DEPARTMENT OF HEALTH

MLS Laboratory Update: Select Agent status changes for *Brucella* spp.

JANUARY 9, 2025

Purpose of this Message:

To inform laboratorians about changes in the Federal Select Agent Program (FSAP) status of *Brucella* spp. and what effects those changes have on reporting and clinical material submission to MDH-PHL.

Action Item:

This regulatory change affects the testing and submission of materials to MDH-PHL.

What changes

- Beginning 1/16/2025, presumptive identification of *Brucella* spp. (including *Brucella melitensis, Brucella abortus,* or *Brucella suis)* in your laboratory will no longer require submission of the FSAP APHIS/CDC Form 4: *Report of the Identification of a Select Agent or Toxin* within 7 days of identification.
- Removal from the regulated select agent list also means that mandatory destruction of clinical and diagnostic material within 7 days is no longer required.
- Immediate transfer of *Brucella* spp. clinical materials for biothreat testing at MDH-PHL will no longer be required; standard submission timelines (as with any other clinical specimen) are acceptable.

What doesn't change

- *Brucella* species causing brucellosis will continue to remain on the list of organisms immediately reportable to the Minnesota Department of Health under the Reportable Disease Rule and submission of clinical materials will also still be required.

Background:

On 12/17/2024 the Federal Select Agent Program (FSAP) announced that *Brucella melitensis*, *Brucella abortus*, and *Brucella suis* are being removed from the list of regulated select agents, effective 1/16/2025. While this changes the regulatory status of the organism – including some of the reporting requirements – brucellosis remains a disease with high morbidity for laboratorians. In addition, *Brucella* spp. causing brucellosis will remain a MN State Reportable Disease, with immediate notification and submission of clinical materials required.

Brucella spp. remain among the most common infectious risks for clinical microbiology laboratorians: these bacteria are readily aerosolized and have a very low infective dose (10 to

100 organisms). A recent meta-analysis (Wang *et al*, 2024) found that more than 50% of all reported laboratory-acquired infections (LAIs) were caused by *Brucella* spp. and the majority of laboratorians were infected while doing routine clinical work without sufficient engineering controls or PPE (personal protective equipment). Thus, regardless of this change in *regulatory* status, continued vigilance to prevent potential brucellosis cases in the laboratory community remain critically important.

While brucellosis is rarely fatal, it does have a high morbidity. Brucellosis typically causes flu-like symptoms (fever, malaise, weakness, weight loss), however, *Brucella* infections classically mimic a number of other pathogens (notably *Mycobacterium tuberculosis)* and brucellosis can present in many atypical forms. Since symptoms can also be milder in some patients, a diagnosis of brucellosis may not be considered clinically. Incubation period can also be highly variable, ranging from 1 week to 2 months (typically 2–4 weeks).

Finally, identification of *Brucella* in the laboratory can be tricky; all clinical isolates that stain as tiny coccobacilli should lead to consideration for *Brucella* spp.

Characteristics of *Brucella* spp. in the laboratory:

- Most commonly grows in blood cultures and typically takes 2-5 days to flag as positive.
- Faintly staining tiny gram-negative coccobacilli, may retain crystal violet stain so often looks like gram-positive or gram-variable cocci
- Catalase, oxidase, and urea positive (oxidase can be variable)
- Slow growth, more than 48 hours for good growth
- Pinpoint colonies at 24-72 hours incubation
- Poor or no growth on MAC

Please call the MDH PHL on-call emergency phone number 612-282-3723 and send all rule-out *Brucella* isolates to MDH-PHL.

Additional Information:

- Changes to the Select Agent and Toxin List – Publication of HHS/USDA Final Rules (https://www.selectagents.gov/regulations/sat-list-changes-2024.htm)
- Brucellosis (*Brucella* species) - MN Dept. of Health (https://www.health.state.mn.us/diseases/brucellosis/index.html)
- Reportable Disease Rule (Communicable Disease Reporting Rule) Infectious Disease Reporting - MN Dept. of Health (https://www.health.state.mn.us/diseases/reportable/rule/index.html)
- Clinical Overview of Brucellosis | CDC (https://www.cdc.gov/brucellosis/hcp/clinical-overview/index.html)
- Laboratory Risks for Brucellosis | CDC (https://www.cdc.gov/brucellosis/hcp/laboratory-risks/index.html)

- Wang M *et al*. 2024. Laboratory-acquired infection in clinical laboratories and the incidence rate after *Brucella* exposure risk events: a systematic review and meta-analysis. *J Hosp Infect*. 18; 155:135-144. doi: 10.1016/j.jhin.2024.10.004. PMID: 39427772 (https://pubmed.ncbi.nlm.nih.gov/39427772/)
- Chow SK. 2022. Uncommon Things Being Common: Gram Variability of *Brucella* as a Cause of Laboratory Exposure. *J Clin Microbiol*. 60(6): e0050722. doi: 10.1128/jcm.00507-22. PMID: 35531666; (https://pmc.ncbi.nlm.nih.gov/articles/PMC9199401/))

Questions:

Please contact: Dr. Aaron Barnes, EPR Laboratory Supervisor, 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.mnlabsystem@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.