

MLS Laboratory Update: Labs using the Biofire Global Fever Special Pathogens (GFSP) Panel for Viral Hemorrhagic Fever testing

AUGUST 10TH, 2026

Purpose of this Message:

To inform labs of a recent (8/5/2026) reminder from Biofire Defense regarding procedures for testing viral hemorrhagic fevers (VHFs) required in the Biofire GFSP Instructions for Use (IFU) document to comply with the FDA 510(k) clearance requirements.

Action Item:

Distribute to laboratorians and clinical teams potentially ordering this panel to ensure understanding of the unique requirements associated with this testing.

Background:

Summary:

While VHFs are rare in the U.S., clinicians and laboratorians should remain vigilant for Ebola—specifically the Bundibugyo strain driving the ongoing outbreak in central Africa. Suspect cases present with compatible illness and recent travel to affected regions. Though near-term risk to the U.S. general public is low, early identification and appropriate infection control measures are essential.

Description:

If you receive a request to perform testing with the BioFire Global Fever Special Pathogens Panel on any patient with suspected Ebola or another regulated VHF (Congo-Crimean, Lassa, Marburg), please contact MDH prior to testing the specimen as there are complex issues to negotiate. Initial contact should be through the 24-hour Epi on-call phone (651-201-5414 or 877-676-5414); for laboratory specific questions, please contact the Biothreat (BT) On Call staff directly (612-282-3723; 24 hrs). Testing for VHFs using the Biofire Global Fever Special Panel (GFSP) has some unusual manufacturer and CDC requirements given the conditions under which the test originally received FDA clearance.

MDH assists with clinical and epidemiologic screening, and provides guidance on infection prevention and control, specimen handling, and alternative diagnoses. This helps ensure appropriate patient care, protects laboratory personnel, and enables a timely public health response, as needed.

Additional Information:

- [CDC: Laboratory Testing for Patients with a Suspected VHF or High-Consequence Disease \(https://www.cdc.gov/viral-hemorrhagic-fevers/php/laboratories/index.html\)](https://www.cdc.gov/viral-hemorrhagic-fevers/php/laboratories/index.html)
- [Biofire Defense Dear Colleague letter: \(https://go.biofiredefense.com/webmail/1115703/1035783414/f19b5c377cb018a866ce935a371d4bc1fd430cbf651cee5782be43565fd70f35\)](https://go.biofiredefense.com/webmail/1115703/1035783414/f19b5c377cb018a866ce935a371d4bc1fd430cbf651cee5782be43565fd70f35)
- [Infectious Disease Lab Forms \(https://www.health.state.mn.us/diseases/idlab/forms.html\)](https://www.health.state.mn.us/diseases/idlab/forms.html)

Questions:

Please contact: Aaron Barnes, M.D., Ph.D. (aaron.m.t.barnes@state.mn.us; 651-201-4184)

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

THE CONTENT OF THIS MESSAGE IS INTENDED FOR PUBLIC HEALTH AND HEALTH CARE PERSONNEL AND RESPONSE PARTNERS WHO HAVE A NEED TO KNOW THE INFORMATION TO PERFORM THEIR DUTIES. IT IS FOR OFFICIAL USE ONLY. DO NOT DISTRIBUTE BEYOND THE INTENDED RECIPIENT GROUPS AS DESCRIBED IN THIS MESSAGE.

Minnesota Laboratory System
Minnesota Department of Health, Public Health Laboratory
601 Robert St. N, St. Paul, MN 55164-0899
651-201-5200
health.mnlabssystem@state.mn.us
www.health.state.mn.us/diseases/idlab/mls/index.html

To obtain this information in a different format, call: 651-201-5200.