Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Update Notes

Update Summary		
New Test Activation	4/27/2021	ADIPO - "Adiponectin"
New Test Activation	4/27/2021	BFGAM - "Beta-fibrinogen-455G->A Mutation"
New Test Activation	4/27/2021	BVVSS - "Bacterial Vaginosis/Vaginitis, SureSwab®"
New Test Activation	4/27/2021	F13MA - "Factor XIII V34L Mutation Analysis"
New Test Activation	4/27/2021	HP6AM - "Herpesvirus 6 Ab (IgM), Serum"
New Test Activation	4/27/2021	HPA1G - "Human Platelet Antigen 1 Genotype"
New Test Activation	4/27/2021	HPCDP - "Histoplasma capsulatum DNA, Real-Time PCR"
New Test Activation	4/27/2021	MGUCR - "Magnesium Urine with Creatinine Urine, Random"
New Test Activation	4/27/2021	RITFC - "Rituxan Sensitivity (CD20)"
Update Existing Test	4/27/2021	ACUTE - "Flow Cytometry, Acute Panel"
Update Existing Test	4/19/2021	BABID - "Blastomyces Antibody, ID"
Update Existing Test	4/27/2021	BCELL - "Flow Cytometry, B-Cell Neoplasia Panel"
Update Existing Test	4/19/2021	CANID - "Candida albicans Antibody, Immunodiffusion"
Update Existing Test	4/19/2021	COCAF - "Coccidioides Antibodies (CF)"
Update Existing Test	4/19/2021	HISCF - "Histoplasma Antibodies (CF)"
Update Existing Test	4/26/2021	KLFU - "Kappa/Lambda Light Chains, Free with Ratio, Urine"
Update Existing Test	4/27/2021	MYE - "Flow cytometry, Plasma Cell Panel"
Update Existing Test	4/26/2021	NTXUR - "N-Telopeptides, Urine, Random"
Update Existing Test	4/12/2021	RAGD - "Rotavirus Ag Detection"
Update Existing Test	4/27/2021	SBCLL - "Flow Cytometry, B-Cell Clonality Screen"
Update Existing Test	4/27/2021	TCELL - "Flow Cytometry, T-Cell Neoplasia Panel"
Inactivate Test With Replacement	4/5/2021	NGONO - "N. gonorrhoeae Ab" replaced by NSGON - "Neisseria gonorrhoeae RNA, TMA, Rectal"
Inactivate Test With Replacement	4/27/2021	TES - "Testosterone" replaced by TESM - "Testosterone, Total, LC/MS/MS"
Inactivate Test With Replacement	4/27/2021	TESFM - "Testosterone (TMS), Female/Ped"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Adiponectin		
Code	ADIPO		
CPT Code(s)	83520 RUO		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Serum separator tube (SST) Collect 1.0 mL serum in a SST. 0.5 mL minimum. Collection Instructions: 1. Collect and label sample according to standard protocols. 2. Gently invert tube 5 times immediately after draw. DO NOT SHAKE. 3. Allow blood to clot for 30 minutes. 4. Centrifuge for 10 minutes. 5. Store serum at 2° - 8°C after collection and ship the same day.		
Stability	Room temperature: 72 hours Refrigerated: 7 days Frozen (-20°C): 21 days Frozen (-70°C): Unacceptable		
Performing Information			
Methodology	Enzyme Linked Immunosorbent Assay		
Reference Range	See report		
Performed Days	Monday - Friday		
Turnaround Time	9 - 12 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	ADIPO		
Interface Order Code	3400285		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400285	Adiponectin	47828-9	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/17/2021 16:28 Received: 03/17/2021 16:28

Test Name	Result	Flag	Ref-Ranges	Units	Site
Adiponectin	50.0			ug/mL	QCRL

Reference Range for Female Adiponectin: BMI (kg/meter squared) <25: 5-37 ug/mL; BMI 25-30: 5-28 ug/mL; BMI >30: 4-22 ug/mL.
This test is performed by an Enzyme Linked Immunosorbent Assay (ELISA) method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab, Inc. is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

