Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Notes

Update Summary

New Test Activation	10/27/2020	CSMUT - "CSF3 Mutation Analysis"
New Test Activation	10/27/2020	MMDSI - "Multiple Myeloma, Daratumumab-Specific, Immunofixation"
New Test Activation	10/27/2020	RBCME - "RBC Membrane Evaluation, B"
New Test Activation	10/27/2020	VONWI - "von Willebrand Disease Gene Sequencing"
Update Existing Test	10/19/2020	ALDMS - "Aldosterone, LC/MS/MS"
Update Existing Test	9/17/2020	CHGTM - "Chlamydia and Neisseria Nucleic Acid by TMA"
Update Existing Test	9/17/2020	CHRNA - "Chlamydia trachomatis Nucleic Acid by TMA"
Update Existing Test	10/19/2020	COPRU - "Copper, Random Urine"
Update Existing Test	9/17/2020	FMP3 - "MyoMarker Panel 3"
Update Existing Test	10/5/2020	FORMA - "Formic Acid, Serum/Plasma"
Update Existing Test	9/17/2020	GCRNA - "Nesseria gonorrhoeae Nucleic Acid by TMA"
Update Existing Test	9/17/2020	IGSUB - "Immunoglobulin G (IgG) Subclasses"
Update Existing Test	9/17/2020	INFX - "Infliximab Quant with Reflex to Ab to Infliximab, Serum"
Update Existing Test	10/26/2020	PMPCR - "PML-RARA t(15;17), Quantitative RT-PCR"
Update Existing Test	8/26/2020	RT3 - "T3, Reverse, LC/MS/MS"
Update Existing Test	9/17/2020	TRIVA - "Trichomonas vaginalis RNA, Qualitative"
Inactivate Test With Replacement	10/27/2020	MUSKQ - "MuSK Antibody Test" replaced by MUSKE - "Muscle-Specific Kinase (MuSK) Antibody, IgG"
Inactivate Test With Replacement	9/28/2020	PNTCP - "Peanut IgE Component Panel" replaced by PNTCT - "Peanut IgE Component Panel"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

New Test Activation

Effective Date	10/27/2020
Name	CSF3 Mutation Analysis
Code	CSMUT
CPT Code(s)	81479 ZB11S
Notes	

Specimen Requirements

Specimen Required	Draw blood in lavender EDTA tube. Send 5.0 mL whole blood (1.0 mL minimum) at room temperature.
Alternate Specimen	Bone marrow aspirate: Lavender EDTA tube or Sodium heparin Whole blood: Sodium heparin tube Cell pellets submitted in Carnoy's or other alcohol-based fixative Extracted DNA from CLIA-certified laboratory
Stability	Room temperature: 7 days; Refrigerated: 7 days; Frozen: Unacceptable

Performing Information

Methodology	Polymerase Chain Reaction-based DNA Sequencing
Reference Range	See report
Performed Days	Sunday - Saturday
Turnaround Time	6 - 9 days
Performing Laboratory	Quest SJC

Interface Information

Legacy Code[1]	CSMUT
Interface Order Code	3400481

Result Code	Name	LOINC Code	AOE/Prompt[2]
3400482	Clinical Indication:	55752-0	**Yes**
3400483	Specimen Source:	31208-2	**Yes**
3400484	Block/Specimen ID:	57723-9	**Yes**
3400485	CSF3R Exon 14/17 Mutation	92674-1	No
3400486	Gene	48018-6	No
3400487	Amino Acid	48005-3	No
3400488	Mutation Frequency	81258-6	No
3400489	Mutation Type	48019-4	No
3400491	Exon	47999-8	No
3400492	Nucleotide Change:	48004-6	No
3400493	Reference	81256-0	No
3400494	Interpretation:	50398-7	No
3400495	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: 09/15/2020 16:19 Received: 09/15/2020 16:19

Test Name	Result	Flag	Ref-Ranges	Units	Site
CSF3 Mutation Analysis					
Clinical Indication:	Unknown				QCRL
Specimen Source:	Whole Blood				QCRL
Block/Specimen ID:	123456				QCRL
CSF3R Exon 14/17 Mutation	NOT DETECTED				QCRL

Reference Range:
NOT DETECTED

Result reported is for TESTING purposes only and does not reflect actual patient results. ELECTRONIC TESTING ONLY.

Gene	.				QCRL
Amino Acid	.				QCRL
Mutation Frequency	.				QCRL
Mutation Type	.				QCRL
Exon	.				QCRL
Nucleotide Change:	.				QCRL
Reference	.				QCRL
Interpretation:	SEE NOTE				QCRL

No mutation is detected in exon 9 of CALR. Insertions up to 30bp and deletions up to 52bp have been successfully detected by the assay.

