Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Update Notes

Update Summary		
New Test Activation	2/23/2021	OXLDL - "Oxidized LDL"
New Test Activation	2/23/2021	WARAT - "Warfarin Accutype"
Update Existing Test	2/16/2021	FLUPH - "Fluphenazine"
Update Existing Test	2/23/2021	HBEAB - "Hepatitis Be Antibody"
Update Existing Test	2/23/2021	HBEAG - "Hepatitis Be Antigen"
Update Existing Test	2/8/2021	MINPR - "Mineral Profile, RBC's"
Update Existing Test	1/26/2021	NMETD - "N-methyl-D-Aspartate Rcptr Ab, IgG, Ser"
Update Existing Test	1/13/2021	PYRBA - "Pyruvate Kinase - Blood"
Update Existing Test	2/16/2021	UTPME - "Tapentadol and Metabolite, Urine, Quantitative"
Update Existing Test	1/13/2021	WNCGM - "West Nile Virus IgG IgM Ab CSF"
Inactivate Test With Replacement	2/23/2021	ADAB - "Adrenal Antibody Screen with Reflex to Titer" replaced by ADABR - "Adrenal Antibody Screen with reflex to Titer"
Inactivate Test With Replacement	1/25/2021	BRCAC - "BRC Avantage, Comprehensive" replaced by BRCAP - "BRCA Panel (BRCA1, BRCA2)"
Inactivate Test With Replacement	2/16/2021	CARIS - "Carisoprodol" replaced by CRISP - "Carisoprodol and Metabolite, Serum/Plasma"
Inactivate Test With Replacement	1/26/2021	FLT3M - "LeukoStrat CDx FLT3 Mutation Assay" replaced by LUFL3 - "LeukoStrat CDx FLT3 Mutation Assay"
Inactivate Test With Replacement	2/23/2021	SYPH - "Syphilis IgG/IgM Antibody" replaced by SYPHR - "Syphilis IgG/IgM Antibody with Reflex"
Inactivate Test Without Replacement	1/13/2021	CANAG - "Candida Antigen"
Inactivate Test Without Replacement	2/16/2021	ORGAP - "Organic Acids, Plasma"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

New Test Activation			
Effective Date	2/23/2021		
Name	Oxidized LDL		
Code	OXLDL		
CPT Code(s)	83520		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA tube. Gently invert tube 8 - 10 times immediatedly after draw. **DO NOT SHAKE**. Centrifuge for 10 minutes. Separate plasma from cells and send 0.5 mL plasma (0.3 mL minimum) refrigerated in a screw capped plastic vial.		
Stability	Room temperature: Unacceptable; Refrigerated: 7 days; Frozen (-20 °C): 28 days; Frozen (-70 °C): 6 months		
Performing Information			
Methodology	Enzyme-linked Immunosorbent Assay (ELISA)		
Reference Range	< 60 U/L		
Performed Days	Monday - Saturday		
Turnaround Time	5 - 8 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	OXLDL		
Interface Order Code	3400282		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400282	Oxidized LDL	54238-1	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Referral Testing

Collected: 01/13/2021 09:44 Received: 01/13/2021 09:44

Test Name	Result	Flag	Ref-Ranges	Units	Site
Oxidized LDL	**65**	**H**	<60	U/L	QCRL

Based on a recent study of an 'apparently healthy' and non-metabolic syndrome population(1), the following cut-offs have been defined for OxLDL: A cut-off of <60 U/L defines a population with a low relative risk of developing metabolic syndrome, a range of 60 to 69 U/L defines a population with a moderate relative risk (2.8 fold) and >=70 U/L defines a population with a high relative risk (3.5-fold). (Reference: 1-Holvoet et al. JAMA. 2008; 299: 2287-2293.)

