Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

Update Notes

Update Summary		
New Test Activation	9/29/2020	ABLKD - "ABL Kinase Domain Mutation in CML, Cell-based"
New Test Activation	9/29/2020	CDS1 - "CNS Demyelinating Disease Eval, Serum"
New Test Activation	8/13/2020	COVPV - "SARS-CoV-2 RT-PCR (Respiratory) "
New Test Activation	9/29/2020	F8ANT - "Factor VIII Antigen"
New Test Activation	9/29/2020	JAKCR - "JAK2 V617F Cascading Reflex"
New Test Activation	9/29/2020	RIVAR - "Rivaroxaban"
New Test Activation	9/29/2020	TP53 - "TP53 Somatic Mutation, Prognostic"
New Website Listing	8/10/2020	CARBX - "Carboxyhemoglobin, Blood"
Update Existing Test	9/3/2020	ASHA - "Arsenic, Hair"
Update Existing Test	9/3/2020	ASNA - "Arsenic, Nails"
Update Existing Test	8/25/2020	COPLV - "Copper - Liver Tissue"
Update Existing Test	8/5/2020	CSFPR - "14-3-3 Protein, CSF (Prion Disease)"
Update Existing Test	8/10/2020	FMP3 - "MyoMarker Panel 3"
Update Existing Test	8/25/2020	ITISS - "Iron, Liver Tissue"
Update Existing Test	9/14/2020	METHX - "Methsuximide as Metabolite, Serum/Plasma"
Inactivate Test Without Replacement	9/29/2020	MPCUL - "Mycoplasma pneumonia Culture"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Test Activation			
Effective Date	9/29/2020		
Name	ABL Kinase Domain Mutation in CML, Cell-based		
Code	ABLKD		
CPT Code(s)	81170 ZB0R6		
Notes			
Specimen Requirements			
Specimen Required	Collect bone marrow (2.1 mL) in EDTA tube. Send refrigerated. **Specimen must arrive at the lab the day of collection due to short stability. Send Monday - Thursday only.**		
Alternate Specimen	Bone marrow: Sodium heparin Whole Blood: EDTA or sodium heparin		
Rejection Criteria	Gross hemolysis, lipemia, frozen samples, clotted whole blood samples, clotted bone marrow samples		
Stability	Room temperature: 72 hours; Refrigerated: 72 hours; Frozen: Unaccepatable		
Performing Information			
Methodology	Nested Polymerase Chain Reaction Real-Time Polymerase Chain Reaction Sequencing		
Reference Range	See report		
Performed Days	Monday - Sunday		
Turnaround Time	4 - 6 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	ABLKD		
Interface Order Code	3400350		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400351	ABL Mutation, Cell-based	55135-8	No
3400352	ABL Possible Mutations	55135-8	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: 08/10/2020 13:34 Received: 08/10/2020 13:34

Test Name	Result	Flag	Ref-Ranges	Units	Site

ABL Kinase Domain Mutation in CML, Cell-based

ABL Mutation, Cell-based SEE NOTE QCRL

Results reviewed by M.R. Sheikholeslami, M.D.

There is a 35-nucleotide insertion detected between exon 8 and exon 9, likely representing an alternative splicing product that would produce a truncated ABL protein that lacks the last 653 residues of the kinase domain. This altered transcript has been noted to be increased in kinase-resistant samples in some reports but may also be a normal variant.

ABL Possible Mutations SEE NOTE QCRL

No additional ABL mutations were detected.

Extracted RNA from leukocytes was subjected to reverse transcription PCR in order to amplify the BCR-ABL fusion transcript. Subsequently, a nested PCR was performed to further selectively amplify the region corresponding to the ABL kinase domain (exons 4 to 9) and sequenced to detect mutations that have been reported to confer resistance to kinase inhibitors. Mutations present outside this region or in the PCR primer binding sites will not be detected. Mutations in rare BCR-ABL1 transcripts may also not be detected in this assay.

For additional information, please refer to
http://education.QuestDiagnostics.com/faq/FAQ113
(This link is being provided for informational/educational purposes only.)