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

C317000011
WX0000003481
Printed D&T: 03/17/21 16:29

Ordered By: CLIENT CLIENT
WX00000000002063

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Beta-fibrinogen-455G->A Mutation		
Code	BFGAM		
CPT Code(s)	81400 ZB0UL		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA Send 5.0 mL whole blood room temperature in a screw capped plastic vial. *Minimum:* 3.0 mL		
Alternate Specimen	Whole blood: ACD solution A or B (yellow top) Lithium heparin Sodium heparin (green top)		
Rejection Criteria	Frozen specimens		
Stability	Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable		
Performing Information			
Methodology	Polymerase Chain Reaction (PCR); Single Nucleotide Primer Extension		
Reference Range	See report		
Performed Days	Thursday		
Turnaround Time	7 - 10 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	BFGAM		
Interface Order Code	3400261		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400261	Beta-fibrinogen-455G->A Mutation	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 32 Y

Referral Testing

Collected: 03/17/2021 16:36 Received: 03/17/2021 16:36

Test Name	Result	Flag	Ref-Ranges	Units	Site
Beta-fibrinogen-455G->A Mutation	SEE NOTE				QCRL

RESULT: HETEROZYGOUS POSITIVE FOR THE c.-455G>A VARIANT IN THE BETA FIBRINOGEN GENE (GENOTYPE G/A)

Interpretation: This individual has one copy of the c.-455G>A variant in the beta fibrinogen gene. Heterozygosity for the c.-455G->A variant is not associated with increased fibrinogen levels.

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

C317000012
WX0000003039
Printed D&T: 03/17/21 16:37

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Bacterial Vaginosis/Vaginitis, SureSwab®		
Code	BVVSS		
CPT Code(s)	87481 x 4, 87512, 87661, 87799 x 3		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* One vaginal swab One vaginal swab collected in an Aptima® Transport tube. Follow instructions in the Aptima® Vaginal Swab collection or Multitest Collector kit (orange label).		
Rejection Criteria	Transport tubes with 2 swabs, transport tubes with Non-Aptima® swabs, swab transport tubes with no swab, specimens in broken containers, swab submitted in VTM, pap vials, male specimens		
Stability	Room temperature: 7 days Refrigerated: 7 days Frozen: 30 days		
Performing Information			
Methodology	Real-Time Polymerase Chain Reaction (PCR); Transcription-Mediated Amplification (TMA)		
Reference Range	**SureSwab® Bacterial Vaginosis DNA, Quantitative, Real-Time PCR** Lactobacillus Species: See Laboratory report Atopobium Species: See Laboratory report Megashaera Species: See Laboratory report Gardnerella Vaginalis: See Laboratory Report **SureSwab® Trichomonas vaginalis RNA, Qualitative, TMA** T. Vaginalis RNA, QL TMA: Not detected **SureSwab® Candidiasis, PCR** C. Albicans, DNA: Not detected C. glabrata, DNA: Not detected C. Tropicalis, DNA: Not detected C. parapsilosis, DNA: Not detected		
Performed Days	Monday - Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	BVVSS		
Interface Order Code	3400317		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400318	T. vaginalis RNA	46154-1	No

3400319	Lactobacillus species	74669-3	No
3400320	Atopobium vaginae	74667-7	No
3400321	Megasphaera species	74762-6	No
3400322	Gardnerella vaginalis	74668-5	No
3400323	C. albicans, DNA	62460-1	No
3400324	C. glabrata, DNA	69563-5	No
3400325	C. tropicalis, DNA	72391-6	No
3400326	C. parapsilosis, DNA	72495-5	No
3400327	BV Category:	69564-3	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/18/2021 08:45 Received: 03/18/2021 08:45

Test Name	Result	Flag	Ref-Ranges	Units	Site
Bacterial Vaginosis/Vaginitis, SureSwab®					
T. vaginalis RNA	NOT DETECTED				QCRL

REFERENCE RANGE: NOT DETECTED

Methodology: Transcription Mediated Amplification (TMA)

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

Test Performed at:
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman MD

Lactobacillus species	NOT DETECTED				QCRL

UNITS OF MEASURE: Log (cells/mL)

