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Area	Laboratory-Safety
Applicability	All Beaumont Hospitals

Clinical Pathology Laboratory Specimen Handling and Precautions for Potential CJD Specimens

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Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. This procedure is to instruct laboratory staff in safe specimen handling precautions so as to prevent the acquisition of Creutzfeldt-Jakob Disease (CJD) and other prion diseases.

II. GENERAL INFORMATION:

A. All of the prion diseases (collectively called transmissible spongiform encephalopathies, (TSE)) are degenerative neurological disorders. A prion is an abnormal, transmissible agent that is able to induce abnormal folding of normal cellular prion proteins in the brain, leading to brain damage and the characteristics signs and symptoms of the disease. In humans, prions cause four forms of Creutzfeld-Jakob disease (CJD) and other neurological diseases. All prion diseases are universally fatal. Although an extremely rare disease, CJD is the most common of these encephalopathies. The incubation period for CJD varies from months to decades, and the disorder is rapidly fatal once symptoms develop. This disease is manifested clinically as a rapidly progressive dementia that includes psychiatric and behavioral abnormalities, coordination deficits, myoclonus and a distinct triphasic and polyphasic electroencephalogram reading. Definitive diagnosis of CJD requires histological examination of the affected brain tissue.

B. CJD is not transmitted by direct contact, droplet or airborne spread. Iatrogenic transmission of CJD has resulted from the direct inoculation, implantation or transplantation of infectious materials. The form of CJD disease of which laboratory workers, in general, and workers in surgical and anatomic settings, in particular, should be aware is the iatrogenic form (iCJD). iCJD is caused by exposure to tissues (especially brain and other neural tissues) during

autopsies, surgery, and preparation of tissues for histology.

C. Prions exhibit unusual resistance to conventional chemical and physical decontamination methods. **Neither sterilization with ethylene oxide nor steam autoclaving at conventional exposure conditions (121°C for 15 min.) inactivates prions**. Additional harsh measures are required to inactivate prions.

D. Prions cannot be cultured in the laboratory. Specimens (Cerebral Spinal Fluid (CSF), blood, brain tissue) can be forwarded to the National Prion Disease Laboratory at Case Western Reserve University for analysis for the 14-3-3 protein that is a marker for some prion diseases such as CJD. This protein can also be present in other neurodegenerative diseases.

E. Potential CJD specimens can be classified by level of risk to laboratory workers.

1. **High-risk** specimens: brain (includes dura mater and spinal cord) and eyes.
2. **Low-risk** specimens: CSF, kidney, liver, spleen, lung and lymph nodes.
3. **No-risk** specimens: peripheral nerve, intestine, bone marrow, blood, leukocytes, serum, thyroid gland, adrenal gland, heart, skeletal muscle, adipose tissue, gingival, prostate, testis, placenta, tears, nasal mucus, saliva, sputum, urine, feces, semen, vaginal secretions and milk.

NOTE: In 2011, the College of American Pathologists stated that CSF could be placed in the group of No-Risk specimens based on the lack of documented infections in laboratory staff and questionable prion transmission studies published in the last 10 years. The World Health Organization and the Centers for Disease Control (CDC) and Prevention have **NOT** removed CSF from the list of Low-risk specimens. **The Prion and Public Health Office at CDC still consider that CSF is a Low-risk specimen but can be handled with strict observance of Standard Precautions. Instruments on which these specimens are tested are to be decontaminated according to the manufacturer's instructions.**

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III. GUIDELINES:

A. **Safety**

1. It is expected that all laboratory staff will follow standard precautions when working with clinical specimens.
2. **Personal Protective Equipment**
    a. The biosafety level classification for prions from human tissue is BSL-2. Human prions propagated in animals should also be handled in BSL-2 conditions. Certain circumstances might require the use of BSL-3 facilities. Laboratory staff must follow standard precautions when working with clinical specimens, including those from suspected cases of CJD, and use appropriate personal protective equipment and engineering controls.
        i. Gloves MUST be worn when handling blood, body fluids or tissue samples.
        ii. Masks and protective eyewear MUST be worn if exposure of mucous membranes to blood/body fluids might occur.
        iii. All clinical specimens MUST be handled in a laminar flow class II (or higher) biological safety cabinet or behind a protective

splash shield when specimen containers are opened.

iv. Only disposable instruments or those amenable to harsh high-level sterilization should be used.

3. **If a patient is suspected of having CJD or a TSE, disposable instruments or those amenable to high-level sterilization must be used.**
4. **Precautions in using sodium hydroxide (NaOH) or sodium hypochlorite (bleach) solutions in autoclaves**
    a. NaOH spills or gas may damage the autoclave if proper containers are not used.
    b. The use of containers with a rim and lid designed for condensation to collect and drip back into the pan is recommended.
    c. Persons who use this procedure should be cautious in handling hot NaOH solution (post-autoclave) and in avoiding potential exposure to gaseous NaOH.
    d. Exercise caution during all sterilization steps
    e. Allow autoclave, instruments and solutions to cool down before removal.
    f. Immersion in sodium hypochlorite bleach can cause severe damage to some instruments.

