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**Lab Dept:** Molecular Diagnostics

**Test Name:** FACTOR V LEIDEN

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***General Information***

**Lab Order Codes:** F5LM

**Synonyms:** Factor V Leiden (R506Q) Mutation Test, Blood; Factor 5 Mutation Test: Leiden Mutation

**CPT Codes:** 81241 – Coagulation factor V gene analysis, Leiden variant

**Test Includes:** Factor V mutation analysis

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***Logistics***

**Test Indications:** Direct mutation analysis for Factor V should be reserved for patients with clinically suspected thrombophilia and: APC-resistance proven or suspected by low APC-resistance ratio, or family history of the FV Leiden mutation.

**Lab Testing Sections:** Molecular Diagnostics (Mpls Campus)

**Phone Numbers:** MIN Lab: 612-813-7103

**Test Availability:** Samples accepted daily, 24 hours  
Testing performed 0600-1400

**Turnaround Time:** 2 days

**Special Instructions:** N/A

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***Specimen***

**Specimen Type:** Whole blood

**Container:** Preferred: Lavender top (EDTA) tube  
Alternate: Blue top (Sodium Citrated) tube

**Draw Volume:** 3 mL (Minimum: 0.5 mL) blood

**Processed Volume:** Same as Draw Volume

**Collection:** A clean venipuncture is essential. Mix thoroughly by gentle inversion.

**Special Processing:** Lab Staff: Do Not centrifuge. Specimen must remain as whole blood.

<b>Storage/Transport:</b>	After receipt in the lab, store at 2-8 °C Sample stability: <ul style="list-style-type: none"><li>● Stable at room temperature (22-28 °C) for up to 24 hours</li><li>● Stable at 2-8 °C for up to 15 days</li><li>● Stable at -10 °C for up to 90 days</li></ul>
<b>Patient Preparation:</b>	None
<b>Sample Rejection:</b>	Specimens other than blood ; anticoagulants other than EDTA or Sodium Citrate; mislabeled or unlabeled specimens

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### ***Interpretive***

**Reference Range:** Negative

**Critical Values:** N/A

- Limitations:**
- The performance of the Xpert Factor II & Factor V Assay was validated using the procedures provided in the package insert only. Modifications to these procedures may alter the performance of the test. Results from the Xpert Factor II & Factor V Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
  - Rare Factor V mutations (A1696G, G1689A, and A1692C) and any additional SNPs in the probe binding region may interfere with the target detection and yield an INVALID result.
  - The performance of the Xpert Factor II & Factor V Assay was not evaluated with samples from pediatric patients during the FDA-approval/clearance application. However, in-house verification of the manufacturer's claims did include pediatric samples and no errors were encountered.
  - Patients on heparin therapy and blood transfusion patients may have blood specimens that potentially interfere with the PCR results and lead to invalid or erroneous results

**Methodology:** Real-time Polymerase Chain Reaction (PCR)

**References:** Xpert Factor II and Factor V Package Insert, 301-0590, Rev B. In. Sunnyvale, CA: Cepheid; 201