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Background

Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV) that primarily affects the liver. An estimated 71 million people (1%) worldwide were infected with hepatitis C in 2017 [1]. For diagnosis, a serologic assay to detect anti-HCV antibodies is required; if a patient is found to be seropositive for HCV infection they must then be confirmed or ruled out using a molecular test that is able to detect the viral HCV RNA in serum or plasma. Decentralization of molecular diagnostics for HCV would provide rapid identification of patients that could benefit from treatments, resulting in higher cure rates and reduced complications and mortality from liver disease. The Genedrive® HCV ID Kit has been developed as a confirmatory diagnostic for chronic HCV. It is a new, rapid, molecular point-of-care test with CE IVD approval and has been designed to be used in low-resource, decentralized settings.

Several evaluations have indicated a good sensitivity and specificity in Europe [2]. Potential use of the Genedrive® HCV ID Kit has been identified in Senegal and thus it is necessary to assess the performance in a Senegalese context.

Method

The performance study was a Case-Control study with Index Test (Genedrive HCV ID Kit) data collected prospectively and Reference Test data collected retrospectively. The study was conducted between November 2018 to January 2019 at IRESSEF (Institut de recherche en santé de surveillance épidémiologique et de formation) in the Virology laboratory.

Cases were identified as such by confirmation of RNA presence by the Abbott RealTime HCV Viral Load Assay. Controls were identified as HCV negative following a negative result using the Atlas Link Inc. One step Nova test HCV test, an anti-HCV antibody test. All plasma specimens were archival and stored at -80°C. The age range of participants providing specimens was between 29 and 76 years old. Specimens were excluded from the study if no reference test results were available or were on a specimen type other than EDTA plasma. A schematic of the study procedure is shown in Figure 1.

Results

<table>
<thead>
<tr>
<th>REFERENCE</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENEDRIVE HCV ID KIT</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>11</td>
</tr>
</tbody>
</table>

Specificity 100%
Sensitivity 100%

Conclusions

✓ Rapid Time-to-Result – Results are available in <90 minutes.
✓ Ease of Use – Suitable for minimally trained workers with minimal sample preparation or pipetting
✓ Excellent Sensitivity
✓ Excellent Specificity
✓ Excellent PPV and NPV

Due to its portability and speed to result, the Genedrive HCV ID Kit would be ideal in a ‘test and treat’ model within a decentralized setting. This would allow the patient to be diagnosed and treated all in the one visit.

One limit of this study is that the number of samples tested was low (N=33), another is the lack of information regarding the HCV genotypes for the positive samples – which was unavailable. We propose to continue this study with a larger number of samples for a more statistically powerful assessment of the Genedrive technology for HCV detection.