

CareStart[™] COVID-19 ANTIGEN RAPID TESTS
EUA Granted

Features

- ▶ Identify individual's current infection status to COVID-19
- ▶ Fast and easy to use in Point-of-Care setting
- ▶ Qualitatively detect the SARS-CoV-2 nucleocapsid protein
- ▶ Use nasopharyngeal (NP) swab specimens
- ▶ Reliable results only in 10 minutes
- ▶ No special equipment or training required
- ▶ All-in-one package including collection swabs
- ▶ High sensitivity (88.4%) and specificity (100%)

Kit Components

- ▶ 20 test devices
- ▶ 20 extraction vials and caps
- ▶ 20 NP swabs
- ▶ 1 positive and 1 negative controls
- ▶ Package insert
- ▶ Quick reference Instructions (QRI)

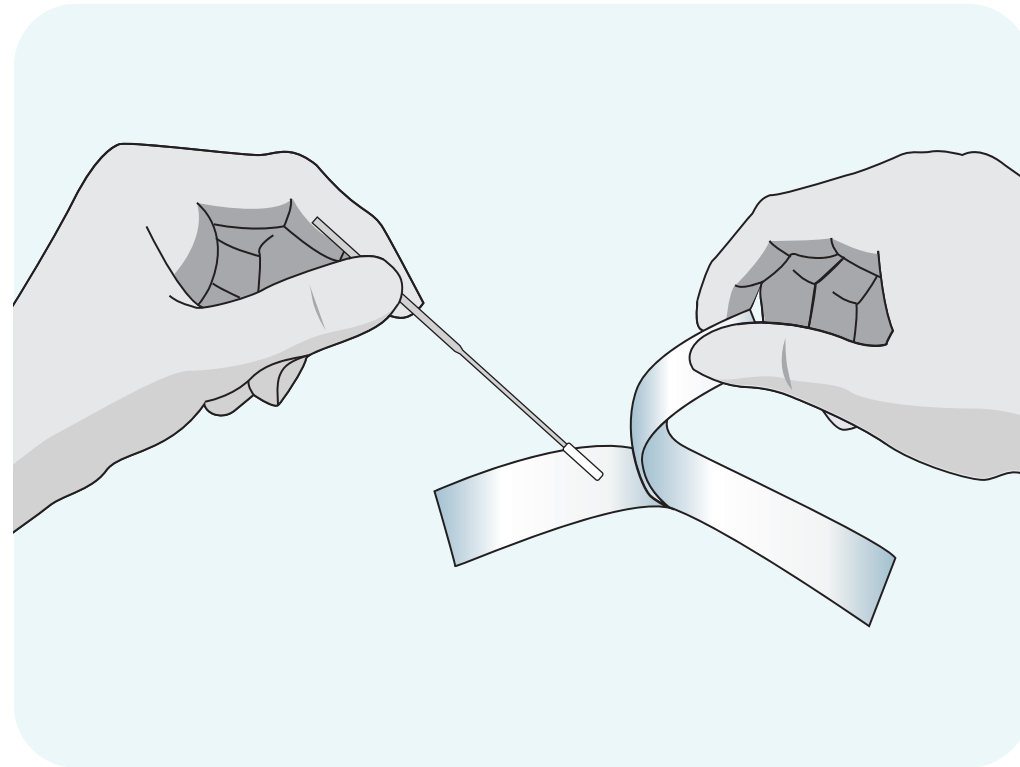


CareStart™ COVID-19 ANTIGEN

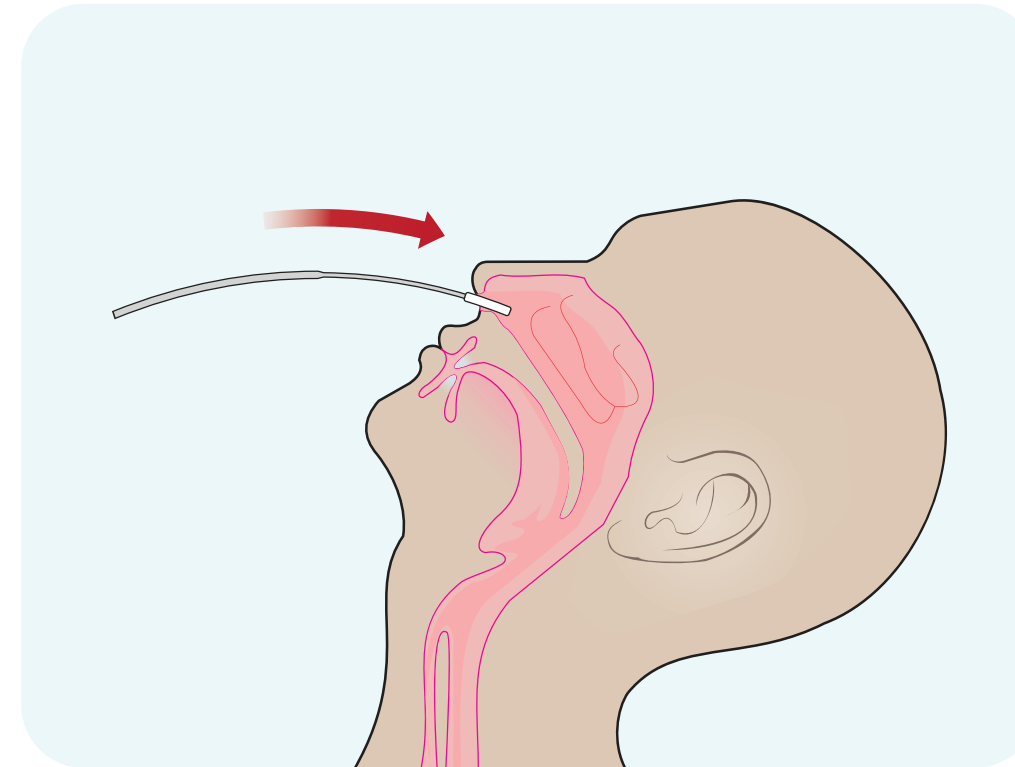
Rapid Diagnostic Test for the Detection
of SARS-CoV-2 Antigen

- For *in vitro* diagnostic use only
- For prescription use only
- FDA Emergency Use Authorization (EUA) Pending