Atopobium vaginae	NOT DETECTED				QCRL

UNITS OF MEASURE: Log (cells/mL)

Megasphaera species	NOT DETECTED				QCRL

UNITS OF MEASURE: Log (cells/mL)

Gardnerella vaginalis	NOT DETECTED				QCRL

UNITS OF MEASURE: Log (cells/mL)

C. albicans, DNA	NOT DETECTED				QCRL
C. glabrata, DNA	NOT DETECTED				QCRL
C. tropicalis, DNA	NOT DETECTED				QCRL
C. parapsilosis, DNA	NOT DETECTED				QCRL

REFERENCE RANGE: NOT DETECTED

Methodology: Real-Time PCR

This test was developed and its analytical performance
characteristics have been determined by Quest Diagnostics
Infectious Disease. It has not been cleared or approved
by FDA. This assay has been validated pursuant to the

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/18/2021 08:45 Received: 03/18/2021 08:45

Test Name	Result	Flag	Ref-Ranges	Units	Site

CLIA regulations and is used for clinical purposes.

Test Performed at:
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman MD

BV Category: NOT DETECTED QCRL

REFERENCE RANGE:
BV Category: NOT SUPPORTIVE

Methodology: Real-Time PCR

NOT SUPPORTIVE OF BV: The pattern of results is not supportive of a diagnosis of BV: 1) Presence of Lactobacillus spp., G. vaginalis levels less than 6.0 log cells/mL, and absence of A. vaginae and Megasphaera spp; or 2) Absence of all targeted organisms; or 3) Absence of Lactobacillus spp. plus G. vaginalis detected at levels less than 6.0 log cells/mL and absence of A. vaginae and Megasphaera spp.

EQUIVOCAL FOR BV: The pattern of results is neither supportive nor not supportive of a diagnosis of BV. The patient may be in transition into or out of BV: Presence of Lactobacillus spp. plus G. vaginalis (greater or equal to 6.0 log cells/mL) and/or one of the other BV-associated pathogens.

SUPPORTIVE OF BV: The pattern of results is supportive of a diagnosis of BV: Absence of Lactobacillus spp. and presence of G. vaginalis greater than or equal to 6.0 log cells/mL and/or one or both of the other BV-associated pathogens.

Concentration for Lactobacilli (L. acidophilus/crispatus, L. jensenii) are collectively reported under the term 'Lactobacillus spp.', as these species are among the peroxide producing Lactobacilli thought to be protective against bacterial vaginosis. Atopobium vaginae, Megasphaera spp., and Gardnerella (greater than 6.0 log cells/mL) have been associated with vaginosis when present in the absence of peroxidase producing Lactobacilli.

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/18/2021 08:45 Received: 03/18/2021 08:45

Test Name	Result	Flag	Ref-Ranges	Units	Site

Infectious Disease. 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 Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman MD

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Factor XIII V34L Mutation Analysis		
Code	F13MA		
CPT Code(s)	81400 ZB0VU		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA 5.0 mL whole blood collected in an EDTA lavender top tube. *Minimum:* 3.0 mL		
Alternate Specimen	ACD solution A or B (yellow top) tube, Lithium heparin (green top) tube, Sodium Keparin (green top) tube.		
Stability	Room temperature: 8 days Refrigerated: 8 days Frozen: Do not freeze		
Performing Information			
Methodology	Polymerase Chain Reaction (PCR); Single Nucleotide Primer Extension		
Reference Range	See report		
Performed Days	Thursday		
Turnaround Time	7 - 10 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	F13MA		
Interface Order Code	3400283		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400283	Factor XIII V34L Mutation Analysis	50750-9	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/18/2021 10:48 Received: 03/18/2021 10:48

Test Name	Result	Flag	Ref-Ranges	Units	Site
Factor XIII V34L Mutation Analysis	SEE NOTE				QCRL

RESULT: HETEROZYGOUS POSITIVE FOR THE p.V34L VARIANT IN THE FACTOR XIII GENE

Interpretation: This patient has one copy of the p.V34L variant in the Factor XIII gene. The p.V34L variant has been associated with a protective effect against myocardial infarction and an increased risk for intracerebral hemorrhage.

