Syphilis Fast latex Agglutination Test: A Rapid Confirmatory Test for Syphilis

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Using 255 serum samples of varying reactivities, we evaluated the Syphilis Fast latex agglutination test against the *Treponema pallidum* Particle Agglutination (TP-PA) test for confirming a diagnosis of syphilis. We found 98.8% agreement between the Syphilis Fast and the TP-PA test. The Syphilis Fast test had several advantages over the TP-PA: (i) the test only takes 8 minutes to perform, (ii) no special equipment other than a rotator is needed, and (iii) the test is easy to read. It appears to be a good confirmatory test for syphilis, especially for point-of-care clinics such as prenatal or STD clinics.
Syphilis traditionally has been diagnosed serologically by performing a nontreponemal test to screen and confirming the results with a treponemal test. All of the current confirmatory tests utilize special equipment such as fluorescent microscopes or microtiter plate readers and/or take from 1 to 2 hours to complete. In point-of-care situations such as sexually transmitted disease (STD) clinic, prenatal clinic, or drug treatment centers, treatment cannot wait for the results of the treponemal test. This is especially true in dealing with clients who are not apt to return to the clinic in a timely manner. Treatment in these situations is usually based on the nontreponemal test result, clinical symptoms, and clinical history. Many clinics where screening and treatment for syphilis are done do not have the capability to perform confirmatory treponemal tests. The confirmatory treponemal test is done, frequently off-site, with the results obtained after the patient has been treated and left the clinic. This sometimes results in persons with false positive nontreponemal test results being treated for syphilis.

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, because of the format of the test, no special equipment such as fluorescent microscopes or microplate readers were required. This would make the test ideal to be considered for point-of-care testing, such as that done in STD clinics.

We looked at the test and compared it to the confirmatory test we were currently using, the Serodia *T. pallidum* passive particle agglutination (TP-PA) test (Fujirebio America, Inc., Fairfield, New Jersey). Two hundred fifty-five serum samples that were originally submitted to the Georgia Department of Human Resources for syphilis testing were unlinked and tested in the
rapid plasma reagin test (RPR), TP-PA, and the Syphilis Fast latex agglutination test (Diesse, Milano, Italy). The RPR (3) and TP-PA (4) were done according to standard procedures. The Syphilis Fast was done according to 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, Atlanta, GA) which was done according to standard procedures (1).

There was 98.8% agreement between the TP-PA and the Syphilis Fast tests results. Of the 92 that were nonreactive in both tests, 12 were reactive in the RPR and 80 were nonreactive (Table 1). There were three specimens that were discordant in the TP-PA and the Syphilis Fast tests. One was RPR and TP-PA reactive but Syphilis Fast nonreactive. The FTA-ABS DS result for this serum sample was nonreactive. Without clinical history, it is difficult to determine whether this sample was a false positive for the RPR and TP-PA or a false negative for the Syphilis Fast and FTA-ABS DS tests. 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 and reactive in the TP-PA, and the other was reactive in the Syphilis Fast and nonreactive in the TP-PA. The FTA-ABS DS results were reactive for the one that was TP-PA reactive and nonreactive for the one that was Syphilis Fast reactive, indicating one false positive and one false negative Syphilis Fast test result.

The Syphilis Fast test would seem to be ideal in point-of-care situations such as STD or prenatal clinics. The results of a nontreponemal test could be confirmed with a treponemal test in less than 20 minutes for both tests. This would allow for treatment of only those patients who had syphilis, rather than also treating those that had biologic false positive nontreponemal test results.
results. This might also prevent some patients from slipping through the cracks and not getting treated when they need to be treated. This is especially important with the syphilis elimination initiative (6). Patients need to be treated before they leave the clinic so that the clinicians are sure that the patient has been treated and so that the person does not spread syphilis to either their sexual partners, or in the case of a pregnant woman, to her unborn child.

The Syphilis Fast test appears to be as sensitive and as specific as the TP-PA test on routine specimens. The reported sensitivity is 96.8% for untreated syphilis and specificity is 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, the 47-, 17-, and 15.5-kDa, are the ones that appear to have some of the highest sensitivity for syphilis detection (2). By using cloned antigens, some of the higher molecular weight proteins, which exhibit more nonspecific reactivity with serum from persons without syphilis (2), are eliminated, which probably contributes to the specificity of the Syphilis Fast test.

The Syphilis Fast test has the advantage of taking approximately the same amount of time as an RPR to perform while requiring no additional equipment other than the rotator that is also used in the RPR. The test is easy to read, with reactions generally being clear cut between the smoothness of the nonreactive test and the agglutination of a reactive serum sample and it agrees well with the TP-PA test.
References


Table 1. Comparison of Syphilis Fast with TP-PA by RPR reactivity.

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NR, nonreactive; R, reactive; Fast, Syphilis Fast; TP-PA, *Treponema pallidum* passive particle agglutination test; RPR, rapid plasma reagin test.

<sup>a</sup>FTA-ABS DS reactive

<sup>b</sup>FTA-ABS DS nonreactive