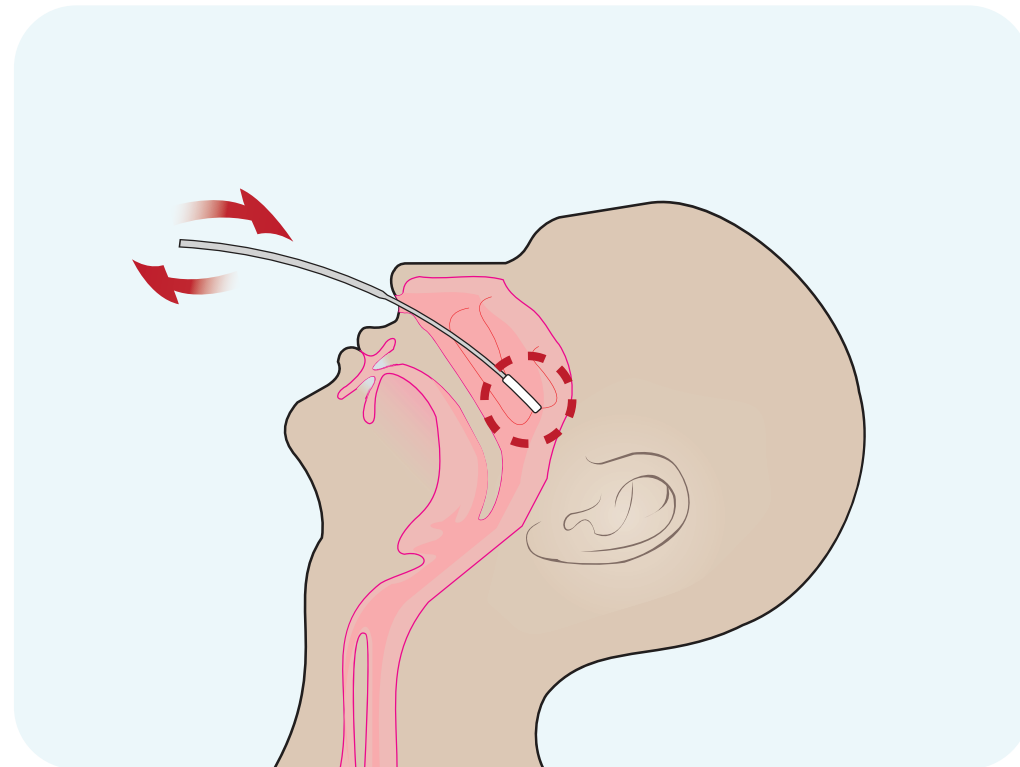
Nasopharyngeal (NP) Swab Collection



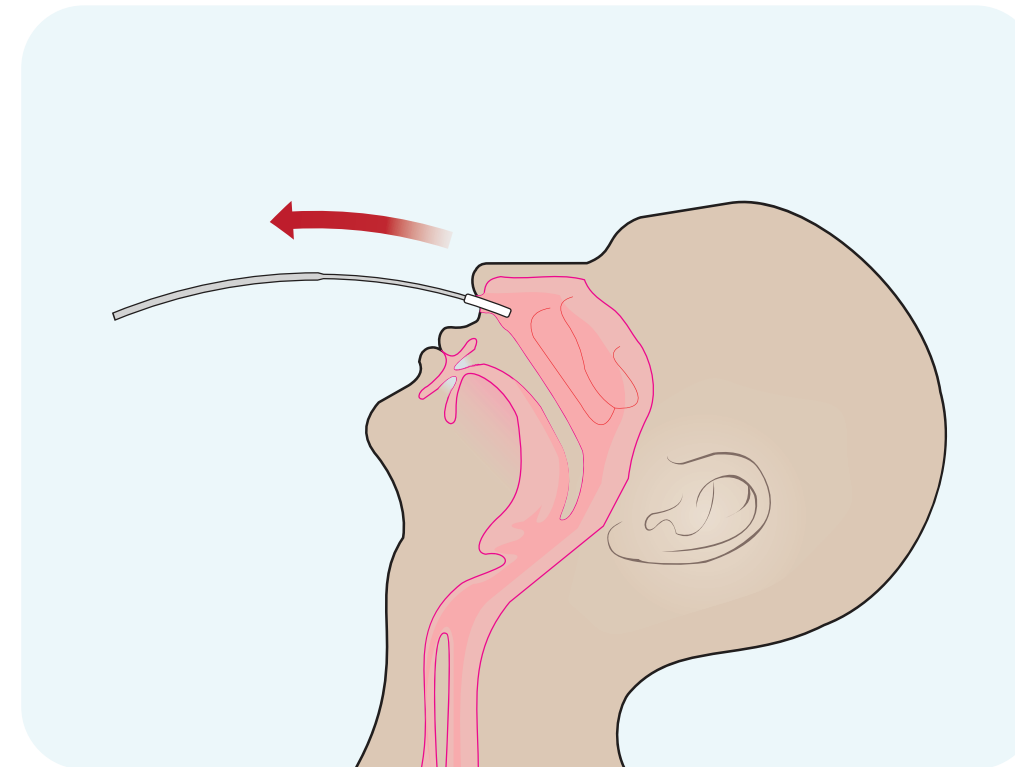
1 Remove a swab from the pouch.



2 Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.



