An evaluation of near patient tests for detecting herpes simplex virus type-2 antibody

Melanie Saville, David Brown, Christine Burgess, Keith Perry, Simon Barton, Frances Cowan, Giorgio Palu, Carlo Mengoli

Objectives: To examine the “in use” test characteristics of the POCkit “near patient” HSV-2 rapid test for the detection of HSV-2 IgG antibodies for use in the clinic. This test relies on a visual interpretation of the result.

Methods: 2093 serum samples, 229 from UK and 919 from Italian genitourinary medicine clinic patients and 945 from obstetric and gynaecology clinic patients in Italy were tested. Tests were carried out according to manufacturers’ protocol in the United Kingdom and Italy. Three readers independently recorded a score for each test carried out and the results were compared.

Results: In the UK study, the three readers disagreed on the result on 5.2% of tests. In the Italian study, there was disagreement in 10.2% of tests.

Conclusions: This study has demonstrated a problem in the subjective nature of the interpretation of the POCKit HSV-2 test. It highlights the need for adequate training of clinic staff and the need for clinics to adopt policies of quality assurance and ongoing monitoring which will ensure the validity and accuracy of this clinic based test.

Keywords: evaluation; herpes simplex virus; POCKit HSV-2 test

Table 1 Scoring system used to read the POCKit HSV 2 rapid test

<table>
<thead>
<tr>
<th>Text spot observation</th>
<th>Test score</th>
<th>HSV-2 antibody status</th>
</tr>
</thead>
<tbody>
<tr>
<td>No red/pink test spot observed</td>
<td>0</td>
<td>Negative</td>
</tr>
<tr>
<td>Some red/pink colour visible in the test but not as a clear spot</td>
<td>1</td>
<td>Ambiguous</td>
</tr>
<tr>
<td>Very weak, but definite test spot</td>
<td>2</td>
<td>Positive</td>
</tr>
<tr>
<td>A medium reaction in test spot</td>
<td>3</td>
<td>Positive</td>
</tr>
<tr>
<td>A strongly reactive specimen</td>
<td>4</td>
<td>Positive</td>
</tr>
</tbody>
</table>

*A pink/red control spot has to be present in each test device to make the test valid.
when it will often be carried out by non-laboratory trained staff. It is clearly important that these staff receive adequate training in the interpretation of these tests, with ongoing evaluation to ensure consensus of interpretation. In this study some patients undergoing testing could have received either a false positive or false negative HSV-2 antibody result with likely unfortunate consequences. This assay is now sold for home testing directly to patients (wellbeing met), which may lead to further diagnostic confusion.

At the time of this evaluation, the POCKit HSV-2 rapid test did not include the option of an “ambiguous” result. However, the manufacturer of the test kit, Diagnology, have responded to this problem by clarifying the interpretation criteria particularly to cases where the test spot is very faint, as being an “indeterminate” result, cautioning users about the possibility of overinterpretation of these faint results. A further serological test 4–6 weeks later is recommended. This response is welcomed and must be publicised.

Importantly, extensive quality assurance schemes exist within laboratories to ensure that test results are reproducible. With the likely increase in near patient test kits, it is essential that large scale evaluations in laboratories are undertaken before clinic use and that clinics adopt policies of quality assurance and ongoing monitoring which will ensure the validity and accuracy of clinic based testing. In addition, it should be established that similar performance characteristics of the near patient test can be guaranteed in non-laboratory settings before they are widely introduced.


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