Test Performed at:
Cleveland HeartLab, Inc
6701 Carnegie Avenue Suite 500
Cleveland, OH 44103-4623 B G Richendollar MD

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

C113000000
WX0000003039
Printed D&T: 01/13/21 09:46

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

New Test Activation			
Effective Date	2/23/2021		
Name	Warfarin Accutype		
Code	WARAT		
CPT Code(s)	81355, 81227 (or 81479) ZB0PB		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA tube. Send 5.0 mL whole blood (3.0 mL minimum) room temperature.		
Alternate Specimen	Whole blood: ACD, heparin		
Rejection Criteria	Received frozen		
Stability	Room temperature: 8 days; Refrigerated: 14 days; Frozen: Unacceptable		
Performing Information			
Methodology	Single Nucleotide Primer Extension		
Reference Range	See report		
Performed Days	Monday, Wednesday, Friday		
Turnaround Time	7 - 10 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	WARAT		
Interface Order Code	3400284		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400284	Warfarin Accutype	54451-0	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Referral Testing

Collected: 01/13/2021 09:49 Received: 01/13/2021 09:49

Test Name	Result	Flag	Ref-Ranges	Units	Site
Warfarin Accutype	SEE NOTE				QCRL

VKORC1: HOMOZYGOUS FOR THE -1639G>A VARIANT
CYP2C9: NORMAL METABOLIZER

CYP2C9: DNA testing indicates this individual does not carry any of the tested variant alleles in the CYP2C9 gene. This individual is predicted to be a normal/extensive metabolizer and would not be at increased risk of warfarin sensitivity caused by CYP2C9 gene common variants tested for in this assay. However, this test cannot rule out the possibility that he or she is a carrier of rare mutations of the CYP2C9 gene causing a poor or intermediate metabolizer phenotype.

To calculate the appropriate warfarin dosage, please go to www.nicholsinstitute.com/coagulation and submit the patient's genotypic and demographic data.

Warfarin (coumadin) therapy is associated with significant complications because of its narrow therapeutic index, and the large inter-patient variation in dosage required for an optimal therapeutic response. This variation is due to both genetic and environmental factors. Genetic factors include variants of the Vitamin K Epoxide Reductase Complex subunit 1 (VKORC1) and Cytochrome P450 2C9 (CYP2C9) genes, which account for approximately 25%-44% and 10%-15% of the variability respectively. Identification of these VKORC1 and CYP2C9 variants could allow a more individualized course of therapy, and reduce the risk of bleeding or thrombotic complications.

This assay detects variants from two genes, VKORC1 and CYP2C9. The variants detected by this assay are: the common warfarin sensitive polymorphism, -1639 G>A, and warfarin resistance polymorphisms, D36Y and V66M, of the VKORC1 gene and the four common poor metabolizer genetic variants of the CYP2C9 gene: CYP2C9*2 (R144C), CYP2C9*3 (I359L), CYP2C9*5 (D360E) and CYP2C9*6 (818delA), as well as the wild type allele (CYP2C9*1). Approximately 42%-46% of Caucasians, 13% of African-Americans and 90%-95% of Asians carry at least one copy of the -1639A VKORC1 variant allele. Approximately 4% of the Ashkenazi Jewish individuals carry the D36Y warfarin resistance allele. Approximately 33% of Caucasians, 3%-13% of Africans, and 2%-8% of Asians are positive for at least one of the CYP2C9 poor metabolizer variant alleles.

The VKORC1 and CYP2C9 variants described above are detected by polymerase chain reaction (PCR) amplification of the appropriate regions of the VKORC1 (promoter exons 1 and 2) and CYP2C9 (exons 3, 5,

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Referral Testing

Collected: 01/13/2021 09:49 Received: 01/13/2021 09:49

Test Name	Result	Flag	Ref-Ranges	Units	Site

and 7) genes, followed by a single nucleotide primer extension reaction and detection of fluorescent extension products on an automated DNA sequencer.

DNA-based testing is highly accurate, but rare false negative/false positive results may occur. Please contact the laboratory if you have questions about these test results. Since genetic variation and other problems can affect the accuracy of direct mutation testing, test results should always be interpreted in light of clinical and familial data.

For assistance with the interpretation of these results, please contact your local Quest Diagnostics Genetic Counselor or call 1-866-GENEINFO (1-866-436-3463).

This test was performed pursuant to a license agreement with Orchid Biosciences, Inc.

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.

