92.72% (95% CI 72.11% to 99.93%), when the Oraquick study was removed from analysis, the pooled sensitivity of all other tests dropped to 77.11% (95% CI 45.49% to 99.61%) see Abstract P3-S5.03 Table 1. Pooled specificity remained high at almost 100% regardless of whether the Oraquick study was included or not.

**Conclusion**

Although Oraquick appears to be the most promising test, authors ties with industry make these results less credible. More independent testing is required to be able to make policy recommendations for the most accurate index test to detect Hepatitis C infection.

Abstract P3-S5.03 Table 1 Results of bayesian meta-analysis: diagnostic accuracy of index tests used to detect Hepatitis C

<table>
<thead>
<tr>
<th>Pooled results</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Including oraquick study</td>
<td>92.72% (72.11% to 99.93%)</td>
<td>99.88% (99.56% to 100%)</td>
</tr>
<tr>
<td>Excluding oraquick study</td>
<td>77.11% (45.49% to 99.61%)</td>
<td>99.99% (99.82% to 100%)</td>
</tr>
</tbody>
</table>

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**P3-S5.04 THE DIAGNOSTIC ACCURACY OF RAPID POINT OF CARE TESTS USED TO DIAGNOSE HEPATITIS B: A BAYESIAN META-ANALYSIS**


1S Shikumar, 1Y Jafari, 1G Lambert, 1C Claessens, 1M Klein, 3J Martinez-Cajas, 4R Peeling, 1L Joseph, 1N Pant Pai. 1McGill University, Montreal, Canada; 2INSPQ, Canada; 3Queen’s University, Canada; 4LSHTM, UK

**Background**

More than 350 million people are infected with the Hepatitis B virus worldwide, with four million new cases every year. The prevalence of the Hepatitis B virus is highest in developing settings where laboratory equipment and diagnostic resources are limited. This creates a need for rapid point-of-care testing in order to screen blood donors and ensure timely diagnosis and treatment of infected individuals. Although studies have been conducted examining the accuracy of different tests, there has not been a synthesis of the available global evidence, or an assessment of the quality of evidence to date.

**Objective**

We conducted a systematic review of the global literature examining the sensitivity and specificity of rapid point-of-care tests used to diagnose Hepatitis B, and meta-analysed the data. Additionally, we conducted a critical appraisal of the quality of included studies.

**Methods**

Two reviewers conducted independent searches of five databases between the years of 1990 and 2010 for global evidence. Meta-analysis was performed grouping studies based on whether the index test identified HBsAg, both HBs and eAg, or antibody to HBsAg. We used Bayesian meta-analysis, accounting for the fact that all of the studies used imperfect reference standards (sensitivity and specificity assumed to range between 90% and 100%). The quality of all included full-text studies was assessed using the QUADAS and STARD checklists.

**Results**

A total of 17 studies were identified, of which 13 were from developing countries and which investigated 22 different index tests. When studies were pooled, the Determine HBsAg test showed a combined sensitivity of 98.76% and a specificity of 99.94%. Other HBsAg tests showed a lower combined sensitivity (96.77%) but comparable specificity (99.89%). The Amrad HBsAg test showed a combined sensitivity of 98.04% and a specificity of 99.04%, while the tests detecting antibody to HBsAg showed a combined sensitivity of 99.77% and a specificity of 96.08%. Studies were of poor-moderate quality with QUADAS scores ranging from 3 to 10/14 and STARD scores ranging from 7 to 14/25 see Abstract P3-S5.04 table 1.

**Conclusion**

The Amrad and Determine tests show the highest pooled accuracy. However, this could be explained by the fact that the other subgroups included studies examining different index tests with a wide range of accuracies. There is a need for more consistently designed studies, using ideal reference standards recommended by the CDC or Health Canada.

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**P3-S5.05 RAPID POINT OF CARE TESTING FOR TEN SEXUALLY TRANSMITTED DISEASES**

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1J Kriessel, 1A Bhatia, 3M Vaughn, 2J Gardner, 1C Barrus, 2P Crisp. 1University of Utah, School of Medicine, Salt Lake City, USA; 2Idaho Technologies Inc., Salt Lake City, USA; 3Salt Lake Valley Health Department, USA

**Background**

Delays in the reporting of STD testing sometimes result in inappropriate patient care where a patient must be called back in for treatment. Some STDs may be missed because not all specimens are tested in a comprehensive manner. We are developing a multiplex point of care test to fill this clinical need. This fully automated system is capable of detecting ten PCR targets from a single specimen in <1 h.

**Methods**

A Sexually Transmitted Disease (STD) Panel was designed for the FilmArray device to detect the following organisms: Chlamydia trachomatis (CT), Neisseria gonorrhoeae (GC), Treponema pallidum, Trichomonas vaginalis, Mycoplasma genitalium, Ureaplasma urealyticum, Ureaplasma parvum, Haemophilus ducreyi, and herpes simplex viruses (HSV-1 and 2). Multiple PCR primers for each of these organisms were multiplexed and validated with the appropriate laboratory strains or plasmids.

**Results**

Three hundred twenty-four subjects have been enrolled from the Salt Lake Valley Health Department STD clinic patient population, providing 600+ specimens for analysis. Ninety-nine clinical specimens have been tested so far. The STD panel test results were compared to the standard CDC recommended clinical tests run in parallel on duplicate specimens. Standard testing included gram staining, CT/GC amplification, wet mount examination, viral culture, and serum syphilis IgG. Sample types included urine (44), vaginal/cervical swabs (7), urethral swabs (5), ulcer swabs (7), oral swabs (20), and rectal swabs (16). Concordance between the new STD panel and standard testing was: C trachomatis (79/81, 98%), N gonorrhoeae (81/81, 100%), HSV1 (6/6, 100%),