



Patient		Physician	
Last Name	Account	Last Name	Physician
First Name	Test	First Name	Test
Middle Name		Middle Name	
Date of Birth	11/11/1999	NPI#	1111111111
MRN	B46724	Address	955 Yonkers Ave YONKERS, NY 10704
Sex	Female		

Requisition ID	Collected	Received	Reported
221021AT00429	10/21/2022 11:32 AM	10/21/22 3:22 PM	10/21/2022 3:28 PM

Testing Ordered	SARS-CoV-2/FluA/FluB Multiplex	Collection Site	Nasopharyngeal
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COVID19

TEST	RESULT	FLAG	REF. RANGE
Influenza A	Negative		Negative
Influenza B	Negative		Negative
SARS-COVID-2-PCR	Negative		Negative

The TaqPath™ COVID-19, FluA, FluB Combo Kit performance was established using nasopharyngeal swabs. Anterior nasal swabs are considered an acceptable specimen type for use with the TaqPath™ COVID-19, FluA, FluB Combo Kit. The assay targets include two SARS-CoV-2 targets (S-gene and N-gene); one Influenza A target; and one Influenza B target. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and Influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high-complexity tests. The performance characteristics of the test were validated by ATVIVO laboratory in agreement with the FDA's Guidance Document "Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency" issued on February 29th, 2020. The TaqPath™ COVID-19, Flu A, Flu B Combo Kit is only for use under the Food and Drug Administration's Emergency Use Authorization. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of the disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2, Influenza A, and/or Influenza B infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information. Invalid results are reported by the laboratory for a specimen that fails to produce a valid result. An invalid test result can mean that only one of the two assay targets was detected, or that the result otherwise did not meet our quality control specifications. In case of invalid results, the healthcare provider should conduct additional confirmation testing with a new specimen, if clinically indicated.

Laboratory Director	Adila Nathu, MD
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The above results and comments are for informational purposes only and are not to be interpreted as medical advice. Please consult your healthcare practitioner for diagnosis and treatment.

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***** END OF REPORT *****

Laboratory Director	Adila Nathu, MD
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