3 Slowly rotate 5 times the swab over the surface of the posterior nasopharynx.

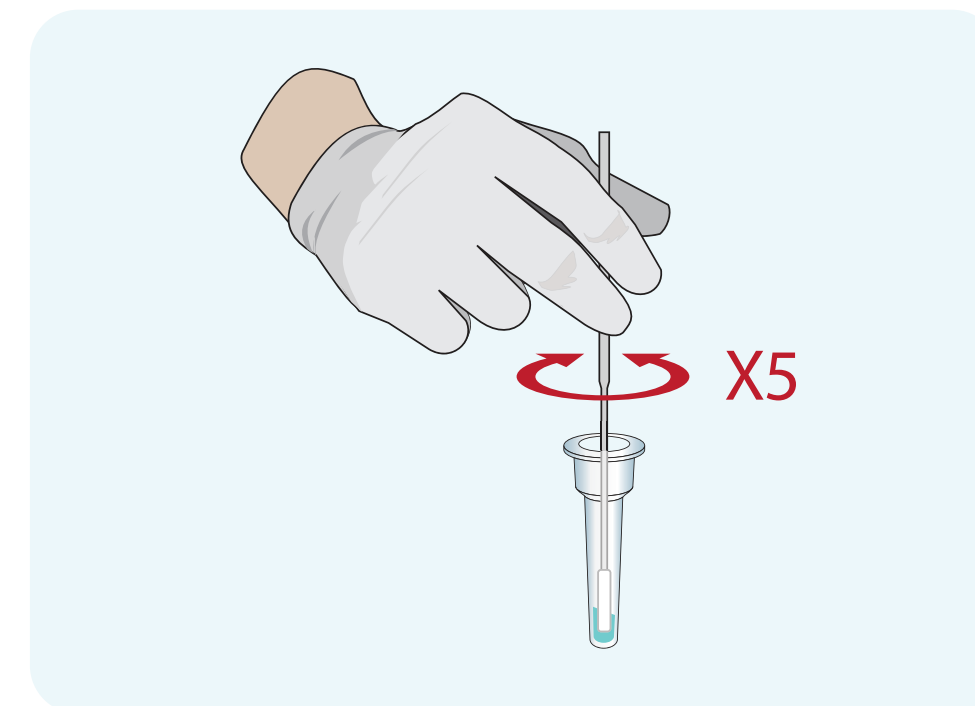


4 Remove the swab from the nostril.

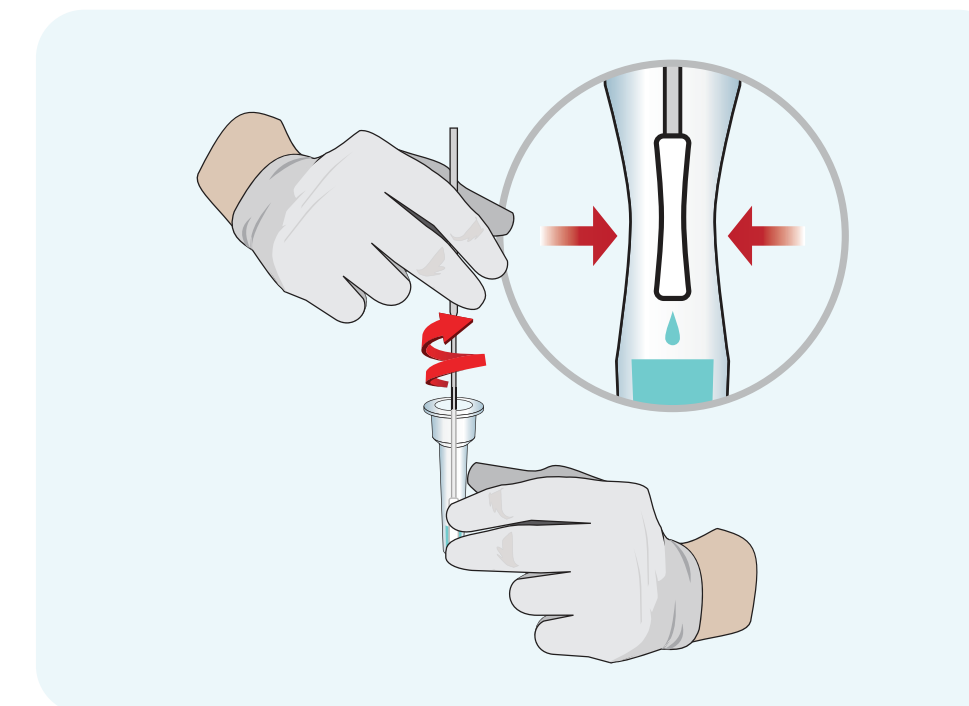
- ▶ Nasopharyngeal is the CDC recommendation for an upper respiratory specimen collection and testing.
- ▶ However, other acceptable collection methods such as anterior nares (nasal) is being evaluated because of its less complex and minimal invasive nature. Nasal specimen can be collected by home or supervised onsite self-collection using a flocked or spun polyester swab