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

Assay Details	SEE NOTE				QCRL

This PCR-based advanced sequencing assay interrogates DNA from leukocytes for the presence of mutations in exon 9 of calreticulin (CALR). 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 this gene will not be detected. Synonymous or known non-synonymous polymorphic changes (SNPs) are not reported. Frameshift mutations in this region of CALR are associated with myeloproliferative neoplasms (MPNs), particularly essential thrombocythemia (ET) and primary myelofibrosis (PMF). Results of this assay should be correlated with morphology and other laboratory testing for final diagnosis and classification. If this test is negative, additional testing that may be useful for workup of MPNs, depending on presenting hematologic features, includes BCR-ABL1 rearrangement (test code 91065 or 12070X) or mutational analysis of JAK2 V617F (polycythemia vera (PV)/ET/PMF, 92473), JAK2 exon 12 (PV, 92474), MPL (ET/PMF, 92476) or CSF3R (chronic neutrophilic leukemia,

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 09/15/2020 16:19 Received: 09/15/2020 16:19

Test Name	Result	Flag	Ref-Ranges	Units	Site

92477). Residual material from this sample may be used except for BCR-ABL1 testing; call lab to add.

DNA was aligned to GRCh37(hg19) for analysis and transcript ID ENST00000316448 was used as reference for CALR sequence.

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

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 09/15/2020 16:45 Received: 09/15/2020 16:45

Test Name	Result	Flag	Ref-Ranges	Units	Site
CSF3 Mutation Analysis					
Clinical Indication:	Unknown				QCRL
Specimen Source:	Whole Blood				QCRL
Block/Specimen ID:	123456				QCRL
CSF3R Exon 14/17 Mutation	**DETECTED**	**AB**			QCRL
Reference Range: NOT DETECTED					
Gene	SEE NOTE				QCRL
JAK2					
Amino Acid	SEE NOTE				QCRL
V617F					
Mutation Frequency	SEE NOTE				QCRL
26.9					
Mutation Type	SEE NOTE				QCRL
missense					
Exon	SEE NOTE				QCRL
Exon 14					
Nucleotide Change:	SEE NOTE				QCRL
chr9:5073770G>T					
Reference	SEE NOTE				QCRL
COSM12600					
Interpretation:	SEE NOTE				QCRL

The JAK2 V617F (c.1849G>T) mutation is detected. JAK2 V617F mutational analysis can be performed on sequential samples to assess for treatment response.

This data was reviewed and interpreted by Test Director ABCDE

Assay Details	SEE NOTE				QCRL

This PCR-based advanced sequencing assay interrogates DNA from leukocytes for the presence of mutations in codon 617 of JAK2. The sensitivity of mutation detection is 5%. Alterations outside of the tested areas of this gene will not be detected. Synonymous or known

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 09/15/2020 16:45 Received: 09/15/2020 16:45

Test Name	Result	Flag	Ref-Ranges	Units	Site

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), and a small subset of 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 correlated with morphology and other laboratory testing for final diagnosis and classification. If this test is negative, additional testing that may be useful for workup of MPNs, depending on presenting hematologic features, includes BCR-ABL1 rearrangement (test code 91065 or 12070X) or mutational analysis of CALR (ET/PMF, 92475), JAK2 exon 12 (PV, 92474), MPL (ET/PMF, 92476) or CSF3R (chronic neutrophilic leukemia, 92477). Residual material from this sample may be used except for BCR-ABL1 testing; call lab to add.

DNA was aligned to GRCh37(hg19) for analysis and transcript ID ENST00000381652 was used as reference for JAK2 sequence.

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

OCTOBER 2020

New Test Activation

Effective Date	10/27/2020
Name	Multiple Myeloma, Daratumumab-Specific, Immunofixation
Code	MMDSI
CPT Code(s)	86334
Notes	Patient Preparation: Overnight fasting is preferred.

Specimen Requirements

Specimen Required	Draw blood in a plain red-top tube. Centrifuge, separate serum from cells, and send 2.0 mL serum (1.0 mL minimum) refrigerated in a screw-capped plastic vial.
Rejection Criteria	Specimens other than serum
Stability	Room temperature: 5 days; Refrigerated: 6 days; Frozen: 6 months

Performing Information

Methodology	Immunofixation
Reference Range	See report
Performed Days	Sunday - Friday
Turnaround Time	5 - 7 days
Performing Laboratory	Quest SJC

Interface Information

Legacy Code[1]	MMDSI
Interface Order Code	3400357

Result Code	Name	LOINC Code	AOE/Prompt[2]
3400357	Multiple Myeloma, Daratumumab-Specific, Immunofixation	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 31 Y

Referral Testing

Collected: 09/15/2020 16:50 Received: 09/15/2020 16:50

Test Name	Result	Flag	Ref-Ranges	Units	Site
Multiple Myeloma, Daratumumab-Specific, Immunofixation	NEGATIVE				QCRL

Daratumumab, the anti-CD38 IgG kappa monoclonal antibody, is currently in clinical use for multiple myeloma (MM) treatment. As an immunoglobulin, Daratumumab may also be detected in IFE and may co-migrate with M-protein. Addition of anti-idiotypic antibodies raised against daratumumab to patient serum containing daratumumab alters its banding pattern (by forming a complex of Daratumumab and anti-Daratumumab) as assessed by IFE (daratumumab shift) helping to distinguish between therapeutic monoclonal antibody and M protein present in patient's serum.

