

**NOVEMBER 2023** 

odate Summary		
New Test Activation	11/28/2023	ARGAB - "Acetylcholine Receptor Ganglionic (Alpha 3) Ab"
New Test Activation	11/28/2023	CN1AG - "Cytosolic 5'-Nucleotidase 1A (cN-1A) Ab (IgG)"
New Test Activation	11/28/2023	DLAU - "D-Lactate, Urine"
New Test Activation	11/28/2023	FSSHN - "Fungal Stain, Calcofluor, Skin, Hair or Nails"
New Test Activation	11/28/2023	METQU - "Methaqualone, Serum/Plasma"
New Test Activation	11/28/2023	MGENR - "Mycoplasma genitalium, rRNA, TMA"
New Test Activation	11/28/2023	MOGAC - "MOG Antibody with Reflex to Titer, CSF"
New Test Activation	11/6/2023	OXYBU - "Oxybutynin and Metabolite, Urine"
New Test Activation	11/28/2023	TSHHT - "TSH with HAMA Treatment"
Update Existing Test	11/13/2023	11DCR - "11-Deoxycortisol"
Update Existing Test	11/13/2023	17OPC - "17-Hydroxyprogesterone, Child"
Update Existing Test	11/7/2023	AMA - "Anti-Mitochondrial Antibody"
Update Existing Test	11/7/2023	ATSHR - "TRAb (TSH Receptor Antibody)"
Update Existing Test	11/13/2023	BASPQ - "Barbiturates, Serum or Plasma, Quantitative"
Update Existing Test	11/7/2023	BMDRP - "Borrelia miyamotoi DNA, Real-Time PCR Misc"
Update Existing Test	11/7/2023	CFBLD - "Culture, Fungus, Blood"
Update Existing Test	11/13/2023	CLOME - "Clobazam and Metabolite, Serum/Plasma"
Update Existing Test	11/7/2023	CUFUN - "Culture, Fungus, Skin, Hair or Nails"
Update Existing Test	11/7/2023	DL - "D-Lactate, Plasma"
Update Existing Test	11/7/2023	FNST - "Fungal Stain"
Update Existing Test	11/13/2023	FXRM1 - "Fragile X (FMR1) with Reflex to Methylation Analysis
Update Existing Test	11/7/2023	GACAG - "Giardia and Cryptosporidium Ag Panel"
Update Existing Test	11/7/2023	NTBNP - "NT proBNP"
Update Existing Test	11/13/2023	TEFFC - "Testosterone Free, Females or Children"
Update Existing Test	11/7/2023	TESBQ - "Testosterone, Free, Bioavailable and Total, MS"
Update Existing Test	11/7/2023	TFTLC - "Testosterone, Free (Dialysis) and Total .LC/MS/MS"
Update Existing Test	11/13/2023	THCSQ - "THC Metabolite, Serum or Plasma, Quantitative"
Inactivate Test With Replacement	11/28/2023	1433P - "14-3-3 eta Protein" replaced by MCVAB - "Mutated
		Citrullinated Vimentin (MCV) Antibody"
Inactivate Test With Replacement	11/13/2023	BBCSF - "B. burgdorferi Abs (EIA), CSF" replaced by BBABC - "B
	44/20/2025	burgdorferi VIsE1/pepC10 Abs, CSF w Reflex"
Inactivate Test With Replacement	11/28/2023	COVW - "SARS-COV-2 Qualitative" replaced by CVPCR - "SAR-COV-2 PCR"
Inactivate Test With Replacement	11/28/2023	CVD - "Comprehensive Virus Detection" replaced by CVP -
mactivate rest with Replacement	11/20/2023	"Comprehensive Virus Panel"

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### **NOVEMBER 2023**

Inactivate Test With Replacement	11/13/2023	<u>DPYD - "Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants"</u>
		replaced by DPYD3 - "Dihydropyrimidine Dehydrogenase (DPYD),
		3 Variants"
Inactivate Test With Replacement	11/13/2023	F13AR - "Factor XIII, Qual w/1:1 Mix" replaced by F13RM - "Factor
mactivate rest with replacement	11/13/2023	13, Qual, Reflex to Factor 13 1:1 Mix "
Inactivate Test With Replacement	11/28/2023	HDMUT - "Huntington Disease Mutation" replaced by HDCAG -
		"Huntington Disease (HD) CAG Repeat Expansion"
Inactivate Test With Replacement	11/13/2023	IKVIE - "Zika Virus IgM Ab Capture (MAC), ELISA" replaced by
т т	, , ,	ZVMAB - "Zika Virus IgM Ab Capture (MAC), ELISA"
	44/42/2022	
Inactivate Test With Replacement	11/13/2023	JK12P - "JAK2 Exon 12 Mutation Analysis by PCR" replaced by
		JAK2P - "JAK2 Exon 12 Mutation Analysis by PCR"
Inactivate Test With Replacement	11/13/2023	PETWB - "Phosphatidylethanol (PEth), Whole Blood" replaced by
		PETHQ - "Phosphatidylethanol (PEth), WB, Quantitative"
Inactivate Test With Replacement	11/28/2023	RCVD - "Respiratory Comprehensive Virus Detection" replaced by
mactivate rest with Replacement	11/20/2023	RCVP - "Respiratory Comprehensive Virus Detection Teplaced by
Inactivate Test With Replacement	11/28/2023	TCVD - "Tissue Comprehensive Virus Detection" replaced by TCVP
		- "Tissue Comprehensive Virus Panel"
Inactivate Test Without Replacement	11/28/2023	B12BC - "Vitamin B12 Binding Capacity"
Inactivate Test Without Replacement	11/13/2023	INFAG - "Influenza A Virus Ab, IgG"
Inactivate Test Without Replacement	11/13/2023	INFBG - "Influenza B Virus Ab, IgG"
Inactivate Test Without Replacement	11/7/2023	MAYFL - "Mayfly (Ephemeorptera) IgE"

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**NOVEMBER 2023** 

<b>New Test Activ</b>	ation			
Effective Date	11/28/2023			
Name	Acetylcholine Receptor Ganglionic (Alpha 3) Ab			
Code		ARGAB		
CPT Code(s)	83519			
Notes	Activate new test			
Notes	New York DOH Approval Status: Yes			
Specimen Requiren	nents			
	Collect: Serum separator tube (SST)			
	Specimen Preparation: Centrifuge, separate se	erum from cells a	nd send 1.0 mL serum in a screw	
Specimen Required	capped plastic vial.			
	Minimum Volume: 0.5 mL			
	Transport Temperature: Frozen			
Alternate Specimen	Red top			
Rejection Criteria	Plasma	Plasma		
	Room temperature: 48 hours			
Stability	Refrigerated: 48 hours			
	Frozen: 75 days			
<b>Performing Informa</b>	ation			
Methodology	Radioimr	munoassay (RIA)		
	Negative: <	<55 pmol/L		
Reference Range	Borderline	: 55 - 160 pmol/	L	
	Positive: >:	160 pmol/L		
Performed Days	Monday, Wednesday			
Turnaround Time	9 - 16 days			
Performing Laboratory	Quest SJC			
Interface Informati	on			
Legacy Code <sup>1</sup>	ARGAB			
Interface Order Code	3	400786		
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>	
3400786	Acetylcholine Receptor Ganglionic (Alpha 3) Ab	42233-7	No	

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:38 Received: 10/20/2023 11:38

Test Name Result Flag Ref-Ranges Units Site

Acetylcholine Receptor Ganglionic (Alpha 3) <55 <55 pmol/L QCRL

Ab

Reference Ranges for Acetylcholine Receptor Ganglionic Antibody:

Negative: <55 pmol/L Borderline: 55-160 pmol/L Positive: >160 pmol/L

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

Reported Date: 2023.10.20 11:38

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

F420000003 WX0000003827 Printed D&T: 10/20/23 11:38 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**NOVEMBER 2023** 

<b>New Test Activ</b>	ation			
Effective Date	11/28/2023			
Name	Cytosolic 5'-Nucleo	Cytosolic 5'-Nucleotidase 1A (cN-1A) Ab (IgG)		
Code		CN1AG		
CPT Code(s)	83516			
Notes	New test activation			
Notes	New York DOH Approved Status: Yes			
Specimen Requiren	nents			
	Collect: Serum separator tube (SST)			
	Specimen Preparation: Centrifuge, separate se	erum from cells a	nd send 0.5 mL serum in a screw	
Specimen Required	capped plastic vial.			
	Minimum Volume: 0.3 mL			
	Transport Temperature: Room temperature			
Alternate Specimen	Plasma: Lavender EDTA			
Rejection Criteria	Moderate to gross hemolysis			
	Room temperature: 7 days			
Stability	Refrigerated: 14 days			
	Frozen: 28 days			
<b>Performing Informa</b>	ation			
Methodology	Enzyme-linked Imn	nunosorbent Assa	y (ELISA)	
	<15 Units	s: Negative		
Reference Range	15 - 19 U	nits: Borderline		
	>=20 Uni	ts: Positive		
Performed Days	Tuesday, Thursday, Saturday			
Turnaround Time	4 - 7 days			
Performing Laboratory	Quest SJC			
Interface Informati	on			
Legacy Code <sup>1</sup>		CN1AG		
Interface Order Code	3	3400784		
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>	
3400784	Cytosolic 5'-Nucleotidase 1A (cN-1A) Ab (IgG)	94097-3	No	

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

**Referral Testing** 

Collected: 10/20/2023 11:40 Received: 10/20/2023 11:40

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Cytosolic 5'-Nucleotidase 1A (cN-1A) Ab (IgG) 14 Units

Reference Range:

<15: NEGATIVE
15-19: BORDERLINE
> OR = 20: POSITIVE

The cN-1A Ab assay is a useful aid for the diagnosis of inclusion body myositis (IBM). The analytical sensitivity of this assay is 35-70%, based on published reports. In our internal validation study with 120 healthy adult subjects, 1.7% had a positive cN-1A Ab result and 6.7% had an equivocal result. However, published reports and our own internal studies suggest that patients with Sjogren's syndrome, systemic lupus erythematosus, dermatomyositis (DM), or polymyositis (PM), are significantly more likely to have a positive cN-1A Ab result. In contrast, patients presenting clinically with IBM rarely produce autoantibodies associated with a diagnosis of DM or PM. Therefore, cN-1A Ab results must be interpreted in context with other details of the patient's clinical evaluation.