Factor XIII (FXIII) plays a crucial role in fibrin crosslinking during the coagulation process. One variant in the FXIII gene, p.V34L, is associated with higher rates of FXIII activity and appears to be protective against myocardial infarction (MI). The presence of the p.V34L variant (with a frequency of 0.50 in the white population) causes an approximate 126% increase in FXIII activity in heterozygotes and 176% in homozygotes (Thromb Haemost 1998; 80:704). The protective effect of elevated FXIII activity is not well understood but it may interfere with fibrin crosslinking directly or indirectly.

The p.V34L variant is detected by polymerase chain reaction amplification of a portion of exon 2 of the FXIII gene, single nucleotide primer extension, and detection of fluorescent extension products on an automated DNA sequencer.

This analysis evaluates only the specified mutation in the FXIII gene and cannot detect other FXIII mutations, or mutations in other genes, that may similarly affect FXIII activity. Furthermore, genetic variation and other factors can affect the accuracy of direct mutation testing. Therefore, the results of this testing should always be interpreted in light of the appropriate 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 (436-3463).

This test is 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

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/18/2021 10:48 Received: 03/18/2021 10:48

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

C318000004
WX0000003481
Printed D&T: 03/18/21 10:54

Ordered By: CLIENT CLIENT
WX00000000002063

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Herpesvirus 6 Ab (IgM), Serum		
Code	HP6AM		
CPT Code(s)	86790		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Red top Send 0.5 mL serum room temperature in a screw capped plastic vial. *Minimum:* 0.1 mL serum		
Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days		
Performing Information			
Methodology	Immunofluorescence assay		
Reference Range	<1:20		
Performed Days	Monday - Friday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	HP6AM		
Interface Order Code	3400287		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400287	Herpesvirus 6 Ab (IgM), Serum	25417-7	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/19/2021 16:00 Received: 03/19/2021 16:00