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

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Test Activation			
Effective Date	9/29/2020		
Name	CNS Demyelinating Disease Eval, Serum		
Code	CDS1		
CPT Code(s)	86255 x 2, plus 86256 x 2 as appropriate, at additional fees		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a red-top tube. Centrifuge, separate, send 3.0 mL serum (2.0 mL minimum) refrigerated in a screw-capped plastic vial.		
Rejection Criteria	Gross hemolysis; gross lipemia; gross icterus		
Stability	Room temperature: 72 hours; Refrigerated: 28 days; Frozen: 28 days		
Performing Information			
Methodology	Flow Cytometry		
Reference Range	See report		
Performed Days	Monday, Tuesday, Thursday		
Turnaround Time	8 - 12 days		
Performing Laboratory	Mayo Clinic Laboratories		
Interface Information			
Legacy Code[1]	CDS1		
Interface Order Code	3800149		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800150	CNS Demyelinating Disease Interp	69048-7	No
3800151	MOG FACS, S	90248-6	No
3800152	MOG FACS Titer, S	84873-9	No
3800153	NMO/AQP4 FACS, S	43638-6	No
3800154	NMO/AQP4 FACS Titer, S	86241-7	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: 08/10/2020 14:44 Received: 08/10/2020 14:44

Test Name	Result	Flag	Ref-Ranges	Units	Site
CNS Demyelinating Disease Eval, Serum					
CNS Demyelinating Disease Interp	SEE BELOW				MMRL
	No informative autoantibodies were detected in this evaluation. A negative result does not preclude a diagnosis of an inflammatory CNS demyelinating disorder.				
MOG FACS, S	Negative		Negative		MMRL
	----------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.				
	Test Performed by: Mayo Clinic Laboratories - Rochester Main Campus 200 First Street SW, Rochester, MN 55905 Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D0404292				
MOG FACS Titer, S	.TNP				MMRL
NMO/AQP4 FACS, S	Negative		Negative		MMRL
	----------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.				
NMO/AQP4 FACS Titer, S	.TNP				MMRL

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

B610000023
WX0000003039
Printed D&T: 08/10/20 14:46

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 31 Y

Referral Testing

Collected: 08/10/2020 15:51 Received: 08/10/2020 15:51

Test Name	Result	Flag	Ref-Ranges	Units	Site
CNS Demyelinating Disease Eval, Serum					
CNS Demyelinating Disease Interp	SEE BELOW				MMRL
	Detection of both MOG and AQP4 autoantibodies is rare and unusual but supports the diagnosis of a neuromyelitis optica spectrum disorder. Seropositivity predicts high risk of relapse for myelitis, optic neuritis or both.				
MOG FACS, S	**Positive**	**AB**	Negative		MMRL
	Screen positive, see confirmatory test results.				
	------------------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.				
	Test Performed by: Mayo Clinic Laboratories - Rochester Main Campus 200 First Street SW, Rochester, MN 55905 Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D0404292				
MOG FACS Titer, S	**Positive 1:100**	**H**	<1:20	titer	MMRL
	------------------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.				
	Test Performed by: Mayo Clinic Laboratories - Rochester Main Campus 200 First Street SW, Rochester, MN 55905 Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D0404292				
NMO/AQP4 FACS, S	**Positive**	**H**	Negative		MMRL
	Screen positive, see confirmatory test results.				
	------------------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.				
NMO/AQP4 FACS Titer, S	**Positive 1:1000**	**AB**	<1:5	titer	MMRL
	------------------ADDITIONAL INFORMATION------------------ This test was developed and its performance characteristics				

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

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 08/10/2020 15:51 Received: 08/10/2020 15:51

Test Name	Result	Flag	Ref-Ranges	Units	Site

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.

Test Performed by:
Mayo Clinic Laboratories - Rochester Main Campus
200 First Street SW, Rochester, MN 55905
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D0404292