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

Reported Date: 2023.10.20 11:40

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

F420000004 WX0000003826 Printed D&T: 10/20/23 11:40 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**NOVEMBER 2023** 

<b>New Test Activ</b>	ation			
Effective Date	11/28/2023			
Name	D-Lac	tate, Urine		
Code		DLAU		
CPT Code(s)	83605	83605		
Notes	New test activation			
Notes	New York DOH Approval Status: No			
Specimen Requirer	nents			
	Patient Preparation: Biochemical Genetics Pati	ient Information	form required.	
	Collect: Random urine			
Specimen Required	Specimen Preparation: send 0.5 mL urine in a s	screw capped pla	stic urine cup. No preservative.	
Specimen Required	Frozen.			
	Minimum Volume: 0.15 mL			
	Transport Temperature: Frozen			
Alternate Specimen	24 hour urine			
Rejection Criteria	Urine collected with preservative			
	Room temperature: 90 days			
Stability	Refrigerated: 90 days			
	Frozen: 90 days			
<b>Performing Informa</b>	ation			
Methodology	Gas Chromatography-Mass Spectrome	etry (GCMS) Stab	le Isotope Dilution Analysis	
Reference Range	0.0 - 0	.25 mmol/L		
Performed Days	Monday, Thursday			
Turnaround Time	5 - 8 days			
<b>Performing Laboratory</b>	Mayo Clinic Laboratories			
Interface Informati	on			
Legacy Code <sup>1</sup>		DLAU		
Interface Order Code	3:	800338		
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>	
3800338	D-Lactate, Urine	14046-7	No	

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:37 Received: 10/20/2023 11:37

 Test Name
 Result
 Flag
 Ref-Ranges
 Units
 Site

 D-Lactate, Urine
 0.15
 0.0-0.25
 mmol/L
 MMRL

-----ADDITIONAL INFORMATION------

Gas Chromatography-Mass Spectrometry (GC-MS) Stable Isotope Dilution Analysis

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

Reported Date: 2023.10.20 11:37

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

F420000002 WX0000003827 Printed D&T: 10/20/23 11:37 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

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**NOVEMBER 2023** 

<b>New Test Activ</b>	ation		
Effective Date	11/28/2023		
Name	Fungal Stain, Calc	ofluor, Skin, Hair	or Nails
Code		FSSHN	
CPT Code(s)	87220		
Notes	New Test Activation  New York DOH Approval Status: Yes		
Specimen Requiren			
Specimen Required	Collect: Skin, hair or nails Specimen Preparation: Skin, hair or nails colle with forceps, scrape skin or scalp scales, clip r alcohol before scraping. Cleanse feet and han dermatophytes. Transport Temperature: Room temperature	nails and include	keratin scrapings. Cleanse skin with
Stability	Room temperature: 7 days Refrigerated: Unacceptable Frozen: Unacceptable		
<b>Performing Informa</b>	ation		
Methodology	Calcoflu	uor White Stain	
Reference Range	Se	ee report	
Performed Days	Sunday - Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Informati	on		
Legacy Code <sup>1</sup>	FSSHN		
Interface Order Code	3	3400763	
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>
3400764	Specimen Source:	31208-2	Yes
3400765	Fungal Stain SHN	21003-9	No

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

**Referral Testing** 

Collected: 10/25/2023 11:12 Received: 10/25/2023 11:12

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Fungal Stain, Calcofluor, Skin, Hair or Nails

Specimen Source: NAILS QCRL

Reported Date: 10/25/2023 -:1

Fungal Stain SHN NO FUNGAL QCRL

**ELEMENTS SEEN** 

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

Reported Date: 10/25/2023 11:12 FSSHN

Performing Site:

Kaial V. Sitwala, MD. PhD - Medical Director

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

F425000002 WX0000003826 Printed D&T: 10/25/23 11:12 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

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**NOVEMBER 2023** 

<b>New Test Activ</b>	ation			
Effective Date	11/28/2023			
Name	Methaqualo	one, Serum/Plasm	na	
Code		METQU		
CPT Code(s)	80368 (G0480)			
Notes	Activate new test  New York DOH Approval Status: Yes			
Specimen Requirer				
Specimen Required	Collect: Red top Specimen Preparation: Centrifuge, separate so screw capped plastic vial. Minimum Volume: 0.7 mL Transport Temperature: Refrigerated	erum from cells ir	nmediately. Send 2.0 mL serum in a	
Alternate Specimen	Plasma: EDTA			
Rejection Criteria	Serum separator tube (SST), Plasma separation tube (PST)			
Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 1 year			
<b>Performing Informa</b>	ation			
Methodology	Gas Chromatography	/Mass Spectrome	etry (GCMS)	
Reference Range	Se	ee report		
Performed Days	Varies			
Turnaround Time	9 - 11 days			
Performing Laboratory	N	IMS Labs		
Interface Informati	on			
Legacy Code <sup>1</sup>		METQU		
Interface Order Code	3	3300319		
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>	
3300319	Methaqualone, Serum/Plasma	3785-3	No	

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:35 Received: 10/20/2023 11:35

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Methaqualone, Serum/Plasma 10 mcg/mL NMRL

Reporting Limit: 0.10 mcg/mL

Synonym(s): Quaalude(R)

Reported blood levels associated with:

Erratic driving: 2-12 mcg/mL Mild Toxicity: 2-16 mcg/mL

Unconsciousness: Greater than 8 mcg/mL

Analysis by Gas Chromatography/Mass Spectrometry

(GC/MS)

This test was developed and its performance

characteristics determined by NMS Labs. It has not

been cleared or approved by the US Food and Drug

Administration.

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

**Reported Date: 2023.10.20 11:35** 

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

F420000001 WX0000003827 Printed D&T: 10/20/23 11:36 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Form: MM RL1 PAGE 1 OF 1

Kaial V. Sitwala, MD. PhD - Medical Director



**NOVEMBER 2023** 

<b>New Test Activ</b>	ation		
Effective Date	11/28/2023		
Name	Mycoplasma genitalium, rRNA, TMA		
Code	MGENR		
CPT Code(s)	87563		
Notes	New test activation		
Specimen Requiren	nents		
Specimen Required	Collect: Swab Specimen Preparation: Endocervical or male urethral swab collected in an Aptima® Unisex Swab Specimen Collection kit Or Vaginal or penile metal swab in Aptima® Multitest swab specimen collection kit. Transport Temperature: Room temperature		
Alternate Specimen	Urine 2.0 mL male or female urine collected in an Aptima® Urine Collection Kit. Minimum Volume: 2.0 mL		
Rejection Criteria	Transport tube with 2 swabs Transport tubes with non-aptima® swabs Swab transport tubes with no swab Swab submitted in non-Aptima® transport containers Urine sample where fluid level is not between the black fill lines Urine submitted in non-Aptima® transport containers		
Stability	Swabs: Room temperature: 60 days Refrigerated: 60 days Frozen: 90 days  Urine: Room temperature: 30 days Refrigerated: 30 days Frozen: 90 days		
<b>Performing Informa</b>	ation		
Methodology	Transcription-Mediated Amplification (TMA)		
Reference Range	Not detected		
· ·	Monday - Saturday		
Turnaround Time	5 - 7 days		
Performing Laboratory	Quest SJC		
Interface Information	on		
Legacy Code <sup>1</sup>	MGENR		
Interface Order Code	3400808		
Result Code	Name LOINC Code AOE/Prompt <sup>2</sup>		
3400808	Mycoplasma genitalium, rRNA, TMA 100706-1 No		

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:42 Received: 10/20/2023 11:42

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Mycoplasma genitalium, rRNA, TMA NOT DETECTED

REFERENCE RANGE: NOT DETECTED

Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway

**Reported Date: 2023.10.20 11:42** 

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

F420000006 WX0000003827 Printed D&T: 10/20/23 11:43 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**NOVEMBER 2023** 

<b>New Test Activ</b>	ation		
Effective Date	11/28/2023		
Name	MOG Antibody	with Reflex to Tit	er, CSF
Code		MOGAC	
CPT Code(s)	86362		
Notes	New test activation		
Notes	New York DOH Approval Status: Yes		
Specimen Requiren	nents		
	Collect: Cerebrospinal Fluid (CSF)		
	Specimen Preparation: Collect Cerebrospinal	fluid (CSF) and se	end 2.0 mL fluid in a screw capped
Specimen Required	plastic vial.		
	Minimum Volume: 0.5 mL		
	Transport Temperature: Refrigerated		
Rejection Criteria	Visible particulate matter		
	Room temperature: 7 days		
Stability	Refrigerated: 14 days		
	Frozen: 21 days		
Performing Informa	ation		
Methodology	Cell-based Imm	unofluorescence	e Assay
Reference Range	MOG Ab Cl	BA, CSF: Negativ	ve
Reference Range	MOG Ab Ti	ter, CSF: <1:2 ti	ter
Performed Days	Wednesday		
Turnaround Time	5 - 9 days		
Performing Laboratory	Quest SJC		
Interface Informati	on		
Legacy Code <sup>1</sup>	MOGAC		
Interface Order Code	;	3400787	
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>
3400788	MOG Ab CBA, CSF	91543-9	No
3400789	MOG Ab Titer, CSF	91542-1	No

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:44 Received: 10/20/2023 11:44

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

MOG Antibody with Reflex to Titer, CSF

MOG Ab CBA, CSF POSITIVE AB NEGATIVE QCRL

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

Test Performed at:

Quest Diagnostics Nichols Institute

33608 Ortega Highway

Reported Date: 2023.10.20 -:1

MOG Ab Titer, CSF 1:16 H <1:2 titer QCRL

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

Test Performed at:

Quest Diagnostics Nichols Institute

33608 Ortega Highway

**Reported Date:** 2023.10.20 11:44 MOGAC

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

F420000007 WX0000003827 Printed D&T: 10/20/23 11:45 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**NOVEMBER 2023** 

<b>New Test Activ</b>	ation			
Effective Date	1:	1/6/2023		
Name	Oxybutynin a	nd Metabolite, U	Jrine	
Code		OXYBU		
CPT Code(s)	80375	30375		
Notes	Activate new test  New York DOH Approval Status: Yes			
Specimen Requiren	nents			
Specimen Required	Collect: Random urine Specimen Preparation: Send 2.0 mL random u Minimum Volume: 1.0 mL Transport Temperature: Refrigerated	rine in a sterile,	screw capped plastic container.	
Rejection Criteria	Room temperature specimen Specimen collected in preservative			
Stability	Room temperature: 24 hours Refrigerated: 30 days Frozen: 30 days			
Performing Informa	ation			
Methodology	Liquid Chromatograph	y/Tandem Mass	Spectrometry	
Reference Range	Se	ee report		
Performed Days	Varies			
Turnaround Time	9 -10 days			
Performing Laboratory	N	IMS Labs		
Interface Informati	on			
Legacy Code <sup>1</sup>	OXYBU			
Interface Order Code	3300316			
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>	
3300317	Oxybutynin		No	
3300318	Desethyl Oxybutynin		No	

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:52 Received: 10/20/2023 11:52

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Oxybutynin, Urine

Oxybutynin 1.0 ng/mL NMRL

Reporting Limit: 0.50 ng/mL
Synonym(s): Ditropan(R)

Analysis by High Performance Liquid Chromatography/

Tandem Mass Spectrometry (LC-MS/MS)

Reported Date: 2023.10.20 -:1

Desethyl Oxybutynin 2.0 ng/mL NMRL

Reporting Limit: 0.50 ng/mL

Desethyl oxybutynin is an oxybutynin

metabolite.

