

## Change in HIV testing

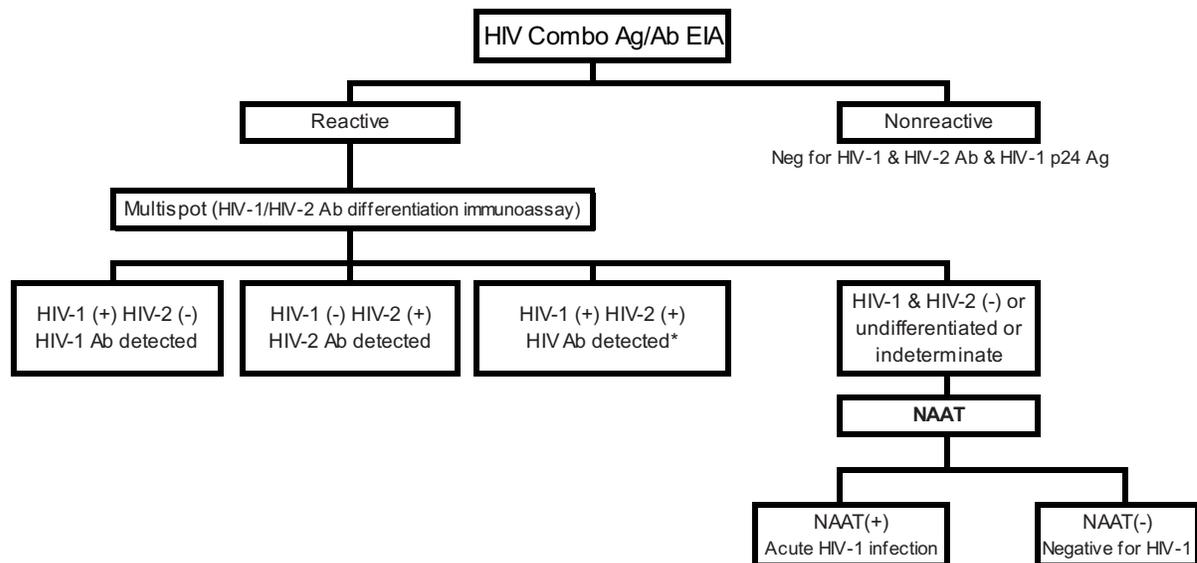
**Effective September 1, 2013**, the DSHS Laboratory in Austin will be using the new HIV diagnostic testing algorithm. HIV screening is performed by the 4th generation HIV Combo Ag/Ab EIA test for HIV detection. Results of this test do not distinguish between the presence of HIV antibodies or antigen in a sample. Additional supplemental tests will be automatically performed to verify the presence of antibodies to HIV-1 or HIV-2 by Multispot HIV-1/HIV-2 rapid test and HIV-1 p24 antigen by Nucleic Acid Amplification Test (NAAT) performed by the Dallas Co. Dept. Of Health and Human Services at: 2377 N. Stemmons Freeway, Dallas TX 75207, CLIA # 45D0672012. A single HIV report will be released with interpretation guidelines. **The serum specimen acceptance criteria for the testing will not change.**

Third- and fourth-generation HIV immunoassays are important advances for HIV testing that improve the ability to detect HIV infections earlier. In the two prospective evaluations described in MMWR (1), the new diagnostic testing algorithm performed better than the current algorithm for identifying HIV infections. With FDA's approval of the Multispot HIV-1/HIV-2 rapid test for use as the second test in this algorithm in March 2013, laboratories can adopt this algorithm, which is a recommended option in the Clinical and Laboratory Standards Institute's (CLSI) Criteria for Laboratory Testing and Diagnosis of HIV Infection; Approved Guideline (2).

**HIV-1 Western Blot (WB) for serum samples will be available for reference testing purposes only. NAAT will be performed only as a follow up testing for the HIV screening using the new HIV diagnostic testing algorithm and will not be offered as a standalone test at the DSHS Laboratory.**

Questions should be directed to the HIVSTD Serology Team at 512-776-7657.