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92690-6130 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

FEBRUARY 2021

Update Existing Test	
Effective Date	2/16/2021
Name	Fluphenazine (Prolixin)
Code	FLUPH
Interface Order Code	3502860
Legacy Code	FLUPHEN
Notes	Updates to test name, rejection criteria and reference range changes.
Required Testing Changes	
Name	**Fluphenazine**
Rejection Criteria	SST, Citrated plasma, **whole blood, hemolyzed specimens, ACD**
Reference Range	**Therapeutic Range: 1.0 - 10.0 ng/mL** **Toxic: >15 ng/mL**

Update Existing Test			
Effective Date	2/23/2021		
Name	Hepatitis Be Antibody		
Code	HBEAB		
Interface Order Code	3000700		
Legacy Code	HBEAB		
Notes	Updates to methodology, alternate specimens, stability, reference range, performed days and TAT.		
Required Testing Changes			
Alternate Specimen	Plasma: EDTA, heparin, **Sodium Citrate**		
Stability	**Room temperature: 4 days, Refrigerated: 7 days**; Frozen: 14 days		
Methodology	**Chemiluminescence Immunoassay**		
Reference Range	**NONREACTIVE** See also Immunology Virology Serology Appendix		
Performed Days	**Sunday - Thursday**		
Turnaround Time	**2 days**		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3000700	Hepatitis Be Ab	22320-6	No

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Update Existing Test			
Effective Date	2/23/2021		
Name	Hepatitis Be Antigen		
Code	HBEAG		
Interface Order Code	3000690		
Legacy Code	HBEAG		
Notes	Updates to methodology, stability, alternate specimen, reference range, performed and TAT.		
Required Testing Changes			
Alternate Specimen	Plasma: EDTA, heparin, **Sodium Citrate**		
Stability	**Room temperature: 4 days**; **Refrigerated: 7 days**; Frozen: 14 days		
Methodology	**Chemiluminescence Immunoassay**		
Reference Range	**NONREACTIVE** See also Immunology Viral Serology Appendix		
Performed Days	**Sunday - Thursday**		
Turnaround Time	**2 days**		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3000690	Hepatitis Be Ag	13954-3	No

Update Existing Test	
Effective Date	2/8/2021
Name	Mineral Profile, RBC's
Code	MINPR
Interface Order Code	3302000
Legacy Code	MINPR
Notes	Updates to specimen requirements, and rejection criteria
Required Testing Changes	
Specimen Required	Draw blood in dark blue EDTA trace metal tube. Centrifuge and remove plasma within 2 hours of collection, leaving RBC's in the original collection container, and secure stopper. Send **2.0 mL** RBC's (1.8 mL minimum) refrigerated.
Rejection Criteria	Specimens received room temperature or frozen. **Plastic container.** Tubes containing heparin-based anticoagulants are not acceptable. ACD, sodium citrate, sodium fluoride, lavender EDTA also not acceptable.
Turnaround Time	**8 - 10 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Update Existing Test	
Effective Date	1/26/2021
Name	N-methyl-D-Aspartate Rcptr Ab, IgG, Ser
Code	NMETD
Interface Order Code	3600159
Legacy Code	NMETD
Notes	Update to the result code component for N-methyl-D-Aspartate Receptor

Required Testing Changes			
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3600208	N-methyl-D-Aspartate Receptor Ab, Serum	80221-5	No
3600168	Bill_NMDA Titer	Not available	No

Update Existing Test	
Effective Date	1/13/2021
Name	Pyruvate Kinase - Blood
Code	PYRBA
Interface Order Code	3619960
Legacy Code	PYRBARP
Notes	Updates to specimen volumes
Required Testing Changes	
Specimen Required	Draw blood in a lavender EDTA tube. Send **1.0 mL** whole blood **(0.5 mL minimum)** refrigerated.

Update Existing Test	
Effective Date	2/16/2021
Name	Tapentadol and Metabolite, Urine, Quantitative
Code	UTPME
Interface Order Code	3622300
Legacy Code	UTPME
Notes	Updates to performed day.
Required Testing Changes	
Performed Days	**Monday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Update Existing Test	
Effective Date	1/13/2021
Name	West Nile Virus IgG IgM Ab CSF
Code	WNCGM
Interface Order Code	3719300
Legacy Code	WNVCSFGM
Notes	Updates to minimum volume.
Required Testing Changes	
Specimen Required	Send 1.0 mL CSF **(0.7 mL minimum)** refrigerated in a screw capped plastic vial.

