



Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Division of STD Prevention

December 20, 2021

Dear Partners in Prevention,

I'm writing to share the [U.S. Food and Drug Administration \(FDA\) alert](#) sent to clinical laboratory staff and health care providers about a syphilis test. The alert reports that false reactivity, or "false-positive," Rapid Plasma Reagin (RPR; non-treponemal) test results, when using the Bio-Rad Laboratories BioPlex 2200 Syphilis Total & RPR kit, can occur in some people who received a COVID-19 vaccine and includes recommendations for addressing these potential false positives.

Historically, false-reactive RPR test results have been observed in people with systemic infections unrelated to syphilis, such as tuberculosis, rickettsial diseases, and endocarditis. False-reactive RPR testing also has been previously observed following immunization (specifically following smallpox vaccine). False reactivity with RPR can also occur during pregnancy.

Per CDC's [2021 STI Treatment Guidelines](#), reactive RPR results should always be confirmed with treponemal testing (e.g., *Treponema pallidum* particle agglutination, TP-PA). This is, in part, because of the above-mentioned issue: false-positive nontreponemal test results can be associated with multiple medical conditions and factors unrelated to syphilis. According to FDA's alert, treponemal testing for syphilis does not appear to be impacted by this issue.

As [syphilis continues to increase](#) in our nation, it is critical that patients receive timely and adequate treatment. According to [CDC guidance](#), some people may need presumptive treatment for early syphilis, even if test results are not immediately available. Providers should consider the patient's risk factors, as well as local epidemiology, when making treatment decisions.

If you need clinical decision-making support, you can reach out to CDC clinicians via [CDC-INFO](#), or you can contact the [STD Clinical Consultation Network](#). For general laboratory information or additional support/guidance on specific testing requirements, please contact DSTDP's STD Laboratory Reference and Research Branch via Weiping Cao (jqz9@cdc.gov), Syphilis/Emerging STIs Team Lead, or Ellen Kersh (egk6@cdc.gov), Branch Chief.

FDA encourages health care providers to report adverse events or suspected adverse events experienced with medical devices, including in vitro diagnostic tests, and the alert linked above includes contact information.

Thank you for your continued collaboration,

/Leandro Mena/

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