

Demo Location 1 200 Medical Drive Carmel, IN 46032 (713) 555-1212

Laboratory Report PARTIAL

PATIENT

Name: Fleck, Authur DOB: 5/18/1955 (Age: 66)

Gender: Male Account: 123-1 Clinic ID: Chart/EMR: **ORDERING PROVIDER**

Strange Steven 200 Medical Drive Carmel, IN 46032

P: (317) 794-3900 F: (713) 555-1212 **SPECIMEN**

Status:

Needs Review

Test Name	Result	Flag	Comments
RPP			
Acinetobacter baumannii	Not Detected		
Adenovirus	Not Detected		
Bordatella pertussis	Detected		
Chlamydophila Pneumoniae	Detected		
Coronavirus (229E, HKU1, NL63, OC43)	Not Detected		
EBV (mononucleosis)	Not Detected		
Enterobacter cloacae	Detected		
Enterovirus species	Not Detected		
Haemophilus Influenza	Not Detected		
HMPV (A & B)	Not Detected		
Klebsiella pneumoniae	Not Detected		
Legionella Pneumophila	Detected		
Moraxella catarrhalis	Detected		
MRSA	Not Detected		
Mycoplasma Pneumoniae	Not Detected		
Parainfluenza virus (types 1-4)	Not Detected		
Respiratory Virus; 12-25 Targets***	Detected		
Rhinovirus (types A & B)	Detected		
RSV, A & B	Detected		
Staphylococcus aureus	Not Detected		
Streptococcus pneumoniae	Not Detected		
Streptococcus pyogenes, Group A	Not Detected		

CoVid-19 Comments

- This test has been authorized by the FDA under an Emergency Use Authorization (EUA). This test has been validated in accordance 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. FDA independent review of this validation is pending. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- The DEMO LAB Cov COVID-19 test is a molecular RT-qPCR FDA Emergency Use Authorized Test. The performance characteristics were developed by Demo Labs, LLC.
- The detection of viral nucleic acid is dependent upon proper specimen collection, handling, transportation and preparation. Failure to observe proper
 procedure in any one of these steps may lead to incorrect results with risk of false positive or false negative results. Specimen should be stored at 2-8
 degrees celcius no more than 72 hours. Store and ship samples at <-20 degrees celcius after 72 hours.
- Negative results do not rule out the possibility of infection. Results should be interpreted in conjunction with other relevant tests and patient's clinical profile.
- If you have any questions, please contact Demo Labs.

END OF REPORT

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