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Inactivate Test With Replacement			
Effective Date	2/23/2021		
Inactivated Test			
Name	Adrenal Antibody Screen with Reflex to Titer		
Code	ADAB		
Legacy Code[1]	ADABSP		
Interface Order Code	3703120		
Notes			
Replacement Test			
Name	Adrenal Antibody Screen with reflex to Titer		
Code	ADABR		
CPT Code(s)	86255, plus 86256 if reflexed to titer, at an additional fee		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a SST. Centrifuge, separate and send 2.0 mL serum (0.5 mL minimum) refrigerated in a screw capped plastic vial.		
Alternate Specimen	Serum: Red-top		
Rejection Criteria	Gross hemolysis, grossly lipemic, grossly icteric		
Stability	Room temperature: 48 hours; Refrigerated: 14 days; Frozen: 30 days		
Performing Information			
Methodology	Indirect Fluorescent Antibody		
Reference Range	Negative, <1:10 titer		
Performed Days	Wednesday		
Turnaround Time	8-10 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	ADABR		
Interface Order Code	3400328		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400329	Adrenal Ab	14232-3	No
3400330	Adrenal Ab, Titer	5043-5	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Referral Testing

Collected: 01/13/2021 12:33 Received: 01/13/2021 12:33

Test Name	Result	Flag	Ref-Ranges	Units	Site
Adrenal Antibody Screen with reflex to Titer					
Adrenal Ab	NEGATIVE		NEGATIVE		QCRL

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.

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

Adrenal Ab, Titer	.TNP				QCRL

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

C113000020
WX0000003039
Printed D&T: 01/13/21 12:34

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 32 Y

Referral Testing

Collected: 01/13/2021 12:35 Received: 01/13/2021 12:35

Test Name	Result	Flag	Ref-Ranges	Units	Site
Adrenal Antibody Screen with reflex to Titer					
Adrenal Ab	**POSITIVE**	**AB**	NEGATIVE		QCRL

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.

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

Adrenal Ab, Titer	**1:20**	**H**	<1:10		QCRL

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

C113000021
WX0000003039
Printed D&T: 01/13/21 12:36

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Inactivate Test With Replacement			
Effective Date	1/25/2021		
Inactivated Test			
Name	BRC Avantage, Comprehensive		
Code	BRCAC		
Legacy Code[1]	BRCAC		
Interface Order Code	3434700		
Notes			
Replacement Test			
Name	BRCA Panel (BRCA1, BRCA2)		
Code	BRCAP		
CPT Code(s)	81162; ZB0PR		
Notes	BRCA1 sequencing, BRCA1 Deletion/Duplication BRCA2 Sequencing, BRCAZ Deletion/Duplication, Comprehensive interpretation		
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA tube. Send 4.0 mL whole blood (5.0 mL minimum) room temperature. Send report of results for family member with known BRCA mutation.		
Alternate Specimen	ACD		
Rejection Criteria	Clotted whole blood		
Stability	Room temperature: 14 days; Refrigerated: 14 days; Frozen: Unacceptable		
Performing Information			
Methodology	DNA Bait Capture; Long Range Polymerase Chain Reaction; Next Generation Sequencing		
Reference Range	See report		
Performed Days	Tuesday, Thursday, Saturday		
Turnaround Time	14 - 21 days from completed pre-authorization		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	BRCAP		
Interface Order Code	3400510		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400511	Result	50398-7	No
3400512	Gene	48018-6	No
3400513	Variant	69548-6	No
3400514	Classification	53037-8	No
3400515	Gene 2	48018-6	No
3400516	Variant 2	69548-6	No
3400517	Classification 2	53037-8	No

3400518	Gene 3	48018-6	No
3400519	Variant 3	69548-6	No
3400520	Classification 3	53037-8	No
3400521	Gene 4	48018-6	No
3400522	Variant 4	69548-6	No
3400523	Classification 4	53037-8	No
3400524	Gene 5	48018-6	No
3400525	Variant 5	69548-6	No
3400526	Classification 5	53037-8	No
3400527	VUS(s)	82939-0	No
3400528	Gene List	36908-2	No
3400529	Clinical Interpretation	50398-7	No
3400530	Variant Interpretation	82939-0	No
3400531	Reviewer	69047-9	No
3400532	Resources	8266-9	No
3400533	Methods and Limitations	77202-0	No
3400534	Additional Information	8266-9	No

