
Lab Dept: Molecular Diagnostics

Test Name: FACTOR V LEIDEN

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

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

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.

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

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