Reviewer’s report

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

Version: 1  Date: 14 July 2015

Reviewer: Edouard Tuaillon

Reviewer’s report:

Helena M Cruz et al, have evaluated the performances of AgHBs testing using three rapid tests. The authors have used reference samples and blood and saliva collected in field studies performed in different populations with different risk level for HBV infection.

A large number of samples have been tested. This study provides interesting data but there is major concerns regarding the methods.

I. Major Compulsory Revisions:

1. The populations tested for HBV infection are clearly described. For example the difference between the reference panel and the group I is not clearly explained. Sentence like “Most of them lived in underserved and impoverished areas in the Rio de Janeiro State” appears approximate. Some of the individuals of the group II lived in the Rio de Janeiro state.

Hence, inclusion criteria need to be simplified and clarified in the text. A map could be included as a new figure to shown location of each group, number of samples, time of collection, population characteristics (general population, poor resource area, high risk group).

2. Authors have written that serological characteristics of the sera are available: “Sera samples (positive for HBsAg) were also assayed for total anti-HBc, IgM anti-HBc, anti-HBs, HBeAg and anti-HBe using commercial EIAs (Diasorin, Italy)”, page 8 line 172. However this important data are not shown.

These results should be shown in a table and discussed.

3. Discordant results EIA +/-rapid test – need to be characterized. DO value of the EIA were low, do the authors are sure that sera were true positive for HBV?

In these cases, further analyses are request: AgHBs neutralization assays, and HBV DNA testing, HBsAg concentration. If this data are not available this major limit should be discussed.

II. Minor Essential Revisions:

- The analytical sensitivity (ex less than or equal to 2 IU/ml (3.8 ng/ml for the Vikia assay based on the manufacturer technical manual) need to be indicated in the method section. It would especially interesting to confirm and compare the
analytical sensitivity for each of the tests using dilution the WHO standard as a first result of the study. Possibility to test capillary blood should also be indicated in the text.

- The following sentence should not be included in this methods section “From 1999 to 2011, 120,343 confirmed HBV cases were reported in Brazil, most of them in the Southeast region (36.3%), where Rio de Janeiro is located (10)”, but in the discussion section.

- The study of Helena M Cruz et al demonstrates that HBsAg testing on saliva using these three rapid tests had low performances. The authors should have nambigous conclusion about this result. The saliva should not be used for HBsAg testing using these devices.

- EIA need to be defined in the abstract (enzyme immunoassays)

- In the abstract: Sensitivity and specificity should be indicated in the abstract section of each test. Conclusion about performances be different should be different in blood versus saliva since the performances is not acceptable in saliva.

- Line 79, page 4: “are labor-intensive and time-consuming” is not appropriate for EIA assays since these in vitro assays are relatively easy to perform.

- Line 84, page 4, replace: “and do not require complex laboratory infrastructure” by « and do not require laboratory infrastructure” since laboratory infrastructure for EIA assays cannot be considered as complex, even in low income countries.

- The sentence line 87, page 4 “patients’ samples are poured over strips containing regnated antibodies to HBsAg conjugated with colloidal gold” is not exact since some lateral flow tests used other techniques (ex. Vikia : BSA-biotinylated complex coupled to blue-dyed polystyrene microspheres).

- Line 115 page 5: need to be modified: “comprising acute, chronic or suspected cases of hepatitis B infections”


Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.