Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Notes

Update Summary		
New Test Activation	1/24/2023	SMNCS - "Spinal Muscular Atrophy Carrier Screening"
New Website Listing	2/15/2023	C6 - "C6 Complement"
Update Existing Test	2/21/2023	ADDS - "DNA (ds) Antibody"
Update Existing Test	2/21/2023	AENA - "Extractable Nuclear Antigens Abs"
Update Existing Test	2/7/2023	AMA - "Anti-Mitochondrial Antibody"
Update Existing Test	2/21/2023	ANARP - "Connective Tissue Disease Antibodies"
Update Existing Test	1/01/2023	APHAG - "Anaplasma phagocytophilum DNA, Qualitative RT-PCR"
Update Existing Test	2/21/2023	ASCLA – "Scledroderma (Scl-70) Antibody
Update Existing Test	2/7/2023	B2GA - "Beta-2 Glycoprotein 1 IgA Ab"
Update Existing Test	2/7/2023	B2GAB - "Beta-2 Glycoprotein 1 IgA/ IgG/ IgM"
Update Existing Test	2/7/2023	B2GG - "Beta-2 Glycoprotein 1, IgG Antibody"
Update Existing Test	2/7/2023	B2GGM - "Beta-2 Glycoprotein 1 IgG/ IgM"
Update Existing Test	2/7/2023	B2GM - "Beta-2 Glycoprotein 1 IgM Ab"
Update Existing Test	1/01/2023	BABDN - "Babesia microti DNA, Real-Time PCR"
Update Existing Test	2/20/2023	BAGMQ - "Babesia Microti IgG, IgM"
Update Existing Test	2/20/2023	BORDN - "Borrelia species DNA, QUAL Real-Time PCR, Tick"
Update Existing Test	2/20/2023	C1EIF – "C1 Esterase Inhibitor, Functional"
Update Existing Test	2/27/2023	C1ESQ - "C1 Esterase Inhibitor, Protein"
Update Existing Test	2/7/2023	CCPAB - "Cyclic Citrullinated Peptide IgG"
Update Existing Test	1/25/2023	DL - "D-Lactate Plasma"
Update Existing Test	1/01/2023	EASRT - "Ehrlichia and Anaplasma Species by Real-Time PCR"
Update Existing Test	2/21/2023	ENAP6 - "Extractable Nuclear Antigens Panel"
Update Existing Test	1/25/2023	FUKAU - "Ustekinumab Quantitation with Antibodies, Serum"
Update Existing Test	2/7/2023	GBM - "Glomerular Basement Membrane IgG Ab"
Update Existing Test	1/25/2023	HAAB - "Hepatitis A Antibody, Total"
Update Existing Test	1/25/2023	HAM - "Hepatitis A Antibody, IgM"
Update Existing Test	1/25/2023	HBCAB - "Hepatitis B Core Antibody, Total"
Update Existing Test	1/25/2023	HBCM - "Hepatitis B Core Antibody, IgM"
Update Existing Test	1/25/2023	HBSAB - "Hepatitis B Surface Antibody"
Update Existing Test	1/25/2023	HBSAG - "Hepatitis B Surface Antigen"
Update Existing Test	1/25/2023	HBVSC - "Hepatitis B Screening Panel"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	1/25/2023	HCVR - "Hepatitis C Antibody, Diagnostic, with reflex to PCR"
Update Existing Test	1/25/2023	HCVSR - "Hepatitis C Antibody, Screening, with reflex to PCR"
Update Existing Test	1/25/2023	HIVUL - "HIV-1 RNA Ultraquant"
Update Existing Test	1/25/2023	ICA - "Calcium, Ionized"
Update Existing Test	2/21/2023	JK12P - "JAK2 Exon 12 Mutation Analysis by PCR"
Update Existing Test	2/21/2023	JO1G - "JO-1 IgG Antibody"
Update Existing Test	2/21/2023	MLH1 - "MLH1 Promoter Methylation"
Update Existing Test	2/21/2023	PNEJ - "Pneumocystis Jirovecii by DFA"
Update Existing Test	2/21/2023	RNP - "RNP Antibody"
Update Existing Test	2/21/2023	SJOAB - "Sjogren's Antibodies (SSA/SSB)"
Update Existing Test	2/21/2023	SM - "SM Antibody"
Update Existing Test	2/21/2023	SSA - "SSA Antibody"
Update Existing Test	2/21/2023	SSB - "SSB Antibody"
Update Existing Test	2/28/2023	TBG - "Thyroxine Binding Globulin"
Update Existing Test	2/20/2023	TICKI - "Tick ID with Reflex to Borrelia species DAN, RT-PCR, Tick"
Inactivate Test Without Replacement	1/25/2023	BAFAT - "Bile Acids, Fractionated And Total (4668X)"
Inactivate Test Without Replacement	2/27/2023	BPCUL - "Bordetella pert/parapert Cult"
Inactivate Test Without Replacement	2/28/2023	HSSMA - "Horizon SMA"
Inactivate Test Without Replacement	2/21/2023	INFAM - "Influenza A Virus Ab, IgM"
Inactivate Test Without Replacement	2/21/2023	INFBM - "Influenza B Virus Ab, IgM"
Inactivate Test Without Replacement	2/21/2023	IVPCR - "Influenza A Virus H1/H3 Subtyping by PCR"
Inactivate Test Without Replacement	1/17/2023	ZSPOR - "Sporothrix AB"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