Analysis by High Performance Liquid Chromatography/

Tandem Mass Spectrometry (LC-MS/MS)

This test was developed and its performance

characteristics determined by NMS Labs. It has not been cleared or approved by the US Food and Drug

Administration.

Testing performed at NMS Labs, Inc.  $\,$ 

200 Welsh Road

Horsham, PA 19044-2208

CLIA 39D0197898

**Reported Date:** 2023.10.20 11:52 OXYBU

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

F420000009 WX0000003827 Printed D&T: 10/20/23 11:52 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**NOVEMBER 2023** 

New Test Activation			
Effective Date		/28/2023	
Name		HAMA Treatment	
Code		TSHHT	
CPT Code(s)	84443 x 2	1311111	
, ,	Activate new test		
Notes	New York DOH Approval Status: Yes		
Specimen Requirer			
Specimen Required	Patient Preparation: Specimen collection after at least 3 days. For patients on hemodialysis, secollect: Red top Specimen Preparation: Centrifuge, separate secapped plastic vial.  Minimum Volume: 1.5 mL  Transport Temperature: Refrigerated	specimen collecti	on should be delayed for 2 weeks.
Rejection Criteria	Serum separator tube (SST)		
Stability	Room temperature: 7 days Refrigerated: 7 days Frozen: 28 days		
Performing Informa	ation		
Methodology	Imn	nunoassay	
Reference Range	Se	e report	
Performed Days	Tuesday - Saturday		
Turnaround Time	4 - 6 days		
Performing Laboratory	Quest SJC		
Interface Informati	on		
Legacy Code <sup>1</sup>		TSHHT	
Interface Order Code	3	400781	
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>
3400782	TSH, HAMA Treated	3016-3	No
3400783	TSH, Untreated	3016-3	No

LAST EDITED: 2023-10-27 PAGE 11 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

#### **EXAMPLE, REPORT W**

WX0000003826 F 12/05/1988 34 Y

Referral Testing Collected: 10/20/2023 11:41 Received: 10/20/2023 11:41 **Test Name** Result Ref-Ranges Flag Units <u>Site</u> TSH with HAMA Treatment QCRL TSH. HAMA Treated 0.41 SEE BELOW mIU/L **Reported Date: 2023.10.20** -:1 TSH, Untreated 1.00 0.40-4.50 mIU/L QCRL

Female Reference Ranges for TSH:

Premature Infants, (28-36) weeks

1st week of life 0.20-27.90 mIU/L

Term infants, (>37 weeks)

Serum or Cord Blood 1.00-39.00 mIU/L

1-2 days 3-4 days 5 days-4 weeks 1-11 months 1-19 years 2 0.70-15.40 mIU/L 1.70-9.10 mIU/L\*\* 0.80-8.20 mIU/L 0.50-4.30 mIU/L > or = 20 years 3.20-34.60 mIU/L

\*\* TSH levels decline rapidly during the first week of life in most children, but may remain transiently elevated in a few individuals despite normal free T4 levels. For proper interpretation of an abnormal TSH from a newborn thyroid screen, a Free T4 by Dialysis (TC 35167) or T4, Total (Thyroxine) (TC 17733) should be considered.

Pregnancy Ranges

First Trimester 0.26-2.66 mIU/LSecond Trimester 0.55-2.73 mIU/LThird Trimester 0.43-2.91 mIU/L

For additional information, please refer to http://education.QuestDiagnostics.com/faq/FAQ138 (This link is being provided for informational/educational purposes only.)
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

Reported Date: 2023.10.20 11:41 TSHHT

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

F420000005 WX0000003826 Printed D&T: 10/20/23 11:42 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 2



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W**WX0000003826 F 12/05/1988 34 Y

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

F420000005 WX0000003826 Printed D&T: 10/20/23 11:42 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 2



**NOVEMBER 2023** 

Update Existing Test		
Effective Date	11/13/2023	
Name	11-Deoxycortisol	
Code	11DCR	
Interface Order Code	3687960	
Legacy Code	11DCOR	
Notes	Changes to Turnaround Time.	
Required Testing C	Required Testing Changes	
Turnaround Time	3 - 10 days	

Update Existing Test		
Effective Date	11/13/2023	
Name	17-Hydroxyprogesterone, Child	
Code	170PC	
Interface Order Code	3670200	
Legacy Code	17OPROGARP	
Notes	Changes to Transport Temperature, Stability, Rejection Criteria	
Required Testing Changes		
Specimen Required	Collect: Serum separator tube (SST) Specimen Preparation: Centrifuge, separate serum from cells within 2 hours and send 1.0 mL in a screw capped plastic vial. Minimum Volume: 0.3 mL Transport Temperature: Frozen	
Rejection Criteria	Grossly hemolyzed specimens	
Stability	After separation from cells: Room temperature: 3 days Refrigerated: 7 days Frozen: 6 months	

Update Existing Test	
Effective Date	11/7/2023
Name	Anti-Mitochondrial Antibody
Code	AMA
Interface Order Code	3002220
Legacy Code	AMA
Notes	Update to rejection criteria.
Required Testing Changes	
Rejection Criteria	Samples other than serum or EDTA plasma, hemolysis, lipemia, microbially contaminated samples

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**NOVEMBER 2023** 

Update Existing Test	
Effective Date	11/7/2023
Name	TRAb (TSH Receptor Antibody)
Code	ATSHR
Interface Order Code	3000316
Legacy Code	ATSHR
Notes	Changes to Rejection Criteria
Required Testing Changes	
Rejection Criteria	Heat-inactivated sample; samples stabilized with azide; specimens other than serum

Update Existing Test	
Effective Date	11/13/2023
Name	Barbiturates, Serum or Plasma, Quantitative
Code	BASPQ
Interface Order Code	3600586
Legacy Code	BASPQ
Notes	Change to Turnaround Time.
Required Testing Changes	
Turnaround Time	3 - 9 days

Update Existing Test	
Effective Date	11/7/2023
Name	Borrelia miyamotoi DNA, Real-Time PCR Misc
Code	BMDRP
Interface Order Code	3400687
Legacy Code	BMDRP
Notes	Changes to Interface Order Code
Required Testing Changes	
Interface Order Code	3400687

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**NOVEMBER 2023** 

Update Existing Test		
Effective Date	11/7/2023	
Name	Culture, Fungus, Blood	
Code	CFBLD	
Interface Order Code	3400724	
Legacy Code	CFBLD	
Notes	Changes to Alternate Specimen, Rejection Criteria	
Required Testing Changes		
Alternate Specimen	Bone marrow in BACTEM™ Myco	
Rejection Criteria	Specimen in lavender EDTA tube, specimen in heparin green top tube, specimens in citrate, ACD. Received frozen, BACTEC Plus Aerobic/F bottle, BACTEC Lytic/10 Anaerobic/F bottle, BACTEC Peds bottle	

Update Existing Test	
Effective Date	11/13/2023
Name	Clobazam and Metabolite, Serum/Plasma
Code	CLOME
Interface Order Code	3300192
Legacy Code	CLOME
Notes	Changes to Turnaround Time
Required Testing Changes	
Turnaround Time	3 - 8 days

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**NOVEMBER 2023** 

Update Existing Test	
Effective Date	11/7/2023
Name	Culture, Fungus, Skin, Hair or Nails
Code	CUFUN
Interface Order Code	3700499
Legacy Code	CUFUN
Notes	Changes to Specimen Preparation, stability, Rejection Criteria
Required Testing C	hanges
Specimen Required	Collect: Skin, Hair or nails  Specimen Preparation: Remove hairs with forceps, scrape skin or scalp scales, clip nails and include keratin scrapings. Cleanse skin with alcohol before scraping. Cleanse feet and hands before collecting nails. Refrigeration is not recommended because it can inhibit dermatophytes.  Minimum Volume: No minimum volume  Transport Temperature: Room temperature
Rejection Criteria	No rejection criteria
Stability	Hair, skin and nail specimens: Room temperature: 14 days Refrigerated: Unacceptable Frozen: Unacceptable  Transport swabs: Room temperature: 72 hours Refrigerated: Unacceptable Frozen: Unacceptable

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**NOVEMBER 2023** 

Update Existing Test		
Effective Date	11/7/2023	
Name	D-Lactate, Plasma	
Code	DL	
Interface Order Code	3501180	
Legacy Code	DL	
Notes	Changes to Specimen Preparation, Minimum Volume, Alternate Specimen, Stability, Methodology, Turnaround Time, Performed Days  New York DOH Approval Status: Yes	
Required Testing Changes		
Specimen Required	Collected: Gray sodium fluoride/potassium oxalate Specimen Preparation: Centrifuge, separate, and send 0.5 mL plasma in a screw capped plastic vial. If collecting in sodium heparin tube, centrifuge within one hour. Minimum Volume: 0.2 mL Transport Temperature: Frozen	
Alternate Specimen	Plasma: Green sodium heparin	
Stability	Room temperature: 91 days Refrigerated: 91 days Frozen: 91 days	
Methodology	Gas Chromatography-Mass Spectrometry (GCMS) Stable Isotope Dilution Analysis	
Performed Days	Monday, Thursday	
Turnaround Time	5 - 8 days	

