Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Update Notes

Update Summary		
Announcement	2/22/2022	Announcement
Update Existing Test	2/22/2022	ALDR - "Aldosterone/Direct Renin Ratio"
Update Existing Test	3/21/2022	BORDN - "Borrelia species DNA PCR -Tick"
Update Existing Test	2/22/2022	CBGLB - "Corticosteroid Binding Glob"
Update Existing Test	2/22/2022	CELIA - "Celiac Disease Panel with TTG and DGP"
Update Existing Test	2/22/2022	CELPS - "Celiac Screen without DGP"
Update Existing Test	3/21/2022	EPBAV - "Epstein-Barr Virus DNA, Quant Real-Time PCR, CSF"
Update Existing Test	2/22/2022	GIDP - "GI Distress Panel"
Update Existing Test	3/21/2022	HIVRG - "HIV-1 RNA, Quantitative, PCR with Reflex to Genotype"
Inactivate Test With Replacement	3/29/2022	FVLMA - "Factor V Leiden Mutation Analysis" replaced by F5LM - "Factor V Leiden Mutation Analysis"
Inactivate Test With Replacement	3/30/2022	FXDNA - "Fragile X (FMR1) with Reflex to Methylation Analysis" replaced by FXRM1 - "Fragile X (FMR1) with Reflex to Methylation Analysis"
Inactivate Test With Replacement	3/29/2022	JCVQT - "JC Polyoma Virus DNA, Quant" replaced by JCVQN - "JC Polyoma Virus DNA Quant RT PCR S/P"
Inactivate Test With Replacement	3/1/2022	LTE4 - "Leukotriene E4, Urine" replaced by RLTE4 - "Leukotriene E4, Random, Urine"
Inactivate Test With Replacement	3/29/2022	LTE4 - "Leukotriene E4, Urine" replaced by TLTE4 - "Leukotriene E4, 24 Hour, Urine"
Inactivate Test With Replacement	3/29/2022	P202A - "Prothrombin 20210A Mutation Analysis" replaced by F2PM - "Prothrombin 20210A Mutation Analysis"
Inactivate Test Without Replacement	3/21/2022	TXGOQ - "Toxoplasma gondii DNA Quant"

Announcement
Due to nationwide reagent shortage, FRDIG - Digoxin, Free, Serum, will be temporarily non-orderable effective immediately.

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Update Existing Test	
Effective Date	2/22/2022
Name	Aldosterone/Direct Renin Ratio
Code	ALDR
Interface Order Code	1003990
Legacy Code	ALDR
Notes	Updates to rejection criteria.
Required Testing Changes	
Rejection Criteria	Aldosterone: Plasma: gross hemolysis, gross lipemia Renin: Hemolysis, grossly lipemic or icteric specimens, non-frozen samples, serum, **dark blue trace element EDTA**

Update Existing Test	
Effective Date	3/21/2022
Name	Borrelia species DNA PCR -Tick
Code	BORDN
Interface Order Code	3425780
Legacy Code	BORRSPTQ
Notes	Updates to transport temperature and stability.
Required Testing Changes	
Specimen Required	*Specimen Preparation:* Send one fresh intact deer tick in 1 - 10 mL 70% ethanol in a sterile screw capped plastic container. ***Transport Temperature:*** **Refrigerated**
Stability	**Room temperature: 72 hours** **Refrigerated: 7 days** **Frozen: 30 days**

Update Existing Test	
Effective Date	2/22/2022
Name	Corticosteroid Binding Glob
Code	CBGLB
Interface Order Code	3511985
Legacy Code	CBGLOB
Notes	Updates to performing laboratory.
Required Testing Changes	
Performing Laboratory	**LabCorp**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Update Existing Test	
Effective Date	2/22/2022
Name	Celiac Disease Panel with TTG and DGP
Code	CELIA
Interface Order Code	3084760
Legacy Code	CELIADP
Notes	Updates to CPT Code(s).
Required Testing Changes	
CPT Code(s)	**86258** x 2, **86364** x 2, 82784

Update Existing Test	
Effective Date	2/22/2022
Name	Celiac Screen without DGP
Code	CELPS
Interface Order Code	3084780
Legacy Code	CELPS
Notes	Update to CPT Code.
Required Testing Changes	
CPT Code(s)	**86364**, 82784

