Purpose of this Message:
To provide awareness to MLS laboratories regarding updated CDC guidance for specimen collection, transport, testing, and submission for patients under investigation for Ebola Virus Disease (EVD) and provide more information regarding EVD.

Action Items:

CDC guidance
It is expected that all laboratorians and other healthcare personnel collecting or handling specimens follow established standards compliant with the OSHA bloodborne pathogens standard, which encompasses blood and other potentially infectious materials. This includes wearing appropriate personal protective equipment (PPE) and adhering to engineered safeguards for all specimens, regardless of whether they are identified as being infectious. These standards should be followed for all patients, even those not suspected of being at risk for Ebola.

Recommendations for specimen collection:
- Full face shield or goggles,
- Masks to cover all of nose and mouth, gloves, fluid resistant or impermeable gowns.
- Additional PPE may be required in certain situations.

Recommendations for laboratory testing:
1. Full face shield or goggles and, mask to cover nose and mouth, gloves, fluid resistant or impermeable gown, AND
2. Use of a certified class II Biosafety cabinet OR plexiglass splash guard, AND
3. Use of manufacturer-installed safety features for instruments.

Note, the above guidance refers to all laboratory work including the routine hematology and clinical chemistry testing that is essential for the appropriate care and treatment of patients.

Additional EVD information
-The following information was prepared by the NYSDOH and NYCDHMH (1)

EVD transmission and decontamination
Please note the following points with regard to EVD:
- A person infected with Ebola virus is not contagious until symptoms appear.
- EVD is transmitted through direct contact (via broken skin or mucous membranes) with blood or body fluids from an EVD patient, or through contact with objects contaminated with blood or body fluids from an EVD patient. There is no evidence of airborne transmission.
- Ebola virus is readily inactivated by standard chemical decontamination procedures used in laboratories.
Ebola virus is present in numerous body fluids of patients in the acute period of EVD, including saliva, stool, tears, and nasal blood (2). Although detected much less frequently, it has also been shown to be present in some environmental samples contaminated with blood or body fluid from an EVD patient consistent with a risk of transmission from fomites. Risk assessments by Baush et. al. have concluded that when recommended infection control guidelines for viral hemorrhagic fevers are followed, the risk of transmission is low (2).

Biosafety classification
Two issues pertaining to Ebola virus biosafety classifications should be clarified. Information provided by the CDC (http://www.cdc.gov/vhf/ebola/hcp/safe-specimen-management.html) has verified that:
- While Ebola virus culture, which is commonly performed at high volume and can attain extremely high titer, is required to be performed at biosafety level 4, the handling of primary clinical specimens from EVD patients need not be restricted to this level of containment.
- According to the Interim Guidance Regarding Compliance with Select Agent Regulations for Laboratories Handling Patient Specimens that are Known or Suspected to Contain Ebola Virus, specimens from suspected EVD patients are not classified as select agents. For patients with confirmed EVD, select agent classification of specimens will be dependent on additional testing and consultation with the CDC.

Information in support of these recommendations is provided below.
- Recent experiments in Canada have demonstrated the absence of airborne Ebola transmission in non-human primate experiments (3).
- An investigation of 173 contacts in 27 households demonstrated Ebola transmission only to those with direct physical contact or exposure to body fluids of the ill household member, and no transmission to the 78 household members who had no physical contact with the ill person (4).
- An investigation of three generations of Ebola transmission during an outbreak in Uganda, demonstrated direct contact with patient body fluids as the strongest risk factor for transmission, with contaminated fomites as a possible lesser risk factor (5).
- During the last several years, several patients have been cared for in US and Western European medical facilities prior to being recognized as having viral hemorrhagic fevers (VHFs). Although these patients were subsequently diagnosed as being infected with Lassa or Marburg fever virus, extensive follow up of hundreds of potentially exposed healthcare workers, including laboratory personnel, have found no instances of transmission of infection (6,7,8,9).
- In 1996, a physician who had been working in West Africa and an anesthetics assistant previously involved in his care, became severely ill in Johannesburg, South Africa. Despite hospitalization for more than a week before being diagnosed with Ebola, and the performance of some potentially high risk medical procedures, none of the more than 300 exposed health-care workers, including laboratory personnel, contracted the virus (10).
- Lassa fever was detected in March/April 2014 in a patient in Minnesota with renal failure. The possibility of a VHF was not initially recognized and numerous health care workers including laboratory personnel were potentially exposed. However, there were no cases of disease transmission (11).
- Guidance documents from the UK note that one to two patients per year are diagnosed there with VHFs (12). Some are not initially recognized as having VHF and are managed with standard precautions, yet there have been no reports of transmissions to health care workers. While VHF refers to a list of agents, not Ebola specifically, all are considered pathogens of “high consequence”.
- Reports in the literature of laboratory-acquired Ebola infections refer to events prior to the implementation of universal precautions and the availability of relevant safety devices such as retractable needles (13) or to infections acquired during the performance of animal necropsy and other animal experiments (14).
On average, routine laboratory testing is performed on a few patients per year collectively at healthcare facilities in the UK, US and Europe. In some cases dozens of samples per case are processed and tested before the patient is diagnosed with VHF. Therefore collectively in these countries since the implementation of universal precautions approximately 30 years ago, it would appear that hundreds of samples have been tested in laboratories using these procedures routinely, with no documented transmission to laboratory workers.

To assist with the current outbreak in West Africa, laboratory personnel have been deployed to the European field laboratory in Guinea since mid-March, the Canadian field laboratory since June, and the two CDC laboratories since early August. Additionally, three other field laboratories set up by international partner groups are operational there. These laboratories process 200-300 specimens per day, yet there have been no documented cases of Ebola transmission to any of the laboratory scientists working at them. Earlier in the outbreak, some local West African laboratory personnel who were not wearing appropriate PPE and were performing procedures such as blood smear preparations without gloves, did acquire EVD. However, this has not occurred in any personnel wearing correct PPE and adhering to recommended procedures.

Nevertheless, Ebola virus is indisputably a highly pathogenic agent (15). All laboratory directors should review their circumstances, facilities, resources and procedures, as well as the training and experience of their staff, in order to perform a thorough biohazard risk assessment and implement appropriate procedures for risk mitigation.

Any additional precautions or procedures should not interfere with the ability to provide appropriate medical care for suspected or confirmed EVD patients.

Testing for Ebola in Minnesota

MDH Public Health Laboratory is one of a limited number of laboratories in the country that is able to perform PCR testing for Ebola virus under Emergency Use Authorization by FDA. Testing will only be performed through consultation with MDH Epidemiology and CDC to determine risk of EVD. Please call MDH Epidemiology to assess risk of potential case patients at 1-877-676-5414 or 651-201-5414. If approved, testing will be completed same day of sample receipt.

References
1. Revised NYS/NYC Laboratory Guidelines for Handling Specimens from patients with Suspected or Confirmed Ebola Virus Disease. 


11. Personal communication, Aaron Devries, Minnesota Department of Health.

12. UK Department of Health, Advisory Committee on dangerous pathogens, Management of Hazard Group4 viral hemorrhagic fevers and similar human infectious diseases of high consequence. Appendix 7: Laboratory Procedures.


Thank you,

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This is an update from the Minnesota Department of Health - Public Health Laboratory (MDH-PHL) and the Minnesota Laboratory System (MLS). This message is being sent to MLS laboratory contacts serving Minnesota residents. You are not required to reply to this message.

**Please forward this to all appropriate personnel within your institution and Health System**

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