Clinical Evaluation of a Multiplex Real-time PCR Assay for the Detection and Quantification of Hepatitis E Virus

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Every year an estimated 20 million individuals are infected by the hepatitis E virus. Over 3.3 million symptomatic cases of hepatitis E and 56,600 hepatitis E related deaths occur as a result [1]. Hepatitis E is a liver disease caused by the hepatitis E virus: a non-enveloped, positive-sense, single-stranded ribonucleic acid (RNA) virus transmitted mainly through the faecal-oral route, via contaminated water and some foods such as pork.

Following exposure to the hepatitis E virus the incubation period ranges from 3 to 8 weeks, and the virus can cause both acute sporadic and epidemic viral hepatitis. Symptomatic infection is most common in young adults aged 15-40 years, with typical signs and symptoms including jaundice, anorexia, enlarged liver, abdominal pain and tenderness, nausea, vomiting and fever.

Outbreaks and sporadic cases of hepatitis E occur around the world. Disease prevalence is highest in developing countries where accesses to essential water, sanitation, hygiene and health services are limited [1]. In developed countries hepatitis E carries a different threat, as disease transmission can occur through the transfusion of blood products. Hepatitis E is usually self-limiting and is not considered to be fatal. However, it is imperative to avoid transmission and disease progression in immunosuppressed, pregnant and transplant patients, and in cases where HBV or HCV infection is negative but symptoms persist [2]. These groups of patients are more susceptible to acute liver failure which can cause death. Therefore it is essential that diagnostics methods utilised are sensitive and specific, to allow accurate patient diagnosis, and prompt treatment options to be employed.

Table 1. Number of samples correctly detected by FTD HEV assay.

<table>
<thead>
<tr>
<th>Evaluation type</th>
<th>Total samples tested</th>
<th>Correctly confirmed positive or negative</th>
<th>% Correctly detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>External evaluation – Quality Control Molecular Diagnostics (QCMD)</td>
<td>8</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>Internal evaluation – specificity, sensitivity and precision analysis</td>
<td>92</td>
<td>92</td>
<td>100</td>
</tr>
</tbody>
</table>

The following comparison study highlights the results of a comparison between the Fast-track diagnostics assay, a competitor assay and in-house assay already used at MHH, to detect hepatitis E virus [3].
compared to men. Disease, and can even be life-threatening. Women carry a 10-20 fold risk of acquiring Graves' disease of thyroid hormone. Left untreated, Graves' disease can lead to miscarriage, birth defects, thyroid eye which are found in over 90% of patients. TSI mimic the activity of TSH, leading to an elevated production Graves' disease is the most common form of hyperthyroidism, and is characterised by the presence of TSI, patient diagnosis and initiation of proper treatment."

"Not only does this automated assay streamline lab operations and enhance efficiency, it also delivers results to clinicians much more quickly enabling faster usability of the FTD HEV assay. This means that the assay can be confidently selected for use in routine diagnostic procedures, to offer patients prompt and accurate treatment options and improved prognosis."

In comparison to the MHH and competitor assays, the FTD HEV assay demonstrated comparably good results, in sensitivity and specificity. For EDTA, serum and CPDA the sensitivity was 100%, however a loss of sensitivity and higher discrepancy of unit logs detected was observed with stool samples. Therefore, due to the results the FTD HEV assay is most suited to the use of EDTA blood, serum, CPDA or ascites as the specimen type to collect for the test of hepatitis E virus. The quantitative results obtained in this study show the satisfactory performance and usability of the FTD HEV assay. This means that the assay can be confidently selected for use in routine diagnostic procedures, to offer patients prompt and accurate treatment options and improved prognosis.

"Siemens Healthcare Laboratory Diagnostics business area announced today the launch of the industry’s first automated quantitative thyroid stimulating immunoglobulin (TSI) assay used in the differential diagnosis of Graves’ disease, an autoimmune disorder which affects approximately 32 million people worldwide. The assay is available on the Siemens IMMULITE 2000 and IMMULITE 2000 XPi immunoassay systems. Unlike TRAB (TSH receptor antibody) assays which detect both stimulating and blocking antibodies, the Siemens TSI assay specifically detects only thyroid stimulating antibodies, which are the hallmark of Graves’ disease. This makes the assay highly specific to aid in the disease’s diagnosis. With a clinical sensitivity and specificity of 98.3% and 99.7% respectively, the new Siemens TSI assay offers laboratories a fast, easy, and specific diagnostic tool for the assessment of Graves’ disease."

"Siemens is very proud to offer the first automated quantitative TSI assay used in the differential diagnosis of Graves’ disease, an autoimmune disorder which affects approximately 32 million people worldwide. The assay is available on the Siemens IMMULITE 2000 and IMMULITE 2000 XPi immunoassay systems. Unlike TRAB (TSH receptor antibody) assays which detect both stimulating and blocking antibodies, the Siemens TSI assay specifically detects only thyroid stimulating antibodies, which are the hallmark of Graves’ disease. This makes the assay highly specific to aid in the disease’s diagnosis. With a clinical sensitivity and specificity of 98.3% and 99.7% respectively, the new Siemens TSI assay offers laboratories a fast, easy, and specific diagnostic tool for the assessment of Graves’ disease."

First Automated and Quantitative TSI Thyroid Assay for Graves’ Disease Launched

Siemens Healthcare Laboratory Diagnostics business area announced today the launch of the industry’s first automated quantitative thyroid stimulating immunoglobulin (TSI) assay used in the differential diagnosis of Graves’ disease, an autoimmune disorder which affects approximately 32 million people worldwide. The assay is available on the Siemens IMMULITE 2000 and IMMULITE 2000 XPi immunoassay systems. Unlike TRAB (TSH receptor antibody) assays which detect both stimulating and blocking antibodies, the Siemens TSI assay specifically detects only thyroid stimulating antibodies, which are the hallmark of Graves’ disease. This makes the assay highly specific to aid in the disease’s diagnosis. With a clinical sensitivity and specificity of 98.3% and 99.7% respectively, the new Siemens TSI assay offers laboratories a fast, easy, and specific diagnostic tool for the assessment of Graves’ disease.

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