Update Existing Test			
Effective Date	3/21/2022		
Name	Epstein-Barr Virus DNA, Quant Real-Time PCR, CSF		
Code	EPBAV		
Interface Order Code	3400475		
Legacy Code	EPBAV		
Notes	Updates to accepted alternate specimens and reference range.		
Required Testing Changes			
Alternate Specimen	Fluid: Bronchoalveolar lavage		
Stability	CSF, tissue, fluids Room temperature: 48 hours Refrigerated: 8 days Frozen: 30 days		
Reference Range	**Result Name**	**Reference Range**	**Unit of Measure**
	EBV DNA, QN PCR	Not detected	copies/mL
	EBV DNA, QN PCR	Not detected	Log copies/mL

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Update Existing Test	
Effective Date	2/22/2022
Name	GI Distress Panel
Code	GIDP
Interface Order Code	3070300
Legacy Code	GIDP
Notes	Updates to CPT Code(s).
Required Testing Changes	
CPT Code(s)	**86258 x 2, 86364 x 2**, 86003 x 12

Update Existing Test	
Effective Date	3/21/2022
Name	HIV-1 RNA, Quantitative, PCR with Reflex to Genotype
Code	HIVRG
Interface Order Code	3515950
Legacy Code	HIVRG
Notes	Updates to specimen requirements, rejection criteria, performed days and reflexed TAT.
Required Testing Changes	
Specimen Required	*Collect:* **Two Lavender EDTA** *Specimen Preparation:* Send **2.0 mL** plasma collected in each of the **two lavender EDTA tubes**. Minimum Volume: **1.0 mL** Transport Temperature: Frozen
Rejection Criteria	**Serum; whole blood greater than 24 hours old; frozen whole blood; samples collected in lithium or sodium heparin.**
Performed Days	**Monday - Saturday**
Turnaround Time	4 - 6 days; **if reflexed additional 4 - 11 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Inactivate Test With Replacement	
Effective Date	3/29/2022
Inactivated Test	
Name	Factor V Leiden Mutation Analysis
Code	FVLMA
Legacy Code[1]	FVLMA
Interface Order Code	3400370
Notes	
Replacement Test	
Name	Factor V Leiden Mutation Analysis
Code	F5LM
CPT Code(s)	81241 ZB770
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 5.0 mL whole blood. *Minimum Volume:* 3.0 mL *Transport Temperature:* Room temperature
Alternate Specimen	None
Rejection Criteria	serum, plasma, heparinized whole blood, tissue, specimen previously tested
Stability	Room temperature: 8 days Refrigerated: 8 days Frozen: 30 days
Performing Information	
Methodology	Polymerase Chain Reaction (PCR)
Reference Range	Wild Type F5
Performed Days	Tuesday, Friday
Turnaround Time	1 - 5 days
Performing Laboratory	Warde Medical Laboratory
Interface Information	

Legacy Code[1]	F5LM		
Interface Order Code	3000306		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3000307	Factor V Leiden Mutation	21668-9	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Molecular

Collected: 02/19/2022 06:04 Received: 02/19/2022 06:04

Test Name	Result	Flag	Ref-Ranges	Units	Site

Factor V Leiden Mutation Analysis

Factor V Leiden Mutation	Negative				WMRL

The pathogenic F5 Leiden variant (c.1691G>A) was NOT DETECTED. The specimen was determined to be homozygous for the wild type (WT) F5 gene. This test does not rule out other mutations that may contribute to venous thrombosis.

This test was performed using the cobas® Factor V Test (Roche) - an in vitro diagnostic device that uses real-time quantitative Polymerase Chain Reaction (qPCR) for the detection and genotyping of the human factor V (F5) gene. The test detects the presence of the wild type (WT) F5 gene and the pathogenic c.1691G>A variant (also known as the F5 Leiden variant) in genomic DNA isolated from whole blood specimens as an aid in diagnosing patients with suspected thrombophilia. The cobas® Factor V Test and the cobas z 480 analyzer are used together for automated amplification and detection. The limit of detection for this test is 0.1 ng/uL of genomic DNA (2.5 ng/PCR reaction).

Performing Site:
WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

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

D419000001
WX0000003039
Printed D&T: 02/19/22 06:04

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Molecular

Collected: 02/19/2022 06:06 Received: 02/19/2022 06:06

Test Name	Result	Flag	Ref-Ranges	Units	Site

Factor V Leiden Mutation Analysis

Factor V Leiden Mutation	**Heterozygous**	**AB**	WMRL

Both the wild type (WT) F5 gene and the pathogenic F5 Leiden variant (c.1691G>A) were detected indicating a heterozygous c.1691G>A genotype for this specimen. Heterozygosity for the c.1691G>A variant is associated with activated protein C resistance and an increased risk for venous thromboembolism (VTE).

