Lab Dept: Molecular Diagnostics

Test Name: PROTHROMBIN 20210A MUTATIONS

General Information

Lab Order Codes:	P2M
Synonyms:	PT Mutation; Factor 2 Mutation; Factor II Mutation; Prothrombin G20210A Genetic Mutation
CPT Codes:	81240 – F2, gene analysis, 20210G>variant
Test Includes:	Prothrombin G20210A mutation analysis

Logistics

Test Indications:	Direct mutation analysis for the Prothrombin G20210A allele should be reserved for patients with clinically suspected thrombophilia. There may be additional indications for direct Prothrombin G20210A mutation testing, such as determining the duration of anticoagulant therapy of venous thromboembolism patients, screening for women contemplating hormone therapy or family history of the Prothrombin G20210A mutation.
Lab Testing Sections:	Molecular Diagnostics (Mpls Campus)
Phone Numbers:	MIN Lab: 612-813-7103
Test Availability:	Samples accepted daily, 24 hours 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 Citrate) 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. Sample must remain as whole blood.
Storage/Transport:	After receipt in the lab, store at 2-8 °C Sample stability: ● 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 mutations 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; 2017