Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2020 UPDATE B

Update Notes
Due to reagent shortage Warde will be temporarily sending the tests in this update to Quest. We are providing the test build for the Quest tests during the interim period. We will inactivate the Warde codes (F5L, MTHFR, P2021) on 8/26/20. The Quest code is available to order 8/18/2020. If you have any questions, please contact Warde Client Services.

Update Summary		
Temporarily Inactivate Test With Replacement	8/18/2020	F5L - "Factor V Leiden Mutation Analysis" replaced by FVLMA - "Factor V Leiden Mutation Analysis"
Temporarily Inactivate Test With Replacement	8/18/2020	MTHFR - "MTHFR Genotyping C677T and A1298C" replaced by MTHFA - "Methylenetetrahydrofolate Reductase"
Temporarily Inactivate Test With Replacement	8/18/2020	P2021 - "Prothrombin 20210A Mutation Analysis" replaced by P202A - "Prothrombin (Factor II) 20210G>A"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2020 UPDATE B

Inactivate Test With Replacement			
Effective Date	8/18/2020		
Inactivated Test			
Name	Factor V Leiden Mutation Analysis		
Code	F5L		
Legacy Code[1]	F5L		
Interface Order Code	3091240		
Notes			
Replacement Test			
Name	Factor V Leiden Mutation Analysis		
Code	FVLMA		
CPT Code(s)	81241 ZB0WL		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA. Send 5.0 mL (3.0 mL minimum) in original tube at room temperature.		
Alternate Specimen	Whole blood: Dark blue EDTA, sodium or lithium heparin, and ACD A		
Stability	Room temperature: 8 days; Refrigerated: 8 days; Frozen: 30 days		
Performing Information			
Methodology	Polymerase Chain Reaction and Detection		
Reference Range	See report		
Performed Days	Sunday - Saturday		
Turnaround Time	5 - 7 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	FVLMA		
Interface Order Code	3400370		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400371	Factor V Leiden Mutation	21668-9	No
3400372	Interpretation	21667-1	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 08/18/2020 10:36 Received: 08/18/2020 10:36

Test Name	Result	Flag	Ref-Ranges	Units	Site

Factor V Leiden Mutation Analysis

Factor V Leiden Mutation — SEE NOTE — QCRL

RESULT: FACTOR V LEIDEN (R506Q) VARIANT NOT DETECTED

Interpretation — SEE NOTE — QCRL

INTERPRETATION: This individual is negative (normal) for the Factor V Leiden (R506Q) variant in the Factor V gene. Increased risk of thrombophilia can be caused by a variety of genetic and non-genetic factors not screened for by this assay.

Laboratory testing supervised and results monitored by Qing Zhang, MD, PhD, FACMG, CGMBS.

MUTATION ANALYSIS:
The Factor V Leiden (R506Q) mutation [NM 000130.2: c.1601G>A (p.R534Q)] in the Factor V gene is one of the most common causes of inherited thrombophilia. This mutation causes resistance to degradation of activated Factor V protein by activated protein C (APC). The Factor V Leiden (R506Q) mutation is detected by amplification of the selected region of Factor V gene by polymerase chain reaction (PCR) and fluorescent probe hybridization to the targeted region, followed by melting curve analysis with a real time PCR system. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data.

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Health care providers, please contact your local Quest Diagnostics' genetic counselor or call 1-866-GENEINFO (866-436-3463) for assistance with interpretation of these results.

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2020 UPDATE B

Inactivate Test With Replacement			
Effective Date	8/18/2020		
Inactivated Test			
Name	MTHFR Genotyping C677T and A1298C		
Code	MTHFR		
Legacy Code[1]	MTHFR		
Interface Order Code	3041200		
Notes			
Replacement Test			
Name	Methylenetetrahydrofolate Reductase Mutation		
Code	MTHFA		
CPT Code(s)	81291 ZB0WQ		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA. Send 5.0 mL (3.0 mL minimum) in original tube at room temperature.		
Alternate Specimen	Whole blood: Dark blue EDTA, sodium or lithium heparin, and ACD A		
Stability	Room temperature: 8 days; Refrigerated: 8 days; Frozen: 30 days		
Performing Information			
Methodology	Polymerase Chain Reaction and Detection		
Reference Range	See report		
Performed Days	Sunday - Saturday		
Turnaround Time	5 -7 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	MTHFA		
Interface Order Code	3400501		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400502	MTHFR Mutation	21709-1	No
3400503	Interpretation	38415-6	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 08/18/2020 10:38 Received: 08/18/2020 10:38

Test Name	Result	Flag	Ref-Ranges	Units	Site

Methylenetetrahydrofolate Reductase

MTHFR Mutation — SEE NOTE — QCRL

RESULT: NO VARIANT DETECTED

Interpretation — SEE NOTE — QCRL

INTERPRETATION: This individual is negative (normal) for the variants, C677T and A1298C, in the MTHFR gene. This result is not associated with an increased risk for coronary artery disease, venous thromboembolism, or adverse pregnancy outcome.