New HIV diagnostic testing algorithm



\* Additional testing required to rule out dual infection with HIV-1 and HIV-2.

**HIV Screening, multispot HIV-1/HIV-2 rapid test, and NAAT results interpretation:**

HIV Combo Ag/Ab EIA	Multispot	Interpretation
Nonreactive	<i>(not performed)</i>	No serologic evidence of infection with HIV. Cannot exclude incubating or early HIV infection. Submit second sample in 3-4 weeks if clinically indicated.
Reactive	HIV-1	<b>Presumptive evidence of HIV-1 infection:</b> Based on EIA and MS HIV-1 Ab positive results, probable active HIV-1 infection. (NAAT is not indicated per CLSI guidelines). <b>Refer to physician for care.</b>
Reactive	HIV-2	<b>Presumptive evidence of HIV-2 infection:</b> Based on EIA and MS HIV-2 Ab positive results, probable active HIV-2 infection. (NAAT is not indicated per CLSI guidelines). <b>Refer to physician for care.</b>
Reactive	Nonreactive or Indeterminate / Undifferentiated	<b>Possible acute infection:</b> Based on EIA and MS results, possible acute HIV infection (AHI). Test for NAAT to rule out AHI; if reactive, possible AHI. <b>Refer to physician for care.</b> If NAAT is nonreactive or not tested, submit second sample in 3-4 weeks to rule out HIV infection <b>with HIV-1 or HIV-2.</b>

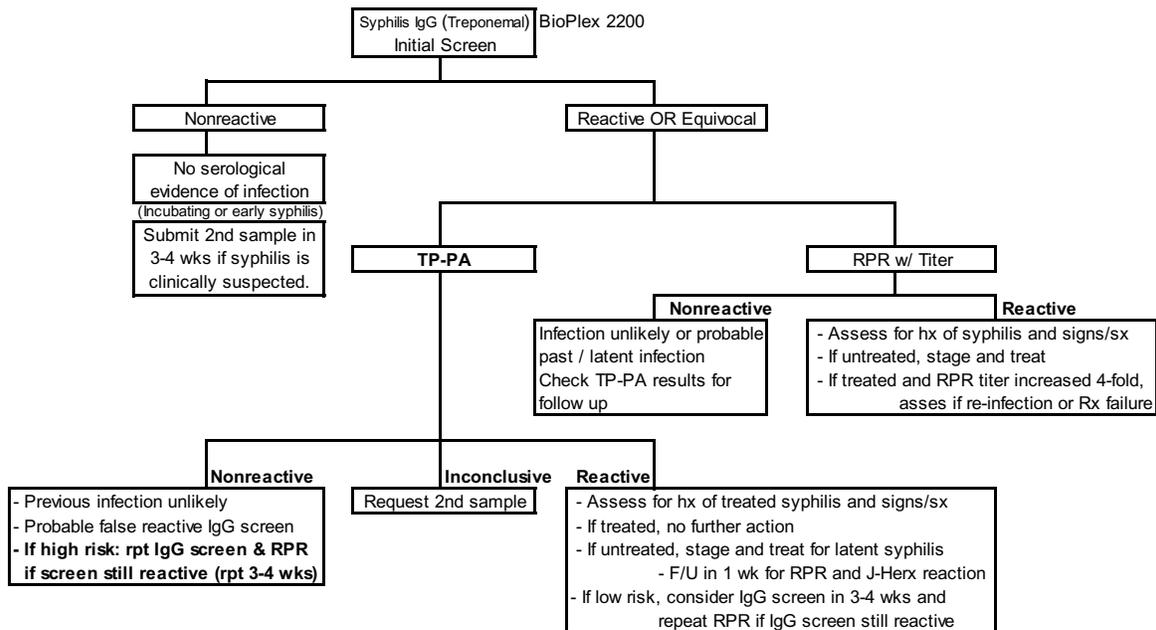
1. Detection of Acute HIV Infection in Two Evaluations of a New HIV Diagnostic Testing Algorithm — United States, 2011–2013. [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6224a2.htm?s\\_cid=mm6224a2\\_e\[7/15/2013 1:08:43 PM\]](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6224a2.htm?s_cid=mm6224a2_e[7/15/2013 1:08:43 PM])
2. Clinical and Laboratory Standards Institute. Criteria for laboratory testing and diagnosis of human immunodeficiency virus infection; approved guideline. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