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Inactivate Test With Replacement			
Effective Date	2/16/2021		
Inactivated Test			
Name	Carisoprodol		
Code	CARIS		
Legacy Code[1]	CARIS		
Interface Order Code	3500600		
Notes			
Replacement Test			
Name	Carisoprodol and Metabolite, Serum/Plasma		
Code	CRISP		
CPT Code(s)	80369		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a red-top tube. Centrifuge and separate serum from cells. Send 2.0 mL serum (0.7 mL minimum) refrigerated in a screw capped plastic vial.		
Alternate Specimen	Plasma: EDTA		
Rejection Criteria	SST or PST		
Stability	Room temperature: 21 days; Refrigerated: 21 days; Frozen: 21 days		
Performing Information			
Methodology	Gas Chromatography/Mass Spectrometry (GCMS)		
Reference Range	Carisoprodol: 0.2 mcg/mL Meprobamate (metabolite): 1.0 mcg/mL		
Performed Days	Varies		
Turnaround Time	8 - 10 days		
Performing Laboratory	NMS Labs		
Interface Information			
Legacy Code[1]	CRISP		
Interface Order Code	3300189		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3300190	Carisoprodol	3437-1	No
3300191	Meprobamate	3753-1	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Referral Testing

Collected: 01/13/2021 12:41 Received: 01/13/2021 12:41

Test Name	Result	Flag	Ref-Ranges	Units	Site
Carisoprodol and Metabolite, Serum/Plasma					
Carisoprodol	10			mcg/mL	NMRL

Reporting Limit: 0.20 mcg/mL
Synonym(s): Soma(R)
Following a 350 mg oral dose of carisoprodol, peak plasma concentrations averaged 2.1 mcg/mL in 1 hour.
Following a 700 mg oral dose of carisoprodol, peak plasma concentrations averaged 3.5 mcg/mL in 0.8 hour.
Analysis by Gas Chromatography/Mass Spectrometry (GC/MS)

Meprobamate	20			mcg/mL	NMRL

Reporting Limit: 1.0 mcg/mL
Synonym(s): Carisoprodol Metabolite
Usual therapeutic range: 10 - 30 mcg/mL.
Analysis by Gas Chromatography/Mass Spectrometry (GC/MS)
This test was developed and its performance characteristics determined by NMS Labs. It has not been cleared or approved by the US Food and Drug Administration.

Testing performed at NMS Labs, Inc.
200 Welsh Road
Horsham, PA 19044-2208
CLIA 39D0197898

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

C113000022
WX0000003039
Printed D&T: 01/13/21 12:42

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Inactivate Test With Replacement	
Effective Date	1/26/2021
Inactivated Test	
Name	LeukoStrat CDx FLT3 Mutation Assay
Code	FLT3M
Legacy Code[1]	FLT3M
Interface Order Code	3741029
Notes	
Replacement Test	
Name	LeukoStrat CDx FLT3 Mutation Assay
Code	LUFL3
CPT Code(s)	0023U ZB4BH
Notes	This test requires a dedicated sample aliquot. If one sample is received for Cytogenetics and LUFL3, cytogenetic/FISH testing will be performed first. This may delay LUFL3 results.
Specimen Requirements	
Specimen Required	Draw blood in a green sodium heparin tube. Send 2.0 mL whole blood (1.0 mL minimum) refrigerated.
Alternate Specimen	Bone Marrow: 0.5mL (0.25 mL minimum) green sodium heparin or lavender EDTA Whole Blood: Lavender EDTA
Rejection Criteria	Specimen collect with anticoagulant other than sodum heparin.
Stability	Room temperature: 7 days; Refrigerated: 7 days; Frozen: Unacceptable
Performing Information	
Methodology	Polymerase Chain Reaction- Restriction Fragment Length Polymorphism
Reference Range	See report
Performed Days	Monday - Saturday
Turnaround Time	3 - 5 days
Performing Laboratory	Quest Valencia
Interface Information	
Legacy Code[1]	LUFL3
Interface Order Code	3700432

Result Code	Name	LOINC Code	AOE/Prompt[2]
3700433	Specimen Type	31208-2	**Yes**
3700434	Final Diagnosis Overall:	34574-4	No
3700435	ITD	79210-1	No
3700436	TKD	72520-0	No

