

American Family Care
4305 Atlanta Highway
Montgomery, AL 36109

FINAL COPY

Patient: Asuncion, David	Acc #: 3113972
Patient #: 2397130	Birth: 12/13/1977
Doctor: Rawls, Wilnadia A	Age: 42 years
Home Phone: (334)221-0919	Gender: Female
	Collection Date: 10/5/2020 11:54 AM
	Received in Lab: 10/5/2020 11:54 AM

Test Name	Result	Units	Flag	Reference Range
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COVID-19 Molecular

Run by: MJW on 10/5/2020 12:12 PM

COVID-19 Molecular

Negative

Negative

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2RNA is generally detectable in respiratory samples during the acute phase of infection. 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. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history, presence of clinical signs and symptoms consistent with COVID-19.

Molecular Internal Procedure Valid
Control

Valid