Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 22, 2020 IMMEDIATE ACTION

Update Notes

Due to federal regulatory requirements, revisions to the Warde in-house tests include the required AOE prompt questions. Requirements for State Health Reporting also include patient demographics and ordering physician address, phone number and NPI. Please check that this information is being sent to Warde electronically in the HL7 message for all COVID-19 and non-COVID-19 State health reportable diseases.

Update Summary

Update Existing Test	7/27/2020	AFOGA - " Anti-Fodrin Antibody, IgG, IgA RDL"
Update Existing Test	7/28/2020	NMH24 - "N-Methylhistamine, 24 Hour, Urine"
Update Existing Test	7/27/2020	PMSCQ - " Anti-PM/Scl-100 Ab RDL"
Inactivate Test With Replacement	7/28/2020	COV2G - "SARS Coronavirus 2 IgG Antibody" replaced by COVG - "SARS Coronavirus 2 IgG Antibody"
Inactivate Test With Replacement	7/28/2020	COVWD - "SARS-COV-2 Qualitative" replaced by COVW - "SARS-CoV-2 Qualitative"
Inactivate Test With Replacement	7/28/2020	NICKU - "Nickel, Urine" replaced by NICRU - "Nickel, Urine"
Inactivate Test Without Replacement	8/3/2020	CANAG - "Candida Antigen"

Update Existing Test

Effective Date	7/27/2020
Name	Alpha-Fodrin Ab IgG, IgA
Code	AFOGA
Interface Order Code	3721100
Legacy Code	AFODGASP
Notes	The test name and the name of the components has changed.

Required Testing Changes

Name	**Anti-Fodrin Antibody, IgG, IgA RDL**		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3721120	**Anti-Fodrin Ab, IgG (RDL)**	Not available	No
3721140	**Anti-Fodrin Ab, IgA (RDL)**	Not available	No

Update Existing Test

Effective Date	7/28/2020
Name	N-Methylhistamine, 24 Hour, Urine
Code	NMH24
Interface Order Code	3800110
Legacy Code	NMH24
Notes	Stability changes

Required Testing Changes

Stability	**Room temperature: 14 days**; Refrigerated: 28 days; Frozen: 28 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 22, 2020 IMMEDIATE ACTION

Update Existing Test			
Effective Date	7/27/2020		
Name	Anti-PM/Scl-100 Ab (EIA)		
Code	PMSCQ		
Interface Order Code	3423685		
Legacy Code	PMSCQ		
Notes	The test name and component name have changed.		
Required Testing Changes			
Name	**Anti-PM/Scl-100 Ab RDL**		
Reference Range	Negative: <20		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3423685	**Anti-PM/Scl-100 Ab (RDL)**	81732-0	No

Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 22, 2020 IMMEDIATE ACTION

Inactivate Test With Replacement	
Effective Date	7/28/2020
Inactivated Test	
Name	SARS Coronavirus 2 IgG Antibody
Code	COV2G
Legacy Code[1]	COV2G
Interface Order Code	3000068
Notes	
Replacement Test	
Name	SARS Coronavirus 2 IgG Antibody
Code	COVG
CPT Code(s)	86769
Notes	
Specimen Requirements	
Specimen Required	Draw blood in a SST. Centrifuge, remove serum from cells and send 0.5 mL serum (0.3 mL minimum) refrigerated in a screw-capped plastic vial.
Alternate Specimen	Serum: Red-top Plasma: Sodium or lithium heparin, EDTA
Rejection Criteria	Gross hemolysis, lipemia
Stability	Room temperature: 8 hours; Refrigerated: 7 days; Frozen: 14 days
Performing Information	
Methodology	Chemiluminescence Immunoassay
Reference Range	Negative: <15.0 AU/mL Positive: >=15.0 AU/mL
Performed Days	Sunday-Friday
Turnaround Time	48 hours
Performing Laboratory	Warde Medical Laboratory
Interface Information	
Legacy Code[1]	COVG
Interface Order Code	3000226

