

Patient Name:	Amira Brown	Physician:	Dominique Thompson
Patient Gender:	Female	Facility:	Fast Test Now
Date of Birth:	12/22/2004	Date Collected:	2023-01-02T11:46:17
Patient Phone:	5512627678	Received:	2023-01-02T12:15:01
Patient Address:	323 1/2 8th St Jersey City, NJ 07302	Released:	2023-01-03T02:22:45
Requisition:	POSCV381791628	Accession:	E19218
		Specimen Type:	Nasopharyngeal Swab

Result:

COVID-19 RT-PCR Diagnostic Panel	
Test	Result
2019-nCoV RT-PCR	Positive

The Fastplex Triplex SARS-CoV-2 Detection Kit has received Emergency Use Authorization (EUA) from U.S. Food & Drug Administration (FDA). The Fastplex Triplex SARS-CoV-2 Detection Kit (RT-digital PCR) is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests. The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines. The Fastplex Triplex SARS-CoV-2 Detection Kit has been designed to minimize the likelihood of false positive test results. A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19. This document shall not be reproduced except in full, without the written approval of Poseidon Diagnostics

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