

A NOVEL HEPATITIS C “TREATMENT-READY” SELF-COLLECT PANEL: HIV, HEPATITIS B SURFACE ANTIGEN, HEPATITIS B CORE ANTIBODY, AND HEPATITIS C RNA ON DRIED BLOOD SPOT AND SERUM SEPARATING CARDS

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Background:

World Health Organization hepatitis C (HCV) elimination targets require diagnosis and treatment of people who inject drugs (PWID) with direct acting antivirals (DAA). Phlebotomy for HCV screening/confirmatory testing and evaluation can be a barrier to DAA initiation for PWID. We developed a Dried blood spot (DBS) and serum separating card (SSC) treatment-ready panel allowing for completion of all tests necessary for HCV treatment except for fibrosis assessment to improve treatment access for PWID.

Methods:

We modified commercial ELISA kits to perform 4th Generation HIV Antigen/Antibody (HIV Ag/Ab), HCV Antibody (HCV Ab), and hepatitis B surface antigen (HBV sAg) assays on DBS, and SSC for hepatitis B core antibody (HBV cAb) assay. HCV Ribonucleic Acid (HCV RNA) test was developed using MagMAX viral and pathogen extraction kit and Taqman assay with real time PCR. Sensitivity and specificity were determined for participant self-collected specimens on DBS and SSC and compared to venous serum collected simultaneously in the community.

Results:

DBS and SSC assays were validated according to CAP/CLIA guidelines. No cross-reactivity was observed in samples collected from patients who have comorbidity of HIV, HBV, and/or syphilis. DBS sensitivity and specificity for HIV Ag/Ab, HBV sAg, and HBV cAb ELISA assays were 100 %. HCV Ab sensitivity was 97.2% with 100% specificity. DBS HCV RNA sensitivity and specificity were 100% with the analytical measurement range of 500-2.5E7IU/mL.

Conclusion:

Our DBS and SSC panel suggests that accurate diagnosis and pre-treatment evaluation of PWID with HCV is feasible without venipuncture. HCV Ab and RNA tests were imperfectly sensitive, though the expanded access provided through decentralized, no venipuncture testing may increase over all diagnosis and linkage to DAA medications.

Disclosure of Interest Statement:

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