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Boston Biopharma CareStart™ Rapid Diagnostic Antigen Test

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1 Works for me dx.doi.org/10.17504/protocols.io.bkzxkx7n

XPRIZE Rapid Covid Testing

tclark

ATTACHMENTS

Abstract XPrize.pdf

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Covid-19 antigen test

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GUIDELINES

For prescription and *in vitro* diagnostic use only.
This test has not been FDA cleared or approved.
As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
Immediately use after opening the test device in the pouch.
In order to obtain accurate results, the test must follow this package insert.
Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasopharynx when collecting specimens.
Do not interpret the test result before 10 minutes and after 15 minutes starting the test.
Do not use if the test device package is damaged.
Do not use the kit contents beyond the expiration date.

MATERIALS TEXT

1 carestart antigen kit

Contents Name	Quantity (in a kit)	Description
Test device	20 each	Foil pouched test device containing one test strip which is encased in plastic device cassette.
Extraction vial / cap	20 vials and caps	The extraction vial contains 400 ml extraction buffer solution.
Nasopharyngeal swab	20 each	swabs for nasopharyngeal specimen collection.
Positive control swab	1 each	Recombinant SARS-CoV-2 nucleocapsid protein antigen is dried on the foam-tipped head.
Negative control swab	1 each	Blank Universal Viral Transport media (BD UVT) is dried on the foam-tipped head.
Package insert	1 each	Instructions for use
Quick Reference Instructions (QRI)	1 each	Quick reference instructions

SAFETY WARNINGS

Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
Nitrile or latex gloves should be worn when performing this test.
If the extraction buffer contacts the skin or eye, flush with copious amounts of water.
Handle all specimens as though they contain infectious agents.
Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces a very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
Do not interchange kit contents from different lots.
Do not re-use any contents in the kit as they are single-use only.

BEFORE STARTING

Store the test kit as packaged between 1 ~ 30°C.
The reagents and materials in the *CareStart*™ COVID-19 Antigen are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.
The test device must remain in the sealed pouch until use.
Do not freeze any contents of the kit.
Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing.

Temperature Equilibrium

1 **Room temperature**

Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing

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Nasopharyngeal Swab Specimen Collection

2 Remove a nasopharyngeal swab from the pouch.

Use only provided or recommended nasopharyngeal swab for specimen collection.
Do not touch the tip (specimen collection area) of the swab.

Acceptable specimen type for testing with the *CareStart*™ COVID-19 Antigen is a direct nasopharyngeal swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

3 Place the swab into one of the patient's nostrils until it reaches the posterior nasopharynx.
Swab Specimen Collection.pdf

- Collect the specimen wearing safety gloves to avoid contamination.

4 Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx. **NP Swab Step 3.pdf**

5 Remove the swab from the nostril. **NP Swab Step 4.pdf**

Test Procedure

6 Remove the *CareStart*™ COVID-19 Antigen test device and extraction vial from its foil pouch immediately before testing.
Test Procedures.pdf

7 Peel off aluminum foil seal. **Test Procedure Step 7.pdf**

8 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times. **Test Procedure Step 8.pdf**

9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. **Test Procedure Step 9.pdf**

Properly discard the swab

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Properly discard the swab.

10 Close the vial with the provided cap and push firmly onto the vial. **Test Procedure Step 10.pdf**

11 Mix thoroughly by flicking the bottom of the tube. **Test Procedure Step 11.pdf**

12 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. **Test Procedure Step 12.pdf**

13 Read and interpret the test result at 10 minutes. The test result should not be read and interpreted after 15 minutes.
00:10:00 Read after 10 minutes but before 15 minutes **Test Procedure Step 13_Timer.pdf**

Interpretation of Results

14 The test results should be read and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes. The test results should not be interpreted using any instruments. **Interpetation of Results.pdf**

15 Positive Result: One red-colored line next to “C” and one blue-colored line next to “T” indicates COVID-19 positive result. **Positive Test Result.pdf**

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

16 Negative Result: One red-colored line only next to “C” indicates a negative result. **Negative Test Result.pdf**

17 Invalid Result: If the red-colored line in the control region “C” is not visible, the result is invalid. Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.
Invalid Test Result.pdf

Limitations

18 The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.

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19 This test will only indicate the presence of SARS-CoV-2 nucleocapsid protein antigen in the specimen from both viable and non-viable SARS-CoV-2 virus.

20 This device is a qualitative test and does not provide information on the viral concentration present in the specimen.

21 This test cannot rule out diseases caused by other bacterial or viral pathogens.

Internal Quality Control

22 The *CareStart*™ COVID-19 Antigen contains a built-in internal procedural control that is included in the test device. A red-colored line appearing in the control region "C" is designed as an internal procedural control. The appearance of the procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. If the procedural control line does not develop in 10 minutes, the test result is considered invalid and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the manufacturer or distributor.

External Quality Control

23 External control is used to demonstrate that the test device and test procedure perform properly. It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the nasopharyngeal swab test procedure provided in this package insert or the quick reference instruction card. If the external control results are invalid, please contact the manufacturer or distributor before testing patient specimens.

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