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:
Dr. Andrew Seaman has received investigator-initiated research funding from Merck pharmaceuticals not directly related to the conduct of this research. He has no financial relationship with Molecular Testing Labs. All other authors have no declarations of interest. Nakano M, Nappi T, Gordecke Z, and Sailey C are employees of Molecular Testing Labs.