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Test Activation			
Effective Date	8/13/2020		
Name	SARS-CoV-2 RT-PCR (Respiratory)		
Code	COVPV		
CPT Code(s)	U0003		
Notes	This is a new sendout alternative for COVID-19 testing. Please contact Warde Client Services for your laboratory's allocation.		
Specimen Requirements			
Specimen Required	Nasal Swab/NP swab/OP swab: Place sterile swab in 2.0 mL of sterile buffered saline or viral transport media. Send refrigerated. CDC recommends collection of NP swabs and no longer recommends collections of both OP and NP swabs.		
Alternate Specimen	Nasal wash BAL OP swab		
Rejection Criteria	Dry swab, wood shafted swab, calcium alginate swab, specimens received in trap containers		
Stability	Room temperature: 7 days; Refrigerated: 7 days; Frozen: 30 days		
Performing Information			
Methodology	Real-Time Reverse Transcriptase Polymerase Chain Reaction		
Reference Range	Not Detected		
Performed Days	Monday - Friday		
Turnaround Time	3 - 4 days		
Performing Laboratory	Viracor Eurofins		
Interface Information			
Legacy Code[1]	COVPV		
Interface Order Code	3300119		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3300121	First Test? (Y/N/U)	95417-2	**Yes**
3300122	Employed in healthcare? (Y/N/U)	95418-0	**Yes**
3300123	Symptomatic as defined by CDC? (Y/N/U)	95419-8	**Yes**
3300124	If yes, then Date of Symptom Onset (yyyyddmm/U/NA)	11368-8	**Yes**
3300125	Hospitalized? (Y/N/U)	77974-4	**Yes**
3300126	ICU Patient? (Y/N/U)	95420-6	**Yes**
3300127	Resident in a congregate care setting? (Y/N/U)	95421-4	**Yes**
3300128	Pregnant? (Y/N/U)	82810-3	**Yes**
3300129	SARS-CoV-2 RT-PCR result	94500-6	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: 08/10/2020 14:33 Received: 08/10/2020 14:33

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS-CoV-2 RT-PCR (Respiratory)					
First Test? (Y/N/U)	U				VIRL
Employed in healthcare? (Y/N/U)	U				VIRL
Symptomatic as defined by CDC? (Y/N/U)	U				VIRL
If yes, then Date of Symptom Onset (yyyymmdd/U/NA)	NA				VIRL
Hospitalized? (Y/N/U)	U				VIRL
ICU Patient? (Y/N/U)	U				VIRL
Resident in a congregate care setting? (Y/N/U)	U				VIRL
Pregnant? (Y/N/U)	U				VIRL
SARS-CoV-2 RT-PCR result	**Detected**	**AB**	Not Detected		VIRL

This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of RNA from SARS-CoV-2 virus and diagnosis of SARS-CoV-2 virus infection, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagnosis of SARS-CoV-2 virus infection under section 564(b)(1) of the Act, 21 U.S.C. section 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
We will continue to follow federal and state requirements for both notification of results and any confirmatory testing that is required by another agency.
This test was developed and its performance characteristics determined by Viracor Eurofins. It has not been cleared or approved by the U.S. Food and Drug Administration. Results should be used in conjunction with clinical findings, and should not form the sole basis for a diagnosis or treatment decision.

Testing Performed At:
Viracor Eurofins
1001 NW Technology Drive
Lee's Summit, MO 64086
(800)305-5198

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Test Activation			
Effective Date	9/29/2020		
Name	Factor VIII Antigen		
Code	F8ANT		
CPT Code(s)	85244		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a light blue 3.2% sodium citrate tube. (See website appendices for coagulation test collection instructions.) Send 1.0 mL platelet-poor plasma (0.5 mL minimum) frozen in a screw-capped plastic vial. **CRITICAL FROZEN**		
Stability	Room temperature: 4 hours; Refrigerated: 48 hours; Frozen: -20 C: 30 days, -70 C: 6 months		
Performing Information			
Methodology	Enzyme-linked Immunosorbent Assay (ELISA)		
Reference Range	By report		
Performed Days	As needed/1x month		
Turnaround Time	4 - 31 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	F8ANT		
Interface Order Code	3400404		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400404	Factor VIII Antigen	3213-6	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: 08/10/2020 15:56 Received: 08/10/2020 15:56

Test Name	Result	Flag	Ref-Ranges	Units	Site
Factor VIII Antigen	1.00		0.60-1.95	IU/mL	QCRL

