



ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Acting Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

November 30, 2018

RE: Changes to the New York State Newborn Screening Program's HIV Algorithm

Dear Health Care Provider,

Please be advised that specimens received and tested as of December 3, 2018 will be screened for exposure to HIV using a new first-tier HIV screening immunoassay and a new second-tier HIV-1/HIV-2 supplemental immunoassay. This new assay has several benefits including the ability to identify newborns exposed to HIV-2.

Results for newborns exposed to HIV will continue to indicate that the newborn screen sample was reactive for HIV antibodies. The protocol for management of newborns exposed to HIV has not changed. However, there will be changes to the newborn screen reports:

1. When HIV antibodies are detected and differentiated as HIV-1 or HIV-2, this new information will be included on the report as "reactive for HIV-1 antibodies" or "reactive for HIV-2 antibodies". In some cases, the type cannot be determined and these results will be reported as "reactive for HIV antibodies".
2. Although expected to be infrequent, there will be indeterminate results for some newborns using this new assay. An indeterminate result will be reported if the first-tier and second-tier immunoassay results do not match. For these cases, the report will indicate that the mother's HIV status must be verified to determine the infant's HIV exposure.

There are limitations to any HIV newborn screening test, and a newborn with an HIV-positive mother could have a negative HIV screening result. If the information submitted with the newborn screen sample indicates that the mother was known to be HIV-positive (B box selected on the newborn screen specimen card), but the newborn's result is NOT reactive to HIV, the newborn screen report will indicate a screen negative result. However, the newborn should still be managed using the protocols for HIV-exposed newborns, unless the "B" box was selected in error.

Thank you for your cooperation in making New York State's Newborn Screening Program the best it can be. Questions can be directed to our main telephone number 518-473-7552.

Sincerely,

Michele Caggana, Sc.D., FACMG
Director, Newborn Screening Program