



State Health Laboratories

50 Orms Street
Providence, RI 02904-2222

401.222.5600
401.222.6985 Fax
TTY: 711

www.health.ri.gov

28 January, 2013

Dear HIV Testing Client

The Rhode Island State Health Laboratory (RISHL) instituted a new HIV screening test two years ago which is called the Abbott HIV Ab/Ag Combo test. This test, run on the Abbott *i1000*_{SR} Architect platform, detects both HIV-1 and HIV-2 antibodies as well as the P24 antigen of HIV-1. Test results, which do not distinguish between antibody or antigen, are reported as REACTIVE or NONREACTIVE. This test is capable of detecting HIV infections earlier than the previous generation Abbott test utilized at the RISHL, giving us the capacity to detect acute infections.

A REACTIVE test result is repeated in duplicate, and second REACTIVE screen test result reflexively orders a confirmatory test. We have implemented two confirmatory tests – the GenProbe APTIMA® HIV-1 RNA Qualitative Assay, and the BioRad MultiSpot Assay. Confirmatory tests are performed in this order.

The GenProbe APTIMA® HIV-1 RNA Qualitative Assay is a NAAT which detects the presence of HIV-1 RNA in clinical specimens. A positive result is reported as REACTIVE which indicates that HIV-1 RNA was detected. For a specimen that is repeatedly REACTIVE on an HIV-1 antibody test and reactive in the APTIMA HIV-1 RNA Qualitative Assay, the individual is considered confirmed infected with HIV-1 and a final interpretation of positive for HIV-1 is reported. A NONREACTIVE result indicates that HIV-1 RNA was not detected, and the second confirmatory test is reflexively ordered.

For patients with repeatedly REACTIVE screen results which test NONREACTIVE with the GenProbe APTIMA® HIV-1 RNA Qualitative Assay, a BioRad MultiSpot confirmatory test is performed. The MultiSpot test is capable of detecting and distinguishing antibodies to either HIV-1 or HIV-2. The results of this test are reported as either REACTIVE or NONREACTIVE. In the former case, the final interpretation is reported as positive for HIV-1 or (HIV-2) antibodies.

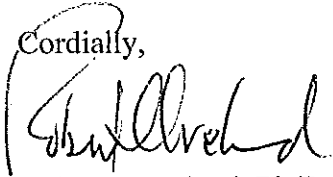
The final interpretation for a REACTIVE screen test result and NONREACTIVE for both confirmatory test result is reported as negative for HIV-1. However, a NONREACTIVE test result does not preclude the possibility of exposure to or infection with HIV-1.

The final interpretation for a REACTIVE screen test result and NONREACTIVE confirmatory test result is reported as negative for HIV-1.

Please refer to the accompanying test algorithm for additional information.

Questions regarding the RISHL HIV testing algorithm or results interpretation should be directed to me.

Cordially,



Robert C. Ireland, Ph.D. HCLD(ABB)
Chief Clinical Laboratory Scientist
Rhode Island State Health Laboratory
Robert.Ireland@health.ri.gov
401-222-5596



Melissa Martin
Laboratory Quality Assurance Office
Rhode Island State Health Laboratory
Melissa.Martin@health.ri.gov
401-222-5560

