Rapid Immunochromatographic Test for Syphilis

Dear Editor,

Confirmatory test for syphilis such as fluorescent treponema antibody-absorption test (FTA-ABS), Treponema pallidum immobilization test (TPI). Treponema pallidum haemagglutination (TPHA) test are technically demanding and not available in most developing country settings outside of reference laboratories. By far, TPHA test has the sensitivity and specificity almost similar to that of FTA-ABS test and is considered as an attractive alternative to the expensive and technically demanding FTA-ABS and TPI test for serodiagnosis of syphilis, however, simple rapid treponema specific tests are urgently required for the use in primary health care, private settings, and for high risk patients who are often untraceable. Therefore, one step dipstick test for syphilis namely Syphicheck kit was used in our hospital for rapid confirmation.

Our study group consisted of 300 pregnant females randomly selected from antenatal clinic (ANC) and 300 high risk patients attending dermatology department of Post Graduate Institute of Medical Sciences, Rohtak, with genital ulcers. Previous history of syphilis was excluded. All samples were initially screened qualitatively and quantitatively by Venereal Disease Research Laboratory (VDRL) test using antigen obtained from Serology Laboratory, Kolkata by standard protocols. All VDRL positive samples were followed by one step dipstick test for syphilis (Syphicheck) obtained from Qualpro diagnostics, Goa, India (Rs. 1375/- for 25 tests). Test was done and interpreted according to manufacturer’s instructions.

Out of 300 ANC cases 210 (70%) were both VDRL and Syphicheck negative. Among ANC only two cases were Syphicheck positive out of which one was VDRL positive in titre R4 and other was VDRL negative. Also Syphicheck detected 88 (29.3%) biological false positive cases (Table).

Out of 300 genital ulcer cases from dermatology department, 81 (27%) were both VDRL and Syphicheck negative. A total of 216 cases were diagnosed as syphilis on clinical and serological grounds; out of which 207 (122 titre >R8, 77 titre R1-R8 and 8 among non-reactive VDRL) were Syphicheck positive while rest 9 (6.8%) cases were VDRL reactive in titre more than R8 but Syphicheck negative and compatible with clinical illness. These nine cases were Syphicheck positive after 15 days. Only three (1.7%) gave biological false positive results and these were still Syphicheck negative after 15 days (Table).

Correlation between negative VDRL test and Syphicheck was 97%. With VDRL titre >R8, 93.1% samples were Syphicheck positive, however, with VDRL titre R1-R8, 46.1% were Syphicheck positive. Also Syphicheck detected 9 (3%) cases which were VDRL negative (Table).

VDRL or Rapid Plasma Reagin (RPR) test is most widely used screening test for syphilis in India as they are rapid and economical. Because neither of these tests assay for syphilis - specific antibodies, there are problems associated with both their specificity and sensitivity. In early primary disease antilipoidal antibodies may not have developed and in late syphilis (late latent and tertiary) upto 30% of individuals may lack antilipoidal antibodies. In addition, because a variety of

<table>
<thead>
<tr>
<th>VDRL titre</th>
<th>Syphicheck</th>
<th>Antenatal</th>
<th>Genital ulcers</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;R8 (n=131)</td>
<td>Positive</td>
<td>0</td>
<td>122</td>
<td>122 (93.1)</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>0</td>
<td>9</td>
<td>9 (6.8)</td>
</tr>
<tr>
<td>R1-R8 (n=169)</td>
<td>Positive</td>
<td>1</td>
<td>77</td>
<td>78 (46.1)</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>88</td>
<td>3</td>
<td>91 (53.8)</td>
</tr>
<tr>
<td>Non-reactive (n=300)</td>
<td>Positive</td>
<td>1</td>
<td>8</td>
<td>9 (3)</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>210</td>
<td>81</td>
<td>291 (97)</td>
</tr>
</tbody>
</table>

Total | 300 | 300 | 600 |

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conditions (e.g., lupus and increased age) lead to antilipoidal antibodies and false positive results; hence a rapid, effective, practical confirmatory test is often required for diagnosis and treatment. Syphicheck is a one step rapid self performing test which can qualitatively detect presence of IgG and IgM class of treponema specific antibodies in serum or plasma within 15 minutes. It uses the principle of immunochromatography, a unique two site immunoassay on membrane. Positive results indicate a past or present infection, however a positive result should always be evaluated in correlation with clinical condition before arriving at final diagnosis. Manufacturers have reported 100% correlation between syphicheck and standard TPHA. Low levels of antibodies to *Treponema pallidum* at a very early primary stage of infection can give a negative result, nine such cases were detected in our study. However, Syphicheck in our study proved to be very helpful to exclude biological false positive results as well as to institute therapy in low titre (R1-R8) VDRL positive cases. As the results are available in 15 minutes and reproducible, it is better than standard TPHA which takes at least 3-4 hours.

Therefore, we conclude that syphicheck is a simple, rapid, point of care type treponema specific test suitable for use in primary health care settings for the diagnosis of syphilis. Evaluating the performance of rapid tests, their utility in a disease control programme and acceptability to patients and health care providers will improve the diagnosis of syphilis in primary health care settings in developing countries and reduce over treatment.

**References**


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**Coinfection of HSV with other Sexually Transmitted Diseases**

Dear Editor,

The emerging prosodemic of AIDS/HIV disease in India has made STD Control as one of the strategies imperative and probably the most important to decrease HIV transmission in community. Among various STDs, prevalence pattern of syphilis and herpes genitalis is pivotal and NACO has already issued guidelines to test for these two diseases in AIDS as well as non-AIDS patients by serology. We conducted this study to analyse the seroepidemiology of HSV in STD patients and to provide data for implementation of the joint STD/HIV control programme.

Sera of 66 patients (22 females and 44 male) with various STD symptoms (21 ulcerative and 45 non-ulcerative) attending the STD clinic, JLN Hospital, Ajmer, was tested for the presence of IgM antibodies to HSV-1 and 2 (to detect primary/first episode genital HSV infection) by ELISA, for syphilis by RPR and TPHA and for HIV by ELISA. Out of 66 STD patients 27 were IgM-HSV positive (40.9%), 15 were syphilis positive (22.7%) and 7 HIV positive (10.6%) (Table). Coinfection rate of HSV in syphilis and HIV positives was 40.6% and 42.9% respectively. However only two out of the 27 IgM-HSV positive patients had clinical herpes genitalis yielding a subclinical HSV coinfection rate of 37.8%. Hence, according to current WHO treatment regimen, 25 cases of primary/first episode genital HSV infections would have been missed clinically leading to inappropriate treatment. This lapse in diagnosis can nevertheless catapult onto grievous consequences like meningoencephalitis, disseminated herpes or even death, especially if the patient becomes immunocompromised or if transmitted from mother to newborn.

In our study a large proportion (40.7%) of HSV positives were females of child bearing age and can act as potential transmitters to their offspring. Transmission of infection from HSV positive males to their sexual partners may further cascade the situation. Detection of subclinical HSV coinfection by serology facilitates counselling regarding advisability of acyclovir therapy (in addition to treating the other coexisting STD), the risk of recurrences and appropriate measures to reduce HSV transmission to contacts.

HIV infection in our STD clinic attendees was 10.6% which is quite alarming. Our study strongly suggests that