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**NOVEMBER 2023** 

Update Existing Test	
Effective Date	11/7/2023
Name	Fungal Stain
Code	FNST
Interface Order Code	3700031
Legacy Code	FNST
Notes	Changes to CPT4 Code(s), Specimen Required, Alternate Specimen, Stability, Rejection Criteria, Methodology, Turnaround Time  New York DOH Approval Status: Yes
Required Testing C	hanges
CPT Code(s)	87206
Specimen Required	Collect: Body fluid, lower respiratory tract specimens, urine or tissue  Specimen Preparation: Send 3.0 mL or 3.0 grams body fluids, lower respiratory tract specimens, urine or fresh (unfixed) tissue collected in sterile, leak-proof container.  Minimum Volume: 1.0 mL or 1 g, 1 swab  Transport Temperature: Refrigerated
Alternate Specimen	1.0 mL or 1 swab wood, exudates, aspirates, lesion material, ocular specimens collected in a sterile, leak-proof container, Amies liquid or gel swab system or Stuarts or ESwab
Rejection Criteria	Whole blood Stool
Stability	Room temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable
Methodology	Calcofluor White Stain
Turnaround Time	3 - 5 days

Update Existing Test		
Effective Date	11/13/2023	
Name	Fragile X (FMR1) with Reflex to Methylation Analysis	
Code	FXRM1	
Interface Order Code	3600211	
Legacy Code	FXRM1	
Notes	Changes to Specimen Required, Alternative Specimen, and Performed Days	
Required Testing Changes		
Specimen Required	Collect: Lavender EDTA Specimen Preparation: Send 2.0 mL whole blood Minimum Volume: 1.0 mL Transport Temperature: Refrigerated New York DOH Approval Status: Yes	
Alternate Specimen	Whole blood: Yellow ACD A	
Performed Days	Varies	

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**NOVEMBER 2023** 

Update Existing Test			
Effective Date	11/7/2023		
Name	Giardia and Cryptosporidium Ag Panel		
Code	GACAG		
Interface Order Code	3400658		
Legacy Code	GACAG		
Notes	Changes to stability		
Required Testing C	Required Testing Changes		
Stability	Total-Fix transport vial: Room temperature: 14 days Refrigerated: Unacceptable Frozen: Unacceptable  10% Formalin: Room temperature: 60 days		
	Refrigerated: Unacceptable		
	Frozen: Unacceptable		

Update Existing Test		
Effective Date	11/7/2023	
Name	NT proBNP	
Code	NTBNP	
Interface Order Code	3000317	
Legacy Code	NTBNP	
Notes	Changes to rejection criteria.	
Required Testing Changes		
Rejection Criteria	Heat-inactivated samples; Samples stabilized with sodium azide	

Update Existing Test			
Effective Date	11/13/2023		
Name	Testosterone Free, Females or Children		
Code	TEFFC		
Interface Order Code	3600009		
Legacy Code	TEFFC		
Notes	Change to Turnaround Time.		
Required Testing Changes			
Turnaround Time	3 - 7 days		

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**NOVEMBER 2023** 

Update Existing Test			
Effective Date	11/7/2023		
Name	Testosterone, Free, Bioavailable and Total, MS		
Code	TESBQ		
Interface Order Code	3422000		
Legacy Code	TESFBTQ		
Notes	Changes to Specimen Preparation, Minimum Volume		
Required Testing Changes			
Specimen Required	Collect: Red top Specimen Preparation: Centrifuge, separate serum from cells and send 4.0 mL serum in a screw capped plastic vial. Minimum Volume: 3.0 mL Transport Temperature: Refrigerated		

Update Existing Test			
Effective Date	11/7/2023		
Name	Testosterone, Free (Dialysis) and Total .LC/MS/MS		
Code	TFTLC		
Interface Order Code	3723600		
Legacy Code	TFTLC		
Notes	Change to Performing Location		
Required Testing Changes			
Performing Laboratory	Quest SJC		

Update Existing Test			
Effective Date	11/13/2023		
Name	THC Metabolite, Serum or Plasma, Quantitative		
Code	THCSQ		
Interface Order Code	3600024		
Legacy Code	THCSQ		
Notes	Changes to Performed Days and Turnaround Time.		
Required Testing Changes			
Performed Days	Sunday, <b>Tuesday, Thursday, Friday</b>		
Turnaround Time	3 - 7 days		

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**NOVEMBER 2023** 

Inactivate Test With Replacement				
Effective Date	11/28/2023			
	Inactivated Test			
Name	14-3-3 eta Protein			
Code		1433P		
Legacy Code <sup>1</sup>	1433P			
Interface Order Code	34	127700		
Notes	Inactivate test with replacement MCVAB			
Replacement Test				
Name	Mutated Citrullinated	Vimentin (MCV)	Antibody	
Code		MCVAB		
CPT Code(s)	83520			
Notes	Inactivate 1433P and activating MCVAB as the replacement  New York DOH Approval Status: Yes			
Specimen Requirements				
Specimen Required	Collect: Red top  Specimen Preparation: Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.  Minimum Volume: 0.5 mL			
Alternate Specimen	Transport Temperature: Refrigerated Serum separator tube (SST)			
Stability	Serum separator tube (SST)  Room temperature: 7 days  Refrigerated: 14 days  Frozen: 6 months			
<b>Performing Informa</b>	ation			
Methodology	Enzyme-linked Imm	unosorbent Assa	y (ELISA)	
Reference Range	<20 U/mL			
Performed Days	Sunday - Saturday			
Turnaround Time	3 - 5 days			
Performing Laboratory	Quest SJC			
Interface Information				
Legacy Code <sup>1</sup>	MCVAB			
Interface Order Code	3400809			
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>	
3400809	Mutated Citrullinated Vimentin (MCV) Antibody		No	

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

**EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:46 Received: 10/20/2023 11:46

**Test Name** Result Ref-Ranges <u>Units</u> <u>Flag</u> <u>Site</u>

QCRL Mutated Citrullinated Vimentin (MCV) Antibody <20 <20 U/mL

Anti-mutated citrullinated vimentin antibody may be used as a second-line marker of rheumatoid arthritis, in addition to rheumatoid factor and anti-cyclic citrullinated peptide (CCP).

Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway

> **Reported Date: 2023.10.20** 11:46

> > 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

F420000008 WX000003827 Printed D&T: 10/20/23 11:47 Ordered By: KAJAL SITWALA, MD, PhD WX0000000002365

Kaial V. Sitwala, MD. PhD - Medical Director Form: MM RL1

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**NOVEMBER 2023** 

Inactivate Test With Replacement			
Effective Date	11/13/2023		
Inactivated Test			
Name		eri Abs (EIA), CSF	
Code		BBCSF	
Legacy Code <sup>1</sup>		BBCSF	
Interface Order Code	3	620860	
	Danis amant Ta		
Replacement Test  B. burgdorferi VIsE1/pepC10 Abs, CSF w Reflex			
Name Code		BBABC	w Kellex
CPT Code(s)	86618; plus 86617 x 2, if reflexed, at additiona		
Notes	New York DOH Approval Status: No		
Specimen Requirements			
Specimen Required	Collect: Cerebrospinal fluid (CSF) Specimen Collection: Send 6.0 mL cerebrospinal fluid (CSF) in a screw capped plastic vial. Minimum Volume: 2.5 mL Transport Temperature: Refrigerated		
Rejection Criteria	Bacterially contaminated, heat-inactivated, he	molyzed, or xantl	hochromic specimens
Stability	Room temperature: 8 hours Refrigerated: 14 days Frozen: 1 month (Avoid repeated freeze thaw cycles)		
Performing Informa		cyclesy	
Methodology	Semi-quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot		
Reference Range	See report		
Performed Days	Sunday - Saturday		
Turnaround Time	3 - 6 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Informati	Interface Information		
Legacy Code <sup>1</sup>	BBABC		
Interface Order Code		600329	
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>
3600331	B. burgdorferi VIsE1/pepC10 Abs, CSF		No
3600332	Borrelia burgdorferi Ab, IgM, IB (CSF)	13203-5	No
3600333	Borrelia burgdorferi Ab, IgG, IB (CSF)	13202-7	No
3600334	Lyme Standard 2-Tier Testing, CSF Interp		No

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

#### **EXAMPLE, REPORT W**

WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 10/20/2023 11:56 Received: 10/20/2023 11:56

**Test Name** Result Flag Ref-Ranges Units <u>Site</u>

B. burgdorferi VIsE1/pepC10 Abs, CSF w Reflex

ARRL B. burgdorferi VIsE1/pepC10 Abs, CSF 6.50 <=0.90 IV н

REFERENCE INTERVAL: B. burgdorferi VlsE1/pepC10 Abs, CSF

0.90 IV or less ...... Negative - VlsE1 and pepC10

antibodies to B. burgdorferi not

detected

0.91-1.09 IV ..... Equivocal - Repeat testing in

10-14 days may be helpful.

1.10 IV or greater .... Positive - VlsE1 and pepC10

antibodies to B. burgdorferi

detected.

The detection of antibodies to Borrelia burgdorferi in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier. Lyme disease diagnosis in serum is recommended prior to any CSF studies.

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

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date:** 2023.10.20 \_·1

ARRL Borrelia burgdorferi Ab, IgM, IB (CSF) **Positive** Negative

INTERPRETIVE INFORMATION: Borrelia burgdorferi Ab, IqM, IB (CSF)

For this assay, a positive result is reported when any 2 or more of the following bands are present: 23, 39, 41 kDa. All other banding paterns are reported as negative.

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

F420000012 WX000003826 Printed D&T: 10/20/23 11:58 Ordered By: KAJAL SITWALA, MD, PhD WX0000000002353

Kaial V. Sitwala, MD. PhD - Medical Director Form: MM RL1 PAGE 1 OF 3



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

**Referral Testing** 

Collected: 10/20/2023 11:56 Received: 10/20/2023 11:56

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

The detection of antibodies to Borrelia burgdorferi in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier.

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

Reported Date: 2023.10.20 -:

Borrelia burgdorferi Ab, IgG, IB (CSF)

Positive

AB Negative

INTERPRETIVE INFORMATION: Borrelia burgdorferi Ab, IgG, IB (CSF)

For this assay, a positive result is reported when any 5 or more of the following 10 bands are present: 18, 23, 28, 30, 39, 41, 45, 58, 66, or 93 kDa. All other banding patterns are reported as negative.

The detection of antibodies to Borrelia burgdorferi in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier.

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

Reported Date: 2023.10.20 -:1

Lyme Standard 2-Tier Testing, CSF Interp Positive AB Negative ARRL

Both IgM and IgG-class antibodies to the Borrelia species causing Lyme disease were detected, suggesting recent or remote past infection.

If both first tier screen test and second tier tests are equivocal, consider repeat testing in 7-14 days if clinically warranted.

