Laboratories*, copublished by the Centers for Disease Control and Prevention and the National Institutes of Health, is a good resource on handling human materials that may contain prions.

The online advisory document states:

> Prions are transmissible by inoculation, ingestion, or transplantation of infected tissues or homogenates. Prion infectivity is high in the brain and other central nervous system tissues and lower in lymphoid tissues including the spleen, lymph node, gut, bone marrow, and blood. A 2017 study indicates the presence of low levels of prion infectivity in the skin of sporadic Creutzfeldt-Jakob disease (sCJD) decedents.

About 400 to 500 people in the United States are diagnosed with a prion disease annually. Patient samples, excluding neurological tissue, are routinely tested by medical laboratory scientists in clinical laboratories using reusable laboratory equipment. According to the aforementioned publication, "Although sCJD infections have occurred in medical specialists and health professionals, including pathologists who encounter cases of CJD post-mortem, no overall increased occupational risk for health professionals has been found."

Although prions can be detected in skin and CSF, they are found in greater abundance in neural tissue. There is not enough data to guarantee that there is zero risk of transmitting a prion disease by handling and processing CSF and non-neural tissue from patients with prion disease. However, the epidemiological risk is between zero and undetectable.

I believe that avoiding testing because of the theoretical risk of prion exposure, when the epidemiological risk is so low, or even nonexistent, is too conservative of an approach. This approach is many times more likely to cause patient harm, by preventing the diagnosis of a treatable disease, than it is to prevent occupational transmission of prion disease.

Each institution should perform its own risk assessment and arrive at its own conclusions. Even if your institution concludes that it is acceptable to process these CSF and other non-neural samples on reusable instrumentation, it is possible that the instrument vendors may not be willing to service these instruments in such circumstances.

Centers for Disease Control and Prevention, National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories*. 6th ed. Revised June 2020. https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

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