3700437	ITD Signal Ratio	Not available	No
3700438	TKD Signal Ratio	Not available	No
3700439	Interpretation:	50398-7	No

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Inactivate Test With Replacement	
Effective Date	2/23/2021
Inactivated Test	
Name	Syphilis IgG/IgM Antibody
Code	SYPH
Legacy Code[1]	SYPHAB
Interface Order Code	3016040
Notes	
Replacement Test	
Name	Syphilis IgG/IgM Antibody with Reflex
Code	SYPHR
CPT Code(s)	86592. Positives reflexed to TP-PA (86780) and RPR Titer (86593), at additional cost
Notes	Syphilis Antibody: Treponema Pallidum enzyme immunoassay screen for suspected primary or secondary syphilis.
Specimen Requirements	
Specimen Required	Draw blood in a SST. Centrifuge, separate and send 1.0 mL serum (0.5 mL minimum) refrigerated in a screw capped plastic vial.
Alternate Specimen	Serum: Red-top
Rejection Criteria	Severely hemolyzed or lipemic specimens
Stability	Room temperature: 8 hours; Refrigerated: 7 days; Frozen: 14 days
Performing Information	
Methodology	Chemiluminescence Immunoassay
Reference Range	<0.9 - Negative: In a patient for whom there is a strong clinical suspicion of syphilis, a second sample collected in 14 days is recommended. 0.9-1.09 – Equivocal >=1.10 - Positive: Reflexed for confirmation to TP-PA and a rapid plasma reagin titer (RPRT) that will be useful in following response to treatment.
Performed Days	Sunday - Friday
Turnaround Time	3 days
Performing Laboratory	Warde Medical Laboratory
Interface Information	
Legacy Code[1]	SYPHR
Interface Order Code	3000172

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Result Code	Name	LOINC Code	AOE/Prompt[2]
3000173	Syphilis IgG/IgM Antibody	63464-2	No
3000174	Syphilis IgG/IgM Interpretation	Not available	No
3000176	Rapid Plasma Reagin (RPR) Titer	31147-2	No
3000177	Treponema pallidum Ab TP-PA	22587-0	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Immunology

Collected: 01/13/2021 12:49 Received: 01/13/2021 12:49

Test Name	Result	Flag	Ref-Ranges	Units	Site
Syphilis IgG/IgM Antibody with Reflex					
Syphilis IgG/IgM Antibody	0.50		<0.90	Index Value	WMRL
Syphilis IgG/IgM Interpretation	Negative				WMRL
	The Syphilis antibody test is Negative. If there is clinical suspicion that the patient may have early Acute Primary Syphilis, repeat testing in 12-14 days is recommended. Serology tests may be falsely negative in patients with immunodeficiency.				
Rapid Plasma Reagin (RPR) Titer	.TNP				WMRL
Treponema pallidum Ab TP-PA	.TNP				WMRL

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

C113000023
WX0000003039
Printed D&T: 01/13/21 12:50

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 32 Y

Immunology

Collected: 01/13/2021 12:50 Received: 01/13/2021 12:50

Test Name	Result	Flag	Ref-Ranges	Units	Site
Syphilis IgG/IgM Antibody with Reflex					
Syphilis IgG/IgM Antibody	**2.90**	**H**	<0.90	Index Value	WMRL
Syphilis IgG/IgM Interpretation	Positive				WMRL
Rapid Plasma Reagin (RPR) Titer	**1:2**	**AB**	Nonreactive		WMRL
Treponema pallidum Ab TP-PA	**Reactive**	**AB**	Nonreactive		WMRL

The syphilis antibody test is confirmed as positive with the TP-PA. Both of these tests remain positive for years and do not decline with therapy. The RPR is positive. The most likely explanation for this combination is active syphilis. The RPR titer is useful to follow treatment.

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

C113000024
WX0000003039
Printed D&T: 01/13/21 12:51

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2021

Inactivate Test Without Replacement	
Effective Date	1/13/2021
Name	Candida Antigen
Code	CANAG
Legacy Code	CANAG
Interface Code	3500590
Notes	Suggested replacement is FNSER, Fungitel AB.

Inactivate Test Without Replacement	
Effective Date	2/16/2021
Name	Organic Acids, Plasma
Code	ORGAP
Legacy Code	ORGAP
Interface Code	3600103
Notes	Suggested replacement is UORGA- Organic Acids, Urine.