New Test Activation			
Effective Date	1/24/2023		
Name	Spinal Muscular Atrophy Carrier Screening		
Code	SMNCS		
CPT Code(s)	81329, 88233 (if appropriate), 88240 (if appropriate)		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Invert several times to mix blood completely. Send 3.0 mL whole blood specimen in original tube. **Do not aliquot.** *Minimum Volume:* 1.0 mL *Transport Temperature:* Room temperature *NY DOH Approval Status:* Yes		
Alternate Specimen	Yellow top ACD		
Rejection Criteria	To ensure minimum volume and concentration of DNA is met, the preferred volume of blood must be submitted. Testing may be canceled if DNA requirements are inadequate.		
Stability	Room Temperature: 96 hours Refrigerated: 96 hours Frozen: Unacceptable		
Performing Information			
Methodology	Dosage Analysis by Digital Droplet Polymerase Chain Reaction (ddPCR)		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	7 - 12 days		
Performing Laboratory	Mayo Clinic Laboratories		
Interface Information			
Legacy Code[1]	SMNCS		
Interface Order Code	**3800298** Revised: 2/3/23		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800299 Revised: 2/3/23	Result Summary	50397-9	No
3800301 Revised: 2/3/23	Result	49857-6	No

3800292	Interpretation	69047-9	No
3800293	Additional Information	48767-8	No
3800294	Specimen	31208-2	No
3800295	Source	31208-2	No
3800296	Released by	18771-6	No
3800297	Informed Consent on file? *Suggested Reponses:* *Y – For Yes* *N – For No* *U – For Unknown* *N/A – For not applicable; Use if consent is not required by patient's State.*	Not available	**Yes*** **(Please note: this result will not be returned to client or appear on report but is required for State(s) where informed consent on file is mandatory.)**

Warde Medical Laboratory

LABORATORY REPORT

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

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 34 Y

Non-invasive Prenatal Testing (NIPT)

Collected: 01/24/2023 12:53 Received: 01/24/2023 12:53

Test Name	Result	Flag	Ref-Ranges	Units	Site

Spinal Muscular Atrophy Carrier Screening

Result Summary — SEE BELOW — MMRL 01/24/2023 12:56

RESULT: NEGATIVE FOR SMN1 DELETION (SEE INTERPRETATION)

Result — SEE BELOW — MMRL 01/24/2023 12:57

Two copies of SMN1 exon 7 were detected.
Two copies of SMN2 were detected.

The g.27134T>G polymorphism is absent.