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

B715000008
WX0000003039
Printed D&T: 09/15/20 16:53

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

New Test Activation	
Effective Date	10/27/2020
Name	RBC Membrane Evaluation, B
Code	RBCME
CPT Code(s)	85557, 88184, 85060
Notes	**Draw Monday - Thursday only. Specimens must be received at Warde Medical Lab the day of collection.**
Specimen Requirements	
Specimen Required	Testing requires a whole blood EDTA specimen from patient, a whole blood EDTA control specimen and 2 well-made peripheral blood smears (Wright stained or fixed in absolute methanol). **Draw Monday - Thursday only. Specimens must be received at Warde Medical Lab the day of collection.** Please include transfusion history, recent CBC and Mayo Metabolic Hematology Patient Information Form Patient: Draw blood in lavender top EDTA tube. Send 4.0 mL blood refrigerated in original tube. In addition, collect 2 well-made peripheral blood smears (Wright stained or fixed in absolute methanol). Normal shipping control: Draw blood in lavender EDTA tube from a healthy, non-smoking person at the same time as patient. Send 4.0 mL blood clearly labeled as control specimen.
Rejection Criteria	Gross hemolysis, clotted
Stability	Room temperature: Unacceptable; Refrigerated: 72 hours; Frozen: Unacceptable
Performing Information	
Methodology	Varies by test
Reference Range	> or = 12 months: 0.50 g/dL NaCl (unincubated): 3-53% hemolysis 0.60 g/dL NaCl (incubated): 14 - 74% hemolysis 0.65 g/dL NaCl (incubated): 4 - 40% hemolysis 0.75 g/dL NaCl (incubated): 1 -11 % hemolysis Interpretive report provided Reference values not established for patients <12 months of age.
Performed Days	Monday - Saturday
Turnaround Time	5 - 7 days
Performing Laboratory	Mayo Clinic Laboratories
Interface Information	
Legacy Code[1]	RBCME

Interface Order Code	3800161		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3800162	Osmotic Fragility, RBC	34964-7	No
3800163	Osmotic Fragility, 0.50 g/dL NaCl	23915-2	No
3800164	Osmotic Fragility, 0.60 g/dL NaCl	23918-6	No
3800165	Osmotic Fragility, 0.65 g/dL NaCl	23920-2	No
3800166	Osmotic Fragility, 0.75 g/dL NaCl	23921-0	No
3800167	Osmotic Fragility Comment	59466-3	No
3800168	Shipping Control Vial	40431-9	No
3800169	Spherocytosis Interpretation	50595-8	No
3800170	Reviewed By	18771-6	No
3800171	Band 3 Fluoresence Staining, RBC	Not available	No
3800172	Peripheral Blood Smear Review	59465-5	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003313 M 09/22/1992 27 Y

Referral Testing

Collected: 09/16/2020 09:48 Received: 09/16/2020 09:48

Test Name	Result	Flag	Ref-Ranges	Units	Site
RBC Membrane Evaluation, B					
Osmotic Fragility, RBC	.				MAYO
Osmotic Fragility, 0.50 g/dL NaCl	5		3-53	%hemol	MAYO
Osmotic Fragility, 0.60 g/dL NaCl	15		14-74	%hemol	MAYO
Osmotic Fragility, 0.65 g/dL NaCl	7		4-40	%hemol	MAYO
Osmotic Fragility, 0.75 g/dL NaCl	2		1-11	%hemol	MAYO

```
------------------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.
```

Osmotic Fragility Comment	.				MAYO
Shipping Control Vial	Received				MAYO
Spherocytosis Interpretation	SEE BELOW				MAYO

```
Osmotic fragility testing: Normal lysis
EMA binding test (Band 3 assay) by flow cytometry:  Normal

Interpretation:  The osmotic fragility and EMA binding
(Band 3) test results are not supportive of a diagnosis of
hereditary spherocytosis.  No EMA binding features of
hereditary pyropoikilocytosis are seen.  Non-hemolytic
hereditary elliptocytosis cases typically show normal
results and these findings do not exclude a red blood cell
membrane disorder.
```

Reviewed By	Wanda Barber				MAYO
Band 3 Fluoresence Staining, RBC	Normal				MAYO

```
------------------REFERENCE VALUE--------------------------
Expected result is normal

------------------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.
```

Peripheral Blood Smear Review	SEE BELOW				MAYO

```
Review of blood smear reveals no diagnostic abnormalities
of erythrocytes.

Test Performed by:
```