Factor V Leiden thrombophilia is inherited in an autosomal dominant manner and adults heterozygous for the F5 Leiden variant have a 3 to 8-fold increased risk of VTE. The prevalence of c.1691G>A heterozygosity is highest in individuals of European ancestry (5.2%). The variant is less common in Americans with Hispanic (2.2%), African (1.2%), Asian (<0.5%), and Native American (1.25%) ancestry. The overall risk of a first VTE in heterozygous individuals is approximately 0.5%. Patients heterozygous for both F5 Leiden and the G20210A (c.*97G>A) prothrombin variant may experience earlier onset of thrombosis that tends to be more severe than individual alleles. Genetic counseling is recommended to help determine the benefit of testing asymptomatic family members.

This test was performed using the cobas® Factor V Test (Roche) - an in vitro diagnostic device that uses real-time quantitative Polymerase Chain Reaction (qPCR) for the detection and genotyping of the human factor V (F5) gene. The test detects the presence of the wild type (WT) F5 gene and the pathogenic c.1691G>A variant (also known as the F5 Leiden variant) in genomic DNA isolated from whole blood specimens as an aid in diagnosing patients with suspected thrombophilia. The cobas® Factor V Test and the cobas z 480 analyzer are used together for automated amplification and detection. The limit of detection for this test is 0.1 ng/uL of genomic DNA (2.5 ng/PCR reaction).

Performing Site:
WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Inactivate Test With Replacement	
Effective Date	3/30/2022
Inactivated Test	
Name	Fragile X (FMR1) with Reflex to Methylation Analysis
Code	FXDNA
Legacy Code[1]	FXDNAARP
Interface Order Code	3671860
Notes	
Replacement Test	
Name	Fragile X (FMR1) with Reflex to Methylation Analysis
Code	FXRM1
CPT Code(s)	81243, plus 81244 if reflexed at additional cost ZB2O1, plus ZB6K3 if reflexed
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 5.0 mL whole blood. *Minimum Volume:* 1.5 mL *Transport Temperature:* Refrigerated
Alternate Specimen	Whole blood: Yellow ACD A
Stability	Room temperature: 7 days Refrigerated: 30 days Frozen: 6 months
Performing Information	
Methodology	Polymerase Chain Reaction/Capillary Electrophoresis
Reference Range	See report
Performed Days	Sunday - Saturday
Turnaround Time	6 - 16 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information			
Legacy Code[1]	FXRM1		
Interface Order Code	3600211		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3600212	Frag X Specimen	66746-9	No
3600213	Fragile X Allele 1	45321-7	No
3600214	Fragile X Allele 2	45322-5	No
3600215	Fragile X Methylation Pattern	41107-4	No
3600216	Fragile X Interpretation	36913-2	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 02/19/2022 06:07 Received: 02/19/2022 06:07

Test Name	Result	Flag	Ref-Ranges	Units	Site
Fragile X (FMR1) with Reflex to Methylation Analysis					
Frag X Specimen	Whole Blood				ARRL
Fragile X Allele 1	15			CGG repeats	ARRL
Fragile X Allele 2	16			CGG repeats	ARRL
Fragile X Methylation Pattern	Normal				ARRL
Fragile X Interpretation	See Note				ARRL

This individual has a FMR1 allele with a CGG repeat size in the normal range; therefore, he is predicted to be neither affected with, nor a carrier of, fragile X syndrome (FXS). This test does not detect rare FMR1 variants causing less than 1% of FXS.

Methylation pattern is normal for gender.