Result Code	Name	LOINC Code	AOE/Prompt[2]
3000227	First Test? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95417-2	**Yes**

3000228	Employed in healthcare? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95418-0	**Yes**
3000229	Symptomatic as defined by CDC? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95419-8	**Yes**
3000231	If yes, then Date of Symptom Onset mm/dd/yy **Acceptable Prompt Responses:** If applicable: mm/dd/yy If not applicable: NA or N/A	11368-8	**Yes**
3000233	Hospitalized? (Y/N/U) **Acceptable Prompt Responses:** Y N U	77974-4	**Yes**
3000237	ICU? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95420-6	**Yes**
3000239	Resident in a congregate care setting? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95421-4	**Yes**
3000241	Pregnant? (Y/N/U) **Acceptable Prompt Responses:** Y N U	82810-3	**Yes**
3000242	SARS Coronavirus 2 IgG Ab	Not available	No
3000243	SARS Coronavirus 2 IgG Ab Interpretation	94563-4	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Immunology

Collected: 07/20/2020 15:00 Received: 07/22/2020 17:01

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS Coronavirus 2 IgG Antibody					
First Test? (Y/N/U)	Y				WMRL
Employed in healthcare? (Y/N/U)	Y				WMRL
Symptomatic as defined by CDC? (Y/N/U)	Y				WMRL
If yes, then Date of Symptom Onset mm/dd/yy	07/01/20				WMRL
Hospitalized? (Y/N/U)	N				WMRL
ICU? (Y/N/U)	N				WMRL
Resident in a congregate care setting? (Y/N/U)	N				WMRL
Pregnant? (Y/N/U)	N				WMRL
SARS Coronavirus 2 IgG Ab	<3.80		<15.00	AU/mL	WMRL
SARS Coronavirus 2 IgG Ab Interpretation	Negative		Negative		WMRL

SARS-CoV-2 IgG antibodies were not detected.

Please note that this does not rule out prior infection with SARS-CoV-2, as negative results may occur in serum collected too soon following infection, in immunosuppressed patients, or in some individuals with prior mild illness. Sensitivity of the assay may be negatively affected if testing is performed less than 15 days after initial diagnosis. This test should NOT be used to diagnose or to exclude active or recent COVID-19. Molecular (PCR) testing is recommended to establish a diagnosis of COVID-19 in symptomatic patients. This test was performed on the Diasorin Liaison analysis platform and is authorized by FDA for use under an emergency use authorization (EUA). Analytical performance characteristics were validated by the manufacturer and by Warde Medical Laboratory in a manner consistent with CLIA requirements.

The FDA requires that a fact sheet be made available for patients and healthcare providers regarding this test.

The fact sheet for patients may be found at http://www.wardelab.com/Diasorin_SARSCoV2_antibody_fact_sheet_for_patients.pdf

The fact sheet for healthcare providers may be found at http://www.wardelab.com/Diasorin_SARSCoV2_antibody_fact_sheet_for_health_care_providers.pdf

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

B522000014
WX0000003039
Printed D&T: 07/22/20 17:02

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Immunology

Collected: 07/21/2020 08:30 Received: 07/22/2020 16:59

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS Coronavirus 2 IgG Antibody					
First Test? (Y/N/U)	Y				WMRL
Employed in healthcare? (Y/N/U)	U				WMRL
Symptomatic as defined by CDC? (Y/N/U)	N				WMRL
If yes, then Date of Symptom Onset mm/dd/yy	NA				WMRL
Hospitalized? (Y/N/U)	N				WMRL
ICU? (Y/N/U)	N				WMRL
Resident in a congregate care setting? (Y/N/U)	N				WMRL
Pregnant? (Y/N/U)	N				WMRL
SARS Coronavirus 2 IgG Ab	**89.00**	**H**	<15.00	AU/mL	WMRL
SARS Coronavirus 2 IgG Ab Interpretation	**Positive**	**AB**	Negative		WMRL

SARS-CoV-2 IgG antibodies were detected.
Results suggest recent or prior infection with SARS-CoV-2.