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

B716000002
WX0000003313
Printed D&T: 09/17/20 14:31

Ordered By: CLIENT CLIENT
WX00000000001887

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
WX0000003313 M 09/22/1992 27 Y

Referral Testing

Collected: 09/16/2020 09:48 Received: 09/16/2020 09:48

Test Name	Result	Flag	Ref-Ranges	Units	Site
	Mayo Clinic Laboratories - Rochester Main Campus				
	200 First Street SW, Rochester, MN 55905				
	Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D0404292				

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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003312 F 09/05/2001 19 Y

Referral Testing

Collected: 09/16/2020 09:46 Received: 09/16/2020 09:46

Test Name	Result	Flag	Ref-Ranges	Units	Site
RBC Membrane Evaluation, B					
Osmotic Fragility, RBC	.				MAYO
Osmotic Fragility, 0.50 g/dL NaCl	**89**	**H**	3-53	%hemol	MAYO
Osmotic Fragility, 0.60 g/dL NaCl	**90**	**H**	14-74	%hemol	MAYO
Osmotic Fragility, 0.65 g/dL NaCl	**91**	**H**	4-40	%hemol	MAYO
Osmotic Fragility, 0.75 g/dL NaCl	**92**	**H**	1-11	%hemol	MAYO

```
------------------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.
```

Osmotic Fragility Comment	.				MAYO
Shipping Control Vial	Received				MAYO
Spherocytosis Interpretation	SEE BELOW				MAYO

```
Osmotic fragility testing: Increased red blood cell lysis
EMA binding test (band 3 assay) by flow cytometry: Decreased

Interpretation: Osmotic Fragility and EMA binding (Band 3)
results are supportive of a diagnosis of hereditary
spherocytosis in the correct clinical context.  However, it
is important to note that similar OF and EMA binding
results can also be seen in congenital dyserythropoietic
anemia, type II. Furthermore, decreased fluorescence has
been reported in other rare blood cell disorders such as
hereditary pyropoikilocytosis, Southeast Asia ovalocytosis,
and cryohydrocytosis.  Therefore, correlation with the
patient's clinical and family history and persistent
peripheral blood smear findings is necessary for a
definitive diagnosis.

If genotyping is desired, a sequencing panel is available.
If applicable, please order the Hereditary Hemolytic Anemia
Comprehensive Sequencing (test code, NGHHA) and fill out
the information sheet.

If splenectomy is under consideration, please see Iolascon
A et al. 2017 PMID 28550188, for disorder-specific
recommendations of indications and contraindications for
splenectomy in hereditary hemolytic anemia.
```

Reviewed By	Wanda Barber				MAYO
Band 3 Fluoresence Staining, RBC	**Decreased**	**AB**			MAYO

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

B716000001
WX0000003312
Printed D&T: 09/17/20 14:33

Ordered By: CLIENT CLIENT
WX00000000001886

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
WX0000003312 F 09/05/2001 19 Y

Referral Testing

Collected: 09/16/2020 09:46 Received: 09/16/2020 09:46

Test Name	Result	Flag	Ref-Ranges	Units	Site

```
-------------------REFERENCE VALUE--------------------------
Expected result is normal

-------------------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.
```

Peripheral Blood Smear Review — SEE BELOW — MAYO

```
RESULT: Review of blood smear reveals a subset of spherocytes.

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
```

Complete and print.

Reset Form

MAYO CLINIC LABORATORIES

Metabolic Hematology Patient Information

Instructions: The information requested below is important for interpretation of test results. To help us provide the best possible service, answer the questions completely and **send the paperwork with the specimen**. All answers will be kept confidential.

Patient Information

Name *(Last, First, Middle)*	Birth Date *(mm-dd-yyyy)*	Gender ☐ Male ☐ Female
Referring Provider Name *(Last, First)*	Phone	Email

Ethnic Origin/Race (Check all that apply.)

☐ African ☐ Arab ☐ Caucasian ☐ Hispanic ☐ Mediterranean ☐ Southeast Asian
☐ Other (specify): _____

Clinical History

CBC Data

HGB: _____
HCT: _____
RBC: _____
MCV: _____
MCH: _____
MCHC: _____
RDW: _____
Retics: _____
Ferritin: _____

Relevant Clinical Information

☐ Asymptomatic ☐ Symptomatic: _____
☐ Acquired ☐ Lifelong/familial
Recent transfusion: ☐ Yes ☐ No Last transfusion date *(mm-dd-yyyy)*: _____
Hydroxyurea: ☐ Yes ☐ No
Family history: ☐ Yes ☐ No Disorder/relation to patient: _____
Blood smear shows: _____

Indication for Testing (See Metabolic Hematology Profile Comparison Chart)

Hemoglobin Disorder (consider THEVP or HBELC)