This result has been reviewed and approved by Rong Mao, M.D.
BACKGROUND INFORMATION: Fragile X (FMR1) with Reflex to Methylation Analysis
CHARACTERISTICS OF FRAGILE X SYNDROME (FXS): Affected males have moderate intellectual disability, hyperactivity, perseverative speech, social anxiety, poor eye contact, hand flapping or biting, autism spectrum disorders and connective tissue anomalies in males. Females are usually less severely affected than males. FXS is caused by FMR1 full mutations.
CHARACTERISTICS OF FRAGILE X TREMOR ATAXIA SYNDROME (FXTAS): Onset of progressive ataxia and intention tremor typically after the fourth decade of life. Females also have a 21 percent risk for primary ovarian insufficiency. FXTAS is caused by FMR1 premutations.
Incidence of FXS: 1 in 4,000 Caucasian males and 1 in 8,000 Caucasian females.
INHERITANCE: X-linked.
PENETRANCE OF FXS: Complete in males; 50 percent in females.
PENETRANCE OF FXTAS: 47 percent in males and 17 percent in females >50 years of age.
CAUSE: Expansion of the FMR1 gene CGG triplet repeat.
  Full mutation: typically >200 CGG repeats (methylated).
  Premutation: 55 to approx 200 CGG repeats (unmethylated).
  Intermediate: 45-54 CGG repeats (unmethylated).
  Normal: 5-44 CGG repeats (unmethylated).
CLINICAL SENSITIVITY: 99 percent.
METHODOLOGY: Triplet repeat-primed polymerase chain reaction (PCR) followed by size analysis using capillary

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 02/19/2022 06:07 Received: 02/19/2022 06:07

Test Name	Result	Flag	Ref-Ranges	Units	Site

electrophoresis. Methylation-specific PCR analysis is performed for CGG repeat lengths of >100 to distinguish between premutation and full mutation alleles.
ANALYTICAL SENSITIVITY AND SPECIFICITY: 99 percent; estimated precision of sizing for intermediate and premutation alleles is within 2-3 CGG repeats.
LIMITATIONS: Diagnostic errors can occur due to rare sequence variations. Rare FMR1 variants unrelated to trinucleotide expansion will not be detected. A specific CGG repeat size estimate is not provided for full mutation alleles. AGG trinucleotide interruptions within the FMR1 CGG repeat tract are not assessed.

PHENOTYPE	NUMBER OF CGG REPEATS
Unaffected	<45
Intermediate	45-54
Premutation	55-200
Affected	>200

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.
Performed by ARUP Laboratories,
500 Chipeta Way, SLC,UT 84108 800-522-2787
www.aruplab.com, Tracy I. George, MD - Lab. Director

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Inactivate Test With Replacement	
Effective Date	3/29/2022
Inactivated Test	
Name	JC Polyoma Virus DNA, Quant
Code	JCVQT
Legacy Code[1]	JCPVQNTQ
Interface Order Code	3426340
Notes	
Replacement Test	
Name	JC Polyoma Virus DNA Quant RT PCR S/P
Code	JCVQN
CPT Code(s)	87799
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preperation:* Send 0.7 mL plasma collected in Lavender EDTA. *Minimum Volume:* 0.3 mL *Transport Temperature:* Frozen
Alternate Specimen	Plasma: Yellow ACD Serum
Stability	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Performing Information	
Methodology	Real-Time Polymerase Chain Reaction (RT-PCR)
Reference Range	Not Detected
Performed Days	Monday - Saturday
Turnaround Time	2 - 4 days
Performing Laboratory	Quest SJC

Interface Information			
Legacy Code[1]	JCVQN		
Interface Order Code	3400637		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400638	Source	31208-2	**Yes**
3400639	JC Virus DNA, QN PCR	Not available	No
3400640	JC Virus DNA, QN PCR	Not available	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 02/19/2022 06:09 Received: 02/19/2022 06:09

Test Name	Result	Flag	Ref-Ranges	Units	Site
JC Polyoma Virus DNA Quant RT PCR S/P					
Source	BLOOD				QCRL
JC Virus DNA, QN PCR	NOT DETECTED			Copies/mL	QCRL
JC Virus DNA, QN PCR	NOT DETECTED			Log cps/mL	QCRL

REFERENCE RANGE: NOT DETECTED

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

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

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

D419000004
WX0000003039
Printed D&T: 02/19/22 06:10

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Inactivate Test With Replacement	
Effective Date	3/1/2022
Inactivated Test	
Name	Leukotriene E4, Urine
Code	LTE4
Legacy Code[1]	LTE4
Interface Order Code	3807700
Notes	
Replacement Test	
Name	Leukotriene E4, Random, Urine
Code	RLTE4
CPT Code(s)	82542, 82570
Notes	
Specimen Requirements	
Specimen Required	Patient Preparation: Patients taking 5-lipoxygenase inhibitor zileuton/Zyflo may have decreased concentrations of leukotriene E4 (LTE4) if dosage has not been discontinued for 48 hours. Collect: Random Urine Specimen Preparation: Send 5.0 mL random urine collection in a screw capped plastic vial. No preservative. Minimum Volume: 2.0 mL Transport Temperature: Refrigerated
Stability	Room temperature: 24 hours Refrigerated: 7 days Frozen: 30 days
Performing Information	
Methodology	Liquid Chromatography – Tandem Mass Spectrometry (LC-MS/MS) Enzymatic Colorimetric Assay
Reference Range	See report
Performed Days	Tuesday, Friday
Turnaround Time	4 - 8 days
Performing Laboratory	Mayo Clinic Laboratories