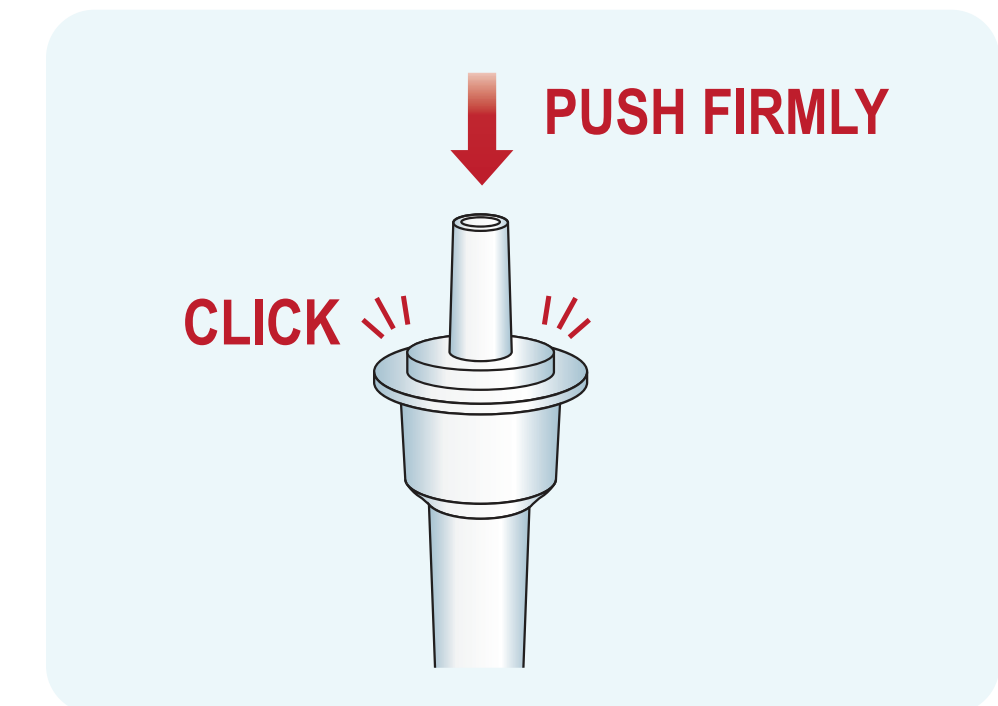
5 Peel off aluminum foil seal.



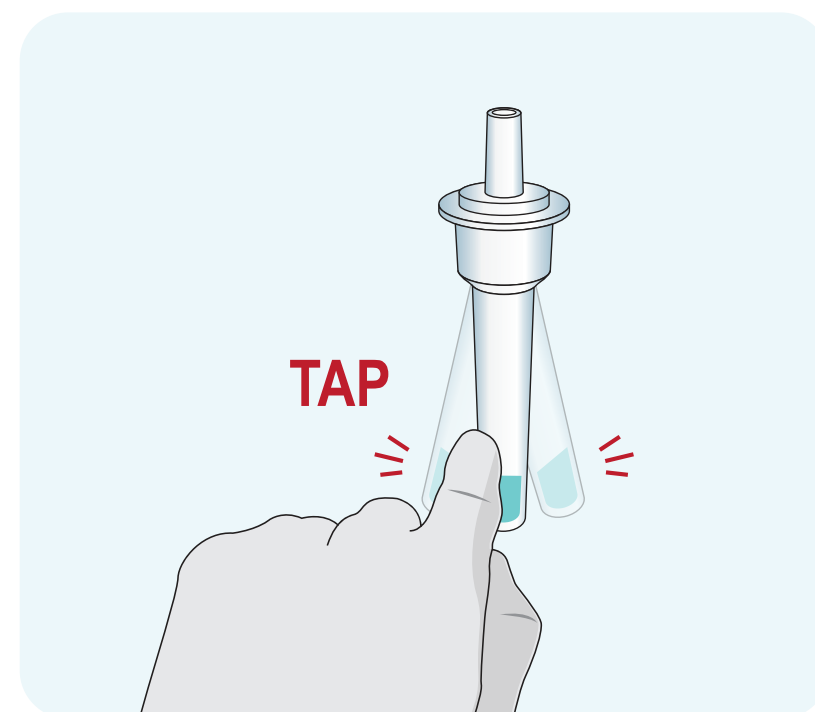
6 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



