

Syphilis Fast Latex Agglutination Test, a Rapid Confirmatory Test

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Using 255 serum samples with various reactivities, we evaluated the Syphilis Fast latex agglutination test (Syphilis Fast) against the *Treponema pallidum* particle agglutination test (TP-PA) for confirming a diagnosis of syphilis. We found 98.8% agreement between the Syphilis Fast and the TP-PA. The Syphilis Fast, however, had a couple of advantages over the TP-PA: the test takes only 8 min to perform and produces results that are easy to read. It appears to be a good confirmatory test for syphilis, especially for point-of-care clinics such as prenatal or sexually transmitted disease clinics.

Traditionally syphilis has been diagnosed serologically with the use of a nontreponemal test for screening and a treponemal test for confirmation of results. All of the current confirmatory tests take from 1 to 2 h to complete. In point-of-care situations, such as sexually transmitted disease clinics, prenatal clinics, or drug treatment centers, any necessary treatment should begin immediately and not be delayed because specific treponemal test results are not available. This is especially true for clients who are not likely to return to the clinic in a timely manner. In these situations, treatment is usually based on the patient's nontreponemal test result, clinical symptoms, and clinical history. Many clinics which provide screening and treatment for syphilis do not have the capability to perform confirmatory treponemal tests. The confirmatory treponemal test is frequently done off-site, with the results being obtained after the patient has been treated and has left the clinic. This sometimes results in unnecessary treatment for persons with false-positive nontreponemal test results.

In 1998, Young et al. (7) reported on a latex agglutination test using cloned treponemal antigens. The test utilized the 47-, 17-, and 15.5-kDa recombinant antigens of *Treponema pallidum* bound to latex particles. The test took only a few minutes to perform and was fairly sensitive and specific. In addition, the format of the test did not require the use of special equipment such as fluorescence microscopes or microplate readers, thus making it an ideal test for point-of-care settings.

We compared this approach to the confirmatory test currently used at the Centers for Disease Control and Prevention (CDC), the Serodia *T. pallidum* particle agglutination test (TP-PA) (Fujirebio America, Inc., Fairfield, New Jersey), which uses a high-performance liquid chromatography-purified sonicate of *T. pallidum* to sensitize the gelatin particles. Two hundred fifty-five serum samples from urban and rural areas of Georgia, which were originally submitted to the Georgia Department of Human Resources for syphilis testing, were unlinked. The serum samples were tested using the rapid plasma reagin test (RPR) (CDC, Atlanta, Ga.), TP-PA, and the Syphilis Fast latex agglutination test (Syphilis Fast) (Diesse, Mon-

teriggioni, Italy). The RPR (3) and TP-PA (4) were done according to standard procedures. The Syphilis Fast, with results reported as either reactive or nonreactive, was done according to the manufacturer's directions. Serum samples that were discordant in the two treponemal tests were tested in the fluorescent treponemal antibody absorption double staining test (FTA-ABS DS) (CDC), which was done according to standard procedures (1). Concordance was based on the agreement between any two treponemal tests (Syphilis Fast, TP-PA, and FTA-ABS).

There was 98.8% agreement between the TP-PA and the Syphilis Fast results. Of the 92 specimens that were nonreactive in both tests, 12 were reactive in the RPR (Table 1). Three specimens were discordant in the TP-PA and the Syphilis Fast. One was RPR and TP-PA reactive but Syphilis Fast and FTA-ABS DS nonreactive, suggesting that the TP-PA and RPR were most likely false positives. Two of the discordant serum samples were nonreactive in the RPR, with discordant results in the TP-PA and the Syphilis Fast tests. One was nonreactive in the Syphilis Fast but reactive in the TP-PA and the FTA-ABS DS, and the other was reactive in the Syphilis Fast and nonreactive in the TP-PA and FTA-ABS, indicating one false-positive and one false-negative Syphilis Fast result. Under normal screening practices, the RPR-nonreactive serum samples would not have been run in a treponemal test unless late latent syphilis, neurosyphilis, or late syphilis was suspected.

The Syphilis Fast test seems ideal for point-of-care situations such as sexually transmitted disease or prenatal clinics. Results for both a nontreponemal test and a confirmatory test could be obtained in less than 20 min. This would allow treat-

TABLE 1. Comparison of Syphilis Fast with TP-PA by RPR reactivity^a

RPR result	No. of specimens with results			
	Fast R, TP-PA R	Fast R, TP-PA NR	Fast NR, TP-PA R	Fast NR, TP-PA NR
R	131	0	1 ^b	12
NR	29	1 ^c	1 ^c	80

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^a NR, nonreactive; R, reactive; Fast, Syphilis Fast.

^b FTA-ABS DS nonreactive.

^c FTA-ABS DS reactive.

ment to be administered only to those patients who had syphilis and eliminate unnecessary treatment for those who had biologic false-positive nontreponemal test results. This might also prevent some patients from “slipping through the cracks” and not getting needed treatment, a major goal of CDC’s initiative to eliminate syphilis in the United States (6). Patients with infectious syphilis need to be treated before they leave the clinic so that they do not transmit their infection to their sexual partners or, in the case of pregnant women, to their unborn children.

The Syphilis Fast test appeared to be as sensitive as and slightly more specific than the TP-PA on routine specimens. Because the clinical diagnosis of the patients from whom the serum samples were collected was unknown, sensitivity and specificity for these samples could not be determined. However, the reported sensitivity for the Syphilis Fast is 96.8% for untreated syphilis, with a specificity of 99.8% (7). For the TP-PA, the reported sensitivity for untreated syphilis is 97.1% and the specificity is 95.3% (5). The proteins used in the Syphilis Fast test, 47, 17, and 15.5 kDa, appear to have some of the highest sensitivity for syphilis detection (2). By using cloned antigens, some of the higher-molecular-weight proteins are eliminated. These proteins exhibit more nonspecific reactivity with serum from persons without syphilis (2), and the elimination of these proteins probably contributes to the specificity of the Syphilis Fast.

The Syphilis Fast has the advantage of taking approximately the same amount of time to perform as the RPR while requiring no equipment other than the rotator which is also used in the RPR. The test results are easy to read, with the distinction between the nonreactive and the reactive serum samples generally being clear cut, and the test agrees well with the TP-PA.

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