Interpretation — SEE BELOW — MMRL 01/24/2023 12:57

This result indicates a reduced carrier risk for Spinal Muscular Atrophy (SMA). Please see the table below for residual risk based on ancestry and absence of SMN1 g.27134T>G (1). Individuals who carry two copies of the SMN1 gene on one chromosome and zero copies of SMN1 on their other chromosome (i.e. 2+0 carriers) are at risk to have an affected child when their partner is also an SMA carrier. Other alterations within the SMN1 gene, such as point mutations, are not detected by this assay.

Patient Ancestry	Pre-test Carrier Frequency	Residual Risk of (2+0) SMA Carrier Status
Ashkenazi Jewish	1 in 41.1	1 in 580
Asian	1 in 53	1 in 701.8
African	1 in 66	1 in 395.7
Latino	1 in 117	1 in 1,762
European	1 in 35	1 in 769.3

The calculations noted in the chart are based on known population carrier frequencies and assume no family history of SMA. We are unable to provide a revised risk assessment for ancestries other than those listed as there is insufficient information available about the SMA carrier frequency for other populations.

A genetic consultation may be of benefit.

----------ADDITIONAL INFORMATION----------
Laboratory developed test (LDT) for SMN1 exon 7, SMN2 exon 7 copy number and SMN1 rs143838139 (g.27134T>G) detection by droplet digital PCR. Mutation nomenclature is based on

Warde Medical Laboratory

LABORATORY REPORT

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

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 34 Y

Non-invasive Prenatal Testing (NIPT)

Collected: 01/24/2023 12:53 Received: 01/24/2023 12:53

Test Name	Result	Flag	Ref-Ranges	Units	Site

the following GenBank Accession number(s) (build GRCh37 (hg19)): NM_022874.

See www.mayoclinicslabs.com (Test ID SMNCS) for additional information about this test.
CAUTIONS:
CLINICAL CORRELATIONS
Test results should be interpreted in context of clinical findings, family history, and other laboratory data. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

If testing was performed because of a family history of Spinal Muscular Atrophy, it is often useful to first test an affected family member.

TECHNICAL LIMITATIONS
Point mutations are undetectable by this assay. Nor can the assay discriminate between two copies of SMN1 on the same chromosome versus two copies on separate chromosomes. Bone marrow transplants from allogenic donors will interfere with testing. Call Mayo Clinic Laboratories for instructions for testing patients who have received a bone marrow transplant.

TEST CLASSIFICATION
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.

Additional Information	SEE BELOW				MMRL 01/24/2023 12:57

REFERENCES
1. Genet Med. 2014 Feb;16(2):149-156. PMID 23788250

Specimen	WB Whole Blood				MMRL 01/24/2023 13:05
Source	.				MMRL 01/24/2023 13:06
Released by	MICHELE DECKER				MMRL 01/24/2023 13:06

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

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

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

E524000002
WX0000003481
Printed D&T: 01/24/23 13:06

Ordered By: CLIENT CLIENT
WX00000000002063

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

New Website Listing			
Effective Date	2/15/2023		
Name	C6 Complement, Functional, Serum		
Code	C6		
CPT Code(s)	86161		
Notes			
Specimen Requirements			
Specimen Required	*Patient Preparation:* Fasting prior to draw preferred *Collect:* Red top *Specimen Preparation:* Place tube on wet ice immediately after collection. Centrifuge, separate serum from clot and send 1.0 mL serum frozen in a screw capped plastic vial. *Minimum Volume:* 0.5 mL *Transport Temperature:* Frozen *New York DOH Approval Status:* Yes		
Rejection Criteria	Non frozen specimens, gross lipemia		
Stability	Room Temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days		
Performing Information			
Methodology	Automated Liposome Lysis Assay		
Reference Range	32 - 57 U/mL		
Performed Days	Monday - Friday		
Turnaround Time	4-6 days		
Performing Laboratory	Mayo Clinic Laboratories		
Interface Information			
Legacy Code[1]	C6		
Interface Order Code	3501000		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3501000	C6 Complement, Functional, Serum	60459-5	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 34 Y