Test Name	Result	Flag	Ref-Ranges	Units	Site
Herpesvirus 6 Ab (IgM), Serum	**1:40**	**H**			QCRL

```
REFERENCE RANGE:     <1:20

         INTERPRETIVE CRITERIA:
                     <1:20  Antibody Not Detected
                     > or = 1:20  Antibody Detected

Human Herpesvirus 6 (HHV-6) infects T-lymphocytes,
and has been identified as an etiologic agent of
exanthema subitum. Rises in antibody titers to
HHV-6 have been detected during infection with
other viruses.

Serologic evidence of acute infection or
reactivation of HHV-6 is demonstrated by a
significant rise or seroconversion of IgG
and IgM titers.

This test was developed and its analytical
performance characteristics have been determined
by Quest Diagnostics Infectious Disease. 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 Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA  92675-2042     H J Batterman 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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Human Platelet Antigen 1 Genotype		
Code	HPA1G		
CPT Code(s)	81105 ZB0VY		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA Send 5.0 mL whole blood at room temperature in a screw capped plastic vial. *Minimum:* 1.0 mL		
Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: Unacceptable		
Performing Information			
Methodology	DNA-Based Capture Binding Assay		
Reference Range	See report		
Performed Days	Tuesday		
Turnaround Time	4 - 6 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	HPA1G		
Interface Order Code	3400286		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400286	Human Platelet Antigen 1 Genotype	50599-0	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/19/2021 16:11 Received: 03/19/2021 16:11

Test Name	Result	Flag	Ref-Ranges	Units	Site
Human Platelet Antigen 1 Genotype	SEE NOTE				QCRL

HPA-1a / 1a Homozygous

4631

HPA-1a is recognized as the common genotype in 97% of the population. The presence of HPA-1b platelet antigen polymorphism is associated with neonatal alloimmune thrombocytopenia and post-transfusion purpura.

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

C319000008
WX0000003481
Printed D&T: 03/19/21 16:12

Ordered By: CLIENT CLIENT
WX00000000002063

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Histoplasma capsulatum DNA, Real-Time PCR		
Code	HPCDP		
CPT Code(s)	87798		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA Send 5.0 mL whole blood refrigerated in a lavender screw capped vial. *Minimum:* 0.5 mL		
Alternate Specimen	Whole blood collected in ACD (yellow top) tube. 1.0 mL bronchial lavage (BAL)/Wash, CSF, Random Urine, Tissue collected in a sterile leak proof container.		
Stability	*Whole blood:* Room temperature: 48 hours Refrigerated: 7 days Frozen: Unacceptable *BAL/Wash/CSF, Urine or Tissue:* Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 7 days		
Performing Information			
Methodology	Real-Time Polymerase Chain Reaction		
Reference Range	Not detected		
Performed Days	Monday - Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	HPCDP		
Interface Order Code	3400277		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400279	Specimen Source	31208-2	**Yes**
3400278	Histoplasma capsulatum DNA	5015-3	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/19/2021 16:16 Received: 03/19/2021 16:16

Test Name	Result	Flag	Ref-Ranges	Units	Site
Histoplasma capsulatum DNA, Real-Time PCR					
Specimen Source	BLOOD				QCRL
Histoplasma capsulatum DNA	**DETECTED**	**AB**			QCRL

REFERENCE RANGE: NOT DETECTED

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Infectious Disease. 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 Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman 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

C319000009
WX0000003481
Printed D&T: 03/19/21 16:17

Ordered By: CLIENT CLIENT
WX00000000002063

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Magnesium Urine with Creatinine Urine, Random		
Code	MGUCR		
CPT Code(s)	83735, 82570		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Random urine Submit 10.0 mL of a well mixed random collection. Adjust pH to <3.0 with 6n HCl prior to aliquoting for testing. Refrigerate during and after collection. *Minimum:* 0.5 mL		
Stability	Room temperature: 4 days Refrigerated: 7 days Frozen: 90 days		
Performing Information			
Methodology	Inductively Coupled Plasma/Mass Spectrometry (ICP/MS)		
Reference Range	**Magnesium, Random Urine** Adult: 22-130 mg/g creat **Creatinine, Random Urine** ≤6 months: 2-28 mg/dL 7 - 11 months: 2-31 mg/dL 1 - 2 years: 2-110 mg/dL 3 - 8 years: 2-130 mg/dL 9 - 12 years: 2-160 mg/dL >12 years Male: 20-320 mg/dL >12 years Female: 20-275 mg/dl		