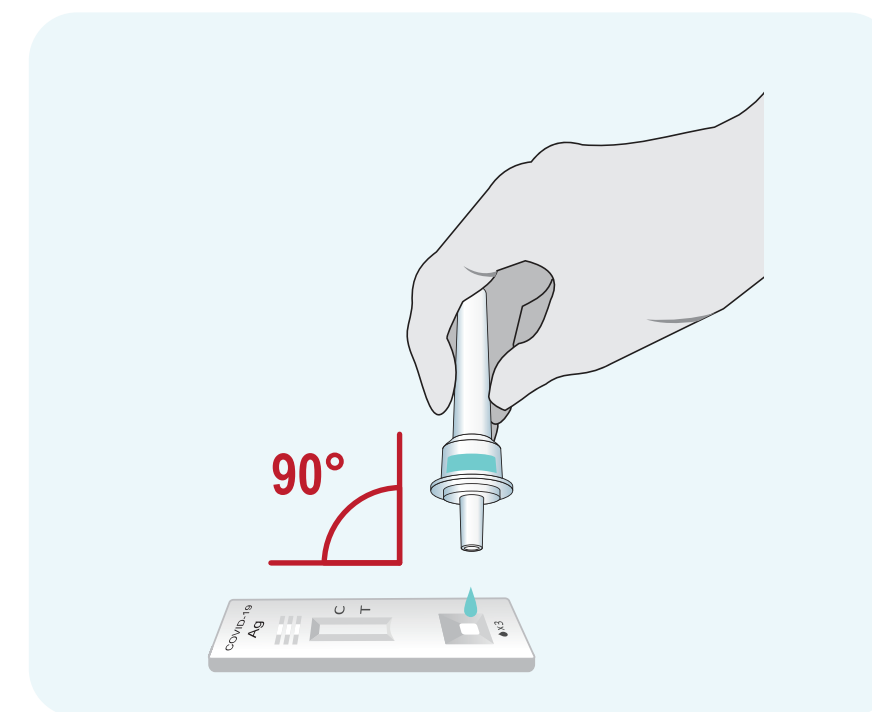
7 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



8 Close the vial by pushing the cap firmly onto the vial.

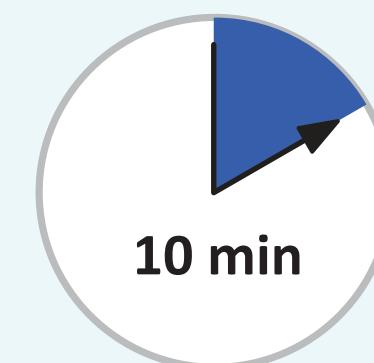


9 Mix thoroughly by flicking the bottom of the tube.



10 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.

Start the timer

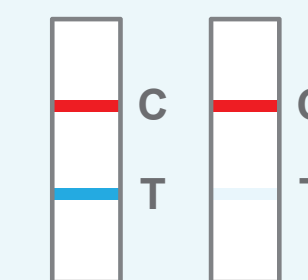


Read the result at 10 minutes. The test result should not be read after 15 minutes.

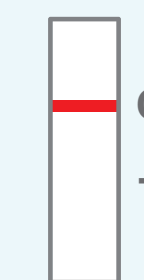


Result Interpretation

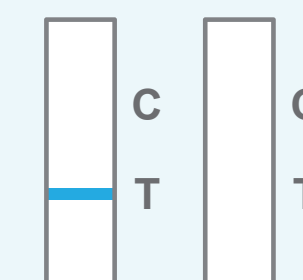
SARS-CoV-2 Positive



Negative



Invalid



NOTES

- The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample.
- Any faint colored line(s) in the test region(s) should be considered as positive.

NOTES

- Re-run the test one time using the remaining specimen in the extraction vial.

Cross-reactivity

Viruses listed below are confirmed not to have cross-reactivity with *CareStart*[™] COVID-19 Antigen.

- ▶ Adenovirus 1
- ▶ Adenovirus 7
- ▶ Enterovirus 71, Tainan/4643/1998
- ▶ Human coronavirus (OC43)
- ▶ Human coronavirus (229E)
- ▶ Human coronavirus (NL63)
- ▶ Human metapneumovirus (hMPV)
- ▶ Influenza A/Michigan/45/2015
- ▶ Influenza B/Wisconsin/01/2010
- ▶ MERS-Coronavirus, Irradiated Lysate
- ▶ Parainfluenza virus type 1
- ▶ Parainfluenza virus type 2
- ▶ Parainfluenza virus type 3
- ▶ Parainfluenza virus type 4
- ▶ Respiratory syncytial virus type B
- ▶ Rhinovirus
- ▶ Pooled human nasal wash

Bacteria listed below are confirmed not to have interference with *CareStart*[™] COVID-19 Antigen.

