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Prion Lab Sample Handling, R-PO-AD-1048-04

PURPOSE

To define the laboratory policy for processing samples for testing that may be infected or suspected of being infected with a group of protein particles known as prion particles.

BACKGROUND

Creutzfeldt-Jakob Disease (CJD) or a variant (vCJD) are the most common diseases containing the prion particle. A protein test called 14-3-3 is also related to CJD and other neuro-degenerative disease. Requests to test for this protein should follow this policy. Samples must be received labeled in accordance with CHI Franciscan patient identification policies. Samples are not sent out for testing until the ordering provider has completed the [National Prion Disease Pathology Surveillance Center Test Form](#) which is bagged separately and sent with the sample. If the patient is to be directly billed, billing information must be sent with the sample. SJMC and Harrison Laboratories are considered the referral hubs for the laboratories within CHI Franciscan. On-site testing for CSF glucose, protein, cell counts is available at each hospital laboratory. Routine cultures are performed at SJMC and Harrison Laboratories.

RISK OF INFECTIVITY

The risk for healthcare transmission of prion particles is dependent upon the probability that an individual has or will develop the disease, the level of infectivity in the individual specimen type, and the route of exposure. Risk assessment and prevention of exposure through the use of personal protective equipment and disposable equipment are the best means to reduce any risk of transmission in the health care setting.

Infectivity Level	Tissue / Specimen Type
High	Brain, dura mater, spinal cord, eye, pituitary gland
Low	Kidney, liver, lung, lymph node / spleen, cerebrospinal fluid (CSF)
No Known Infectivity	Heart, skeletal muscle, peripheral nerves, adipose tissue, gingival tissue, intestine, adrenal gland, thyroid, prostate, testes, or in bodily secretions/excretions such as tears, sweat, sputum, stool, urine, semen, and breast milk
No known transmission risk	Blood

RELATED DOCUMENTS

CHI Franciscan [Creutzfeldt-Jakob Disease Management Protocol, 911.00](#)

[National Prion Lab Test Requisition](#)

[Prion / High Risk Pathogen Process](#) -HEME


[Prion/High Risk Pathogen Microbiology](#)

PRECAUTIONS FOR POTENTIALLY INFECTIVE SPECIMEN TYPES

- Review all lab policies before proceeding with processing a sample designated as "Prion" or for Prion testing. Inform supervisor/manager when a sample of this type has been received.
- Standard precautions for blood and body fluid exposure apply to staff use of personal protective equipment.
- Samples with potential prion particles are hand delivered to the laboratory or pathology and "handed off" to laboratory staff as "Prion Protocol". Once received in the laboratory, sample aliquots must be labeled with the word "PRION" somewhere on the sample in permanent marker or with a taped label, if not already labeled by the department where the sample was collected.
- Disposable equipment is preferred when handling samples considered suspect for prion particles. Equipment is discarded, after soaking in freshly made 10% bleach, into an incineration box provided by Environmental Services (EVS). For non-disposable equipment, extended soaking of all equipment used during sample analysis in a fresh 10% bleach solution for 1 hour is required.
- Personal Protective Equipment (PPE) consisting of a face shield, gloves and lab coat is required to handle specimens for Prion testing and should be disposed of after one use.
- Minimize the number of different staff involved in the sample handling of a potential prion sample to reduce exposure risk.

COMMUNICATION

The CHI Franciscan Prion and Creutzfeldt-Jakob Disease Management protocol 911.00 is activated when there is an admission, diagnosis, or surgical procedure scheduling of a patient with known or suspected CJD/vCJD or other prion disease. Once laboratory receives the sample communication is escalated.

1. The microbiology manager, main lab, or pathologist (on-call if after hours) should be notified as part of the Prion and Creutzfeldt-Jakob Disease Management protocol 911.00. The lab person receiving notification communicates with other laboratory managers, supervisors, tech in charge, and specimen center staff when the protocol has been implemented.
2. Upon receipt of the sample, the laboratory staff member who accepts the specimen will notify the microbiology manager, their manager, supervisor, or tech in charge that a prion sample is in the laboratory. This notification is critical for the proper handling and/or testing, and disposal of the sample and equipment after testing.
3. Dry ice may be obtained Monday-Friday from hospital distribution (couriers) at 253-426-6152,  for all laboratory sites.
4. The referral laboratories(SJMC and Harrison) must be notified by the sending laboratory before sending samples.

5. Environmental Services (EVS) must be contacted to deliver an incineration box to the laboratory for disposal of all prion suspected specimens and any other infectious material generated. If extra CSF sample is frozen and to be disposed of at a later date, the same disposal process applies.