This test was performed on the Diasorin Liaison analysis platform and is authorized by FDA for use under an emergency use authorization (EUA). Analytical performance characteristics were validated by the manufacturer and by Warde Medical Laboratory in a manner consistent with CLIA requirements. This test should NOT be used for primary diagnosis of COVID-19 or SARS-CoV-2 infection. Furthermore, the relationship between detectable antibody via qualitative assay and protective immunity has NOT been established, and no inference should be made on presumed immunity to infection based on this result.

The FDA requires that a fact sheet be made available for patients and healthcare providers regarding this test.

The fact sheet for patients may be found at http://www.wardelab.com/Diasorin_SARSCoV2_antibody_fact_sheet_for_patients.pdf

The fact sheet for healthcare providers may be found at http://www.wardelab.com/Diasorin_SARSCoV2_antibody_fact_sheet_for_health_care_providers.pdf

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

B522000013
WX0000003039
Printed D&T: 07/22/20 17:00

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 22, 2020 IMMEDIATE ACTION

Inactivate Test With Replacement	
Effective Date	7/28/2020
Inactivated Test	
Name	SARS-COV-2 Qualitative
Code	COVWD
Legacy Code[1]	COVWD
Interface Order Code	3000065
Notes	
Replacement Test	
Name	SARS-CoV-2 Qualitative
Code	COVW
CPT Code(s)	U0003
Notes	**Please contact Warde Client Services for allocated sample volume for your Laboratory.**
Specimen Requirements	
Specimen Required	One nasopharyngeal swab sent frozen in viral transport media.
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 wood shaft, received room temperature or >72 hours refrigerated
Stability	Room Temperature: Not Recommended; Refrigerated: 72 hours; **Frozen: 2 weeks**
Performing Information	
Methodology	Real-Time Polymerase Chain Reaction (PCR)
Reference Range	Not detected
Performed Days	Sunday - Saturday
Turnaround Time	**2 - 4 days**
Performing Laboratory	Warde Medical Laboratory
Interface Information	
Legacy Code[1]	COVW
Interface Order Code	3000089

Result Code	Name	LOINC Code	AOE/Prompt[2]
3000091	First Test? (Y/N/U) **Acceptable Prompt Responses:** Y	95417-2	**Yes**

	N U		
3000092	Employed in healthcare? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95418-0	**Yes**
3000093	Symptomatic as defined by CDC? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95419-8	**Yes**
3000094	if yes, then Date of Symptom Onset mm/dd/yy **Acceptable Prompt Responses:** If applicable: mm/dd/yy If not applicable: NA or N/A	11368-8	**Yes**
3000096	Hospitalized? (Y/N/U) **Acceptable Prompt Responses:** Y N U	77974-4	**Yes**
3000097	ICU? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95420-6	**Yes**
3000098	Resident in a congregate care setting? (Y/N/U) **Acceptable Prompt Responses:** Y N U	95421-4	**Yes**
3000099	Pregnant? (Y/N/U) **Acceptable Prompt Responses:** Y N U	82810-3	**Yes**
3000066	SARS-CoV-2 Qual RT PCR	94500-6	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Molecular

Collected: 07/14/2020 11:00 Received: 07/15/2020 12:33

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS - COV - 2 Qualitative					
First Test? (Y/N/U)	Y				WMRL
Employed in healthcare? (Y/N/U)	U				WMRL
Symptomatic as defined by CDC? (Y/N/U)	Y				WMRL
if yes, then Date of Symptom Onset (mm/dd/yy)	07/11/20				WMRL
Hospitalized? (Y/N/U)	U				WMRL
ICU? (Y/N/U)	N				WMRL
Resident in a congregate care setting? (Y/N/U)	N				WMRL
Pregnant? (Y/N/U)	N				WMRL
SARS-CoV-2 Qual RT PCR	**DETECTED**	**AB**	Not detected		WMRL

This test was performed via the Abbott RealTime SARS-CoV-2 assay and has been authorized by FDA under an Emergency Use Authorization (EUA). The assay is validated for nasopharyngeal (NP) and oropharyngeal (OP) swabs in transport media. The limit of detection of the assay is approximately 100 copies per milliliter; however, detection of SARS-CoV-2 may be affected by the sample collection and transport methods, patient factors (e.g., presence of symptoms, and/or stage of infection), and a negative result does not rule out the possibility of infection. For updated information, refer to the Center for Disease Control website: www.cdc.gov/coronavirus.

