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SCOTT M. SHONE, PhD, HCLD (ABB) • Laboratory Director, State Laboratory of Public Health

Memo

To: North Carolina Clinical Laboratories

From: Scott M. Shone, PhD, HCLD (ABB), Director, State Laboratory of Public Health

Date: January 16, 2025

Re: Removal of *Brucella* from the Select Agent and Toxin list

The intended audience of this message is laboratorians, laboratory supervisors, and infection control and prevention staff responsible for identification and reporting of *Brucella* species from clinical specimens.

Background

As of today, January 16, 2025, *Brucella* species (*B. abortus, B. melitensis, and B. suis*) has been removed from the Federal Select Agent and Toxins list. *Brucella canis* was not previously listed as a Select Agent. The Federal Select Agents and Toxins list is maintained by the United States Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA). Agents and toxins are added or removed from the Select Agent or Toxin list based on four main criteria: 1) Effect on human health, 2) Degree of contagiousness, 3) Availability and effectiveness of pharmacotherapies, and 4) Other criteria, including decontamination and restoration, matrix stability, and ease of production.

In 2020, CDC published an advance notice of proposed rulemaking seeking comments on potential changes to the current list of HHS/USDA Select Agents and Toxins. Comments received from the public broadly supported removal of *Brucella* species from the Select Agent and Toxins list due to the low-mortality rate associated with infection, rare human-to-human transmission, and availability of therapeutics.

While removing *Brucella* from the Select Agent and Toxins List will eliminate the need to complete and submit specific <u>Select Agent Forms</u>, it <u>will not</u> remove the need to continue implementing previously established biosafety measures, since working with *Brucella* species on the benchtop continues to be the most commonly reported laboratory acquired infections (see https://www.cdc.gov/brucellosis/hcp/laboratory-risks/).

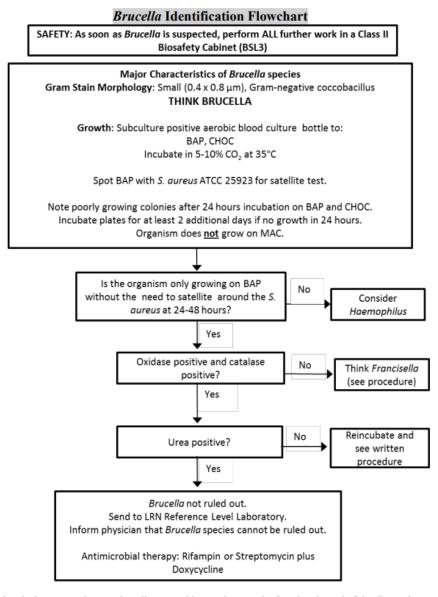
Action Items

Clinical laboratories should continue to:

1. Report all suspected and confirmed cases of Brucellosis to the Epidemiologist on Call at 919-733-3419.

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- Submit suspect *Brucella* species isolates (refer to the ASM *Brucella* Identification flowchart below) to the North Carolina State Laboratory of Public Health (NCSLPH) Bioterrorism and Emerging Pathogens (BTEP) Unit for confirmation and speciation. Contact the BTEP 24/7 Duty Phone (919-807-8600) to coordinate submission using the <u>DHHS-5010 BT and Emerging Pathogens form</u> and ship following Category A Packing and Shipping regulations.
- 3. Work with all suspect *Brucella* species isolates within a Biosafety Cabinet (BSC) with appropriate PPE which includes, gloves, gown, and eye protection.



Note: Biochemical test procedures and quality control instructions can be found at the end of the *General Recommendation and Biochemical Testing Procedures* document.

Source: LRN Sentinel Level Clinical Laboratory Protocols