MLS Laboratory Update: Recent Issues with Commercial Influenza Molecular Diagnostic Reagents and Reduced Availability of Oseltamivir

DECEMBER 20, 2022

Purpose of this Message:

- Inform MLS labs of recent reagent issues affecting two commercial in vitro diagnostics (IVD) influenza molecular assays
- Inform MLS labs of a recent communication issued through the MN Health Alert Network (HAN) informing public health and medical professionals of anecdotal reports of reduced supplies of the antiviral oseltamivir.

Action Items:

- Diagnostic Assay Issues: Please contact your sales/technical representative if you use either of these assays and you have concerns.
- Communicate resources to clinician and public health partners faced with oseltamivir shortages

Background:

Diagnostic Assay Issues:

The Association of Public Health Laboratories (APHL) recently notified laboratories of reagent issues with two commercial IVD assays: Abbott Alinity m Resp-4-Plex amp kit and Roche COBAS® SARS-CoV-2 and Influenza A/B and COBAS® Influenza A/B & RSV UC assays. Specific details include:

Abbott Alinity m Resp-4-Plex Kit:

- False positive test results for Influenza B were reported to Abbott by multiple users.
- Abbott determined the root cause as a reagent issue.
- Abbott has rectified the issue and has reached out to labs using the Alinity platform with instructions to document the destruction of the affected reagents.

Roche COBAS® SARS-CoV-2 and Influenza A/B and COBAS® Influenza A/B & RSV UC assays:

- Roche is aware of false negative Influenza A results and significant loss of sensitivity in detecting influenza A (H1N1) pdm09 viruses with both kits.

- These observations are specific to influenza A (H1N1) pdm09 viruses carrying M-gene mutations C124A and C124A + G141A which emerged in 2021 and are now associated with the dominant HA subgroup of influenza A (H1N1) pdm09 circulating in Europe. Detection of the M-gene mutations also being reported in the Americas.
- Roche issued a global notification to affiliate organizations on November 24, 2022 regarding the ongoing investigation.

Please refer to the APHL news release Influenza News 22-23:8 for the source of this messaging:

- APHL Influenza News 22-23:8

Oseltamivir Shortage:

MDH as well as CDC have received anecdotal reports of reduced availability for *generic* oseltamivir. To address these spot shortages, you can use the following resources:

- Finding Oseltamivir
    - Reach out to partnering pharmacies or health care facilities.
    - Check with other distributors of oseltamivir: FDA Availability of Antiviral Medications (https://www.fda.gov/media/120654/download)
- Prioritizing Oseltamivir
    - Review CDC Health Advisory for guidance on prioritizing oseltamivir for treatment among hospitalized patients, in outpatient settings, and in institutional settings (such as long-term care facilities, etc.). Further details can be found at CDC Interim Guidance for Clinicians to Prioritize Antiviral Treatment of Influenza in the Setting of Reduced Availability of Oseltamivir (https://emergency.cdc.gov/han/2022/pdf/CDC_HAN_482.pdf)
- Please refer to the MDH HAN Communication dated 12/16/2022 for the source of this messaging. MDH HAN 12/16/2022 (https:/www.health.state.mn.us/communities/ep/han/2022/dec16flu.pdf)

Questions:
For specimen or assay-specific questions, please contact:
Scott Cunningham, Virology Unit Supervisor at Scott.Cunningham@state.mn.us

Thank you for your partnership.

Scott Cunningham
Virology Unit Supervisor
Phone: 651-201-5032
Scott.Cunningham@state.mn.us

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.