FUSION DIAGNOSTICS LABORATORIES
210 MALAPARDIS ROAD/SUITE 103 CEDAR KNOLLS, NJ 07927-1121
Tel: (973)998-8189 ▪ Fax: (973)998-8192
FusionDiagnostics.com | 1-866-FusionLab
CLIA ID# 31D2033824
Lab. Dir: George Jour M.D.

Patient:	**WANG, ZHUO**	Client: **FUSION DIAGNOSTICS**	1
DoB:	09/27/1987 Age:33 Sex: F	210 MALAPARDIS ROAD	
Phone:	(845) 800-6577	CEDAR KNOLLS, NJ 07927-	
ID#:	A2109170228	(973) 998-8189	
Route#:	0 Page: 1	Phys:	

Acc# **2109170228**	Coll. Date: 09/17/21	Recv. Date: 09/17/21	Print Date: 12/23/21
Chart#	Coll. Time: 20:21	Recv. Time:22:21	Print Time: 16:17
First reported on:	09/19/21	Final report date:	09/19/21

Test Name	Normal	Abnormal	Normal Range	Units

Report Status: FINAL

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COVID 19 PCR NEGATIVE NEGATIVE *1

Interpretation:
The iAMP COVID-19 Detection Kit is a real-time fluorescent reverse transcription isothermal assay(PCR) intended for the qualitative detection of
nucleic acid from the SARS-CoV-2 in nasopharyngeal (NP), and oropharyngeal (OP) swabs from patients suspected of COVID-19 by their health care provider.
Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens 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.

Negative results mean that SARS-CoV-2 was not present at the limit of detection. RNA Negative 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.

Limitations and disclaimers:
1. This assay is for in vitro diagnostic use under FDA Emergency Use Authorization only.
2. This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. ?263a, that meet the requirements to perform high complexity tests.
3. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

4. 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

(Continued on Next Page)

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********** (Continued)

Section 564(b)(1) of the Act, 21 U.S.C. ? 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
5. Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
6. Negative results do not rule out SARS-CoV-2 infection,particularly in those who have been in contact with the virus. Repeat testing with another molecular diagnostic should be considered to evaluate for active infection
in these individuals.
7. Performance of the iAMP COVID-19 Detection Kit was established for OP and NP swab specimens only. Other specimen type have not been evaluated.
8. Improper collection, transport, or storage of specimens may impact the ability of the assay to perform as indicated.

9. False-negative results may arise from: Improper sample collection,storage and transport and resulting in degradation of the SARS-CoV-2 RNA,the presence of RT-PCR inhibitors,Mutation in the SARS-CoV-2 virus,and/or failure to follow instructions for use. 10. The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated.
11. The iAMP COVID-19 Detection Kit cannot rule out respiratory diseases caused by other bacterial or viral pathogens.

END OF REPORT

**1) Unless otherwise noted, Tests Performed at :*
INFINITY DIAGNOSTICS LAB(2696), TETERBORO, NJ 07608 CLIA# 31D2068211