Performed Days	Tuesday - Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	MGUCR		
Interface Order Code	3400288		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400290	Magnesium, Random Urine	13474-2	No
3400289	Creatinine, Random Urine	2161-8	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/19/2021 16:42 Received: 03/19/2021 16:42

Test Name	Result	Flag	Ref-Ranges	Units	Site
Magnesium, Urine with Creatinine, Random					
Magnesium, Random Urine	**145**	**H**	22-130	mg/g creat	QCRL
Creatinine, Random Urine	432		20-275	mg/dL	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

C319000010
WX0000003481
Printed D&T: 03/19/21 16:43

Ordered By: CLIENT CLIENT
WX00000000002063

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

New Test Activation			
Effective Date	4/27/2021		
Name	Rituxan Sensitivity (CD20)		
Code	RITFC		
CPT Code(s)	86356		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Green sodium heparin Send 5.0 mL whole blood room temperature in a screw capped plastic vial. *Minimum:* 1.0 mL		
Alternate Specimen	Whole blood or Bone marrow in lavender EDTA tube, or Yellow ACD B, Fresh (unfixed) tissue, Buffy coat, CSF, Tissue (Biopsy fluid, Pleural fluid)		
Rejection Criteria	Clotted, frozen of fixed sample		
Stability	Room temperature: 72 hours Refrigerated: Unacceptable Frozen: Unacceptable		
Performing Information			
Methodology	Flow Cytometry		
Reference Range	See report		
Performed Days	Sunday - Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	RITFC		
Interface Order Code	3400295		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400296	Specimen Source	31208-2	**Yes**
3400297	Appearance	33511-7	No
3400298	Viable cells/100 cells	33194-2	No
3400299	Cells CD20/100 cells	20595-5	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/19/2021 16:48 Received: 03/19/2021 16:48

Test Name	Result	Flag	Ref-Ranges	Units	Site
Rituxan Senitivity (CD20)					
Specimen Source	BLOOD				QCRL
Appearance	SEE NOTE				QCRL

The sample consists of 41% granulocytic cells, 46% lymphocytoid cells, and 8% monocytoid cells.

Viable cells/100 cells	64			%	QCRL
Cells CD20/100 cells	SEE NOTE				QCRL

0% of the lymphocytes express the CD19+phenotype.

0% of selected lymphocytes are positive for CD20.

Interpretive Guide:

Rituxan is a genetically engineered chimeric murine/human monoclonal antibody directed against CD20 antigen found on the surface of normal and malignant B lymphocytes (1). This antigen is expressed on the surface of >90% of B cell non-Hodgkin's lymphomas (NHL) and binding to it is a necessary prerequisite for Rituxan's antitumor effect (2). As subtypes of NHL may differ in their response to Rituxan (3,4), determination of drug sensitivity is important in choosing therapy.

References:

1. Reff et a. Depletion of B-cells in vivo by a chimeric mouse human monoclonal antibody to CD20. Blood 83:435-445, 1994.

2. Anderson et al. Expression of human B cell associated antigens on leukemias and lymphomas: A model of human B cell differentiation. Blood 63:1424-1433, 1984.

3. Maloney et al. Results of phase 1 multiple-dose trial in patients with relapsed non-Hodgkin's lymphoma. J Clin Oncol 14:3266-3274, 1997.

4. Maloney et al. IDEC-C2B8 (Rituximab) anti-CD20 monoclonal antibody therapy in patients with relapsed low-grade non-Hodgkin's lymphoma. Blood 90:2188-2195, 1997.

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

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Referral Testing

Collected: 03/19/2021 16:48 Received: 03/19/2021 16:48

Test Name	Result	Flag	Ref-Ranges	Units	Site

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

APRIL 2021

Update Existing Test	
Effective Date	4/27/2021
Name	Acute Leukemia
Code	ACUTE
Interface Order Code	3205300
Legacy Code	ACUTE
Notes	The name of this test is changing.
Required Testing Changes	
Name	**Flow Cytometry, Acute Panel**

Update Existing Test	
Effective Date	4/19/2021
Name	Blastomyces Antibody, ID
Code	BABID
Interface Order Code	3422300
Legacy Code	BABIDQ
Notes	Updates to specimen requirements, and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* Red top Centrifuge, separate serum from cells and send 1.0 mL serum **room temperature** in a screw capped plastic vial. ***Minimum:*** **0.2 mL** ***Transport temperature:*** **Room temperature**
Rejection Criteria	**Gross hemolysis; lipemia; CSF; pleural fluid**
Performing Laboratory	Quest Infectious Disease

Update Existing Test	
