

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

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

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

6508000435
WX0000072099

Ordered By: CLIENT CLIENT
WX00000000404674

Printed D&T: 05/08/20 12:48

William G. Finn, M.D. - Medical Director

Form: MM RL1

PAGE 1 OF 1



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

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: 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

6508000444
WX0000072099
Printed D&T: 05/08/20 12:47

Ordered By: CLIENT CLIENT
WX00000000404674

William G. Finn, M.D. - Medical Director
Form: MM RL1
PAGE 1 OF 1

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 aminoquanidine 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	PLACEHOLDER		
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 Code¹	NMHR		
Interface Order Code	3800107		
Result Code	Name	LOINC Code	AOE/Prompt²
3800108	N-Methylhistamine, Random	13781-0	No
3800109	Creatinine, Random, U	2161-8	No



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

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: 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.

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Creatinine, Random, U, 150, mg/dL, MMRL

-----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

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

Inactivate Test With Replacement			
Effective Date	5/14/2020		
Inactivated Test			
Name	N-Methylhistamine, Urine		
Code	UMIAA		
Legacy Code¹	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 aminoquanidine 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	NMH24: 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 Code¹	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



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

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: N-Methylhistamine, 24 Hour, Urine; Result: 100; Ref-Ranges: 30-200; Units: mcg/g Cr; Site: 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.

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Creatinine, 24 Hour, U; Result: 1950; Units: mg/24 h; Site: 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.

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Collection Duration 24 h; Row 2: Urine Volume 3250 mL; Row 3: Creatinine Concentration 60 mg/dL

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