



**Demo Location 1**  
123 Evergreen Terrace  
Springfield, MI 48346

**Lab Director:** Dr. Doc Mcstuffins  
**CLIA:** XXD1234567  
**Phone:** (123) 456-7890  
**Fax:**

<b>Patient Name</b> Sample, Covid		<b>Date of Birth</b> 1/30/2021		<b>Gender</b> M	<b>Ordering Physician</b> Hey, Wayne D		<b>Client ID</b> <b>Demo Location 1</b> 123 Evergreen Terrace Springfield, MI 48346	
<b>Specimen ID</b> 100204 (Swab)	<b>Requisition Number</b>	<b>Collected Date</b> 3/30/2021 9:01:44 AM	<b>Received Date</b> 3/30/2021 10:02:20 AM	<b>Reported Date</b>	<b>Panel #</b>			

Category	Test	Result	Comment
COVID ANTIBODY	SARS CoV-2 (COVID-19) IgG	Negative	
--	SARS CoV-2 (COVID-19) IgM	Negative	
COVID ANTIGEN	Sofia 2 SARS Antigen FIA	Negative	
<b>COVID PCR</b>	<b>SARS CoV-2 (COVID-19) PCR</b>	<b>Positive</b>	

**Notes:**

This test has been validated according to the FDA guidelines. Our laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests CLIA#XXD1234567. This test has not been Food and Drug Administration (FDA) cleared or approved. The assay is submitted for authorization by FDA under an Emergency Use Authorization (EUA). The SARS-CoV-2 test is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients.

Testing methodology is real-time PCR. If received as separate collection devices, nasopharyngeal and oro-pharyngeal specimens are combined for analysis. Test results must have clinical correlation with patient history and other diagnostic information necessary to determine patient infection status. Test performance can be affected because the clinical spectrum of infection caused by SARS-CoV-2 is not fully known. SARS-CoV-2 RNA NOT DETECTED. Not Detected results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

Negative results must be combined with clinical observations, patient history, and epidemiological information. Not Detected results are concluded based on the inability of probes annealing to all three (ORF1ab, N gene, S gene) specific SARS-CoV-2 target sequences (from the sample submitted) located between three (3) unique forward and reverse primers, resulting in no Amplification signals during real-time PCR.

The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences. SARS-CoV-2 RNA DETECTED. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Detected results are concluded based on the probes annealing to two out of three (ORF1ab, N gene, S gene) specific SARS-CoV-2 target sequences (from the sample submitted) located between three (3) unique forward and reverse primers, resulting in Amplification signals during real-time PCR.

The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences. SARS-CoV-2 RNA INCONCLUSIVE. INCONCLUSIVE results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Inconclusive results must be combined with clinical observations, patient history, and epidemiological information. Inconclusive results are concluded based on detection of only one of three (ORF1ab, N gene, S gene) specific SARS-CoV-2 target sequences. Detection of only one of three (ORF1ab, N gene, S gene) specific SARS-CoV-2 target sequences triggers a recommendation of recollection