Effective Date	4/27/2021
Name	BCELL
Code	BCELL
Interface Order Code	3205000
Legacy Code	BCELL
Notes	The name of this test has changed.
Required Testing Changes	
Name	**Flow Cytometry, B-Cell Neoplasia Panel**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Update Existing Test	
Effective Date	4/19/2021
Name	Candida albicans Antibody, Immunodiffusion
Code	CANID
Interface Order Code	3680440
Legacy Code	CANABAR
Notes	Updates to minimum volume and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* Serum separator tube (SST) Centrifuge, separate serum from cells and send 1.0 mL serum refrigerated in a screw capped plastic vial. ***Minimum:*** **0.2 mL**
Rejection Criteria	**Gross hemolysis; lipemia; CSF; pleural fluid**

Update Existing Test	
Effective Date	4/19/2021
Name	Coccidioides Antibodies (CF)
Code	COCAF
Interface Order Code	3422800
Legacy Code	COCABCFQ
Notes	Updates to rejection criteria.
Required Testing Changes	
Rejection Criteria	**Gross hemolysis; grossly icteric; grossly lipemic**
Performing Laboratory	Quest Infectious Disease

Update Existing Test	
Effective Date	4/19/2021
Name	Histoplasma Antibodies (CF)
Code	HISCF
Interface Order Code	3701970
Legacy Code	HISABCFSP
Notes	Updates to rejection criteria.
Required Testing Changes	
Rejection Criteria	**Gross hemolysis; grossly icteric; grossly lipemic**
Performing Laboratory	Quest Infectious Disease

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Update Existing Test	
Effective Date	4/26/2021
Name	Kappa/Lambda Light Chains, Free with Ratio, Urine
Code	KLFU
Interface Order Code	3434060
Legacy Code	KLFU
Notes	Updates to CPT code, stability, performed days, rejection criteria and reference range.
Required Testing Changes	
CPT Code(s)	**83520 x2** *(Please note this CPT code was corrected from code: 83500 x2 to 83520 x2 which was sent on original April 2021 update.)*
Rejection Criteria	**Microbial contaminated; gross hemolysis**
Stability	Room temperature: 7 days Refrigerated: 21 days **Frozen: 30 days**
Methodology	**Immunoturbidimetry**
Reference Range	**Kappa Light Chain, Free, Urine: ≤ 32.90 mg/L** **Lambda Light Chain, Free, Urine: ≤ 3.79 mg/L** **Kappa/Lambda Light Chains Free with Ratio, Urine: ≤ 8.69**
Performed Days	**Monday - Saturday**

Update Existing Test	
Effective Date	4/27/2021
Name	Myeloma
Code	MYE
Interface Order Code	3205400
Legacy Code	MYE
Notes	The name of this test has changed.
Required Testing Changes	
Name	**Flow cytometry, Plasma Cell Panel**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Update Existing Test	
Effective Date	4/26/2021
Name	N-Telopeptides, Urine, Random
Code	NTXUR
Interface Order Code	3715700
Legacy Code	NTXURSP
Notes	Updates to reference range.
Required Testing Changes	
Reference Range	N-Telopeptides/Creatinine *Male* 0-17 years **Not established** 18-29 years 12-99 nM BCE/mM creat 30-59 years 9-60 nM BCE/mM creat >59 years **Not established** *Female* Premenopausal 4-64 nM BCE/mM creat

Update Existing Test	
Effective Date	4/12/2021
Name	Rotavirus Ag Detection
Code	RAGD
Interface Order Code	3716440
Legacy Code	RAGDSP
Notes	Updates to specimen requirements, alternate specimens and rejection criteria.
Required Testing Changes	
Specimen Required	*Patient Preparation:* **For patients requiring the use of diapers, first line the diaper with clean plastic to prevent absorption. Then transfer 5 g or 5.0 mL of stool specimen from the plastic lined diaper to the sterile container. Do not submit the diaper itself. Cap securely.** *Collect:* Stool **Send 5 g or 5.0 mL fresh stool in a clean, dry, screw capped container without preservative or media.** ***Minimum:* 1.0 mL or 1 g, pea-sized portion of stool**
Alternate Specimen	Rectal swab with fecal material in culturette (no gel).
Rejection Criteria	Leaky specimens and specimens submitted in non screw capped containers are not acceptable and will be rejected. Culturettes with gel are not acceptable. Transport systems containing media, serum, preservatives or detergent. **Diaper**.

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Update Existing Test	
Effective Date	4/27/2021
Name	Shortbcell
Code	SBCLL
Interface Order Code	3205200
Legacy Code	SBCLL
Notes	The name of this test has changed.
Required Testing Changes	
Name	**Flow Cytometry, B-Cell Clonality Screen**

Update Existing Test	
Effective Date	4/27/2021
Name	TCELL
Code	TCELL
Interface Order Code	3205100
Legacy Code	TCELL
Notes	The name of this test has changed.
Required Testing Changes	
Name	**Flow Cytometry, T-Cell Neoplasia Panel**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Inactivate Test With Replacement			