Referral Testing

Collected: 01/24/2023 12:50 Received: 01/24/2023 12:50

Test Name	Result	Flag	Ref-Ranges	Units	Site
C6 Complement, Functional, Serum	50		32 - 57	U/mL	MMRL 01/24/2023 12:50

```
------------------ADDITIONAL INFORMATION------------------
This test was developed and its performance characteristics
determined by Mayo Clinic in a manner consistent with
CLIA requirements. This test has not been cleared or
approved by the U.S. Food and Drug Administration.

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55905
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592
```

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/21/2023
Name	DNA (ds) Antibody
Code	ADDS
Interface Order Code	3000200
Legacy Code	ADDS
Notes	Change to alternate specimen, rejection criteria, methodology, reference range and stability.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<10 U/mL Negative** **10 - 15 U/mL Equivocal** **>15 U/mL Positive**

Update Existing Test	
Effective Date	2/21/2023
Name	Extractable Nuclear Antigens Abs
Code	AENA
Interface Order Code	3007850
Legacy Code	AENA
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, and reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis, lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**See individual tests**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/7/2023
Name	Anti-Mitochondrial Antibody
Code	AMA
Interface Order Code	3002220
Legacy Code	AMA
Notes	Changes in alternate specimen, stability, rejection criteria, methodology, and reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 weeks** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<4 U/mL Negative** **4 - 6 U/mL Equivocal** **>6 U/mL Positive**

Update Existing Test	
Effective Date	2/21/2023
Name	Connective Tissue Disease Antibodies
Code	ANARP
Interface Order Code	3007840
Legacy Code	REFANAP
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range, and performed days.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**See individual tests**
Performed Days	**Monday - Friday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/01/2023
Name	Anaplasma phagocytophilum DNA, Qualitative RT-PCR
Code	APHAG
Interface Order Code	3429050
Legacy Code	APHAG
Notes	CPT4 Code change
Required Testing Changes	
CPT Code(s)	**87468**

Update Existing Test	
Effective Date	2/21/2023
Name	Scleroderma (SCL70) Antibody
Code	ASCLA
Interface Order Code	3007925
Legacy Code	ASCLAB
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 – 10 U/mL Equivocal** **>10 U/mL Positive**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/7/2023
Name	Beta-2 Glycoprotein 1 IgA Ab
Code	B2GA
Interface Order Code	3017660
Legacy Code	B2GABA
Notes	Change to alternate specimen, stability, rejection criteria, methodology, reference range, performed days
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**< 7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**
Performed Days	**Monday - Friday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/7/2023
Name	Beta-2 Glycoprotein 1 IgA/ IgG/ IgM
Code	B2GAB
Interface Order Code	3017600
Legacy Code	B2GAB
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range, performed days.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**
Performed Days	**Monday - Friday**

Update Existing Test	
Effective Date	2/7/2023
Name	Beta-2 Glycoprotein 1, IgG Antibody
Code	B2GG
Interface Order Code	3017620
Legacy Code	B2GABG
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range, performed days
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**
Performed Days	**Monday - Friday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/7/2023
Name	Beta-2 Glycoprotein 1 IgG/ IgM
Code	B2GGM
Interface Order Code	3017590
Legacy Code	B2GGM
Notes	Changes In alternate specimen stability, rejection criteria, methodology, reference range, performed days
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**
Performed Days	**Monday - Friday**

Update Existing Test	
Effective Date	2/7/2023
Name	Beta-2 Glycoprotein 1 IgM Ab
Code	B2GM
Interface Order Code	3017640
Legacy Code	B2GABM
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range, performed days
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**
Performed Days	**Monday - Friday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/01/2023
Name	Babesia microti DNA, Real-Time PCR
Code	BABDN
Interface Order Code	3428200
Legacy Code	BABDN
Notes	CPT4 Code change
Required Testing Changes	
CPT Code(s)	**87469**