## Change in syphilis testing

Effective September 1, 2013, the DSHS Laboratory in Austin will no longer be using the RPR as the syphilis screening test. The RPR screen will be replaced with the *Treponema pallidum* (*T. pallidum*) IgG EIA test following Reverse Syphilis Algorithm. Please order **Syphilis, Screening IgG (per G2A form)** when syphilis screening is needed. The IgG test will be performed daily (Monday-Friday). If the IgG test is reactive the reflex RPR Qualitative with titer and TP-PA testing will be performed on the same day or next day and a single report will be released with interpretation guidelines. The serum specimen acceptance criteria for the testing will not change.

*T. pallidum* IgG EIA has equal sensitivity and greater specificity than RPR, which detects anticardiolipin antibodies. The IgG test remains positive for many years following eradication of the disease. Therefore, the RPR test is essential to demonstrate active disease, to monitor therapy, detect treatment failure, and re-infection. RPR standalone test with titer will be available for treatment follow up. TP-PA standalone test will be available for confirmation of RPR results performed by other laboratories. FTA-ABS test will not be used to confirm discordant treponemal screening results per CDC recommendations and will be discontinued at the DSHS Laboratory.

This new algorithm is commonly used in laboratories and is included in the Centers for Disease Control and Prevention STD screening guidelines (1, 2). Questions should be directed to the HIVSTD Serology Team at 512-776-7657.



**BioPlex 2200 Syphilis IgG, TP-PA IgG, and non-treponemal RPR results interpretation:**

Syphilis IgG	RPR_QUAN	TP-PA	Interpretation
Nonreactive	(not performed)	(not performed)	No serologic evidence of infection with <i>T. pallidum</i> . Cannot exclude incubating or early syphilis. Submit second sample in 3-4 weeks if clinically indicated.
Reactive/Equivocal	Nonreactive	Reactive	<b>Probable past or latent infection:</b> Based on IgG, RPR, and TPPA results, probable past or treated or latent infection with <i>T. pallidum</i> .
Reactive/Equivocal	Nonreactive	Nonreactive	<b><i>T. pallidum</i> infection unlikely:</b> Based on IgG, RPR, and TPPA results, previous <i>T. pallidum</i> infection unlikely. Submit second sample in 3-4 weeks if clinically indicated.
Reactive/Equivocal	Nonreactive	Inconclusive	<b>Request second sample:</b> Based on IgG, RPR, and TPPA results, a second sample should be sent. Repeat testing in 3-4 weeks if high risk of acquiring syphilis infection.
Reactive/Equivocal	Reactive (1:X)	Reactive	<b>Presumptive evidence of current infection:</b> Based on IgG, RPR, and TPPA results, probable active <i>T. pallidum</i> infection.
Reactive/Equivocal	Reactive (1:X)	Nonreactive	<b>Possible infection with <i>T. pallidum</i> or biological false positive:</b> Based on IgG, RPR, and TPPA results, possible infection or biological false positive. Submit second sample in 3-4 weeks if clinically indicated.
Reactive/Equivocal	Reactive (1:X)	Inconclusive	<b>Request second sample:</b> Based on IgG, RPR, and TPPA results, a second sample should be sent for repeat testing in 3-4 weeks.

3. CDC. STD treatment guidelines 2006. Morbid Mortal Wkly Rep 2006;55(RR-11):1-94.
4. Pope V. Use of treponemal tests to screen for syphilis. Infect Med 2004;21:399–402.