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

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

B610000027
WX0000003039
Printed D&T: 08/10/20 15:57

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Test Activation			
Effective Date	9/29/2020		
Name	JAK2 V617F Cascading Reflex		
Code	JAKCR		
CPT Code(s)	81270, plus 81219 CALR; 81403 Exon 12 JAK2; 81402 MPL; 81479 CSF3R as appropriate, at additional fees		
Notes			
Specimen Requirements			
Specimen Required	Send 5.0 mL whole blood or 1.0 mL bone marrow collected in EDTA lavender top tube. Send room temperature.		
Alternate Specimen	Whole blood or bone marrow aspirate: sodium heparin tube Extracted DNA from CLIA-certified laboratory		
Stability	**Whole blood, Bone marrow, Cell pellet:** Room temperature: 7 days; Refrigerated: 7 days; Frozen: Unacceptabe **Extracted DNA:** Room temperature: 7 days; Refrigerated: 14 days; Frozen: 1 year		
Performing Information			
Methodology	Polymerase Chain Reaction-based DNA Sequencing		
Reference Range	See report		
Performed Days	Monday - Sunday		
Turnaround Time	6 - 9 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	JAKCR		
Interface Order Code	3400380		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400381	Clinical Indication:	55752-0	**Yes**
3400382	Specimen Source:	31208-2	**Yes**
3400383	Block/Specimen ID:	52463-7	**Yes**
3400384	JAK2 V617F Mutation	43399-5	No
3400385	CALR Exon 9 Mutation	77174-1	No
3400386	JAK2 Exon 12 Mutation	55300-8	No
3400387	MPL Exon 10 Mutation	62947-7	No
3400388	CSF3R Exon 14/17 Mutation	92674-1	No
3400389	Gene	48018-6	No
3400390	Amino Acid	48005-3	No
3400391	Mutation Frequency	81258-6	No
3400392	Mutation Type	48019-4	No
3400393	Exon	47999-8	No
3400394	Nucleotide Change	48004-6	No

3400395	Reference	81256-0	No
3400396	Interpretation	50398-7	No
3400397	Assay Details	8266-9	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: 08/10/2020 16:12 Received: 08/10/2020 16:12

Test Name	Result	Flag	Ref-Ranges	Units	Site
JAK2 V617F Cascading Reflex					
Clinical Indication:	Unknown				QCRL
Specimen Source:	Whole Blood				QCRL
Block/Specimen ID:	123456				QCRL
JAK2 V617F Mutation	NOT DETECTED				QUESC

Reference Range:
NOT DETECTED

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

CALR Exon 9 Mutation	NOT DETECTED				QUESC

Reference Range:
NOT DETECTED

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

JAK2 Exon 12 Mutation	NOT DETECTED				QUESC

Reference Range:
NOT DETECTED

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

MPL Exon 10 Mutation	NOT DETECTED				QUESC

Reference Range:
NOT DETECTED

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

CSF3R Exon 14/17 Mutation	NOT DETECTED				QUESC

Reference Range:
NOT DETECTED

Test Performed at:
Quest Diagnostics Nichols Institute

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: 08/10/2020 16:12 Received: 08/10/2020 16:12

Test Name	Result	Flag	Ref-Ranges	Units	Site
33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
Gene	.				QUESC
Amino Acid	.				QUESC
Mutation Frequency	.				QUESC
Mutation Type	.				QUESC
Exon	.				QUESC
Nucleotide Change	.				QUESC
Reference	.				QUESC
Interpretation	SEE NOTE				QUESC
Assay Details	SEE NOTE				QUESC

No mutations were detected in codon 617 or exon 12 of JAK2, or exon 9 of CALR, or exon 10 (codons 505 and 515) of MPL, or exons 14 and 17 of CSF3R. Insertions up to 30bp and deletions up to 52bp have been successfully detected by the assay. The absence of mutation does not exclude the presence of a myeloproliferative neoplasm. See below for additional recommendations on testing.