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

F420000012 WX0000003826 Printed D&T: 10/20/23 11:58 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

Form: MM RL1 PAGE 2 OF 3

Kaial V. Sitwala, MD. PhD - Medical Director



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

**Referral Testing** 

Collected: 10/20/2023 11:56 Received: 10/20/2023 11:56

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

INTERPRETIVE INFORMATION: Lyme Standard 2-Tier, CSF, 2nd Tier

IgG: For this assay, a positive result is reported when any five or more of the following 10 bands are present: 18, 23, 28, 30, 39, 41, 45, 58, 66, or 93 kDa. All other banding patterns are reported as negative.

IgM: For this assay, a positive result is reported when any two or more of the following bands are present: 23, 39, or 41 kDa. All other banding patterns are reported as negative.

The detection of antibodies to Borrelia burgdorferi in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier. Lyme disease diagnosis in serum is recommended prior to any CSF studies.

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

Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date:** 2023.10.20 11:57 BBABC

Performing Site:

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

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

F420000012 WX0000003826 Printed D&T: 10/20/23 11:58 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 3 OF 3



**NOVEMBER 2023** 

Inactivate Test	With Replacement		
Effective Date	11/	/28/2023	
Inactivated Test			
Name	SARS-CO <sup>N</sup>	V-2 Qualitative	
Code		COVW	
Legacy Code <sup>1</sup>	COVW		
Interface Order Code	30	000089	
	Replacement Te	st	
Name	SAR-	CoV-2 PCR	
Code		CVPCR	
<b>CPT Code(s)</b> 87635			
Specimen Requiren	nents		
Specimen Required	Collect: Nasopharyngeal swab  Specimen Preparation: One nasopharyngeal swab sent frozen in 3.0 mL viral transport media.  Minimum Volume: 1.0 mL minimum  Transport Temperature: Frozen		
Alternate Specimen	One oropharyngeal swab or NP/OP sent frozen in viral transport media.  Nasal swab sent frozen in viral transport media.  Our internal studies show that Phosphate Buffered Saline (PBS) and sterile saline do not interfere with the analytical performance of the COVID-19 assay. Liquid Amies buffer may decrease the analytical sensitivity of the assay and should be used only when other transport media are not available.		
Rejection Criteria	Calcium Alginate swabs, cotton swabs with wo	od shaft, receive	ed room temperature or >72 hours
Stability	Room temperature: Not Recommended Refrigerated: 72 hours Frozen: 2 weeks		
<b>Performing Informa</b>	ation		
Methodology	Real-Time Polymerase Chain Reaction (PCR)		
Reference Range	Not detected		
Performed Days	Sunday - Saturday		
Turnaround Time	24 - 48 hours		
Performing Laboratory	Warde Medical Laboratory		
Interface Informati	on		
Legacy Code <sup>1</sup>	CVPCR		
Interface Order Code	3000878		
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>
3000879	Specimen Source		Yes
3000881	SAR-CoV-2		No

LAST EDITED: 2023-10-27 PAGE 22 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

Molecular

Collected: 10/20/2023 12:17 Received: 10/20/2023 12:17

Test Name Result Flag Ref-Ranges Units Site

**SAR-CoV-2 PCR** 

Specimen Source Nasopharyngeal Swab WMRL

Reported Date: 2023.10.20 -:1

SAR-CoV-2 Not detected Not detected WMRL

This test utilizes a real-time reverse-transcriptase polymerase chain reaction procedure to amplify and detect the 5'-nontranslated region of the rhinovirus genome. This procedure will detect all of the >200 rhinovirus types. This procedure cannot differentiate the individual rhinovirus types. The analytical sensitivity of this assay is 200 copies/mL. A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

Reported Date: 2023.10.20 12:17 CVPCR

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

F420000021 WX0000003826 Printed D&T: 10/20/23 12:17 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353



**NOVEMBER 2023** 

	With Replacement
Effective Date	11/28/2023
	Inactivated Test
Name	Comprehensive Virus Detection
Code	CVD
Legacy Code <sup>1</sup>	CVD
Interface Order Code	3099000
	Replacement Test
Name	Comprehensive Virus Panel
Code	CVP
CPT Code(s)	Varies: Adenovirus PCR 87798; CMV PCR 87496; Enterovirus PCR 87498; HSV1/2 PCR 87529 x 2 Norovirus 1/2 87798 x 2; Rhinovirus PCR 87798; VZV PCR 87798
oecimen Requiren	nents
Specimen Required	Specimen Preparation: Swab specimens in viral transport medium.  CSF and body fluids undiluted in sterile, leak-proof container - 3.0 mL (1.5 mL minimum).  Body fluids undiluted in sterile, leak-proof container - 1.0 mL (1.0 mL minimum).  Biopsy/tissue specimens should be ordered for Tissue Comprehensive Virus Detection (TCVD).  Stool in IATA-approved screw-capped container - 2.0 mL (1.0 mL minimum) liquid stool or marb size solid stool.  Undiluted urine in an IATA-approved screw-capped container - 2.0 mL (1.0 mL minimum).  Blood in EDTA (lavender top) tube - 3.0 mL (2.0 mL minimum).  Bone Marrow in EDTA - 1.0 mL (0.5 mL minimum).  For respiratory specimens order RCVP Respiratory Comprehensive Virus Panel  Minimum Volume: Determined by specimen type, see stability
Alternate Specimen	Stool in Cary Blair medium.  The Laboratory Director or Supervisor must approve testing of specimens other than those liste
Rejection Criteria	Rectal swabs and stool preserved in formalin, SAF, or PVA.  Stool specimens received with diapers, tissue paper, tongue depressors, sticks, and other object Serum will not be tested due to decreased virus concentrations.  Urine in Grey-Top (boric acid) urine vacutainers. Specimens in Amplicor, EIA, Gen-Probe, or ProbeTec transport media.  Specimens in bacterial transport media, Stewart medium (Culturettes) and specimens in bacteriological blood culture media.  Dry swabs, wooden swabs, calcium alginate swabs, and swabs in gel transports.  Specimens received in non-sterile or leaking containers will not be tested.  Respiratory specimens (Order RCVP)
Stability erforming Informa	Room temperature (18-25°C): 4 hours; Refrigerated (2-8°C): 7 days; Frozen (-20°C): 7 days Frozen (-70°C): 3 months

LAST EDITED: 2023-10-27 PAGE 23 OF 35



**NOVEMBER 2023** 

Methodology	Source-driven panels. Polymerase Chain Reaction			
Reference Range	·	Negative		
Performed Days	Monday - Saturday			
Turnaround Time	2 days			
Performing Laboratory	Warde N	Лedical Laboratory	,	
Interface Informati	on			
Legacy Code <sup>1</sup>		CVP		
Interface Order Code		3000846		
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>	
3000847	Specimen Source	31208-2	Yes	
3000848	Herpes simplex Type 1	16130-7	No	
3000849	Herpes simplex Type 2	16131-5	No	
3000851	Varicella Zoster Virus	11483-5	No	
3000852	Cytomegalovirus	5000-5	No	
3000853	Adenovirus	21055-9	No	
3000854	Enterovirus	29591-5	No	
3000856	Rhinovirus	40990-4	No	
3000857	Norovirus Group 1	54905-5	No	
3000858	Norovirus Group 2	54906-3	No	

LAST EDITED: 2023-10-27 PAGE 24 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

#### **EXAMPLE, REPORT W**

WX0000003827 M 07/08/1978 45 Y

	Molecula	r				
	Collected:	10/20/2023	12:15	Received	d: 10/20/202	3 12:15
<u>Test Name</u>	Result	<u>Flag</u>	Ref-Ra	<u>nges</u>	<u>Units</u>	<u>Site</u>
Comprehensive Virus Panel Specimen Source	CSF					WMRL
Herpes simplex Type I	Not detected	Reported	I Date: Not det	2023.10.20 ected	-:1	WMRL
Herpes simplex Type 2	Not detected	Reported	I Date: Not det	2023.10.20 ected	-:1	WMRL
Varicella Zoster Virus	Not detected	Reported	l Date: Not det	2023.10.20 ected	-:1	WMRL
Cytomegalovirus	Not detected	Reported	I Date: Not det	2023.10.20 ected	-:1	WMRL
Adenovirus	Not detected	Reported	I Date: Not det	2023.10.20 ected	-:1	WMRL
Enterovirus	Not detected	Reported	I Date: Not det	2023.10.20 ected	-:1	WMRL
Rhinovirus	.TNP	Reported	l Date:	2023.10.20	-:1	WMRL
Norovirus Group 1	.TNP	Reported	l Date:	2023.10.20	-:1	WMRL
Norovirus Group 2	.TNP	Reported	l Date:	2023.10.20	-:1	WMRL
		Reported	l Date:	2023.10.20	12:16	CVP

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

F420000020 WX0000003827 Printed D&T: 10/20/23 12:16 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1

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

Performing Site:



**NOVEMBER 2023** 

<b>Inactivate Test</b>	With Replacement				
Effective Date	1	1/13/2023			
	Inactivated To	est			
Name	Dihydropyrimidine De	hydrogenase (DP)	(D), 3 Variants		
Code	, ,,	DPYD			
Legacy Code <sup>1</sup>		DPYD			
Interface Order Code		3689500			
	Replacement 1	Test			
Name	Dihydropyrimidine De	hydrogenase (DP)	/D), 3 Variants		
Code		DPYD3			
CPT Code(s)					
Notes	New York DOH Approval Status: Yes				
Specimen Requiren	nents				
Specimen Required	Collect: Lavender EDTA Specimen Preparation: Send 3.0 mL whole blood. Minimum Volume: 1.0 mL Transport Temperature: Refrigerated				
Alternate Specimen	Whole blood: Yellow ACD A or B				
Rejection Criteria	Plasma or serum, heparinized specimens. Fr	Plasma or serum, heparinized specimens. Frozen specimens in glass collection tubes.			
Stability	Room temperature: 72 hours Refrigerated: 7 days Frozen: 30 days				
<b>Performing Informa</b>	ation				
Methodology	Polymerase Chain Reacti	on (PCR)/Fluoresc	ence Monitoring		
Reference Range		See report			
Performed Days	Varies				
Turnaround Time	7 - 12 days				
Performing Laboratory		ference Laborator	у		
Interface Informati	on				
Legacy Code <sup>1</sup>		DPYD3			
Interface Order Code		3600323			
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>		
3600324	DPYD Specimen	31208-2	No		
3600326	DPYD Genotype	45284-7	No		
3600327	DPYD Phenotype	79719-1	No		
3600328	EER Dihydropyrimidine Dehydrogenase	11526-1	No		

LAST EDITED: 2023-10-27 PAGE 25 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 12:06 Received: 10/20/2023 12:06

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants

DPYD Specimen Whole Blood ARRL

Reported Date: 2023.10.20 -:1

DPYD Genotype Cmpnd Hetero AB

Reported Date: 2023.10.20 -:1

DPYD Phenotype Normal ARRL

This result has been reviewed and approved by Yuan Ji, Ph.D. BACKGROUND INFORMATION: Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants

CHARACTERISTICS: 5-Fluorouracil (5-FU) is the most frequently used chemotherapeutic drug for the treatment of many types of cancer, particularly colorectal adenocarcinoma. Grade III-IV drug toxicity attributed to 5-FU occurs in approximately 16 percent of patients, and may include hematologic, gastrointestinal, and dermatologic complications. In some cases, this toxicity can cause death. When 5-FU is metabolized in the body, approximately 80 percent is catabolized by the dihydropyrimidine dehydrogenase (DPD) enzyme. Variants in the DPYD gene can lead to reduced 5-FU catabolism, resulting in the aforementioned toxicity complications.

