NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
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HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

Potential for False Results with Roche Molecular Systems, Inc. cobas SARS-CoV-2 & Influenza Test for use on the cobas Liat System

This notification only applies to physician practices performing waived influenza testing using the Roche Molecular Systems, Inc. cobas SARS-CoV-2 & Influenza Test for use on the cobas Liat System. For information on possible false positives using this system, please see the FDA website and contact information below.

Please be advised that all medical practices in New York State are receiving this notification from the New York State Physician Office Laboratory Evaluation Program (POLEP), whether they perform this testing or not. Please contact POLEP at clia@health.ny.gov if you have questions related to why you've received this notification.

The U.S. Food and Drug Administration (FDA) issued a Letter to Clinical Laboratory Staff, Point-of-Care Staff, and Health Care Providers to alert them that false positive results can occur with the Roche Molecular Systems, Inc. cobas SARS-CoV-2 and Influenza A/B Nucleic Acid Test for use on the cobas Liat System.

For additional information, see the FDA website at https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-results-roche-molecular-systems-inc-cobas-sars-cov-2-influenza-test-use-cobas-liat.

This Letter to Health Care Providers includes important information about the cobas SARS-CoV-2 and Influenza A/B Nucleic Acid Test for use on the cobas Liat System, including:

- Details on potential causes of false results with the cobas SARS-CoV-2 and Influenza A/B Nucleic Acid Test.
- Recommendations for cobas Liat System operators using the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test.
- Actions the FDA has taken to address the issues.
- Instructions for reporting adverse events with a device to the FDA.

If you have questions, email COVID19Dx@fda.hhs.gov.