This data was reviewed and interpreted by Charles Ma, PhD. HCLD(ABB)

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

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: 08/10/2020 15:59 Received: 08/10/2020 15:59

Test Name	Result	Flag	Ref-Ranges	Units	Site
JAK2 V617F Cascading Reflex					
Clinical Indication:	Unknown				QCRL
Specimen Source:	Whole Blood				QCRL
Block/Specimen ID:	123456				QCRL
JAK2 V617F Mutation	**DETECTED**	**AB**			QCRL

Reference Range:
NOT DETECTED

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

CALR Exon 9 Mutation	**DETECTED**	**AB**			QCRL

Reference Range:
NOT DETECTED

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

JAK2 Exon 12 Mutation	**DETECTED**	**AB**			QCRL

Reference Range:
NOT DETECTED

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

MPL Exon 10 Mutation	**DETECTED**	**AB**			QCRL

Reference Range:
NOT DETECTED

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

CSF3R Exon 14/17 Mutation	**DETECTED**	**AB**			QCRL

Reference Range:
NOT DETECTED

Test Performed at:
Quest Diagnostics Nichols Institute

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 08/10/2020 15:59 Received: 08/10/2020 15:59

Test Name	Result	Flag	Ref-Ranges	Units	Site
33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
Gene	DETECTED				QCRL
Amino Acid	DETECTED				QCRL
Mutation Frequency	DETECTED				QCRL
Mutation Type	DETECTED				QCRL
Exon	DETECTED				QCRL
Nucleotide Change	DETECTED				QCRL
Reference	DETECTED				QCRL
Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
Interpretation	SEE NOTE				QCRL

mutations were detected in codon 617 or exon 12 of JAK2, or exon 9 of CALR, or exon 10 (codons 505 and 515) of MPL, or exons 14 and 17 of CSF3R. Insertions up to 30bp and deletions up to 52bp have been successfully detected by the assay. The absence of mutation does not exclude the presence of a myeloproliferative neoplasm. See below for additional recommendations on testing.

This data was reviewed and interpreted by Charles Ma, PhD. HCLD(ABB)

Assay Details	SEE NOTE				QCRL

ADEQUATE FUNCTIONAL C1ESTERASE INHIBITOR PRESENT.
This PCR-based advanced sequencing assay interrogates DNA from leukocytes for the presence of mutations in codon 617 and exon 12 of JAK2, exon 9 of CALR, exon 10 (codons 505 and 515) of MPL and exons 14 and 17 of CSF3R. The sensitivity of mutation detection is approximately 5%, but may vary depending on the particular mutation type. Insertions up to 30bp and deletions up to 52bp have been successfully detected by the assay. Alterations outside of the tested areas of these genes will not be detected. Synonymous or known non-synonymous polymorphic changes (SNPs) are not reported. JAK2 V617F mutation is associated with myeloproliferative neoplasms (MPNs), including polycythemia vera (PV), essential thrombocythemia (ET) and primary myelofibrosis (PMF); JAK2 exon 12 mutations with PV; CALR exon 9 indels with ET and PMF; MPL exon 10 mutations with ET and PMF and CSF3R mutations with atypical chronic myeloid leukemia (aCML), chronic neutrophilic leukemia (CNL) and other myeloid neoplasms. Increasing allele burden of JAK2 V617F in MPNs has been shown in a number of studies to be associated with increased symptoms including pruritis, splenomegaly, and leukocytosis. Results of this assay should be

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 08/10/2020 15:59 Received: 08/10/2020 15:59

Test Name	Result	Flag	Ref-Ranges	Units	Site

correlated with morphology and other laboratory testing for final diagnosis and classification. To further evaluate for MPNs if this assay is negative, additional testing for BCR-ABL1 rearrangement (test code 91065 or 12070X) can be performed.

Tests not indicated have been cancelled and credited.

DNA was aligned to GRCh37(hg19) for analysis. The transcripts IDs used as reference sequences are ENST00000381652 (JAK2), ENST00000316448 (CALR), ENST00000372470 (MPL) and ENST00000373103 (CSF3R).

For additional information, please refer to
http://education.QuestDiagnostics.com/faq/FAQ211
(This link is being provided for informational/educational purposes only.)

