

### Update Notes

**April 6, 2020 Update:**

Please see updated information below for Alternate Specimen and Turnaround Time.

### Update Summary

<b>New Test Activation</b>	3/24/2020	<a href="#">COVWD - "SARS-CoV-2 Qualitative"</a>
----------------------------	-----------	--

### New Test Activation

<b>Effective Date</b>	3/24/2020
<b>Name</b>	SARS-CoV-2 Qualitative
<b>Code</b>	COVWD
<b>CPT Code(s)</b>	87635 (U0002)
<b>Notes</b>	

### Specimen Requirements

<b>Specimen Required</b>	One nasopharyngeal swab sent frozen in viral transport media.
<b>Alternate Specimen</b>	One oropharyngeal swab or NP/OP sent frozen in viral transport media.  <b>Our internal studies show that 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.</b>
<b>Rejection Criteria</b>	Calcium Alginate swabs, cotton swabs with wood shaft, received room temperature or >72 hours refrigerated
<b>Stability</b>	Room Temperature: Not Recommended; Refrigerated: 72 hours; Frozen: -70 °C

### Performing Information

<b>Methodology</b>	Real-Time Polymerase Chain Reaction (PCR)
<b>Reference Range</b>	Not Detected
<b>Performed Days</b>	Sun - Sat
<b>Turnaround Time</b>	24 - 48 hours
<b>Performing Laboratory</b>	Warde Medical Laboratory

### Interface Information

<b>Legacy Code<sup>1</sup></b>	COVWD		
<b>Interface Order Code</b>	3000065		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt<sup>2</sup></b>
3000066	SARS-CoV-2 Qual RT PCR	94500-6	No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT

WX0000072099 M 12/05/1988 31 Y

Molecular

Collected: 03/23/2020 15:35 Received: 03/23/2020 15:35

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: SARS-CoV-2 Qualitative, Not detected, 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.

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

6323000773 Ordered By: CLIENT CLIENT
WX0000072099 WX00000000404674
Printed D&T: 03/23/20 15:44

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

Molecular

Collected: 03/23/2020 15:41

Received: 03/23/2020 15:41

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: SARS-CoV-2 Qualitative, 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.

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

6323000789
WX0000072099
Printed D&T: 03/23/20 15:45

Ordered By: CLIENT CLIENT
WX00000000404674

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

Molecular

Collected: 03/23/2020 15:41 Received: 03/23/2020 15:41

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: SARS-CoV-2 Qualitative, Inhibitory to PCR, AB, Not detected, WMRL.

Inhibitory result. This specimen contains substances that interfere with PCR amplification of the nucleic acids. Interfering substances include, but are not limited to, heme, heparin and other chelating agents, detergents, complex polysaccharides, proteases, nucleases, and DNA binding proteins. Please consider sending another specimen for testing.

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.

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

6323000791 Ordered By: CLIENT CLIENT
WX0000072099 WX00000000404674
Printed D&T: 03/23/20 15:46

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