Update Existing Test			
Effective Date	2/20/2023		
Name	Babesia microti IgG IgM Abs		
Code	BAGMQ		
Interface Order Code	3702425		
Legacy Code	BAGMQ		
Notes	Changes are new test name, performed days, performing location and LOINC change.		
Required Testing Changes			
Name	***Babesia microti* Antibodies (IgG, IgM), IFA**		
Performed Days	**Tuesday - Saturday**		
Performing Location	**Quest SJC**		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3703430	**Babesia microti Ab (IgG)**	16117-4	No
3703440	**Babesia microti AB (IgM)**	16118-2	No
3703445	Interpretation	**88700-0**	No

Update Existing Test	
Effective Date	2/20/2023
Name	Borrelia species DNA PCR -Tick
Code	BORDN
Interface Order Code	3425780
Legacy Code	BORRSPTQ
Notes	Test name change
Required Testing Changes	
Name	**Borrelia species DNA, QUAL Real-Time PCR, Tick**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/27/2023
Name	C1 Esterase Inhibitor, Functional
Code	C1EIF
Interface Order Code	3700120
Legacy Code	C1ESTINH
Notes	Changes to performing location and performed days.
Required Testing Changes	
Performing Laboratory	**Quest SJC**
Performed days	**Monday - Saturday**

Update Existing Test	
Effective Date	2/27/2023
Name	C1 Esterase Inhibitor, Protein
Code	C1ESQ
Interface Order Code	3707010
Legacy Code	C1ESTQSP
Notes	Changes to performing location
Required Testing Changes	
Performing Laboratory	**Quest SJC**

Update Existing Test	
Effective Date	2/7/2023
Name	Cyclic Citrullinated Peptide IgG
Code	CCPAB
Interface Order Code	3091050
Legacy Code	CCPAB
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range, performed days.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**
Performed Days	**Monday - Friday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/25/2023
Name	D-Lactate Plasma/Body Fluid
Code	DL
Interface Order Code	3501180
Legacy Code	DL
Notes	Update to test name.
Required Testing Changes	
Name	**D-Lactate, Plasma**

Update Existing Test	
Effective Date	1/01/2023
Name	Ehrlichia and Anaplasma Species by Real-Time PCR
Code	EASRT
Interface Order Code	3600090
Legacy Code	
Notes	CPT4 Code change
Required Testing Changes	
CPT Code(s)	**87468; 87484; 87798 x 2**

Update Existing Test	
Effective Date	2/21/2023
Name	Extractable Nuclear Antigens Panel
Code	ENAP6
Interface Order Code	3007890
Legacy Code	ENAP6
Notes	Changes to alternate specimen, rejection criteria, methodology, stability, reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**See individual tests**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/25/2023
Name	Ustekinumab Quantitation with Antibodies, Serum
Code	FUKAU
Interface Order Code	3800208
Legacy Code	
Notes	Changes to rejection criteria.
Required Testing Changes	
Rejection Criteria	**Gross icterus**

Update Existing Test	
Effective Date	2/7/2023
Name	Glomerular Basement Membrane IgG Ab
Code	GBM
Interface Order Code	3016100
Legacy Code	GBMAB
Notes	Changes in alternate specimen stability, rejection criteria, methodology, reference range, performed days
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 – 10 U/mL Equivocal** **>10 U/mL Positive**
Performed Days	**Monday - Friday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis A Antibody, Total
Code	HAAB
Interface Order Code	3000710
Legacy Code	HAAB
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis A Antibody, IgM
Code	HAM
Interface Order Code	3010010
Legacy Code	HAM
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis B Core Antibody, Total
Code	HBCAB
Interface Order Code	3000680
Legacy Code	HBCAB
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis B Core Antibody, IgM
Code	HBCM
Interface Order Code	3010200
Legacy Code	HBCM
Notes	
Required Testing Changes	
Specimen Required	Update to performed days.
Performed Days	**Monday - Saturday**