☐ Genetic counseling or prenatal
☐ Abnormal newborn screen
☐ Anemia ☐ Microcytosis
☐ Other: _____
☐ Monitoring of Hb fractions (order HGBCE)
☐ Cyanosis/Hypoxia (order MEVP + P50B)

Hemolytic Anemia (consider HAEVP, RBCME, or EEEVP)

Suspect
☐ HS ☐ HE ☐ HPP ☐ HSt
☐ Enzyme disorder: _____
Coombs: ☐ Pos ☐ Neg
Splenectomy: ☐ Yes ☐ No

Erythrocytosis (consider REVE)

JAK2 V617F: ☐ Pos ☐ Neg ☐ Not done
JAK2 Exon 12: ☐ Pos ☐ Neg ☐ Not done
Serum Epo: _____ p50 result: _____
Phlebotomy: ☐ Yes ☐ No
☐ Smoker ☐ Sleep apnea
☐ Cardio/pulmonary Hx
☐ _____

Test Reflex Options

As part of HBELC, THEVP, HAEVP, REVE and MEVP evaluations, the following 4 options are available:

1. Do **NOT** perform molecular testing.
2. Add only alpha globin deletion/duplication testing for common alpha thalassemias.
3. Mayo expert selection of relevant molecular testing (if needed) to explain/exclude: _____
4. Perform the following tests regardless of protein results: _____

Additional Clinical Information

Print

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

New Test Activation

Effective Date	10/27/2020
Name	von Willebrand Disease Gene Sequencing
Code	VONWI
CPT Code(s)	81408 ZB6I4
Notes	

Specimen Requirements

Specimen Required	Draw blood in lavender EDTA tube. Send 5.0 mL whole blood (3.0 minimum) at room temperature.
Alternate Specimen	Yellow top (ACD) Sodium heparin green top
Rejection Criteria	Plasma
Stability	Room temperature: 14 days; Refrigerated: 14 days; Frozen: Unacceptable

Performing Information

Methodology	Next Generation Sequencing
Reference Range	See report
Performed Days	Weekly
Turnaround Time	4 - 6 weeks
Performing Laboratory	Quest SJC

Interface Information

Legacy Code[1]	VONWI
Interface Order Code	3400356

Result Code	Name	LOINC Code	AOE/Prompt[2]
3400355	vWF Disease Gene Seq	40970-6	No
3400354	Clinical Info	55752-0	**Yes**

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003091 M 06/30/1962 58 Y

Referral Testing

Collected: 07/27/2020 13:58 Received: 07/27/2020 13:58

Test Name	Result	Flag	Ref-Ranges	Units	Site

von Willebrand Disease Gene Sequencing

vWF Disease Gene Seq — SEE NOTE — QUESC

RESULT: NEGATIVE

Interpretation: Nucleotide sequence analysis indicates that this individual is negative for clinically significant single nucleotide variants, small insertions and deletions, and larger copy number variants in the analyzed regions (see below) of the von Willebrand Factor (vWF) gene. Benign and likely benign variants/polymorphisms are not reported. This negative result does not rule out a clinical diagnosis of all types of von Willebrand disease.

von Willebrand disease (VWD) is the most common inherited bleeding disorder, affecting approximately 1% of the general population. It results from quantitative or qualitative defects of the von Willebrand factor (VWF) protein. Pathogenic variants in the VWF gene (located on chromosome 12p13.3) can cause reduced synthesis of VWF protein, or structural and functional abnormalities in the VWF protein, leading to various types of VWD.

In this assay, sheared genomic DNA fragments representing the entire coding region and the splice junction sites of the VWF gene (NM 000552.3) are selectively enriched through exon capture, and then subjected to nucleotide sequence analysis on a massively parallel sequencing platform. To avoid pseudogene interference, long range PCR (LR-PCR) is performed for exons 23-28. The LR-PCR product is processed and included in the sequencing reaction. Exon level, copy number variants are detected by bioinformatic analysis of the sequencing and confirmed by a custom targeted microarray. However, due to the pseudogene, exons 23-28 are excluded from copy number analysis. This analysis will identify variants associated with Type II (subtypes, A, B, M, and N) and some forms of Type I and Type III VWD (see http://www.shef.ac.uk/vwf/vwd.html). Since genetic variation and other factors can affect the accuracy of this test, results should always be interpreted in light of clinical and familial data. Benign and likely benign variants with no known clinical significance are reported only by request.

The classification and interpretation of the variants identified in this DNA assessment reflect the current state of Quest Diagnostics' understanding at the time this report was issued. Variant classification and interpretation are subject to professional judgment, and may change for a variety of reasons, including but not limited to, improvements in classification techniques, availability of

Example Client, XYZ123
1234 Warde Road
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003091 M 06/30/1962 58 Y

Referral Testing

Collected: 07/27/2020 13:58 Received: 07/27/2020 13:58

Test Name	Result	Flag	Ref-Ranges	Units	Site

additional information, and observation of a variant in more patients. Health care providers should verify a variant's classification prior to taking any clinical action. This test result should be used in conjunction with the health care provider's clinical evaluation and other medically established means to help with a diagnosis and treatment plan. For questions regarding variant classification updates, please call Quest Diagnostics at 866-GENEINFO (436-3463) to speak to a genetic counselor or laboratory director.

