

CareStart™ COVID-19 Antigen Home Test

QUICK REFERENCE INSTRUCTIONS



Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.
 Store the CareStart™ COVID-19 Antigen Home Test between 1-30°C (34-86°F). Ensure all kit contents are at room temperature before use.
 Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.
 For more information on expiration dating for COVID-19 antigen tests, please refer to <http://www.fda.gov/covid-tests>.



IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result. If you do not swab your nose, the device will produce a false negative result.

1 Wash your hands thoroughly for at least 20 seconds before the test.

2 Unpack the test components from the tray.

3 Remove the test cassette and place it on a flat, clean surface.

4 Locate the extraction vial and gently peel off the aluminum foil seal, being sure to keep the vial upright and place it in the packaging tray.

5 Locate a nasal swab and remove from the pouch. Be careful not to touch the swab tip.

6 Gently insert the swab no more than 3/4 inch into the **LEFT** nostril. Then, slowly rotate the swab at least **5 times** in a circular path pressing gently against the inside walls of your nostrils for a total of **15 seconds**. **Do not just spin the swab.** If you have questions, see the CDC Guidelines.

7 Gently remove the swab from the **LEFT** nostril and place directly into the **RIGHT** nostril, repeating the process of rotating at least **5 times** in a circular path pressing gently against the inside walls of your nostrils for a total of **15 seconds**. **Do not just spin the swab.** Remove the swab from the **RIGHT** nostril.

8 Place the swab into the extraction vial and rotate the swab at least **5 times against the walls of the vial.**

9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.

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

11 With your finger, mix thoroughly by flicking the bottom of the vial.

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.

13 Start a timer.
Read the result at **10 minutes**. The test result should not be read after 15 minutes.

IMPORTANT
Do not move or lift the test cassette during this time. Do not exit the mobile app during this process.

Disposal
Dispose of all used test kit components and swab samples in household trash.

Using Mobile Application Scan the QR code to download

- Ensure you have an internet connection and download the App prior to starting the test
- Ensure you are using a compatible smartphone. (For a list of compatible smartphone OS systems, visit www.accessbio.net/app)
- Only open the foil pouch packaging of test cassette when the App instructed to do so.

Please start the test and follow the in-app self-paced, step-by-step test instructions.

- Download and open App, Othena Mobile Application
- Answer a few questions in the App
- Watch the instructional video.
- Follow step-by-step instructions for your test.
- Test result

The App will assist in your visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device, and then look at the test cassette and answer questions about the result interpretation.

Results Interpretation

Make sure you wait the full 10 minutes.

You will be able to interpret your test results by following the in-app interpretation instructions or those provided in this section.

NOTE:
Do not read test results before 10 minutes or after 15 minutes. Results read before 10 minutes or after 15 minutes may lead to a false positive, false negative, or invalid result.

Serial (Repeat) Testing

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
Negative	Negative	Negative	Negative for COVID-19	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

+ COVID-19 Detected (Positive)

If the Purple-colored Control (C) line and the Blue-colored Test (T) line are visible, the test is positive. Any faint visible Blue-colored Test (T) line with the Purple-colored Control (C) line should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

IMPORTANT Look very closely! The color intensity in the test region will vary. Any faint colored line in the test region should be considered as positive.

A Positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

- COVID-19 Not Detected (Negative)

If the Purple-colored Control (C) line is visible, but the Blue-colored Test (T) line is not visible, the test is negative. **To increase the chance that the negative result for COVID-19 is accurate, you should:**

- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

? Invalid

If the Purple-colored Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

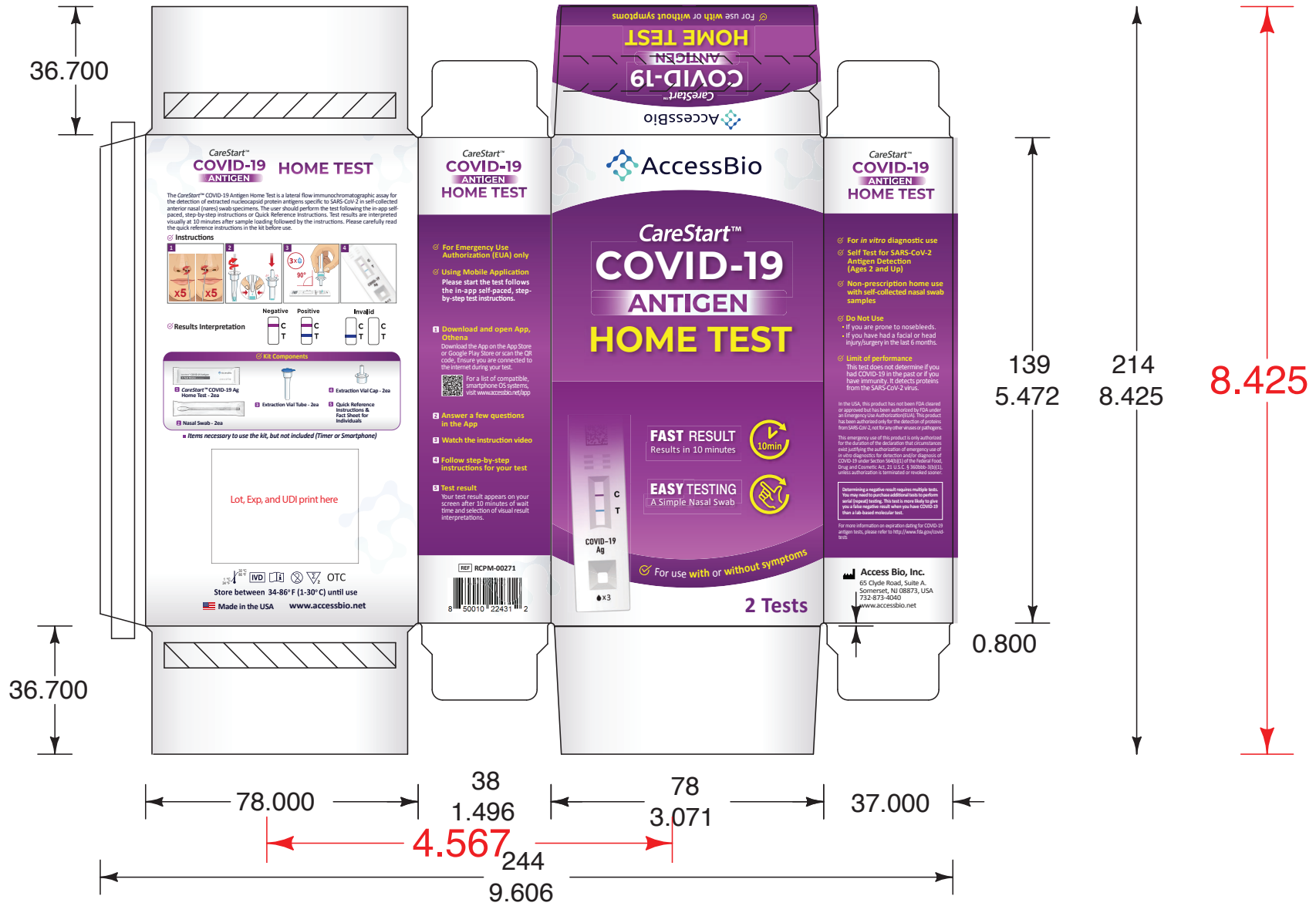
Report your test result(s) at MakeMyTestCount.Org (<https://makemytestcount.org>) - this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.



Part# PKCS0TC1AB
 Design Date : 01/26/23
 Designed by JSK DESIGN
 JSK Version. E

41939R1 10/17/2022
 Access Bio
 Home Test Kit
 seal end
 78 x 38 x 139
 (3.071 x 1.496 x 5.472)
 exterior view
 horizontal grain .018 sbs

