HIGH ACCURACY OF SELF-COLLECTION TESTING OF HEPATITIS B CORE ANTIBODY ON SERUM SEPARATOR CARDS

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Background:
Detection of hepatitis B core antibody (HBV cAb) is necessary for safe initiation of direct acting antivirals (DAA) for hepatitis C treatment. Currently, only traditional serum laboratory options are available for HBV cAb detection, presenting a barrier for populations unable to access phlebotomy. Dried blood spots (DBS), a commonly used alternative to phlebotomy specimen collection in HCV treatment globally is possible; however, whole blood often causes high background and interferes with kit performance. We validated HBV cAb EIA testing by self-collection serum separating card (SSC) to provide a more reliable, low barrier mechanism HBV cAb detection in hard-to-reach populations.

Methods:
Bio-Rad MonoLisa anti-HBc IgG/IgM EIA was used to compare serum, DBS, and SSC. Between serum and SSC accuracy was evaluated using 60 paired serum and SSC community-collected specimens. Medication interference (Pibrentasvir, Glecaprevir, Velpatasvir) and sexually transmitted infection (STI) cross-reactivity was evaluated. Stability at extreme temperatures mimicking a three-day shipment and storage stability at room temperature was conducted.

Results:
DBS samples displayed high optical density values regardless of the titer or negativity of HBcAb, whereas SSC had a concordant limit of detection compared to serum. The sensitivity and specificity of SSC were 100%. The medications did not interfere with the assay, and analytical specificity using other STI was confirmed. SSC were stable at extreme temperatures followed by the 2-month storage at ambient temperature.

Conclusion:
SSC is a feasible replacement for traditional serum for HBV cAb testing. Access to self-collection mechanisms for HBV cAb may allow for lower barrier completion of pre-treatment workup for hepatitis C treatment in vulnerable populations and low resource settings.

Disclosure of Interest Statement:
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