QUIDEL

QuickVue®

Results. Right. Now.

AVAILABLE FOR SALE IN THE USA AS EUA

SARS Antigen

Test and Treat Today®!

- Identifies SARS-CoV-2 antigens in 10 minutes for better patient management decisions
- Accurate detection with direct anterior nares swab samples: 96.6% PPA and 99.3% NPA
- Simple workflow follows a similar format to CLIA-waved QuickVue assays, just sample, dip, and read
- Each kit contains everything needed to perform the test, including nasal swabs and Positive and Negative Controls
- Room temperature storage

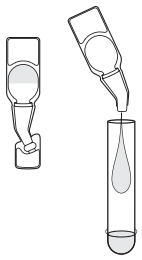
Quidel | Rapid Diagnostics | quidel.com | 800.874.1517 | 858.552.1100

Nasal swab procedure:

1

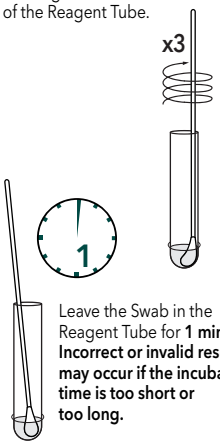
Dispense all of the Reagent Solution into the Reagent Tube. Swirl the Reagent Tube to dissolve its contents.

NOTE: The Reagent Tube should remain in the tube holder for the entirety of the testing



2

Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.



Leave the Swab in the Reagent Tube for **1 minute. Incorrect or invalid results may occur if the incubation time is too short or too long.**

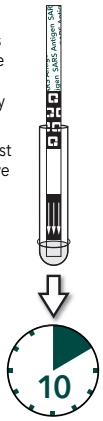
3

Express all liquid from the swab head by rolling the swab a minimum of three (3) times as the swab is being removed. Discard the swab in accordance with your biohazard waste disposal protocol.

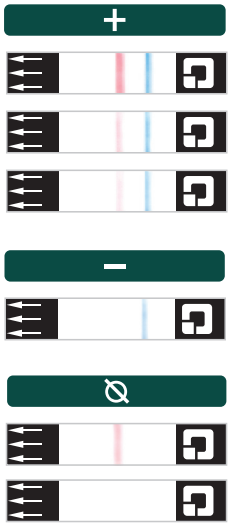
4

Place the Test Strip into the Reagent Tube with the arrows pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.

At **10 minutes**, remove the Test Strip and read result within five (5) minutes.



Test strips should be read between 10-15 minutes. False positive, false negative or invalid results may occur if the strip is read beyond the recommended time period.



Comparison of QuickVue SARS Antigen Test and an authorized EUA Molecular Comparator Assay with Matched Anterior Nares Swabs*

Specimen Type	Number Tested	True Positive	False Positive	True Negative	False Negative	PPA%	NPA%	PPA 95% CI	NPA 95% CI
Fresh Specimens	138	30	1	106	1	96.8	99.1	83.8 to 99.4	94.9 to 99.8
Frozen Specimens	56	26	0	29	1	96.3	100	81.7 to 99.3	88.3 to 100
Combined Specimens	194	56	1	135	2	96.6	99.3	88.3 to 99.0	96.0 to 99.9

*Please refer to the Package Insert for full study design and explanation.

The QuickVue SARS Antigen Test has not been FDA cleared or approved but has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.

SL3207 | SS2038703EN00 (05/22)

QuickVue SARS Antigen Test – 25 Test Kit (anterior nares swab): Cat. #20387
QuickVue SARS Antigen Swab Transport Tube Set – Cat. #20385

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