Xpert® HemosIL® FII & FV Kit

The Xpert HemosIL FII & FV assay is a qualitative in vitro diagnostic genotyping test for the rapid detection of Factor II (FII) and Factor V (FV) alleles from sodium citrate or EDTA anticoagulated whole blood. The test is performed on the Cepheid GeneXpert System. This test is intended to provide results for FII (G20210A) and FV Leiden (G1691A) mutations as an aid in the diagnosis in individuals with suspected thrombophilia.

Technology

- Each cartridge contains freeze-dried beads with all necessary components for PCR: DNA polymerase, nucleotides, primers and scorpions
- Scorpions include probes and primers specific for FII and FV normal and mutated DNA
- Each scorpion sequence is labeled with a specific fluorophore
- Through the PCR cycles, the specific binding of the scorpion sequence to the target mutation is detected by the system in real-time

Performance of Xpert HemosIL FII & FV

In an FDA-reviewed multi-center study, more than 1,000 samples were tested with Xpert HemosIL FII & FV and results compared with the gold standard, bi-directional sequencing. Both FV Leiden and FII G20210A mutations demonstrated 99.3% overall accuracy relative to bi-directional sequencing (no discordant results).

Additional Performance Studies

Xpert HemosIL FII & FV was evaluated in comparison to the Roche LightCycler system on 109 samples from consecutive patients suspected of thrombophilia (Morelli et al, 2008). In this study, both FV Leiden and FII G20210A mutations demonstrated 100% agreement when compared to Roche LightCycler.
Self-contained, Fully Integrated, Real-time PCR Offers Efficiency for the Lab and Enhances Service to Physicians and Patients

Simple
- DNA extraction, amplification and detection in one cartridge
- No specialized personnel or lab facilities required
- Run daily or weekly, with complete thrombophilia panel

Clinically Validated
- Multi-site study verified over 1,000 patient sample results as comparable to those obtained with bi-directional sequencing

Fast
- FII and FV genotyping in approximately 30 minutes
- No wait-time to obtain complete thrombophilia work-up

Cost-efficient
- Avoids expensive ‘send-outs’ to reference labs

Combine Xpert HemosIL FII & FV on the GeneXpert System with HemosIL Assays on ACL TOP® Systems for a Complete Thrombophilia Work-up on the Same Citrated Sample

<table>
<thead>
<tr>
<th>GENEXPERT SYSTEM</th>
<th>ACL TOP FAMILY</th>
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<tbody>
<tr>
<td>FII G20210A</td>
<td>Antithrombin</td>
</tr>
<tr>
<td>FV Leiden</td>
<td>Protein C (clotting)</td>
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<tr>
<td></td>
<td>Protein C (chromogenic)</td>
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<tr>
<td></td>
<td>Protein S (clotting)</td>
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<tr>
<td></td>
<td>Protein S (antigen)</td>
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<td></td>
<td>Homocysteine</td>
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<tr>
<td></td>
<td>Lupus Anticoagulants</td>
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</tbody>
</table>

PATIENT REPORT

City Hospital
Hemostasis Lab
Patient ID 12345

Thrombophilia Screening Results
FII G20210A
FV Leiden
Antithrombin
Protein C
Protein S
Homocysteine
Lupus Anticoagulants

Comments:
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References