INHERITANCE: Autosomal codominant.

CAUSE: DPYD gene mutations.

DPYD Variants Tested:

Non-functional alleles and toxicity risk: \*13 (rs55886062, c.1679T>G) - Increased risk \*2A (rs3918290, c.1905+1G>A) - Increased risk Decreased function allele and toxicity risk: c.2846A>T (rs67376798) - Increased risk

A result of  ${\rm *1}$  indicates no variants detected and is predictive of functional alleles and normal enzymatic activity.

CLINICAL SENSITIVITY: Estimated at 31 percent for the DPYD variants analyzed.

METHODOLOGY: Polymerase chain reaction (PCR) and fluorescence monitoring.

ANALYTICAL SENSITIVITY and SPECIFICITY: 99 percent. LIMITATIONS: Only the targeted DPYD variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. 5-FU drug metabolism, efficacy and risk for toxicity may be affected by genetic and non-genetic factors that are not evaluated by this test.

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

F420000015 WX0000003827 Printed D&T: 10/20/23 12:07 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 12:06 Received: 10/20/2023 12:06

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Genotyping does not replace the need for therapeutic drug monitoring or clinical observation.

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

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

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reported Date: 2023.10.20 -:1

EER Dihydropyrimidine Dehydrogenase EERUnavailable

Performed By: ARUP Laboratories

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date:** 2023.10.20 12:07 DPYD3

Performing Site:

ARRL

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

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

F420000015 WX0000003827 Printed D&T: 10/20/23 12:07 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365



**NOVEMBER 2023** 

Inactivate Test With Replacement							
Effective Date	11/13/2023						
Inactivated Test							
Name	Factor XIII,	, Qual w/1:1 Mix					
Code		F13AR					
Legacy Code <sup>1</sup>		F13AR					
Interface Order Code	3	514900					
	Replacement Te						
Name	Factor 13, Qual, Re		1:1 Mix				
Code		-13RM					
CPT Code(s)	85291; plus 85291 if 1:1 Mix performed at add	itional cost					
Notes	New York DOH Approval Status: Yes						
Specimen Requirer	,						
Specimen Required	Collect: Light blue sodium citrate  Specimen Preparation: Send 2.0 mL plasma in a screw capped plastic vial. CRITICAL FROZEN.  Minimum Volume: 1.0 mL  Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered.						
Rejection Criteria	Serum, EDTA plasma, clotted or hemolyzed sp	ecimens					
Stability	Room temperature: 4 hours Refrigerated: Unacceptable Frozen: 14 days						
<b>Performing Informa</b>	ation						
Methodology	Qualitative	Solubility Assay					
Reference Range	Se	e report					
Performed Days	Sunday - Saturday						
Turnaround Time	4 - 6 days						
Performing Laboratory	ARUP Refe	rence Laboratory					
Interface Informati	on						
Legacy Code <sup>1</sup>	F	-13RM					
Interface Order Code	3	600306					
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>				
3600307	Factor XIII, Qualitative	3241-7	No				
3600308	Factor XIII, 1:1 Mix	ctor XIII, 1:1 Mix 3241-7 No					

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 12:02 Received: 10/20/2023 12:02

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Factor 13, Qual, Reflex to Factor 13 1:1 Mix

Factor XIII, Qualitative Lysis AB No Lysis ARRL

Performed By: ARUP Laboratories

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

Reported Date: 2023.10.20 -:1

Factor XIII, 1:1 Mix Lysis AB

Performed By: ARUP Laboratories

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date:** 2023.10.20 12:02 F13RM

Performing Site:

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

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

F420000013 WX0000003827 Printed D&T: 10/20/23 12:03 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365



**NOVEMBER 2023** 

Inactivate Test	With Replacement						
Effective Date	11/28/2023						
Lincolive Date	Inactivated Test						
Name		Disease Mutation	0				
Code		IDMUT	1				
Legacy Code <sup>1</sup>		IDMUT					
Interface Order Code		514250					
Notes	Inactivating HDMUT and replacing with HDCA						
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	machine in an a replacing with the or a						
	Replacement Te	est					
Name	Huntington Disease (	-	Expansion				
Code		HDCAG					
CPT Code(s)	81271						
Notes	Inactivating HDMUT and replacing with HDCA	3					
o : p :	New York DOH Approval Status: Yes						
Specimen Requiren							
Specimen Required		Collect: Lavender EDTA  Specimen Preparation: 2.0 mL whole blood collected in Lavender EDTA tube.  Minimum Volume: 1.0 ml					
	Transport Temperature: Refrigerated	Transport Temperature: Refrigerated					
Alternate Specimen	Whole blood: Yellow ACD A or B						
Rejection Criteria	Plasma or serum, heparinized specimens. Froz	en specimens in	glass collection tubes				
	Room temperature: 7 days						
Stability	Refrigerated: 1 month						
	Frozen: Unacceptable						
Performing Informa							
Methodology	Polymerase Chain Read		ient Analysis				
Reference Range		e report					
Performed Days	Varies						
Turnaround Time	,						
Performing Laboratory		rence Laboratory					
Interface Informati		IDCAC					
Legacy Code <sup>1</sup> Interface Order Code		HDCAG 600317					
Result Code	Name 3	LOINC Code	AOE/Prompt <sup>2</sup>				
3600318	Huntington Disease Specimen	31208-2	No				
3600319	Huntington Disease Specimen  Huntington Disease Allele 1	49637-2	No				
3600321	Huntington Disease Allele 2	49637-2	No				
	9						
3600322	Huntington Disease Interpretation	untington Disease Interpretation 50621-2 No					

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

**EXAMPLE, REPORT W** 

M 07/08/1978 45 Y WX000003827

Referral Testing

Collected: 10/20/2023 11:53 Received: 10/20/2023 11:53

**Test Name** Result Flag Ref-Ranges Units <u>Site</u>

Huntington Disease (HD) CAG Repeat Expansion

**Huntington Disease Specimen** Whole Blood ARRL

Reported Date: 2023.10.20 -:1

15 **CAG** Repeats ARRL **Huntington Disease Allele 1** 

> Reported Date: 2023.10.20 -:1

**Huntington Disease Allele 2** 16

**CAG** Repeats

ARRL

Reported Date: 2023.10.20 -:1

ARRL **Huntington Disease Interpretation** See Note

BACKGROUND INFORMATION: Huntington Disease (HD) CAG Repeat

Expansion

CHARACTERISTICS: Neurodegenerative disorder causing progressive cognitive, motor, and psychiatric disturbances typically beginning at 35-44 years of age. An estimated 5 percent of individuals with HD are symptomatic as juveniles and 25 percent of individuals after age 50.

INCIDENCE: 1 in 15,000.

INHERITANCE: Autosomal dominant.

CAUSE: Expanded number of CAG repeats in the HTT gene. HD allele with reduced penetrance 36-39 CAG repeats; HD allele with full penetrance 40 or more CAG repeats. CLINICAL SENSITIVITYE AND SPECIFICITY: 99 percent. METHODOLOGY: Triplet repeat-primed polymerase chain reaction (PCR) followed by size analysis using capillary electrophoresis. Repeat sizing precision is  $\pm$ - 2 for alleles less than or equal to 50 repeats, +/- 3 for alleles with 51 to 75 repeats, and  $\pm$  4 for alleles greater than

75 repeats. ANALYTIC SENSITIVITY AND SPECIFICITY: 99 percent. LIMITATIONS: Other neurodegenerative disorders will not be detected. Diagnostic errors can occur due to rare sequence

variations. Interpretation of this test result may be impacted if this patient has had an allogeneic stem cell

transplantation.

Number of CAG Repeats Phenotype

Normal allele less than or equal to 26 Mutable normal (intermediate) allele 27-35

HD allele with reduced penetrance 36-39

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

WX000003827 Printed D&T: 10/20/23 11:54

F420000010

Ordered By: KAJAL SITWALA, MD, PhD WX0000000002365



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 11:53 Received: 10/20/2023 11:53

Test Name Result Flag Ref-Ranges Units Site

HD allele with full penetrance greater than or equal to 40

COMPLIANCE STATEMENT: Laboratory Developed Test

(LDT)/Genetic

Performed By: ARUP Laboratories

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date:** 2023.10.20 11:53 HDCAG

Performing Site:

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

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

F420000010 WX0000003827 Printed D&T: 10/20/23 11:54 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365



**NOVEMBER 2023** 

Inactivate Test	With Replacement					
Effective Date	11/13/2023					
Inactivated Test						
Name		b Capture (MAC),	FLISA			
Code	21/4 11/43 18/11/11	IKVIE	213/1			
Legacy Code <sup>1</sup>		IKVIE				
Interface Order Code	3	600580				
	Replacement Te	est				
Name	Zika Virus IgM A	b Capture (MAC),	ELISA			
Code		ZVMAB				
CPT Code(s)	86794					
Notes	New York DOH Approval Status: Yes					
Specimen Requiren	nents					
Specimen Required	Collect: Serum separator tube (SST)  Specimen Preparation: Centrifuge, separate serum from cells within 2 hours of collection and send 2.0 mL serum in a screw capped plastic vial. Include patient history.  Minimum Volume: 1.0 mL  Transport Temperature: Refrigerated					
Alternate Specimen	Serum: Red top					
Rejection Criteria	•	Bacterially contaminated, Hemolysis, lipemic, heat-inactivated specimens, icteric, or turbid				
Stability	Room temperature: 48 hours Refrigerated: 14 days Frozen: 1 year	Room temperature: 48 hours Refrigerated: 14 days				
<b>Performing Informa</b>	ation					
Methodology	Semi-quantitative Enzym	e-Linked Immund	osorbent Assay			
Reference Range	N	egative				
Performed Days	Monday, Friday					
Turnaround Time	3 - 9 days	-				
Performing Laboratory	ARUP Refe	rence Laboratory				
Interface Informati	on					
Legacy Code <sup>1</sup>		ZVMAB				
Interface Order Code	3	600309				
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>			
3600309	Zika Virus IgM Antibody Capture (MAC), by ELISA	80824-6	No			

