

TEST DIRECTORY UPDATE

APRIL 8, 2020 CORONAVIRUS UPDATE

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Update Summary		
Inactivate Test With Replacement	4/9/2020	COVNP - "SARS Coronavirus with CoV-2 RNA, Qual Real-Time RT-
		PCR" replaced by COVWD - "SARS-CoV-2 Qualitative"

Inactivate Test With Rep	lacement
Effective Date	4/9/2020
	Inactivated Test
Name	SARS Coronavirus with CoV-2 RNA, Qual Real-Time RT-PCR
Code	COVNP
Legacy Code ¹	COVNP
Interface Order Code	3400271
Notes	
	Replacement Test
Name	SARS-CoV-2 Qualitative
Code	COVWD
CPT Code(s)	87635 (U0002)
Notes	
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. 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. Warde now accepts all media listed above.
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: -70 °C
Performing Information	
Methodology	Real-Time Polymerase Chain Reaction (PCR)
Reference Range	Not Detected
Performed Days	Sun - Sat



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Turnaround Time	24 - 48 hours					
Performing Laboratory	Warde Medical Laboratory					
Interface Information						
Legacy Code ¹	COVWD					
Interface Order Code	3000065					
Result Code	Name	LOINC Code	AOE/Prompt ²			
3000066	SARS-CoV-2 Qual RT PCR	94500-6	No			



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 EXAMPLE, REPORT WX0000072099 M 12/05/1988 31 Y

	Molecula	r				
	Collected:	03/23/2020	15:35	Received:	03/23/2020	15:35
Test Name	<u>Result</u>	<u>Flag</u>	Ref-Ranges	<u>.</u>	<u>Units</u>	<u>Site</u>
SARS-CoV-2 Qualitative						
SARS-CoV-2 Qual RT PCR	Not detected		Not detecte	d		WMRL
This test was performed assay and has been authon Authorization (EUA). The nasopharyngeal (NP) and transport media. The lin approximately 100 copies detection of SARS-CoV-2 collection and transport presence of symptoms, an negative result does not infection. For updated for Disease Control webs	prized by FDA under an e assay is validated for oropharyngeal (OP) swa mit of detection of the s per milliliter; howev may be affected by the t methods, patient fact nd/or stage of infection t rule out the possibil information, refer to	Emergency r bs in assay is er, sample ors (e.g. n), and a ity of the Cente	7 Use			

Performing Site: WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 EXAMPLE, REPORT WX0000072099 M 12/05/1988 31 Y

	Molecular						
	Collected: 0	3/23/2020) 15:41	Received:	03/23/2020	15:41	
Test Name	<u>Result</u>	Flag	Ref-Ranges	<u>.</u> .	<u>Units</u>	<u>Site</u>	
SARS-CoV-2 Qualitative							
SARS-CoV-2 Qual RT PCR	DETECTED	AB	Not detecte	d		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.							

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Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 EXAMPLE, REPORT WX0000072099 M 12/05/1988 31 Y

		Molecular					
		Collected: 0	3/23/2020) 15:41	Received:	03/23/2020	15:41
<u>Test Name</u>		Result	Flag	Ref-Range	<u>s l</u>	<u>Units</u>	<u>Site</u>
SARS-C	oV-2 Qualitative						
SARS-CoV	-2 Qual RT PCR	Inhibitory to PCR	AB	Not detecte	ed		WMRL
	Inhibitory result. This specin that interfere with PCR amplit acids. Interfering substances limited to, heme, heparin and detergents, complex polysaccha nucleases, and DNA binding pro- sending another specimen for the This test was performed via the assay and has been authorized Authorization (EUA). The assay nasopharyngeal (NP) and oropha transport media. The limit of approximately 100 copies per r detection of SARS-CoV-2 may be collection and transport methor presence of symptoms, and/or s negative result does not rule infection. For updated inform for Disease Control website: w	fication of the nuc s include, but are other chelating ag arides, proteases, oteins. Please con- testing. The Abbott RealTime by FDA under an Er y is validated for aryngeal (OP) swabs detection of the a- milliliter; however affected by the so ods, patient factor stage of infection) out the possibility mation, refer to the	cleic not gents, hsider SARS-Co mergenc; s in assay i: c, sample cs (e.g d, and a cy of he Cento	y Use s ., a		Perfori	ming Site:

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

Ordered By: CLIENT CLIENT WX00000000404674