Reviewer's report

**Title:** Evaluating HBsAg rapid tests performance in different biological samples from low- and high infection rates settings & populations

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**Reviewer:** SIMON François

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Evaluating HBsAg rapid tests performance in different biological samples from low- and high infection rates settings & populations

Helena M Cruz, et al

Helena Cruz et al compare the performances of 3 point-of-care rapid tests for HBs antigen detection (Biomerieux, Wama and Doles) on different biological matrices in populations with low and high prevalence for HBV infection. The importance of HBs rapid test (RDT) performances and the need of comparative studies between RDT are well defined by the authors. Sensitivity of rapid tests for HbsAg detection led to more than thirty publications in recent months pointing to the importance of the subject.

The methods including statistical analysis are appropriate. EIA was considered as the gold standard. 393 samples from a reference panel from of the National Referral Center were used to determine the sensitivity and specificity. Samples from field studies targeting suspected HBV cases (G I, n-371), remote part of Brazil (G II n-881), and highly vulnerable individuals (G III n-251). Blood as well as oral fluid were tested.

The reproducibility and repeatability studies was conducted with two serum samples and 2 samples of spiked oral fluid in 11 replicate by two different operators in 2 consecutive days. A serum sample was positive the other not.

Results shows that WAMA test lacks sensitivity (93%) on the reference panel. Specificity is correct in G2 and G3. Reproducibility and repeatability of the tests yield values of 100% compared to EIA results. Altogether, the 3 RDT performances look correct but in the low prevalence population is a limiting factor (Group 2 and 3) to establish the true negative predictive value. According to the results, these RDT are not adapted to oral fluid; this is not surprising as they have not been developed for such detection.

Comments

This study is well-conducted in term of reproducibility and repeatability evaluations. Results are based onto interesting groups of subject with a large number of samples allowing a real comparative study between the RDTs

Major comments:

- Are the 3 RDT FDA approved and/or CE IVD? With a WHO registration? This a
major information for the publication in an international peer review

- Identify always the test with the same designation as Vikia HBsAg, HBsAg Teste Rápido or Imuno-Rápido HBsAg all along the paper. Better than by their manufacturers (BioMerieux, Doels or Wama) and better than the present mix

- OF/ Saliva results are poorly informative and complicates the presentation. These samples were probably collected during previous HCV study for HCV and OF data brings little to the article. Could be deleted