

New HIV Screening Test Methodology for HIV-1/2 Antigen and Antibodies, Reflex to Differentiation (HIV RFLX) Test

EFFECTIVE JUNE 19, 2018

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Effective June 19, 2018, Wisconsin Diagnostic Laboratories will offer a new HIV screening test (Elecsys HIV combi PT, Roche Diagnostics), which will allow improved workflow, turn-around time (TAT), and equivalent clinical performance.

This test is a 4th generation test, with HIV-1 p24 Ag and HIV-1/2 antibodies detection integrated into one result.

There are **no** changes to the test orderable: HIV-1/2 Antigen and Antibodies, Reflex to Differentiation (HIV RFLX).

Clinical Considerations:

- Results will be reported as **Reactive** or **Non-reactive** for HIV-1 p24 Ag and HIV-1/2 antibodies.
- Reactive results will be repeated in duplicate and reflexed to a supplementary assay for differentiation (HIV CONF), according to the CDC algorithm (see Appendix).
- The new test will replace the current 5th generation test (Bio-Rad Laboratories), which reported HIV p24 Ag, HIV-1 Ab and HIV-2 Ab separately.
- Improved TAT
 - Non-Reactive results - 1.5 hr from arrival in the laboratory
 - Reactive results (repeated in duplicate) - 2.5 hr from arrival in the laboratory
- Samples should not be taken from patients receiving therapy with **high biotin doses** (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

Specimen Requirements:

- **Preferred:** SST Serum
- **Acceptable:** PST Plasma, EDTA plasma, Red Top serum
- **Minimum Volume:** 2.0 mL Serum/ Plasma
- **Transportation:** Refrigerated
- **Stability:** 4 weeks refrigerated, 7 days at room temp, 3 months frozen

For questions and additional information, please contact:

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