- ▶ *Bordetella pertussis*
- ▶ *Candida albicans*
- ▶ *Chlamydomonas pneumoniae*
- ▶ *Haemophilus influenzae*
- ▶ *Legionella pneumophila*
- ▶ *Mycoplasma pneumoniae*
- ▶ *Streptococcus pneumoniae*
- ▶ *Streptococcus pyogenes, Group A*
- ▶ Acetaminophen
- ▶ Acetyl salicylic acid
- ▶ Beclomethasone
- ▶ Benzocaine
- ▶ Budesonide
- ▶ Chlorpheniramine maleate
- ▶ Dexamethasone
- ▶ Dextromethorphan HBr
- ▶ Diphenhydramine HCl
- ▶ Ephedrine HCl
- ▶ Flunisolide

Endogenous Interference Substances Studies:

Interfering substances listed below are confirmed not to have interference with *CareStart*[™] COVID-19 Antigen.

- ▶ Acetaminophen
- ▶ Acetyl salicylic acid
- ▶ Beclomethasone
- ▶ Benzocaine
- ▶ Budesonide
- ▶ Chlorpheniramine maleate
- ▶ Dexamethasone
- ▶ Dextromethorphan HBr
- ▶ Diphenhydramine HCl
- ▶ Ephedrine HCl
- ▶ Flunisolide
- ▶ Fluticasone
- ▶ Guaiacol Glyceryl Ether
- ▶ Histamine Dihydrochloride
- ▶ Menthol
- ▶ Mometasone
- ▶ Mucin
- ▶ Mupirocin
- ▶ OTC Throat drop (Halls)
- ▶ OTC Throat drop (Ricola)
- ▶ OTC Nasal spray (Afrin)
- ▶ OTC Nasal spray (VicksSinex)
- ▶ OTC Nasal spray (Zicam)
- ▶ Oxymetazoline HCl
- ▶ Phenylephrine HCl
- ▶ Phenylpropanolamine
- ▶ Tobramycin
- ▶ Triamcinolone
- ▶ Whole Blood
- ▶ Zanamivir

CareStart™ COVID-19 Antigen (retrospective samples) Against Comparator PCR Method with Nasopharyngeal Swabs

CareStart™ COVID-19 Antigen	PCR Comparator		
	Positive	Negative	Total
Positive	38	0	38
Negative	5	63	68
Total	43	63	106
Positive Percent Agreement (PPA)	88.4% (95% CI: 75.52% - 94.93%)		
Negative Percent Agreement (NPA)	100% (95% CI: 94.25% - 100%)		

CareStart™ COVID-19 Antigen (near cut-off samples) Against Comparator PCR Method with Nasopharyngeal Swabs

Samples	Overall % Agreement
True negative (zero analytes)	100% (10/10)
Low positive (2x LoD)	100% (10/10)

Test	Access Bio	Becton Dickinson	Quidel*
Technique	Lateral flow chromatographic immunoassay	Lateral flow chromatographic immunoassay	Lateral flow immunofluorescent
Instrument	No	Veritor Plus Analyzer (\$400)	Sofia 2 Analyzer (\$3,000)
Preparation Time	None	None	Yes (Sofia calibration)
Known Cross Reactivity	No	No	SARS-CoV-1
Processing time	10 minutes	15 minutes	15 minutes
Clinical Sensitivity	88.4%	84%	96.7%
Clinical Specificity	100%	100%	100%
Specimen Type	Nasopharygeal swabs	Nasal swabs	Nasopharygeal and Nasal swabs
Analytical Sensitivity (LOD)	8×10^2 TCID ₅₀ /mL	1.4×10^2 TCID ₅₀ /mL	3.4×10^2 TCID ₅₀ /mL
Point-of-Care	Yes	Yes	Yes
Target	Nucleocapsid antigen	Nucleocapsid antigen	Nucleocapsid antigen

* Quidel Requires 3 year contract of flu tests in order to purchase antigen tests