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LETTERS TO THE EDITOR

Validation of Whole Blood Rapid Diagnosis Test for Hepatitis B

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We recently published a report validating point-of-care rapid diagnostic tests (RDT) for the diagnosis of Hepatitis B virus (HBV) infection in serum. In the current report, we validated a whole-blood RDT for HBsAg in the form of a test-strip. The test was validated in 55 HBV positive individuals across all genotypes other than F, and in 20 HBV negative individuals in the Netherlands. The RDT showed 100% sensitivity and specificity. The low cost and use in whole blood allows this RDT to be useful in resource-limited locations, further validation in such settings will be of importance.

To the editor:

We recently published a report validating point-of-care rapid diagnostic tests (RDT) for the diagnosis of Hepatitis B virus (HBV) infection [1]. We believe that expedited and cost-effective diagnosis of HBV infection via RDT is critical to understand the epidemiology of HBV in resource-limited settings and implement prevention and treatment strategies [2]. In that report, a whole-blood rapid test for HBV surface antigen (HBsAg), the universally accepted test to diagnose chronic HBV infection, in the form of "cassette" did not produce reliable results, with a sensitivity of only 56% (albeit a specificity of 100%). In the current report, we validated a whole-blood RDT for HBsAg in the form of a test-strip (PRECHECK Bio Inc, Korea). The test was validated in 55 HBV positive (HBV-pos) and 20 HBV negative (HBV-neg) individuals in the Netherlands. The median age was 38 years (IQR 3–47) in the HBV-pos group, with 60% being male and 33 years (IQR 30–37) in the HBV-neg group, with 85% being male. The RDT showed 100% sensitivity and specificity, with complete correlation for HBsAg positive and negative results with the local gold standard at Erasmus University, Rotterdam (LIAISON XL, Diaorin, Italy). All HBV-pos individuals were negative for hepatitis C and D virus, as well as human immunodeficiency virus. The samples included individuals on treatment and inactive carriers, all HBV genotypes other than F, with the most common genotypes being D (23%), C (20%), and A (15%). Median HBV DNA was 20 IU/ml (IQR 20–285), median HBsAg level 510 IU/ml (IQR 150–2900), and 16 subjects (29%) were HBeAg positive. Seventy percent of HBV+ individuals were on treatment (47% on entecavir and 21% on tenofovir).

We believe this addition to our previous study is important as it provides validation of a RDT for HBsAg using whole blood, in a rapid and cost-effective manner, therefore allowing the test to be used without the need of any laboratory resources. Our test was validated in one institution (Erasmus MC, the Netherlands) in a variety of genotypes. However, we believe further validation in resource-constrained settings will be of importance.

Data Accessibility Statement

Study data will be made available upon request of the corresponding author.

Ethics and Consent

Ethical approval was given by the ethical committee of the Erasmus MC, Rotterdam. MEC-2017_1140.

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Competing Interests

The authors have no competing interests to declare.

Author Contributions

Jose D. Debes: study design, data analysis, writing; Gertine van Oord: data collection, writing; Andre Boonstra: study design, data analysis, writing.

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