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

Clinical Info blood QCRL

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Existing Test	
Effective Date	10/19/2020
Name	Aldosterone, LC/MS/MS
Code	ALDMS
Interface Order Code	3435340
Legacy Code	ALDMS
Notes	Alternate specimen changes.
Required Testing Changes	
Alternate Specimen	Plasma: Lavender EDTA, Sodium heparin (green-top), Lithium heparin (green-top)

Update Existing Test	
Effective Date	9/17/2020
Name	Chlamydia and Neisseria Nucleic Acid by TMA
Code	CHGTM
Interface Order Code	3091010
Legacy Code	CHGCRNA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required for testing. Endocervical, vaginal or male urethral swab specimens in APTIMA Combo II or **Aptima Multitest** transport medium. First catch urine in APTIMA Combo II Urine Transport Tube. Liquid level must fall between the two black indicator lines. Minimum 2.0 mL Aptima Combo II Urine transport media is currently unavailable.
Alternate Specimen	**No alternate available.**
Stability	Swab in APTIMA Combo II or **Aptima Multitest** transport medium Urine in Aptima Combo II urine transport tube Room temperature: 30 days Refrigerated: 30 days Frozen -20°C: 90 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Existing Test	
Effective Date	9/17/2020
Name	Chlamydia trachomatis Nucleic Acid by TMA
Code	CHRNA
Interface Order Code	3091100
Legacy Code	CHRNA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required for testing. Endocervical, vaginal, or male urethral swab specimens in APTIMA Combo II or **Aptima Multitest** transport medium. First catch urine in APTIMA Combo II Urine Transport Tube. Liquid level must fall between the two black indicator lines. Minimum 2.0 mL. Dedicated specimens are required. If Chlamydia and Neisseria are both ordered one sample may be sent. Specimens used in other assay will not be tested. Aptima Combo II Urine transport media is currently unavailable.
Alternate Specimen	**No alternate available.**
Stability	Swab in APTIMA Combo II or **Aptima Multitest** transport medium Urine in Aptima Combo II urine transport tube Room temperature: 30 days Refrigerated: 30 days Frozen -20°C: 90 days

Update Existing Test	
Effective Date	10/19/2020
Name	Copper, Random Urine
Code	COPRU
Interface Order Code	3700000
Legacy Code	COPRU
Notes	Reference range change.
Required Testing Changes	
Reference Range	**<87 mcg/g creat**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Existing Test	
Effective Date	9/17/2020
Name	MyoMarker Panel 3
Code	FMP3
Interface Order Code	3800044
Legacy Code	FMP3
Notes	Specimen volume changes
Required Testing Changes	
Specimen Required	Draw blood in a red-top tube. Centrifuge, separate and send **5.0 mL** serum (**4.0 mL** minimum) refrigerated in a screw-capped plastic vial.

Update Existing Test	
Effective Date	10/5/2020
Name	Formic Acid, Serum/Plasma
Code	FORMA
Interface Order Code	3502910
Legacy Code	FORMIC
Notes	
Required Testing Changes	
Specimen Required	Draw blood in a plain red-top tube. Centrifuge, separate serum from cells, and send 2.0 mL serum **(0.7 mL minimum)** refrigerated in a screw-capped plastic vial.
Stability	Room temperature: 7 days; Refrigerated: 30 days; **Frozen: 15 months**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Existing Test	
Effective Date	9/17/2020
Name	Nesseria gonorrhoeae Nucleic Acid by TMA
Code	GCRNA
Interface Order Code	3091200
Legacy Code	GCRNA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required for testing. Endocervical, vaginal or male urethral swab specimens in APTIMA Combo II or **Aptima Multitest** transport medium. First catch urine in APTIMA Combo II Urine Transport Tube. Liquid level must fall between the two black indicator lines. Minimum 2.0 mL urine in sterile specimen cup. Dedicated specimens are required. If Chlamydia and Neisseria are both ordered one sample may be sent. Specimens used in other assays will not be tested. Aptima Combo II Urine Transport media is currently unavailable.
Alternate Specimen	**No alternate available.**
Stability	Swab in APTIMA Combo II or **Aptima Multitest** transport medium Urine in APTIMA Combo II urine transport tube Room temperature: 30 days Refrigerated: 30 days Frozen -20°C: 90 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Existing Test

Effective Date	9/17/2020
Name	Immunoglobulin G (IgG) Subclasses
Code	IGSUB
Interface Order Code	3004000
Legacy Code	IGGSUB
Notes	Reference range change.