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

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Test Activation			
Effective Date	9/29/2020		
Name	Rivaroxaban		
Code	RIVAR		
CPT Code(s)	80299		
Notes			
Specimen Requirements			
Specimen Required	Collect samples 2-4 hours post dose. Draw blood in a light blue 3.2 % sodium citrate tube. Centrifuge and send 1.0 mL plasma (0.5 mL minimum) frozen in a screw-capped plastic vial. **CRITICAL FROZEN**		
Rejection Criteria	Samples received refrigerated or at room temperature		
Stability	Room temperature: Unacceptable; Refrigerated: Unacceptable: Frozen: 28 days		
Performing Information			
Methodology	Chromogenic		
Reference Range	See report		
Performed Days	Monday, Wednesday, Friday		
Turnaround Time	2 - 6 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	RIVAR		
Interface Order Code	3400398		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400398	Rivaroxaban	72624-0	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: 08/10/2020 16:23 Received: 08/10/2020 16:23

Test Name	Result	Flag	Ref-Ranges	Units	Site
Rivaroxaban	<30			mcg/L	QCRL

Dosage	Peak mcg/L(at steady state)	Trough mcg/L
20 mg qD	182 - 408	3 - 153
15 mg qD	180 - 408	2 - 161
10 mg qD	91 - 196	1 - 38

* The lower limit of detection for this assay is 30 mcg/L. The ranges are based on literature references (see FAQs).

For additional information, please refer to
http://education.questdiagnostics.com/faq/FAQ96
(This link is being provided for informational/
educational purposes only.)

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. 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 Chantilly
Nichols Institute, 14225 Newbrook Dr.
Chantilly, VA 20153-0841 P W Mason MD, PhD

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Test Activation			
Effective Date	9/29/2020		
Name	TP53 Somatic Mutation, Prognostic		
Code	TP53		
CPT Code(s)	81405 ZBQ29		
Notes			
Specimen Requirements			
Specimen Required	Send 6.0 mL whole blood (3.0 mL minimum) in EDTA lavender top tube. Send refrigerated.		
Alternate Specimen	Formalin-fixed paraffin embedded tissue submitted in paraffin embedded tissue block Bone Marrow (3.0 mL) collected in EDTA lavender top tube		
Rejection Criteria	Frozen samples		
Stability	**Whole blood or bone marrow:** Room temperature: 72 hours; Refrigerated: 7 days; Frozen: Unacceptable **Formalin-fixed paraffin embedded tissue:** Room temperature: indefinite; Refrigerated: Indefinite; Frozen: Unacceptable		
Performing Information			
Methodology	Polymerase Chain Reaction/Sequencing		
Reference Range	See report		
Performed Days	Tuesday, Thursday		
Turnaround Time	4 - 6 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	TP53		
Interface Order Code	3400331		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400332	Specimen Type	21739-8	**Yes**
3400333	Block Number	52463-7	**Yes**
3400334	P53 Mutation, Leumeta	21739-8	No
3400335	Exon 4	21739-8	No
3400336	Exon 5	21739-8	No
3400337	Exon 6	21739-8	No
3400338	Exon 7	21739-8	No
3400339	Exon 8	21739-8	No
3400340	Exon 9	21739-8	No
3400341	Interpretation	21739-8	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: 08/10/2020 16:26 Received: 08/10/2020 16:26

Test Name	Result	Flag	Ref-Ranges	Units	Site
TP53 Somatic Mutation, Prognostic					
Specimen Type	Blood				QCRL
Block Number	N/A				QCRL
P53 Mutation, Leumeta	NEGATIVE		NEGATIVE		QCRL
Exon 4	NEGATIVE				QCRL
Exon 5	NEGATIVE				QCRL
Exon 6	NEGATIVE				QCRL
Exon 7	NEGATIVE				QCRL
Exon 8	NEGATIVE				QCRL
Exon 9	SEE NOTE				QCRL

SEE INTERPRETATION

Interpretation — SEE NOTE — QCRL

Results reviewed by Alireza Bazooband, M.D.

Mutations in p53 tumor suppressor gene occur in greater than 50% of adult human cancers. The p53 gene mutations usually correlate with poor outcome and early recurrence in cancer. Testing was performed on P53 exon 4-9 which account for >90% mutations in p53 gene. We cannot rule out the possibilities of mutation in other sites of the gene.

The total nucleic acid was extracted from patient's plasma, PB/BM cells or paraffin embedded tissues. PCR reactions are performed to amplify exon 4-9 of p53 gene. The PCR products are then purified and sequenced in both forward and reverse directions. All mutations, deletions and insertions detected in the P53 exons 4-9 will be reported.