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis B Surface Antibody
Code	HBSAB
Interface Order Code	3001640
Legacy Code	HBSAB
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis B Surface Antigen
Code	HBSAG
Interface Order Code	3000660
Legacy Code	HBSAG
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis B Screening Panel
Code	HBVSC
Interface Order Code	3000530
Legacy Code	HBVSC
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis C Antibody, Diagnostic, with reflex to PCR
Code	HCVR
Interface Order Code	3001440
Legacy Code	HCVR
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Update Existing Test	
Effective Date	1/25/2023
Name	Hepatitis C Antibody, Screening, with reflex to PCR
Code	HCVSR
Interface Order Code	3001452
Legacy Code	HCVSR
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Saturday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	1/25/2023
Name	HIV-1 RNA Ultraquant
Code	HIVUL
Interface Order Code	3041700
Legacy Code	HIVULTRA
Notes	Updates to methodology and reference range.
Required Testing Changes	
Methodology	Abbott RealTime HIV-1 system uses an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the detection and quantitation of the diverse group M subtypes A-H as well as group O and N isolates. The lower limit of quantitation is **20 copies/mL (1.30 log copies/mL)** and the upper limit of quantitation is 10,000,000 copies/mL (7.0 log copies/mL). The qualitative limit of detection is 20 copies/mL (1.30 log copies/mL). Specimens reported as DETECTED but **<20** copies/mL contain detectable levels of HIV-1 RNA even though the viral load is below the limit of quantitation.
Reference Range	HIV-1 RNA: Not detected **HIV-1 RNA Quantitative: <20 copies/mL** **LOG HIV CP U/mL: <1.3**

Update Existing Test	
Effective Date	1/25/2023
Name	Calcium, Ionized
Code	ICA
Interface Order Code	1000790
Legacy Code	ICA
Notes	Performing laboratory change and reference range.
Required Testing Changes	
Performing Laboratory	Quest SJC
Reference Range	See report

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/21/2023
Name	JAK2 Exon 12 Mutation Analysis by PCR
Code	JK12P
Interface Order Code	3623000
Legacy Code	JK12P
Notes	Changes to minimum volume, alternate specimen accepted, and stability accepted.
Required Testing Changes	
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 *New York DOH Approval Status:* Yes
Alternate Specimen	Bone marrow: EDTA - 3.0 mL
Stability	Whole bood, Bone marrow: Room temperature: 24 hours Refrigerated: 4 days Frozen: Unacceptable

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/21/2023
Name	JO-1 IgG Antibody
Code	JO1G
Interface Order Code	3700010
Legacy Code	JO1IGG
Notes	Changes to alternate specimen, rejection criteria, methodology, stability, reference range
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**

Update Existing Test	
Effective Date	2/21/2023
Name	MLH1 Promoter Methylation
Code	MLH1
Interface Order Code	3624180
Legacy Code	MLH1
Notes	Changes to alternate specimen, transport temperature, CPT4 codes
Required Testing Changes	
CPT Code(s)	**81288**
Alternate Specimen	Extracted DNA collection removed

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/21/2023
Name	Pneumocystis Jirovecii by DFA
Code	PNEJ
Interface Order Code	3620720
Legacy Code	PNEUMOARP
Notes	Changes to specimen requirement, alternate specimen, methodology
Required Testing Changes	
Specimen Required	*Collect:* Bronchial washing *Specimen Preparation:* Send 5.0 mL bronchial washing in a sterile, screw capped plastic container. Specimen source required. **Place each specimen in an individually sealed bag.** *Minimum volume:* 0.5 mL *Transport Temperature:* Refrigerated *New York DOH Approval Status:* Yes
Alternate Specimen	Bronchoalveolar lavage, **induced sputum**
Methodology	Direct Immunofluorescent **Stain**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/21/2023
Name	RNP Antibody
Code	RNP
Interface Order Code	3007852
Legacy Code	RNP
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<5 U/mL Negative** **5 - 10 U/mL Equivocal** **>10 U/mL Positive**