LAST EDITED: 2023-10-27 PAGE 28 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 10/20/2023 12:08 Received: 10/20/2023 12:08

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Zika Virus IgM Antibody Capture (MAC), by Negative Negative ARRL

ELISA

INTERPRETIVE INFORMATION: Zika Virus IgM Ab Capture (MAC),  ${\tt ELISA}$ 

The possibility of false-positive or false-negative results must be considered. RT-PCR testing on both a serum and urine specimen is recommended by the Centers for Disease Control and Prevention (CDC) to rule out false-negative IgM results in patients experiencing symptoms for less than 2 weeks. Specimens collected for IgM testing greater than or equal to 2 weeks after symptom onset do not require any additional testing. For more information, please review the current clinical guidelines for Zika virus testing at: www.cdc.gov/zika/

Performed By: ARUP Laboratories

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

Reported Date: 2023.10.20 12:08

Performing Site:

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

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

F420000016 WX0000003826 Printed D&T: 10/20/23 12:09 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353



**NOVEMBER 2023** 

In a stirrate Test	With Danie coment					
	With Replacement	44.0.40.00				
Effective Date	11/13/2023					
	Inactivated Test					
Name	JAK2 Exon 12 M	utation Analysis b	by PCR			
Code		JK12P				
Legacy Code <sup>1</sup>		JK12P				
Interface Order Code	3	3623000				
	Replacement To	est				
Name	JAK2 Exon 12 M	utation Analysis b	by PCR			
Code		JAK2P				
CPT Code(s)	81279					
Notes	New York DOH Approval Status: Yes					
Specimen Requiren	nents					
Specimen Required	Collect: Lavender EDTA Specimen Preparation: Send 5.0 mL whole blood. Minimum Volume: Whole blood: 1.0 mL; Bone marrow: 1.0 mL Transport Temperature: Refrigerated					
Alternate Specimen	Bone marrow: Lavender EDTA - 3.0 mL					
Rejection Criteria	Plasma, serum, FFPE tissue blocks/slides, frozen tissue, specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.					
Stability	Whole blood, Bone marrow: Room temperature: 24 hours Refrigerated: 4 days Frozen: Unacceptable					
Performing Informa	ation					
Methodology		Chain Reaction (Po	CR)			
Reference Range	-	ee report	•			
Performed Days		•				
Turnaround Time	5 - 11 days					
Performing Laboratory	ARUP Refe	erence Laboratory	1			
Interface Informati	on					
Legacy Code <sup>1</sup>		JAK2P				
Interface Order Code	3	3600302				
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>			
3600303	JAK2 EX12, Source	31208-2	No			
3600304	JAK2 Exon 12 Mutation Analysis by PCR	63421-2	No			

LAST EDITED: 2023-10-27 PAGE 29 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 10/20/2023 12:05 Received: 10/20/2023 12:05

Test Name Result Flag Ref-Ranges Units Site

JAK2 Exon 12 Mutation Analysis by PCR

JAK2 EX12. Source Whole Blood

**Reported Date:** 2023.10.20 -:1

JAK2 Exon 12 Mutation Analysis by PCR

Positive

ARRL

There is evidence of a JAK2 mutation in Exon 12.

This result has been reviewed and approved by Jay Patel, M D

INTERPRETIVE INFORMATION: JAK2 Exon 12 Mutation Analysis by PCR

DNA from whole blood or bone marrow is isolated and subjected to PCR amplification in the presence of a short blocking oligonucleotide homologous to exon 12 (codons 537-544) of the wild-type JAK2 gene. The oligonucleotide is designed to specifically suppress PCR amplification of wild-type JAK2 exon 12 sequence. In contrast, JAK2 exon 12 mutations located between codons 537-544 disrupt proper binding of the blocking oligonucleotide during PCR amplification resulting in a product of approximately 225 base-pairs. Each assay includes control DNA from mutation positive and wild-type negative samples; all samples are tested in paired reactions with and without blocking oligonucleotide. A PCR product formed in the presence of blocking oligonucleotide indicates the presence of a mutation.

Results of this test must always be interpreted in the context of clinical and other relevant laboratory data such as erythropoietin level, exclusion of other causes of elevated hemoglobin, and should not be used alone for a diagnosis of polycythemia vera which is a form of malignancy, i.e, myeloproliferative disorder.

This test is expected to detect 1 out of 1000 normal cells harboring a JAK2 exon 12 mutation.

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

Performed By: ARUP Laboratories

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

F420000014 WX0000003827 Printed D&T: 10/20/23 12:05 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

**EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 10/20/2023 12:05 Received: 10/20/2023 12:05

Test Name Result Ref-Ranges <u>Units</u> <u>Site</u> <u>Flag</u>

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date:** 2023.10.20 12:05 JAK2P

Performing Site:

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

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

F420000014 WX000003827 Printed D&T: 10/20/23 12:05 Ordered By: KAJAL SITWALA, MD, PhD WX0000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1

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**NOVEMBER 2023** 

Inactivata Tast	With Ponlacement					
Inactivate Test	11/13/2023					
Effective Date						
•		Inactivated Test				
Name	Phosphatidyletha		e Blood			
Code		PETWB				
Legacy Code <sup>1</sup>		5002598				
Interface Order Code	3	600281				
	Replacement To					
•	Replacement Te					
Name	Phosphatidylethano		antitative			
Code		PETHQ				
CPT Code(s)	80321 (G0480)					
Notes	New York DOH Approval Status: Yes					
Specimen Requiren						
	Collect: Lavender EDTA					
Specimen Required	Specimen Preparation: Send 1.0 mL whole blood					
	Minimum Volume: 0.5 mL					
		Transport Temperature: Refrigerated				
Alternate Specimen	Gray potassium oxalate, green lithium heparin					
Rejection Criteria	Serum separator tube (SST), Red top, light blue	e sodium citrate,	yellow ACD or SPS			
	Room temperature: 2 hours					
Stability	Refrigerated: 14 days					
	Frozen: 30 days					
Performing Informa	ation					
Methodology	Quantitative Liquid Chromato	graphy/Tandem I	Mass Spectrometry			
Reference Range	Se	e report				
Performed Days	Sunday - Saturday					
Turnaround Time	3 - 6 days					
Performing Laboratory		rence Laboratory	,			
Interface Informati	on					
Legacy Code <sup>1</sup>		PETHQ				
Interface Order Code	3	600311				
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>			
3600312	PEth 16:0/18:1 (POPEth)	97607-6	No			
3600313	PEth 16:0/18:2 (PLPEth)	97606-8	No			
3600314	EER_Phosphatidylethanol	11502-2	No			
3600316	PEth Interpretation		No			

LAST EDITED: 2023-10-27 PAGE 30 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

**EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 10/20/2023 12:10 Received: 10/20/2023 12:10

**Test Name** Result Flag Ref-Ranges Units <u>Site</u>

Phosphatidylethanol (PEth), WB, Quantitative

ARRL PEth 16:0/18:1 (POPEth) na/mL

PEth 16:0/18:1 (POPEth)

Less than 10 ng/mL.....Not detected

Less than 20 ng/mL...........Abstinence or light alcohol

consumption

20 - 200 ng/mL......Moderate alcohol consumption Greater than 200 ng/mL......Heavy alcohol consumption or

chronic alcohol use

(Reference: W. Ulwelling and K Smith 2018 J. Forensic Sci)

**Reported Date: 2023.10.20** -:1

ARRL PEth 16:0/18:2 (PLPEth) 48 ng/mL

Reference ranges are not well established.

Reported Date: 2023.10.20 -:1

ARRL EER Phosphatidylethanol See Note

> Reported Date: 2023.10.20 -:1

ARRL PEth Interpretation See Note

Phosphatidylethanol (PEth) is a group of phospholipids formed in the presence of ethanol, phospholipase D and phosphatidylcholine. PEth is known to be a direct alcohol biomarker. The predominant PEth homologues are PEth 16:0/18:1 (POPEth) and PEth 16:0/18:2 (PLPEth), which account for 37-46% and 26-28% of the total PEth homologues, respectively. PEth is incorporated into the phospholipid membrane of red blood cells and has a general half-life of 4-10 days and a window of detection of 2-4 weeks. However, the window of detection is longer in individuals who chronically or excessively consume alcohol. The limit of quantification is 10 ng/mL. Serial monitoring of PEth may be helpful in monitoring alcohol abstinence over time. PEth results should be interpreted in the context of the patient's clinical and behavioral history. Patients with advanced liver disease may have falsely elevated PEth concentrations (Nguyen VL et al 2018, Alcoholism Clinical & Experimental Research).

