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# ClearLab Flu+COVID19 Antigen Assay IFU

petercb3<sup>1</sup><sup>1</sup>Chris Baker MD (Aardvark Medical, Inc), Roger Kang (Princeton BioMediTech)

In Development

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

Coronavirus Method Development Community



petercb3

## 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](https://dx.doi.org/10.17504/protocols.io.bj8fkrtn)

## PROTOCOL CITATION

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## IMAGE ATTRIBUTION

image is from Princeton BioMediTech Corporation

## CREATED

Aug 24, 2020

## LAST MODIFIED

Aug 30, 2020

## PROTOCOL INTEGER ID

40935

## DISCLAIMER:

This device is currently under review for EUA by FDA

- 1 Collect specimen with Clearinse Nasal Wash Aspiration System

- 2 Pipette 100 uL 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 50uL 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.