ClearLab Flu+COVID19 Antigen Assay IFU

petercb3

1. Collect specimen with Clearinse Nasal Wash Aspiration System

ABSTRACT

Indication: Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal aspirate specimens directly or after the aspirate have been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories and other authorized testing locations.

EXTERNAL LINK

http://www.clearmynose.com

DOI

dx.doi.org/10.17504/protocols.io.bj8fkrtn

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IMAGE ATTRIBUTION

Image is from Princeton BioMediTech Corporation

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40935

DISCLAIMER:

This device is currently under review for EUA by FDA
2 Pipette 100 μL out from specimen chamber (up to first mark of graduated transfer pipette)

3 Dispense entire sample from pipette into the assay cassette’s extraction well.

4 Then, pipette 50μL reagent into the assay cassette’s extraction well and let sit for one minute.

5 Raise assay cassette upright and let stand for 2 seconds

6 Lay device back down and read results in 10 minutes.