Providers should also refer to the fact sheet available at the following link:
http://www.wardelab.com/Abbott_COVID_test_fact_sheet_for_providers.pdf

Patients should also refer to the fact sheet available at the following link:
http://www.wardelab.com/Abbott_COVID_test_fact_sheet_for_patients.pdf

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

B515000007
WX0000003039
Printed D&T: 07/22/20 16:53

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 22, 2020 IMMEDIATE ACTION

Inactivate Test With Replacement	
Effective Date	7/28/2020
Inactivated Test	
Name	Nickel, Urine
Code	NICKU
Legacy Code[1]	NICKU
Interface Order Code	3600080
Notes	
Replacement Test	
Name	Nickel, Urine
Code	NICRU
CPT Code(s)	83885
Notes	
Specimen Requirements	
Specimen Required	Patients are encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over the counter medication. Abstinence from iodine - containing medications or contrast agents for at least 1 month prior to urine collection is recommended. Collect 24 hour urine, refrigerate during collection. Send 8.0 mL urine (1.0 mL minimum) refrigerated in a blue-capped ARUP metal-free screw-capped plastic vial. Record total volume and collection time interval on container.
Alternate Specimen	Urine, random
Rejection Criteria	Acid preserved urine, specimens contaminated with blood or fecal material, urine collected within 24 hours of gadolinium administration (contrast media)
Stability	Room temperature: 7 days; Refrigerated: 14 days; Frozen: 1 year
Performing Information	
Methodology	Quantitative Inductively Coupled Plasma - Mass Spectrometry
Reference Range	By report
Performed Days	Sunday-Saturday
Turnaround Time	3 - 11 days
Performing Laboratory	ARUP Reference Laboratory
Interface Information	
Legacy Code[1]	NICRU
Interface Order Code	3600183

Result Code	Name	LOINC Code	AOE/Prompt[2]
3600184	Hours collected	30211-7	**Yes**

3600185	Total Volume	19153-6	**Yes**
3600186	Creatinine, Urine - per volume	2161-8	No
3600187	Creatinine, Urine - per 24h	2162-6	No
3600188	Nickel, Urine - per volume	14099-6	No
3600189	Nickel, Urine - per 24h	5705-9	No
3600191	Nickel, Urine - ratio to CRT	29936-2	No

Inactivate Test Without Replacement

Effective Date	8/3/2020
Name	Candida Antigen
Code	CANAG
Legacy Code	CANAG
Interface Code	3500590
Notes	

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 07/16/2020 16:36 Received: 07/22/2020 16:36

Test Name	Result	Flag	Ref-Ranges	Units	Site
Nickel, Urine					
Hours collected	6			hr	ARRL
Total Volume	500			mL	ARRL
Creatinine, Urine - per volume	76			mg/dL	ARRL
Creatinine, Urine - per 24h	1520		1000-2500	mg/d	ARRL
Nickel, Urine - per volume	**11.0**	**H**	0.0-10.4	ug/L	ARRL

TEST INFORMATION: Nickel, Urine

Measurement of nickel is not recommended in asymptomatic individuals or in individuals with a low likelihood of exposure. Elevations in nickel urine should be interpreted with caution in individuals with no exposure risks, and may indicate contamination of the specimen.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS

Nickel, Urine - per 24h	**22.0**	**H**	0.0-14.9	ug/d	ARRL
Nickel, Urine - ratio to CRT	**14.5**	**H**	0.0-9.9	ug/g CRT	ARRL

Performed by ARUP Laboratories,
500 Chipeta Way, SLC,UT 84108 800-522-2787
www.aruplab.com, Julio Delgado, MD - Lab. Director

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