Interface Information			
Legacy Code[1]	RLTE4		
Interface Order Code	3800268		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800269	Leukotriene E4, Random, U	33343-5	No
3800270	Creatinine, Random, U	2161-8	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 02/19/2022 06:11 Received: 02/19/2022 06:11

Test Name	Result	Flag	Ref-Ranges	Units	Site
Leukotriene E4, Random, Urine					
Leukotriene E4, Random, U	100		<=104	pg/mg Cr	MMRL

Cautions: Systemic mast cell disease is a heterogeneous disorder; therefore not all patients with a diagnosis of systemic mastocytosis will exhibit abnormal Leukotriene E(4) (LTE4) concentrations. If this is a random urine collection consider repeating the analysis on a 24-hour urine collection. LTE4 will be decreased in individuals on therapeutic 5-lipoxygenase inhibitors (Zileuton).

----------ADDITIONAL INFORMATION----------
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Creatinine, Random, U	100		16 - 326	mg/dL	MMRL

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55901
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592

Performing Site:
MMRL: MAYO MEDICAL REFERENCE LAB 3050 Superior Drive NW Rochester MN 55901

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

D419000005
WX0000003039
Printed D&T: 02/19/22 06:12

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Inactivate Test With Replacement	
Effective Date	3/29/2022
Inactivated Test	
Name	Leukotriene E4, Urine
Code	LTE4
Legacy Code[1]	LTE4
Interface Order Code	3807700
Notes	
Replacement Test	
Name	Leukotriene E4, 24 Hour, Urine
Code	TLTE4
CPT Code(s)	82542
Notes	
Specimen Requirements	
Specimen Required	*Patient Preparation:* Patients taking 5-lipoxygenase inhibitor zileuton/Zyflo may have decreased concentrations of leukotriene E4 (LTE4) if dosage has not been discontinued for 48 hours. *Collect:* 24 hour Urine *Specimen Preparation:* Send 5.0 mL 24 hour urine collection in a screw capped plastic vial. No preservative. *Minimum Volume:* 2.0 mL *Transport Temperature:* Frozen
Stability	Room temperature: 24 hours Refrigerated: 7 days Frozen: 30 days
Performing Information	
Methodology	Liquid Chromatography – Tandem Mass Spectrometry (LC-MS/MS) Enzymatic Colorimetric Assay
Reference Range	See report
Performed Days	Tuesday, Friday
Turnaround Time	4 - 8 days
Performing Laboratory	Mayo Clinic Laboratories

Interface Information			
Legacy Code[1]	TLTE4		
Interface Order Code	3800271		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800272	Collection Duration	13362-9	**Yes**
3800273	Urine Volume	3167-4	**Yes**
3800274	Leukotriene, E4, U	IN PROCESS	No
3800275	Creatinine, 24 HR, U	2162-6	No
3800276	Creatinine Concentration, 24 HR, U	20624-3	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 02/19/2022 06:13 Received: 02/19/2022 06:13

Test Name	Result	Flag	Ref-Ranges	Units	Site
Leukotriene E4, 24 Hour, Urine					
Collection Duration	24			h	MMRL
Urine Volume	1000			mL	MMRL
Leukotriene, E4, U	<20		<=104	pg/mg Cr	MMRL

Cautions: Systemic mast cell disease is a heterogeneous disorder; therefore not all patients with a diagnosis of systemic mastocytosis will exhibit abnormal Leukotriene E(4) (LTE4) concentrations. LTE4 will be decreased in individuals on therapeutic 5-lipoxygenase inhibitors (Zileuton).