Laboratory testing supervised and results monitored by Bernard Joseph Ilagan, MD, MHA, FACMG, CGMBS.

Reduced methylenetetrahydrofolate reductase (MTHFR) enzyme activity is a genetic risk factor for hyperhomocysteinemia, especially when present with low serum folate levels. Two common variants in the MTHFR gene result in reduced enzyme activity. The "thermolabile" variant C677T [NM 005957.3: c.665C>T (p.A222V)] and A1298C [c. 1286A>C (p.E429A)] occur frequently in the general population.

Mild to moderate hyperhomocysteinemia has been identified as a risk factor for coronary artery disease and venous thromboembolism. Hyperhomocysteinemia is multifactorial, involving a combination of genetic, physiologic and environmental factors. Recent studies do not support the previously described association of increased risk for coronary artery disease and venous thromboembolism with mild hyperhomocysteinemia caused by reduced MTHFR activity. Therefore, the utility of MTHFR variant testing is uncertain and is not recommended by The American College of Medical Genetics and Genomics (ACMG) or the American Congress of Obstetricians and Gynecologists (ACOG) in the evaluation of venous thromboembolism or adverse pregnancy outcome.

Modest positive association has also been found between the "thermolabile" variant of the MTHFR gene and many other medical complications, such as recurrent pregnancy loss, risk of offspring with neural tube defects, neuropsychiatric disease, and chemotherapy toxicity. Increased risk of coronary artery disease, venous thromboembolism and increased plasma homocysteine can be caused by a variety of genetic and non-genetic factors not screened for by this assay. If indicated by personal or family history of thromboembolism, consider additional testing such as plasma homocysteine levels, factor V Leiden and prothrombin gene mutations.

The C677T and A1298C variants are detected by amplification of the selected regions of MTHFR gene by polymerase chain reaction (PCR) and

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1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 08/18/2020 10:38 Received: 08/18/2020 10:38

Test Name	Result	Flag	Ref-Ranges	Units	Site

fluorescent probes hybridization to the targeted regions, followed by melting curve analysis with a real time PCR system. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data. Health care providers, please contact your local Quest Diagnostics' genetic counselor or call 866-GENEINFO (866-436-3463) for assistance with interpretation of these results.

For additional information, please refer to:
http://education.QuestDiagnostics.com/faq/FAQ66
(This link is being provided for informational/educational purposes only.)

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33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2020 UPDATE B

Inactivate Test With Replacement			
Effective Date	8/18/2020		
Inactivated Test			
Name	Prothrombin 20210A Mutation Analysis		
Code	P2021		
Legacy Code[1]	PRO2021		
Interface Order Code	3091280		
Notes			
Replacement Test			
Name	Prothrombin (Factor II) 20210G>A Mutation		
Code	P202A		
CPT Code(s)	81240 ZB0WB		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA. Send 5.0 mL (3.0 mL minimum) in original tube at room temperature.		
Alternate Specimen	Whole blood: Dark blue EDTA, sodium or lithium heparin, and ACD A		
Stability	Room temperature: 8 days; Refrigerated: 8 days; Frozen: 30 days		
Performing Information			
Methodology	Polymerase Chain Reaction and Detection		
Reference Range	See report		
Performed Days	Sunday - Saturday		
Turnaround Time	5 -7 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	P202A		
Interface Order Code	3400504		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400505	Prothrombin (Factor II)	24475-6	No
3400506	Interpretation	24476-4	No

Warde Medical Laboratory

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Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 08/18/2020 10:41 Received: 08/18/2020 10:41

Test Name	Result	Flag	Ref-Ranges	Units	Site

Prothrombin (Factor II) 20210G>A

Prothrombin (Factor II)	SEE NOTE				QCRL

RESULT: G20210A variant not detected

Interpretation	SEE NOTE				QCRL

INTERPRETATION: This individual is negative (normal) for the G20210A variant in the Prothrombin/Factor II gene. Increased risk of thrombophilia can be caused by a variety of genetic and non-genetic factors not screened for by this assay.

Laboratory testing supervised and results monitored by Carole Oddoux, Ph.D., DABMGG, CGMBS.

The G20210A mutation [AF478696.1: g.21538G>A (c.*97G>A)] in the Prothrombin/Factor II gene is the second most common inherited risk factor for thrombosis occurring in approximately 2% of Caucasians. Presence of the mutation is associated with an elevation of prothrombin levels to about 30% above normal in heterozygotes and to 70% above normal in homozygotes.

Prothrombin (G20210A) mutations are detected by amplification of their selected gene regions by polymerase chain reaction (PCR) and fluorescent probe hybridization to the targeted region, followed by melting curve analysis with a real time PCR system. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data.

Health care providers, please contact your local Quest Diagnostics' genetic counselor or call 1-866-GENEINFO (866-436-3463) for assistance with interpretation of these results.

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Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

B618000003
WX0000003039
Printed D&T: 08/18/20 10:42

Ordered By: CLIENT CLIENT
WX00000000001595

William G. Finn, M.D. - Medical Director
Form: MM RL1