Performance evaluation of the Elecsys® Syphilis immunoassay in blood screening


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Background:
Although syphilis is comparatively less common than other infections, epidemiological data and case notifications have been on the rise, with estimates of 1.15 million in 2001 and 3.6 million cases in 2011. 3

• Due to the lengthy period before patients present with symptoms, and because there are no overt markers, syphilis is easily transmitted between individuals. 4

To prevent infections from blood transfusions, World Health Organization and International Union against Sexually Transmitted Infections recommend mandatory screening of all donations for specific infectious diseases. 5

In Europe, the ‘gold standard’ for confirmation is the treponemal antibody test of a different type from the primary test. 6 The Elecsys® Syphilis assay uses an innovative enzymatic reaction for the in vitro qualitative determination of total antibodies to T. pallidum in human serum and plasma.

Aims:
To evaluate the specificity and sensitivity of the Elecsys® Syphilis immunoassay in blood donations, including Asian Pacific populations, and compare performance with that of state-of-the-art screening tests.

Materials and methods:

Composers' methods and analysis

• Each study was conducted according to the Elecsys Syphilis guidelines and at least one of the following comparator assays: ARCHITECT® Syphilis TPHA (Abbott Laboratories, Wiesbaden, Germany); 7 LIAISON® Treponema Screen (Diasorin, Saluggia, Italy); 8 cobas e 411 (Roche Diagnostics, Penzberg, Germany). 9

• The Elecsys® Syphilis assay results were considered negative if the signal:cut-off ratio (s/co) was < 1.00 and positive if the s/co was ≥ 1.0.7 Samples with an initial reactive result were retested in duplicate using the Elecsys® Syphilis assay and considered to be repeatedly reactive, and subjected to confirmatory testing, if either of the results was ≥ 1.0.7

Figure 1: Principle of the Elecsys® Syphilis assay

• The specificity calculation.

• Serum with the high-volume of sample for the in vitro qualitative determination of total antibodies to T. pallidum in human serum and plasma.

Table 1: Specificity of the assays tested as determined by the individual centers

<table>
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<tr>
<th>Indicated</th>
<th>Specificity (%) with 95% confidence limits (2-sided)</th>
<th>Specificity (%)</th>
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</thead>
<tbody>
<tr>
<td>Elecsys®</td>
<td>TP Screen (lot B)</td>
<td>99.95%</td>
<td>99.95%</td>
</tr>
<tr>
<td></td>
<td>TP Screen (lot C)</td>
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<tr>
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Table 2: Sensitivity of the assays tested as determined by the individual centers

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Conclusions:
• The Elecsys® Syphilis assay is suitable for blood bank use and compares favorably with other well-established screening tests.

References:

Life needs answers