Update Existing Test	
Effective Date	2/21/2023
Name	Sjogren's Antibodies (SSA/SSB)
Code	SJOAB
Interface Order Code	3007950
Legacy Code	SJOAB
Notes	Changes to alternate specimen, stability, rejection criteria, methodology, reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/21/2023
Name	SM Antibody
Code	SM
Interface Order Code	3007855
Legacy Code	SM
Notes	Changes to alternate specimen, rejection criteria, methodology, stability, reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**<7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**

Update Existing Test	
Effective Date	2/21/2023
Name	SSA Antibody
Code	SSA
Interface Order Code	3007952
Legacy Code	SSA
Notes	Changes to alternate specimen, rejection criteria, stability, methodology, reference range.
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**< 7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/21/2023
Name	SSB Antibody
Code	SSB
Interface Order Code	3007955
Legacy Code	SSB
Notes	Change to alternate specimen, rejection criteria, stability, methodology, reference range
Required Testing Changes	
Alternate Specimen	**Lavender EDTA**
Rejection Criteria	**Heparinized plasma; hemolysis; lipemia**
Stability	Room temperature: 8 hours Refrigerated: **14 days** Frozen: **Undetermined**
Methodology	**Fluorescence Enzyme Immunoassay (FEIA)**
Reference Range	**< 7 U/mL Negative** **7 - 10 U/mL Equivocal** **>10 U/mL Positive**

Update Existing Test	
Effective Date	2/28/2023
Name	Thyroxine Binding Globulin
Code	TBG
Interface Order Code	1000837
Legacy Code	TBG
Notes	Changes to transport temperature
Required Testing Changes	
Specimen Required	*Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.5 mL *Transport Temperature:* **Frozen**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Update Existing Test	
Effective Date	2/20/2023
Name	Tick ID-Reflex to Lyme DNA
Code	TICKI
Interface Order Code	3515060
Legacy Code	TICKINFLX
Notes	Test name change
Required Testing Changes	
Test Name	**Tick ID with Reflex to *Borrelia* species DNA, RT-PCR, Tick**

Inactivate Test Without Replacement	
Effective Date	1/25/2023
Name	Bile Acids, Fractionated And Total (4668X)
Code	BAFAT
Legacy Code	BAFAT
Interface Code	3400742
Notes	Recommended replacement is BACF - Bile Acids, Fractionated.

Inactivate Test Without Replacement	
Effective Date	2/27/2023
Name	Bordetella pert/parapert Cult
Code	BPCUL
Legacy Code	BPCUL
Interface Code	3719800
Notes	Recommended replacement is BPPCR – Pertussis PCR Panel

Inactivate Test Without Replacement	
Effective Date	2/28/2023
Name	Horizon SMA
Code	HSSMA
Legacy Code	HSSMA
Interface Code	3302870
Notes	Recommended replacement is new test code: SMNCS - Spinal Muscular Atrophy Carrier Screening

Inactivate Test Without Replacement	
Effective Date	2/21/2023
Name	Influenza A Virus Ab, IgM
Code	INFAM
Legacy Code	INFLAABMAR
Interface Code	3684040
Notes	No suggested replacement.

Warde Medical Laboratory

TEST DIRECTORY UPDATE

FEBRUARY 2023

Inactivate Test Without Replacement	
Effective Date	2/21/2023
Name	Influenza B Virus Ab, IgM
Code	INFBM
Legacy Code	INFLBABMAR
Interface Code	3684060
Notes	No suggested replacement.

Inactivate Test Without Replacement	
Effective Date	2/21/2023
Name	Influenza A Virus H1/H3 Subtyping by PCR
Code	IVPCR
Legacy Code	IVPCR
Interface Code	3702365
Notes	No suggested replacement.

Inactivate Test Without Replacement	
Effective Date	1/17/2023
Name	Sporothrix AB
Code	ZSPOR
Legacy Code	SPOROAB
Interface Code	3510015
Notes	No suggested replacement.