B. **Notification of Laboratory Staff**
Notification of laboratory personnel that potential CJD patient specimens are present can be given to or received from several areas of the laboratory and hospital: anatomic pathology, hospital epidemiology, infection control, referral (send-out) testing, surgery, central processing, etc. Anyone receiving this notification should notify laboratory staff by group text page/email of a specimen from a potential CJD patient (see notification procedure). Persons receiving this notification should check to see if specimens were received from this patient, the type of specimen, and if the specimens were handled appropriately.

C. **Handling and processing tissues from suspected CJD patients**
    1. Refer to: Handling Anatomic Pathology Specimens and Autopsies with Potential Prion Disease or Transmissible Spongiform Encephalopathies (TSE)-Creutzfeld-Jakob Disease (CJD)
    2. **Anatomic Pathology Laboratory staff must follow specific guidelines identified for his/her specific section in handling, processing and disposal of CJD/TSE specimens.**

D. **Storage and Disposal of Specimens**
If suspect or proven CJD specimens are to be stored, appropriate employees should be notified that special handling of these specimens is necessary. High-risk specimens should be incinerated with a minimum secondary temperature of 1,000°C. Pathological incinerators should maintain a primary chamber temperature in compliance with state regulations. Medical waste incinerators should also be in compliance with state regulations. Low-risk and no-risk specimens may be discarded in the conventional manner.
NOTE: Autoclaving and incineration is not available at Dearborn, Farmington Hills, Grosse

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Pointe, Taylor, Trenton, Troy or Wayne.

IV. MATERIALS AND EQUIPMENT:

A. **Personal Protective Equipment**

1. Disposable Gowns
2. Disposable Gloves
3. Face Masks
4. Protective Eyewear

B. **Other Supplies/Equipment**

1. Disposable instruments or those amenable to high-level sterilization
2. Splash Shield
3. Class II Biological Safety Cabinet
4. Shipping materials (obtain from National Prion 216-368-0587). The Send-Out Laboratory will maintain a supply of these containers.

C. **Reagents**

1. NaOH Reagent
2. Sodium Hypochlorite (Bleach)

D. **Working Solutions**

1. Sodium Hydroxide
    a. Prepare stock solution of 10 N NaOH (40 grams of NaOH in 100 mL water)
    b. 2N NaOH is used for decontaminating heat sensitive instruments and surfaces
        i. dilute the 10N stock solution 1:5 with water (1 part 10N NaOH plus 5 parts water)
        ii. Prepare fresh each day of use
    c. 1N NaOH is used for decontaminating instruments and surfaces
        i. this equals 40 grams of NaOH per liter of water
        ii. alternately, you can make a 1:10 dilution (1 part 10N NaOH plus 9 parts water)
    d. Prepare the working solution fresh for each day of use.
2. Sodium hypochlorite
    a. 20,000 ppm sodium hypochlorite equals a 2% solution.
    b. Most commercial household bleach contains 5.25% sodium hypochlorite, therefore make a 1:2.5 dilution (1 part 5.25% bleach plus 1.5 parts water) to produce a 20,000 ppm solution.

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c. This ratio can also be stated as two parts 5.25% bleach to three parts water.

d. Working solutions MUST be prepared daily.

3. **CAUTION: Above solutions are corrosive and require suitable personal protective equipment and proper secondary containment. These strong corrosive solutions require careful disposal in accordance with local regulations. They must be neutralized and all liquids absorbed prior to disposal.**

V. PROCEDURE:

A. **Notification of Laboratory Staff**

1. Notification of potential CJD patients may be received from various sources including, but not limited to:
    a. Anatomic Pathology
    b. Hospital Epidemiology
    c. Send-Out Laboratory
    d. Surgery
    e. Central Processing Department

2. Anyone receiving this notification MUST send out a notification following their campus notification policy (text page/phone call/email/Teams) to the following groups with a message to check your Outlook email for information about a specimen from a potential CJD patient. The notification should begin by stating "Potential CJD patient. See email." The email sent to email group CHE-13950_BL_Admin_Supervisors, should include the patient's name, medical record number, which site the patient is located, and any other pertinent info (e.g. if the specimen was potentially transported, if the specimen was shared between departments, etc.)
    a. Royal Oak Anatomic Pathology pager group 56497
    b. Royal Oak Clinical Pathology pager group 54241
    c. Troy pager group 56285
    d. Grosse Pointe pager group 55549
    e. Farmington Hills:
        i. Monday-Friday (all shifts) 947-521-2580
        ii. Saturday-Sunday (dayshift and afternoon shift) 947-521-2580
        iii. Saturday-Sunday (midnight shift) 947-521-5252
    f. Dearborn: 24/7 - 313-593-7900
    g. Taylor:
        i. Monday – Friday (8am to 3 pm) - 313-295-5365
        ii. Any other time – 313-295-5368