change to standard
 T-16 zipper



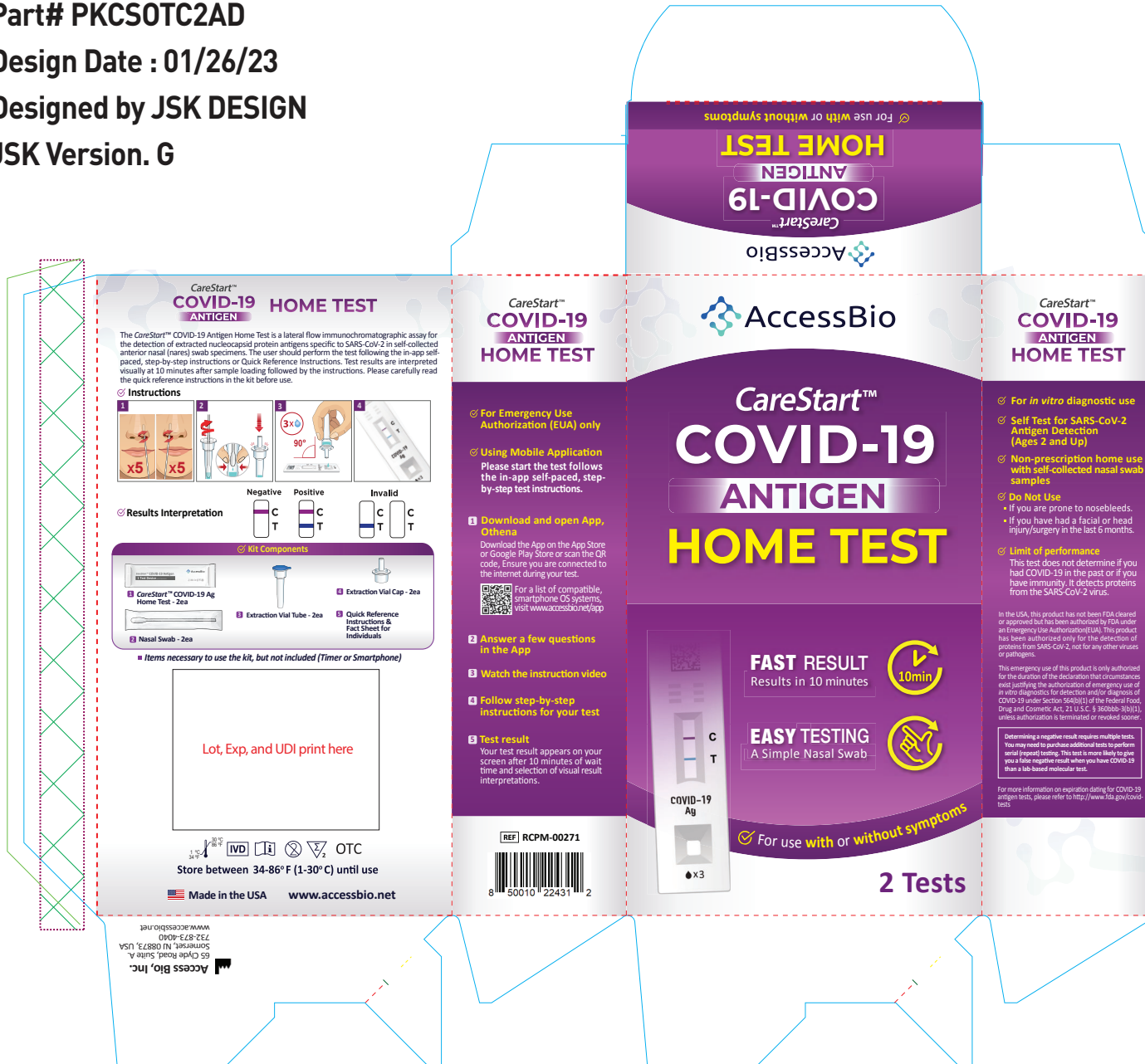
Dimension : 3.053 x 5.500 x 1.503 inch

Part# PKCS0TC2AD

Design Date : 01/26/23

Designed by JSK DESIGN

JSK Version. G



Part# PKCS0TC4AC
 Design Date : 01/26/23
 Designed by JSK DESIGN