----------ADDITIONAL INFORMATION----------
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Creatinine, 24 HR, U	1000		603 - 1783	mg/24 h	MMRL
Creatinine Concentration, 24 HR, U	100			mg/dL	MMRL

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55901
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592

Performing Site:
MMRL: MAYO MEDICAL REFERENCE LAB 3050 Superior Drive NW Rochester MN 55901

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

D419000006
WX0000003039
Printed D&T: 02/19/22 06:15

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Inactivate Test With Replacement	
Effective Date	3/29/2022
Inactivated Test	
Name	Prothrombin 20210A Mutation Analysis
Code	P202A
Legacy Code[1]	P202A
Interface Order Code	3400504
Notes	
Replacement Test	
Name	Prothrombin 20210A Mutation Analysis
Code	F2PM
CPT Code(s)	81240 ZB766
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 5.0 mL whole blood. *Minimum Volume:* 3.0 mL *Transport Temperature:* Room temperature
Rejection Criteria	Serum, plasma, heparinized whole blood, tissue specimens previously tested.
Stability	Room temperature: 8 days Refrigerated: 8 days Frozen: 30 days
Performing Information	
Methodology	Polymerase Chain Reaction (PCR)
Reference Range	Wild Type F2
Performed Days	Tuesday, Friday
Turnaround Time	1 - 5 days
Performing Laboratory	Warde Medical Laboratory

Interface Information			
Legacy Code[1]	F2PM		
Interface Order Code	3000308		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3000309	Prothrombin 20210A Mutation Analysis	24475-6	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Molecular

Collected: 02/19/2022 06:15 Received: 02/19/2022 06:15

Test Name	Result	Flag	Ref-Ranges	Units	Site

Prothrombin 20210A Mutation Analysis

Prothrombin 20210A Mutation Analysis	Negative				WMRL

The pathogenic c.*97G>A variant (G20210A) was NOT DETECTED.
The specimen was determined to be homozygous for the wild type (WT) F2 gene. This test does not rule out other mutations that may contribute to venous thrombosis.

This test was performed using the cobas® Factor II Test (Roche) - an in vitro diagnostic device that uses real-time quantitative Polymerase Chain Reaction (qPCR) for the detection and genotyping of the human Factor II (F2) gene. The test detects the presence of the wild type (WT) F2 gene and the pathogenic c.*97G>A variant (also known as G20210A) in genomic DNA isolated from whole blood specimens as an aid in diagnosing patients with suspected thrombophilia. The cobas® Factor II Test and the cobas z 480 analyzer are used together for automated amplification and detection. The limit of detection for this test is 0.1 ng/uL of genomic DNA (2.5 ng/PCR reaction).

Performing Site:
WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

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

D419000007
WX0000003039
Printed D&T: 02/19/22 06:16

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Molecular

Collected: 02/19/2022 06:16 Received: 02/19/2022 06:16

Test Name	Result	Flag	Ref-Ranges	Units	Site

Prothrombin 20210A Mutation Analysis

Prothrombin 20210A Mutation Analysis	**Heterozygous**	**AB**	WMRL

Both the wild type (WT) F2 gene and the c.*97G>A pathogenic variant (G20210A) were detected indicating a heterozygous c.*97G>A genotype for this specimen. Heterozygosity for the c.*97G>A variant is associated with overproduction of F2 prothrombin and an increased risk for venous thrombosis.

Prothrombin thrombophilia is inherited in an autosomal dominant manner and adults heterozygous for the c.*97G>A variant have a 2 to 5-fold increased risk of thrombosis. The prevalence of c.*97G>A heterozygosity is 2-5% in individuals of European descent. The variant is extremely rare in individuals of African, Asian, or Native American descent. The clinical expression of prothrombin thrombophilia is variable. Many heterozygous individuals never develop thrombosis. Patients heterozygous for both c.*97G>A variant and the Factor V Leiden mutation often experience earlier onset of thrombosis that tends to be more severe than presence of the individual alleles. Genetic counseling is recommended to help determine the benefit of testing asymptomatic family members.

This test was performed using the cobas® Factor II Test (Roche) - an in vitro diagnostic device that uses real-time quantitative Polymerase Chain Reaction (qPCR) for the detection and genotyping of the human Factor II (F2) gene. The test detects the presence of the wild type (WT) F2 gene and the pathogenic c.*97G>A variant (also known as G20210A) in genomic DNA isolated from whole blood specimens as an aid in diagnosing patients with suspected thrombophilia. The cobas® Factor II Test and the cobas z 480 analyzer are used together for automated amplification and detection. The limit of detection for this test is 0.1 ng/uL of genomic DNA (2.5 ng/PCR reaction).

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Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2022

Inactivate Test Without Replacement	
Effective Date	3/21/2022
Name	Toxoplasma gondii DNA Quant
Code	TXGOQ
Legacy Code	TOXQNTQ
Interface Code	3423700
Notes	