Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020 UPDATE C

Update Notes
Warde Medical Laboratory will now be testing for SARS Coronavirus 2 IgG Antibody, please see test build **COV2G**.

Update Summary		
New Test Activation	5/12/2020	COV2G - "SARS Coronavirus 2 IgG Antibody"
New Test Activation	5/14/2020	NMHR - "N-Methylhistamine, Random, Urine"
Update Existing Test	5/18/2020	INT1G - "Interleukin 1 beta, Serum"
Update Existing Test	5/4/2020	PROG - "Progesterone"
Inactivate Test With Replacement	5/14/2020	UMIAA - "N-Methylhistamine, Urine" replaced by NMH24 - "N-Methylhistamine, 24 Hour, Urine"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020 UPDATE C

New Test Activation			
Effective Date	5/12/2020		
Name	SARS Coronavirus 2 IgG Antibody		
Code	COV2G		
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]	COV2G		
Interface Order Code	3000068		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3000068	SARS Coronavirus 2 IgG Antibody	94505-5	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 31 Y

Immunology

Collected: 05/07/2020 10:00 Received: 05/08/2020 12:14

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS Coronavirus 2 IgG Antibody	5.00		<15.00	AU/mL	WMRL

Interpretation:

Negative: 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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 31 Y

Immunology

Collected: 05/07/2020 05:00 Received: 05/08/2020 12:16

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS Coronavirus 2 IgG Antibody	**18.00**	**H**	<15.00	AU/mL	WMRL

Interpretation:

Positive: 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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020 UPDATE C

New Test Activation			
Effective Date	5/14/2020		
Name	N-Methylhistamine, Random, Urine		
Code	NMHR		
CPT Code(s)	82542, 82570		
Notes	Patient must not be taking monoamine oxidase inhibitors (MAOIs) or aminoguanidine as these medications increase N-methylhistamine levels.		
Specimen Requirements			
Specimen Required	Collect a random urine specimen within a few hours of symptom onset. Send 5.0 mL urine (3.0 mL minimum) refrigerated in a screw-capped plastic vial.		
Stability	Room temperature: 28 days; Refrigerated: 28 days; Frozen: 28 days		
Performing Information			
Methodology	NMH: Liquid Chromatography - Tandem Mass Spectrometry; Creatinine: Enzymatic Colorimetric Assay		
Reference Range	0-5 years: 120-510 mcg/g creatinine 6-16 years: 70-330 mcg/g creatinine >16 years: 30-200 mcg/g creatinine		
Performed Days	Tuesday, Thursday		
Turnaround Time	4-6 days		
Performing Laboratory	Mayo Medical Laboratories		
Interface Information			
Legacy Code[1]	NMHR		
Interface Order Code	3800107		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800108	N-Methylhistamine, Random	13781-0	No
3800109	Creatinine, Random, U	2161-8	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 05/07/2020 10:00 Received: 05/08/2020 13:04

Test Name	Result	Flag	Ref-Ranges	Units	Site
N-Methylhistamine, Random, Urine					
N-Methylhistamine, Random	167		30-200	mcg/g Cr	MMRL

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

Creatinine, Random, U	150			mg/dL	MMRL

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-------------------REFERENCE VALUE---------------------------
Interpret with other
clinical data.

-------------------ADDITIONAL INFORMATION--------------------
This test has been modified from the manufacturer's
instructions. Its performance characteristics were
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 55901
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020 UPDATE C

Update Existing Test	
Effective Date	5/18/2020
Name	Interleukin 1 beta
Code	INT1G
Interface Order Code	3503990
Legacy Code	INT1G
Notes	The name of this test has changed.
Required Testing Changes	
Name	**Interleukin 1 beta, Serum**

Update Existing Test	
Effective Date	5/4/2020
Name	Progesterone
Code	PROG
Interface Order Code	1010200
Legacy Code	PROG
Notes	
Required Testing Changes	
Stability	Room Temperature: 72 hours; Refrigerated: 7 days; Frozen: **28 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020 UPDATE C

Inactivate Test With Replacement			
Effective Date	5/14/2020		
Inactivated Test			
Name	N-Methylhistamine, Urine		
Code	UMIAA		
Legacy Code[1]	UMIAA		
Interface Order Code	3505300		
Notes			
Replacement Test			
Name	N-Methylhistamine, 24 Hour, Urine		
Code	NMH24		
CPT Code(s)	82542		
Notes	Patient must not be taking monoamine oxidase inhibitors (MAOIs) or aminoguanidine as these medications increase N-methylhistamine levels		
Specimen Requirements			
Specimen Required	Collect urine for 24 hours without preservative. Mix urine well and send 5.0 mL urine aliquot (3.0 mL minimum) refrigerated in a screw-capped plastic vial.		
Stability	Room temperature: 28 days Refrigerated: 28 days Frozen: 28 days		
Performing Information			
Methodology	NMH: Liquid Chromatography – Tandem Mass Spectrometry Creatinine: Enzymatic Colorimetric Assay		
Reference Range	0-5 years: 120-510 mcg/g creatinine 6-16 years: 70-330 mcg/g creatinine >16 years: 30-200 mcg/g creatinine		
Performed Days	Tuesday, Thursday		
Turnaround Time	4-6 days		
Performing Laboratory	Mayo Medical Laboratories		
Interface Information			
Legacy Code[1]	NMH24		
Interface Order Code	3800110		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800111	N-Methylhistamine, 24 Hr, U	44340-8	No
3800112	Creatinine, 24 Hour, U	2162-6	No
3800113	Collection Duration	13362-9	**Yes**
3800114	Urine Volume	3167-4	**Yes**
3800115	Creatinine Concentration	20624-3	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 05/07/2020 08:15 Received: 05/08/2020 13:12

Test Name	Result	Flag	Ref-Ranges	Units	Site
N-Methylhistamine, 24 Hour, Urine					
N-Methylhistamine, 24 Hr, U	100		30-200	mcg/g Cr	MMRL
------------------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.					
Creatinine, 24 Hour, U	1950			mg/24 h	MMRL
------------------REFERENCE VALUE--------------------------- The expected creatinine excretion per 24 hrs for males: 955-2936 mg/24 hrs or 13-29 mg/kg/24 hrs. Note: To convert to mg/kg of body weight/24 hrs, divide the mg/24 h result by the weight in kg.					
------------------ADDITIONAL INFORMATION------------------ This test has been modified from the manufacturer's instructions. Its performance characteristics were 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.					
Collection Duration	24			h	MMRL
Urine Volume	3250			mL	MMRL
Creatinine Concentration	60			mg/dL	MMRL

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55901
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592

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

B308000003
WX0000003039
Printed D&T: 05/08/20 13:16

Ordered By: CLIENT CLIENT
WX00000000001595

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