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

F420000017 WX000003826 Printed D&T: 10/20/23 12:11 Ordered By: KAJAL SITWALA, MD, PhD WX0000000002353

Kaial V. Sitwala, MD. PhD - Medical Director Form: MM RL1

PAGE 1 OF 2



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

**EXAMPLE, REPORT W** 

WX000003826 F 12/05/1988 34 Y

**Referral Testing** 

Collected: 10/20/2023 12:10 Received: 10/20/2023 12:10

**Test Name** Result <u>Units</u> <u>Flag</u> Ref-Ranges <u>Site</u>

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes. Performed By: ARUP Laboratories 500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date: 2023.10.20 PETHQ** 12:11

Performing Site:

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

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

F420000017 WX000003826 Printed D&T: 10/20/23 12:11 Ordered By: KAJAL SITWALA, MD, PhD WX0000000002353



**NOVEMBER 2023** 

<b>Inactivate Test</b>	With Replacement				
Effective Date	11/28/2023				
Inactivated Test					
Name	Respiratory Compr	ehensive Virus D	etection		
Code		RCVD			
Legacy Code <sup>1</sup>		RCVD			
Interface Order Code	3	000386			
	Replacement Te	est			
Name	Respiratory Com	prehensive Virus	Panel		
Code		RCVP			
CPT Code(s)	Adenovirus PCR 87798; CMV PCR 87496; Enter 87529 x 2; Parainfluenza 1/2/3 87631; Rhinovi				
Notes	Inactivating RCVD and replacing with RCVP New York DOH Approval Status: No				
Specimen Requiren	nents				
Specimen Required	Collect: Variable Specimen types  Specimen Preparation: Swab specimens in viral transport medium. Specimen source required.  Send 3.0 mL Bronchoalveolar lavage/wash in sterile, leak-proof container.  Send 3.0 mL Nasal washes in sterile, leak-proof container.  Send 1.0 mL Nasal aspirates in vacuum trap.  Minimum Volume: Bronchoalveolar lavage/wash: 1.5 mL  Nasal washes: 1.5 mL  Nasal aspirates: 0.5 mL  Transport Temperature: Refrigerated				
Alternate Specimen	The Laboratory Director or Supervisor must ap	prove testing of	specimens other than those listed.		
Rejection Criteria	Specimens in Amplicor, EIA, Gen-Probe, or Pro Specimens in bacterial transport media, Stewa bacteriological blood culture media.	beTec transport	media.		
Stability	Room temperature: 4 Hours Refrigerated (2-8°C): 7 Days Frozen (-70°C): 3 months				
<b>Performing Informa</b>	ation				
Methodology	Quantitative Poly	merase Chain Re	action		
Reference Range	N	egative			
Performed Days	Monday - Saturday				
Turnaround Time	2 Days				
Performing Laboratory	Warde Me	dical Laboratory			
Interface Informati	on				
Legacy Code <sup>1</sup>		RCVP			
Interface Order Code		000859			
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>		
3000861	Specimen Source	31208-2	Yes		

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**NOVEMBER 2023** 

3000862	Herpes simplex Type 1	16130-7	No
3000863	Herpes simplex Type 2	16131-5	No
3000864	Cytomegalovirus	5000-5	No
3000866	Adenovirus	21055-9	No
3000867	Enterovirus	29591-5	No
3000868	Influenza A	34487-9	No
3000869	Influenza B	40982-1	No
3000871	Respiratory Syncytial Virus	40988-8	No
3000872	Rhinovirus	40990-4	No
3000873	Parainfluenza 1	29908-1	No
3000874	Parainfluenza 2	29909-9	No
3000876	Parainfluenza 3	29910-7	No
3000877	SAR-CoV-2		No

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

#### **EXAMPLE, REPORT W**

WX0000003827 M 07/08/1978 45 Y

Molecular							
	Collected:	10/20/2023	12:12	Received:	10/20/2023	12:12	
<u>Test Name</u>	Result	Flag	Ref-Ranges	<u>s</u> !	<u>Units</u>	<u>Site</u>	
Respiratory Comprehensive Virus Panel							
Specimen Source	Respiratory - Lower					WMRL	
Herpes simplex Type I	Not detected	Reported	d Date: 202 Not detecte		-:1	WMRL	
Herpes simplex Type 2	Not detected	Reported	Date: 202 Not detecte		-:1	WMRL	
Cytomegalovirus	Not detected	Reported	d Date: 202 Not detecte		-:1	WMRL	
Adenovirus	Not detected	Reported	Date: 202 Not detecte		-:1	WMRL	
Enterovirus	Not detected	Reported	Date: 202 Not detecte		-:1	WMRL	
Influenza A	DETECTED	Reported AB	d Date: 202 Not detecte		-:1	WMRL	
Influenza B	Not detected	Reported	Date: 202 Not detecte		-:1	WMRL	
Respiratory Syncytial Virus	Not detected	Reported	d Date: 202 Not detecte		-:1	WMRL	
Rhinovirus	Not detected	Reported	d Date: 202 Not detecte		-:1	WMRL	
Parainfluenza 1	Not detected	Reported	d Date: 202 Not detecte		-:1	WMRL	
Parainfluenza 2	Not detected	Reported	d Date: 202 Not detecte		-:1	WMRL	
Parainfluenza 3	Not detected	Reported	d Date: 202 Not detecte		-:1	WMRL	

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

F420000018 WX0000003827 Printed D&T: 10/20/23 12:13 Ordered By: KAJAL SITWALA, MD, PhD WX000000000002365



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

**EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

Molecular

Collected: 10/20/2023 12:12 Received: 10/20/2023 12:12

**Test Name** Result Flag Ref-Ranges <u>Units</u> <u>Site</u>

> **Reported Date: 2023.10.20** -:1

WMRL SAR-CoV-2 Not detected Not detected

> **Reported Date:** 2023.10.20 **RCVP** 12:13

> > 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

F420000018 WX000003827 Printed D&T: 10/20/23 12:13 Ordered By: KAJAL SITWALA, MD, PhD WX0000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1

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**NOVEMBER 2023** 

	With Replacement		
Effective Date		/28/2023	
	Inactivated Tes	st	
Name	Tissue Compreh	ensive Virus Deto	ection
Code		TCVD	
Legacy Code <sup>1</sup>		TCVD	
Interface Order Code	3	099040	
	Replacement Te	est	
Name	Tissue Compre	ehensive Virus Pa	anel
Code		TCVP	
CPT Code(s)	Varies: Adenovirus PCR 87798, CMV PCR 8749 87529 x 2, Influenza A & B PCR 87502, Parainfl PCR 87634, VZV PCR 87798		
Notes	Inactivating TCVD and replacing with TCVP  New York DOH Approval Status: No		
Specimen Requiren	nents		
Specimen Required	Collect: Biopsy/tissue specimens  Specimen Preparation: Biopsy/tissue specimens in saline or viral transport medium (SNAP frozen - 20°C).  Transport Temperature: Frozen		
Alternate Specimen	The Laboratory Director or Supervisor must ap	prove testing of	specimens other than those listed.
Rejection Criteria	Bone marrow (see Comprehensive Virus Detection) Non-tissue specimens Swab specimens Specimens in preservatives such as formalin or other tissue preservatives Specimens in bacterial transport or culture medium		
Stability	Specimens received in non-sterile or leaking containers  Room temperature: 4 hours  Refrigerated: 3 days  Frozen: 30 days		
Performing Informa			
Methodology	Source-driven panels.		in Reaction
Reference Range	Not detected		
Performed Days	Monday - Saturday		
Turnaround Time	2 days		
Performing Laboratory	Warde Medical Laboratory		
Interface Informati	on		
Legacy Code <sup>1</sup>	TCVP		
Interface Order Code	3000827		
Result Code	Name	LOINC Code	AOE/Prompt <sup>2</sup>
3000828	Specimen Source	31208-2	Yes
3000829	Herpes simplex Type 1	16130-7	No

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**NOVEMBER 2023** 

3000831	Herpes simplex Type 2	16131-5	No
3000832	Varicella Zoster Virus	11483-5	No
3000833	Cytomegalovirus	5000-5	No
3000834	Adenovirus	21055-9	No
3000836	Enterovirus	29591-5	No
3000837	Influenza A	34487-9	No
3000838	Influenza B	40982-1	No
3000839	Respiratory Syncytial Virus	40988-8	No
3000841	Rhinovirus	40990-4	No
3000842	Parainfluenza 1	29908-1	No
3000843	Parainfluenza 2	29909-9	No
3000844	Parainfluenza 3	29910-7	No

LAST EDITED: 2023-10-27 PAGE 34 OF 35



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

#### **EXAMPLE, REPORT W**

WX0000003826 F 12/05/1988 34 Y

	Molecula		
	Collected:	10/20/2023 12:13 Received: 10/20/2023	12:13
<u>Test Name</u>	Result	<u>Flag</u> <u>Ref-Ranges</u> <u>Units</u>	<u>Site</u>
Tissue Comphrensive Virus Panel Specimen Source	Lung Tissue		WMRL
Herpes simplex Type 1	Not detected	Reported Date: 2023.10.20 -:1  Not detected	WMRL
Herpes simplex Type 2	Not detected	Reported Date: 2023.10.20 -:1  Not detected	WMRL
Varicella Zoster Virus	NO BILL	<b>Reported Date:</b> 2023.10.20 -:1	WMRL
Cytomegalovirus	Not detected	Reported Date: 2023.10.20 -:1  Not detected	WMRL
Adenovirus	Not detected	Reported Date: 2023.10.20 -:1  Not detected	WMRL
Enterovirus	Not detected	Reported Date: 2023.10.20 -:1  Not detected	WMRL
Influenza A	Not detected	Reported Date: 2023.10.20 -:1  Not detected	WMRL
Influenza B	Not detected	Reported Date: 2023.10.20 -:1  Not detected	WMRL
Respiratory Syncytial Virus	Not detected	Reported Date: 2023.10.20 -:1 Not detected	WMRL
Rhinovirus	Not detected	Reported Date: 2023.10.20 -:1 Not detected	WMRL
Parainfluenza 1	Not detected	Reported Date: 2023.10.20 -:1 Not detected	WMRL
Parainfluenza 2	Not detected	Reported Date: 2023.10.20 -:1 Not detected	WMRL

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

F420000019 WX0000003826 Printed D&T: 10/20/23 12:15 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

**EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 34 Y

Molecular

Collected: 10/20/2023 12:13 Received: 10/20/2023 12:13

**Test Name** Result Flag Ref-Ranges <u>Units</u> <u>Site</u>

> **Reported Date: 2023.10.20** -:1

WMRL Parainfluenza 3 Not detected Not detected

> **Reported Date:** 2023.10.20 **TCVP** 12:14

> > 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

F420000019 WX000003826 Printed D&T: 10/20/23 12:15 Ordered By: KAJAL SITWALA, MD, PhD WX0000000002353

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1

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**NOVEMBER 2023** 

Inactivate Test Without Replacement	
Effective Date	11/28/2023
Name	Vitamin B12 Binding Capacity
Code	B12BC
Legacy Code	B12BCARP
Interface Code	3681540
Notes	Test discontinued.

Inactivate Test Without Replacement		
Effective Date	11/13/2023	
Name	Influenza A Virus Ab, IgG	
Code	INFAG	
Legacy Code	INFLAABGAR	
Interface Code	3684030	
Notes	Test discontinued. Suggest Warde test FLPCR as replacement	

Inactivate Test Without Replacement	
Effective Date	11/13/2023
Name	Influenza B Virus Ab, IgG
Code	INFBG
Legacy Code	INFLBABGAR
Interface Code	3684050
Notes	Test discontinued. Suggest Warde test FLPCR as replacement

Inactivate Test Without Replacement		
Effective Date	11/7/2023	
Name	Mayfly (Ephemeorptera) IgE	
Code	MAYFL	
Legacy Code	MAYFL	
Interface Code	3300047	
Notes	Test discontinued.	

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