Required Testing Changes

Reference Range

Years:	IgG1 mg/dL	IgG2 mg/dL	IgG3 mg/dL	IgG4 mg/dL
0-2	194-842	23-300	19-85	1-78
2-4	315-945	36-225	17-68	1-54
4-6	306-945	61-345	10-122	2-113
6-8	288-918	44-375	16-85	1-99
8-10	432-1020	72-430	13-85	2-93
10-12	423-1060	76-355	17-173	2-115
12-14	342-1150	100-455	28-125	4-136
14-18	315-855	64-495	23-196	11-157
>18	382-929	242-700	22-176	**4-86**

Update Existing Test

Effective Date	9/17/2020
Name	Infliximab Quant with Reflex to Ab to Infliximab, Serum
Code	INFX
Interface Order Code	3516100
Legacy Code	INFX
Notes	

Required Testing Changes

Specimen Required	Draw blood in a red-top tube. Centrifuge, separate serum from cells, and send 1.0 mL serum (0.5 mL minimum) frozen in a screw-capped plastic vial. **For 12 hours before specimen collection do not take supplements or vitamins containing biotin (vitamin B7).**
Rejection Criteria	Grossly hemolyzed or icteric samples, **SST**
Methodology	Infliximab: Selective Reaction Monitoring LC-MS/MS Antibody: Electrochemiluminescent Bridging Immunoassay with Acid Dissociation

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Existing Test	
Effective Date	10/26/2020
Name	PML-RARA t(15;17), Quantitative RT-PCR
Code	PMPCR
Interface Order Code	3427400
Legacy Code	PMPCR
Notes	Changes to specimen requirements, Performed days, TAT and LOINC updates.

Required Testing Changes	
Specimen Required	Draw blood in a lavender EDTA tube. Send **5.0** mL whole blood (4.0 mL minimum) room temperature in original tube.
Performed Days	**Sunday - Saturday**
Turnaround Time	**6 - 7 days**

Result Code	Name	LOINC Code	AOE/Prompt[2]
3427410	Specimen Source	31208-2	**Yes**
3427420	Sample ID	**57723-9**	**Yes**
3427430	PML-RARA transcript level	**72274-4**	No
3427440	Interpretation	**50398-7**	No

Update Existing Test	
Effective Date	8/26/2020
Name	T3, Reverse, LC/MS/MS
Code	RT3
Interface Order Code	3426700
Legacy Code	RT3Q
Notes	

Required Testing Changes	
Rejection Criteria	SST, Grossly lipemic or hemolyzed samples, plasma

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Update Existing Test	
Effective Date	9/17/2020
Name	Trichomonas vaginalis RNA, Qualitative
Code	TRIVA
Interface Order Code	3093500
Legacy Code	TRIVA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required. Collect endocervical, vaginal or male urethral swab and place in Aptima Combo II or **Aptima Multitest** transport media. First void urine in Aptima urine transport tube. Liquid level must fall between the two black indicator lines. Dedicated specimens are required. **Aptima Combo II Urine transport media is currently unavailable.**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2020

Inactivate Test With Replacement

Effective Date	10/27/2020

Inactivated Test

Name	MuSK Antibody Test
Code	MUSKQ
Legacy Code[1]	MUSKQ
Interface Order Code	3429400
Notes	

Replacement Test

Name	Muscle-Specific Kinase (MuSK) Antibody, IgG
Code	MUSKE
CPT Code(s)	83519
Notes	

Specimen Requirements

Specimen Required	Draw blood in SST. Centrifuge, separate serum from cells, and send 2.0 mL serum (0.5 mL minimum) refrigerated in a screw-capped plastic vial.
Rejection Criteria	Grossly lipemic, icteric, or hemolyzed specimens
Stability	Room temperature: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month

Performing Information

Methodology	Quantitative Radioimmunoassay
Reference Range	Negative 0.00 - 0.03 nmol/L Positive 0.04 nmol/L or greater
Performed Days	Monday, Thursday
Turnaround Time	3 - 9 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information

Legacy Code[1]	MUSKE
Interface Order Code	3600115

Result Code	Name	LOINC Code	AOE/Prompt[2]
3600115	Muscle-Specific Kinase (MuSK) Antibody, IgG	51716-9	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003094 F 07/12/2010 10 Y

Referral Testing

Collected: 08/27/2020 10:03 Received: 08/27/2020 10:03

Test Name	Result	Flag	Ref-Ranges	Units	Site
Muscle-Specific Kinase (MuSK) Antibody, IgG	**0.05**	**H**	0.00-0.03	nmol/L	ARUP

```
INTERPRETIVE INFORMATION: Muscle-Specific Kinase (MuSK) Ab,
                          IgG
Negative . . . . . 0.00-0.03 nmol/L
Positive . . . . . 0.04 nmol/L or greater

Muscle-specific kinase (MuSK) antibody is found in a subset
of patients with myasthenia gravis, primarily those
seronegative for muscle acetylcholine receptor (AChR)
antibody. Decreasing antibody levels may be associated with
therapeutic response; therefore, clinical correlation must
be strongly considered. A negative test result does not
rule out a diagnosis of myasthenia gravis.

Test developed and characteristics determined by ARUP
Laboratories. See Compliance Statement A: aruplab.com/CS
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Julio C. Delgado, MD, MS
```