This assay does not detect large deletions in the p53 gene. For (17p-) please refer to FISH assay. The sensitivity of this sequencing assay is 20% of mutant cell in the background of normal cells.

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

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: 08/10/2020 16:26 Received: 08/10/2020 16:26

Test Name	Result	Flag	Ref-Ranges	Units	Site
	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

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

New Website Listing			
Effective Date	8/10/2020		
Name	Carboxyhemoglobin, Blood		
Code	CARBX		
CPT Code(s)	82375		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA. **Do NOT open tube.** Send specimen refrigerated. Minimum volume: 0.5 mL		
Alternate Specimen	Whole blood: Heparin		
Rejection Criteria	Fluoride oxalate (grey top tube), clotted specimen, tube that has been opened.		
Stability	Room temperature: 5 days; Refrigerated: 10 days; Frozen: Unacceptable		
Performing Information			
Methodology	Spectrophotometry		
Reference Range	See report		
Performed Days	Sunday - Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	CARBOXQ		
Interface Order Code	3424260		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3424260	Carboxyhemoglobin, Blood	20563-3	No

Update Existing Test	
Effective Date	9/3/2020
Name	Arsenic, Hair
Code	ASHA
Interface Order Code	3805360
Legacy Code	ARHM
Notes	Reference Range changes.
Required Testing Changes	
Reference Range	0-15 years: Not established **≥16 years: <1.0 mcg/g of hair**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

Update Existing Test	
Effective Date	9/3/2020
Name	Arsenic, Nails
Code	ASNA
Interface Order Code	3805380
Legacy Code	ARNM
Notes	Reference range changes.
Required Testing Changes	
Reference Range	0-15 years: Not established **≥16 years: <1.0 mcg/g of nails**

Update Existing Test	
Effective Date	8/25/2020
Name	Copper - Liver Tissue
Code	COPLV
Interface Order Code	3501750
Legacy Code	COPLV
Notes	Reference range changes.
Required Testing Changes	
Reference Range	**<50 mcg/g dry weight**

Update Existing Test			
Effective Date	8/5/2020		
Name	14-3-3 Protein, CSF (Prion Disease)		
Code	CSFPR		
Interface Order Code	3700101		
Legacy Code	CSFPR		
Notes	The name of the component has changed.		
Required Testing Changes			
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3700102	**Likelihood of prion dis**	Not available	No
3700103	RT-QuIC (CSF)*	Not available	No
3700104	T-tau protein (CSF)	Not available	No
3700105	14-3-3 protein (CSF)	31989-7	No
3700106	Comment	48767-8	No

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

Update Existing Test	
Effective Date	8/10/2020
Name	MyoMarker Panel 3
Code	FMP3
Interface Order Code	3800044
Legacy Code	FMP3
Notes	Minimum volume changes. Update to Methodology and TAT.
Required Testing Changes	
Specimen Required	Draw blood in a red-top tube. Centrifuge, separate and send 3.0 mL serum (**2.0 mL minimum**) refrigerated in a screw-capped plastic vial.
Methodology	**Enzyme Linked Immunoassay** **RIPA Gel Radiography**
Turnaround Time	**20 - 22 days**

Update Existing Test	
Effective Date	8/25/2020
Name	Iron, Liver Tissue
Code	ITISS
Interface Order Code	3801000
Legacy Code	ITISSM
Notes	Reference range changes.
Required Testing Changes	
Reference Range	Males: 200-2400 mcg/g dry weight **Females: 200-1800 mcg/g dry weight** Iron Index: <1.0 mcmol/g/year (≥13 years) Reference values have not been established for patients that are less than 13 years of age.

Update Existing Test	
Effective Date	9/14/2020
Name	Methsuximide as Metabolite, Serum/Plasma
Code	METHX
Interface Order Code	3504930
Legacy Code	METHSUX
Notes	Stability changes.
Required Testing Changes	
Stability	Room temperature: 7 days; Refrigerated: 14 days; **Frozen: 15 months**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020

Inactivate Test Without Replacement	
Effective Date	9/29/2020
Name	Mycoplasma Pneumonia Culture
Code	MPCUL
Legacy Code	MPCUL
Interface Code	3719700
Notes	Suggested replacement MYCP - Mycoplasma Pneumoniae DNA (PCR) to ARUP