Effective Date	4/5/2021		
Inactivated Test			
Name	N. gonorrhoeae Ab		
Code	NGONO		
Legacy Code[1]	NGONO		
Interface Order Code	3505305		
Notes			
Replacement Test			
Name	Neisseria gonorrhoeae RNA, TMA, Rectal		
Code	NSGON		
CPT Code(s)	87591		
Notes			
Specimen Requirements			
Specimen Required	Use the ATPIMA Unisex Swab Specimen Collection kit (white label) or the APTIMA Vaginal Swab Specimen Collection kit or Multi-Test Collection (orange label). Insert the small, blue shafted collection swab (Unisex kit, NOT the larger white shafted cleansing swab) or the small, pink shafted collection swab (Vaginal kit) approximately 3-5 cm into the rectum. Rotate swab against the rectal wall at least 3 times. Withdraw the swab carefully. Swabs that are grossly contaminated with feces should be discarded and the collection repeated. Remove the cap from the swab specimen transport tube and immediately place the swab into the transport tube. Carefully break the swab shaft at the score line. Re-cap the swab specimen transport tube tightly, label and send room temperature.		
Rejection Criteria	Transport tubes with 2 swabs, transport tubes with non-APTIMA® swabs, broken containers, swab in M4 transport media, swabs submitted in Viral Culture Media (VCM).		
Stability	Room temperature: 30 days Refriegerated: 30 days Frozen: 30 days		
Performing Information			
Methodology	Transcription-Mediated Amplification (TMA)		
Reference Range	Not detected		
Performed Days	Sunday - Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest Infectious Disease		
Interface Information			
Legacy Code[1]	NSGON		
Interface Order Code	3400417		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400417	Neisseria gonorrhoeae RNA, TMA, Rectal	80366-8	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: 03/19/2021 17:46 Received: 03/19/2021 17:46

Test Name	Result	Flag	Ref-Ranges	Units	Site
Neisseria gonorrhoeae RNA, TMA, Rectal	NOT DETECTED				QCRL

Test Performed at:
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman 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

C319000012
WX0000003039
Printed D&T: 03/19/21 17:47

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Inactivate Test With Replacement			
Effective Date	4/27/2021		
Inactivated Test			
Name	Testosterone		
Code	TES		
Legacy Code[1]	TES		
Interface Order Code	1000820		
Notes			
Replacement Test			
Name	Testosterone, Total, LC/MS/MS		
Code	TESM		
CPT Code(s)	84403		
Notes	**Please note TESM is also the replacement code for TESFM (legacy code: TMSTESFEM)**		
Specimen Requirements			
Specimen Required	*Collect:* Red top Centrifuge, separate serum from cells within 2 hours of collection and send 1.0 mL serum refrigerated in a screw capped plastic vial. *Minimum:* 0.5 mL		
Rejection Criteria	SST, plasma, grossly lipemic, grossly hemolyzed, past stability		
Stability	Room temperature: 8 hours Refrigerated: 7 days Frozen: 2 months		
Performing Information			
Methodology	Liquid Chromatography - Tandem Mass Spectrometry		
Reference Range	Age / Males (ng/dL) / Females (ng/dL) 1-5 years / ≤5 / ≤8 6-7 years / ≤25 / ≤20 8-10 years / ≤42 / ≤35 11 years / ≤260 / ≤40 12-13 years / ≤420 / ≤40 14-17.9 years / ≤1000 / ≤40 ≥18 years / 250 – 1100 / 2 – 45		
Performed Days	Tuesday, Thursday, Friday		
Turnaround Time	2 - 5 days		
Performing Laboratory	Warde Medical Laboratory		
Interface Information			
Legacy Code[1]	TESM		
Interface Order Code	3000169		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3000169	Testosterone, Total, LC/MS/MS	2986-8	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 32 Y

Immunochemistry

Collected: 03/19/2021 18:14 Received: 03/19/2021 18:14

Test Name	Result	Flag	Ref-Ranges	Units	Site
Testosterone, Total, LC/MS/MS	**1,015**	**H**	2 - 45	ng/dL	WMRL

This test was developed and its performance characteristics determined by Warde Medical Laboratory in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for patient testing purposes. It should not be regarded as investigational or for research.

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

C319000013
WX0000003481
Printed D&T: 03/19/21 18:14

Ordered By: CLIENT CLIENT
WX00000000002063

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

APRIL 2021

Inactivate Test With Replacement	
Effective Date	4/27/2021
Name	Testosterone (TMS), Female/Ped
Code	TESFM
Legacy Code	TMSTESFEM
Interface Code	3719140
Notes	The replacement test for this code is TESM. Please see specimen and build information for TESM listed above.