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

Inactivate Test With Replacement

Effective Date	9/28/2020

Inactivated Test

Name	Peanut IgE Component Panel
Code	PNTCP
Legacy Code[1]	PNTCP
Interface Order Code	3000134
Notes	

Replacement Test

Name	Peanut IgE Component Panel
Code	PNTCT
CPT Code(s)	86008 x 6
Notes	This panel does not include a peanut allergen screen.

Specimen Requirements

Specimen Required	Draw blood in a SST. Centrifuge, remove serum from cells and send 1.0 mL serum (0.5 mL minimum) refrigerated in a screw-capped plastic vial.
Alternate Specimen	Serum: Red-top
Stability	Room temperature: Unacceptable; Refrigerated: 7 days; Frozen: 14 days

Performing Information

Methodology	Fluorescent Enzyme Immunoassay
Reference Range	Ara h 1 (f422) <0.10 kU/L Ara h 2 (f423) <0.10 kU/L Ara h 3 (f424) <0.10 kU/L Ara h 6 (f447) <0.10 kU/L Ara h 8 (f352) <0.10 kU/L Ara h 9 (f427) <0.10 kU/L
Performed Days	Monday - Friday
Turnaround Time	1 - 3 days
Performing Laboratory	Warde Medical Laboratory

Interface Information

Legacy Code[1]	PNTCT
Interface Order Code	3000337

Result Code	Name	LOINC Code	AOE/Prompt[2]
3000338	Ara h 1 (f422)	58779-0	No
3000339	Ara h 1 Class	81991-2	No
3000340	Ara h 2 (f423)	58778-2	No

3000341	Ara h 2 Class	81991-2	No
3000342	Ara h 3 (f424)	58777-4	No
3000343	Ara h 3 Class	81992-0	No
3000344	Ara h 6 (f447)	90880-6	No
3000345	Ara h 6 Class	87718-3	No
3000346	Ara h 8 (f352)	63477-4	No
3000347	Ara h 8 Class	81982-1	No
3000348	Ara h 9 (f427)	64965-7	No
3000349	Ara h 9 Class	81994-6	No
3069000	Allergy Interpretation	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 31 Y

Allergy Testing - Panels

Collected: 09/17/2020 14:35 Received: 09/17/2020 14:35

Test Name	Result	Flag	Ref-Ranges	Units	Site
Peanut Component Panel					
Ara h 1 (f422)	**0.94**	**H**	<0.10	kU/L	WMRL
Ara h 1 Class	CLASS 2				WMRL
Ara h 2 (f423)	**1.07**	**H**	<0.10	kU/L	WMRL
Ara h 2 Class	CLASS 2				WMRL
Ara h 3 (f424)	<0.10		<0.10	kU/L	WMRL
Ara h 3 Class	CLASS 0				WMRL
Ara h 6 (f447)	**0.83**	**H**	<0.10	kU/L	WMRL
Ara h 6 Class	CLASS 2				WMRL
Ara h 8 (f352)	<0.10		<0.10	kU/L	WMRL
Ara h 8 Class	CLASS 0				WMRL
Ara h 9 (f427)	**1.29**	**H**	<0.10	kU/L	WMRL
Ara h 9 Class	CLASS 2				WMRL

Sensitization to Ara h 1, Ara h 2, Ara h 3, and Ara h 6 may indicate an increased risk of systemic allergic response upon exposure to peanut. Sensitization to Ara h 8 and Ara h 9 may be associated with cross-reactivity and sensitization to birch pollen and peaches and peach related fruits, respectively. Reactivity to whole peanut without reactivity to peanut components may indicate low to moderate sensitization to peanut. Results from peanut-specific IgE testing must be interpreted in the context of patient's clinical evaluation and history of allergen reactivity.

Allergy Interpretation — See Below — WMRL

CLASS	kU/L	Level of Allergen Specific IgE Antibody
0	<0.10	Undetectable
0/1	0.10 - 0.34	Very Low Level
1	0.35 - 0.69	Low Level
2	0.70 - 3.49	Moderate Level
3	3.50 - 17.4	High Level
4	17.5 - 49.9	Very High Level
5	50.0 - 100.0	Very High Level
6	>100.0	Very High Level

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

B717000004
WX0000003039
Printed D&T: 09/17/20 15:00

Ordered By: CLIENT CLIENT
WX00000000001595

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