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h. Trenton: 24/7 - 734-671-3866

i. Wayne: 24/7 - 734-467-4274 option 1

3. Persons receiving this notification will check to see if specimens were received from this patient, the type of specimen and whether they were handled appropriately. If not, additional educational measures are necessary and must be documented.
4. Persons receiving this notification must notify his/her section medical/technical director if identified patient's specimens are found.

B. **Storage and Disposal of Specimens**

1. If storing these specimens, identify as CJD specimens so that staff are aware of special handling if necessary.
2. Specimen disposal:
    a. High-risk specimens should be incinerated with a minimum secondary temperature of 1000°C
        i. Pathological incinerators should maintain a primary chamber temperature in compliance with state regulations
        ii. Medical waste incinerators should also be in compliance with state regulations
    b. Low-risk and no-risk specimens may be discarded in the conventional manner.

C. **Decontamination of Instruments and Surfaces, and Inactivation of Prions**

1. Contact with low/no risk specimens:
    a. Instruments are cleaned and disinfected by conventional protocols, heat, or chemical sterilization.
    b. Clean environmental surfaces with a hospital/laboratory approved disinfectant.
2. Contact with high-risk specimens:
    a. Instruments should be kept moist to prevent fluids and tissues from drying on the instruments.
    b. Decontaminate all non-disposable instruments before treating the instruments to inactivate prions.
    c. To minimize surface contamination, use disposable cover sheets on work surfaces.
3. Decontaminating Heat Sensitive Instruments and Surfaces
    a. Treat surfaces and heat-sensitive instruments with 2N NaOH or 20,000 ppm hypochlorite for 1 hour.
    b. Ensure surfaces remain wet for the entire time period, and then rinse well with water.
    c. Before chemical treatment, it is strongly recommended that gross

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contamination of surfaces be reduced because the presence of excess organic material will reduce the strength of either NaOH or sodium hypochlorite solutions.

4. Options for Inactivation of Prions on Reusable Instruments (select one of the following methods)
    a. Immerse in 1 N NaOH, and heat in a gravity displacement autoclave at 121°C for 30 minutes. Clean and sterilize by conventional means.
    b. Immerse in 1 N NaOH or sodium hypochlorite (20,000 ppm) for 1 hour. Transfer into water and autoclave (gravity displacement) at 121°C for 1 hour. Clean and sterilize by conventional means.
    c. Immerse in 1N NaOH or sodium hypochlorite (20,000 ppm) for 1 hour. Rinse instruments with water, transfer to open pan and autoclave at 121°C (gravity displacement) or 134°C (porous load) for 1 hour. Clean and sterilize by conventional means.
5. Precautions when using NaOH or sodium hypochlorite solutions in autoclaves
    a. NaOH spills or gas can damage an autoclave if appropriate containers are not used.
    b. The use of containers with a rim and lid designed for condensation to collect and drip back into the pan is recommended.
    c. Persons who use this procedure should be cautious when handling hot NaOH solutions (post-autoclave) and in avoiding potential exposure to gaseous NaOH.
    d. Exercise caution during all sterilization steps. Allow autoclave, instruments and solutions to cool before removal.

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D. **CAUTION**: Immersion in sodium hypochlorite bleach can cause severe damage to some instruments.

E. **NOTE**: Autoclaving and incineration is not available at Dearborn, Farmington Hills, Grosse Pointe, Taylor, Trenton, Troy or Wayne.

VI. REFERENCES:

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Biosafety in Microbiological and Biomedical Laboratories 5th Edition U.S. Department of Health and Human Services, Revised December 2009.

B. CLSI. 2005. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition. M29-A3. CLSI, 940 West Valley Road, Suite 1400, Wayne PA 19087-1898, pp.89-95.

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F. Rutala, W.A., D.J. Weber. 2010. Reply to Belay et al. Infect. Cont. Hosp. Epidemiol. 31:1306-1308.

G. Isolation Practices,

H. Standard Precautions

I. Creutzfeldt-Jakob Disease Infection Control Policy

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	1/8/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	1/3/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	12/27/2023
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	12/26/2023
CLIA Site Licensed Medical Directors	Vaishali Pansare: Chief, Pathology	12/26/2023
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	12/19/2023
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	12/19/2023
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	12/19/2023
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

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