EPIC ORDERS

Once testing has been approved, confirm the proper order was placed in Epic for the requested testing. If testing is not approved, cancel testing with appropriate comments in LIS after *consultation* from manager or medical director.

SAMPLE HANDLING AFTER IMPLEMENTATION OF THE PROTOCOL

Laboratory staff will stabilize the samples until approval is obtained. Testing will not be performed at a CHI-Franciscan Laboratory until the manager or medical director has approved and necessary paperwork completed by ordering provider, as needed.

- Hematology and Microbiology have department specific procedures for processing these samples within the department using disposable equipment.
- CSF protein and glucose may be performed on lab instrumentation due to low infectivity using disposable equipment. Waste is handled per Storage and Disposal instructions.
- For pathology samples, if there is a differential diagnosis of prion, routine pathology examination will not be performed until the prion diagnosis has been determined by the referral laboratory.
- For brain tissue samples, consult with pathology is required.

STORAGE AND DISPOSAL

Store CSF and urine in -20 C freezer when being transported to the National Prion Lab for testing. For testing performed on-site store per test directory requirements. Store tissue preserved in formalin in the appropriate sample bin for the site. The sample should be marked "do not dispose". All samples continue to be labeled as "Prion" and when ready to dispose of call Environmental Services for a special container

- Environmental Services (EVS) must be contacted to deliver an incineration box to the laboratory for disposal of all prion suspected specimens and any other infectious material generated through processing or testing. If extra CSF/URINE sample is frozen and to be disposed of at a later date, the same disposal process applies.
- When the incineration box is ready for pickup EVS is notified by the tech in charge or MT Coordinator. This box should be picked up by EVS within an hour of notification.

SAMPLE TRANSPORT AND PACKAGING

TRANSPORT WITHIN THE HOSPITAL

Specimens from prion protocol patients must be hand-delivered to the laboratory as PRION samples to laboratory or pathology staff. DO NOT USE THE TUBE SYSTEM. The samples will arrive double bagged and the word "PRION" will be marked on the outside of the bag in the lab, if not already labeled. **Note:** CSF samples for referral must be frozen immediately until National Prion Lab paperwork containing patient history is completed by the ordering provider. Brain tissue samples will be sent in formalin. Samples are stabilized until test request is evaluated and approved by manager and/or medical director.

TRANSPORT BETWEEN LABORATORIES TO THE REFERRAL HUB (SJMC or Harrison)

The Paperwork (LIS packing list and National Prion Lab Test requisition) sent with the specimens to referral hub (SJMC lab/Harrison lab) must be kept separated from the samples so that lab staff are able to review the paperwork without disturbing the packaging that has been performed.

- **CSF AND/OR URINE SAMPLES**

Place the Labeled CSF and /or urine tubes marked as PRION in a transport bag with sufficient absorbent material to absorb all of the sample (if there was a leak), and then into a small box. Note: Urine is an optional sample type that should be sent if available.

- Obtain dry ice when ready to transport if testing is to be referred to the National Prion testing lab.
- Place the smaller box containing only the CSF/urine sample(s) labeled as PRION is into a styrofoam box containing enough dry ice to keep the CSF/urine frozen during transport to the referral hub (SJMC Lab/Harrison Lab) where it will be sent out to the reference lab.
- The mandatory National Prion Lab Test Requisition must be completed by the ordering provider for patient history information, bagged separately, and sent with the LIS packing list.

- **BRAIN TISSUE SAMPLES**

Biopsy samples are placed in a screw top container identified per policy. Samples must be fixed in formalin so pathology must be consulted. The container is labeled as PRION, then placed in a specimen transport bag, then in another transport bag. The requisition is separated from the biopsy and placed in the second transport bag. The biopsy package and paperwork is then placed in a transport box to the main hub for pathology. If prion testing is requested on the biopsy, but no routine pathology ordered, the biopsy sample may be processed through the main referral hub after consultation with pathology.

REFERENCE

APIC TEXT of Infection Control and Epidemiology 10/3/2014; *Creutzfeldt-Jakob Disease and Other Prion Diseases*; Beth Ann Kavanaugh, MT(ASCP), MS, MBA, CIC, University Health System San Antonio, TX

Attachments:

No Attachments

Approval Signatures

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Applicability

CHI Franciscan Health, Harrison Medical Center, Highline Medical Center, St. Anthony Hospital, St. Clare Hospital, St. Elizabeth Hospital, St. Francis Hospital, St. Joseph Medical Center

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