EVALUATION OF THE HOLOGIC APTIMA HCV QUANT DX ASSAY FOR DETECTION OF HCV RNA FROM DRIED BLOOD SPOTS

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Introduction:
The availability of safe and effective direct acting antiviral therapy for hepatitis C virus (HCV) has led to a need for simplified diagnostic pathways. Barriers to treatment uptake in people who inject drugs, may be overcome by utilizing novel collection methods, such as dried blood spots (DBS). However, there are currently no registered assays for HCV RNA testing from DBS samples. The aim of this study was to evaluate the performance of the Aptima HCV Dx Quant assay for HCV RNA detection with paired venepuncture and DBS (spotted whole blood) samples.

Methods:
Paired plasma and DBS samples were prepared from de-identified remnant samples of HCV antibody positive individuals. We compared the sensitivity and specificity of the Aptima HCV Dx Quant assay for HCV RNA detection from DBS with plasma (gold standard).

Results:
Among 107 paired samples from HCV antibody positive individuals, 80.3% (n=86) had detectable HCV RNA. Sensitivity of the Aptima HCV Dx Quant assay for HCV RNA detection in DBS was 94.2% (95% CI 86.9-98.1%) and specificity was 100% (95% CI 83.9-100%). Sensitivity for HCV RNA quantification in DBS (≥10 IU/mL in plasma) was 97.5% (95% CI 91.3% to 99.7%) and specificity was 100% (95% CI 87.2% to 100%). The sensitivity of HCV RNA detection ≥1,000 IU/mL in DBS (based on a clinically relevant threshold obtained from EASL guidelines) was 100% (95% CI 95.3-100%) and specificity was 100% (95% CI 88.8-100%).

Conclusion:
The Aptima HCV Dx Quant can detect active infection from a DBS sample with good sensitivity and specificity, particularly when using a threshold of 1000 IU/mL. This novel study demonstrates DBS as a suitable alternative to plasma for HCV RNA analysis on the Aptima assay. Further evaluation is needed to evaluate real world performance with the aim of enabling registration of a kit insert claim.

Disclosure of Interest Statement:
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