 JSK Version. G



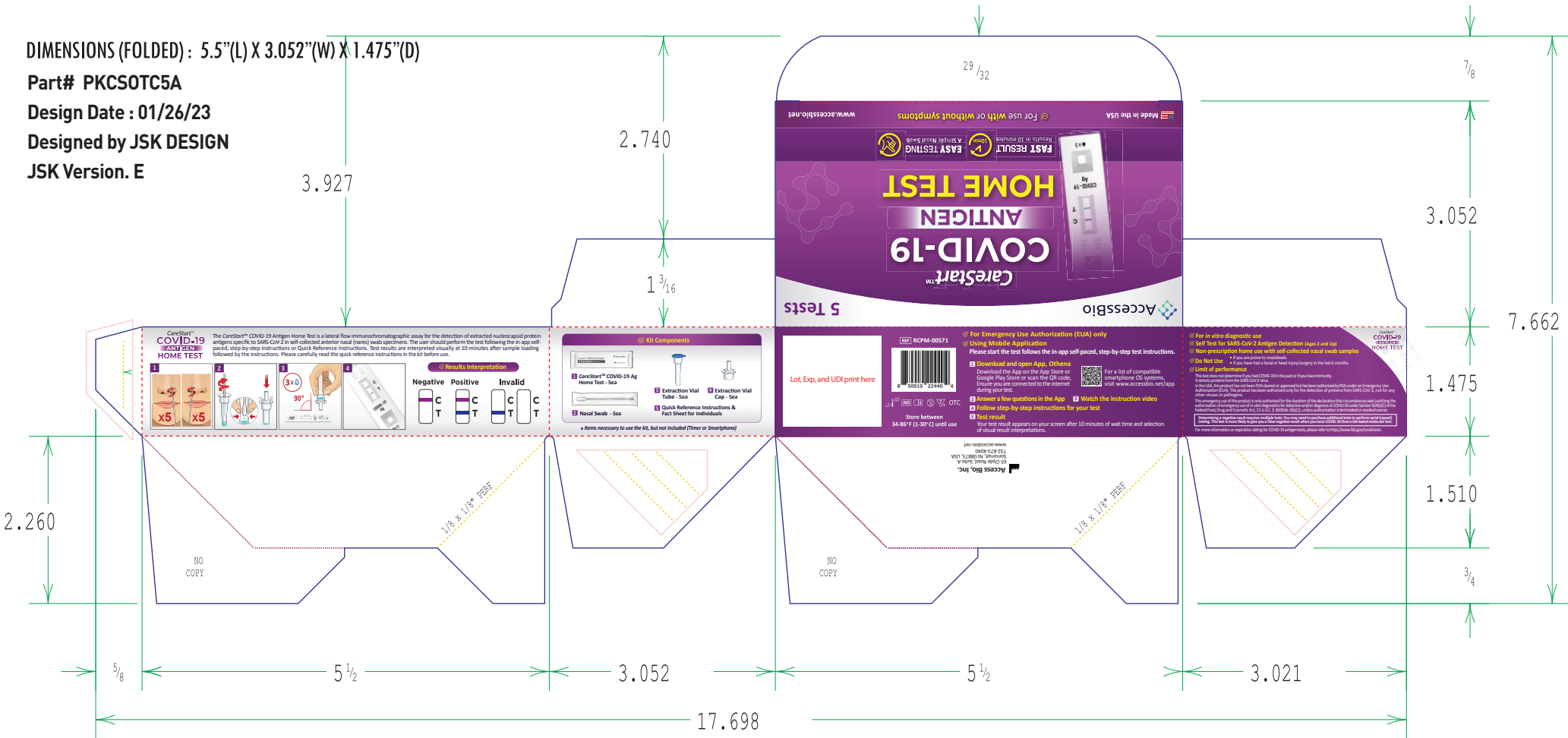
DIMENSIONS (FOLDED) : 5.5"(L) X 3.052"(W) X 1.475"(D)

Part# PKCS0TC5A

Design Date : 01/26/23

Designed by JSK DESIGN

JSK Version. E



DIMENSIONS (FOLDED)

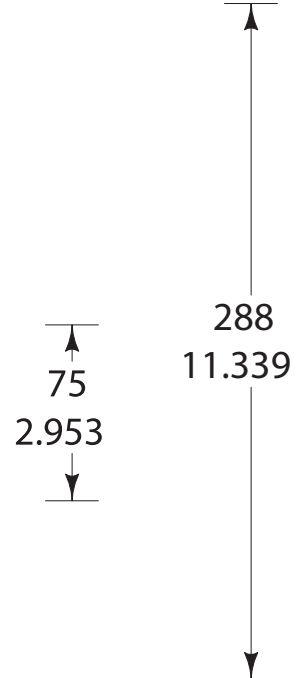
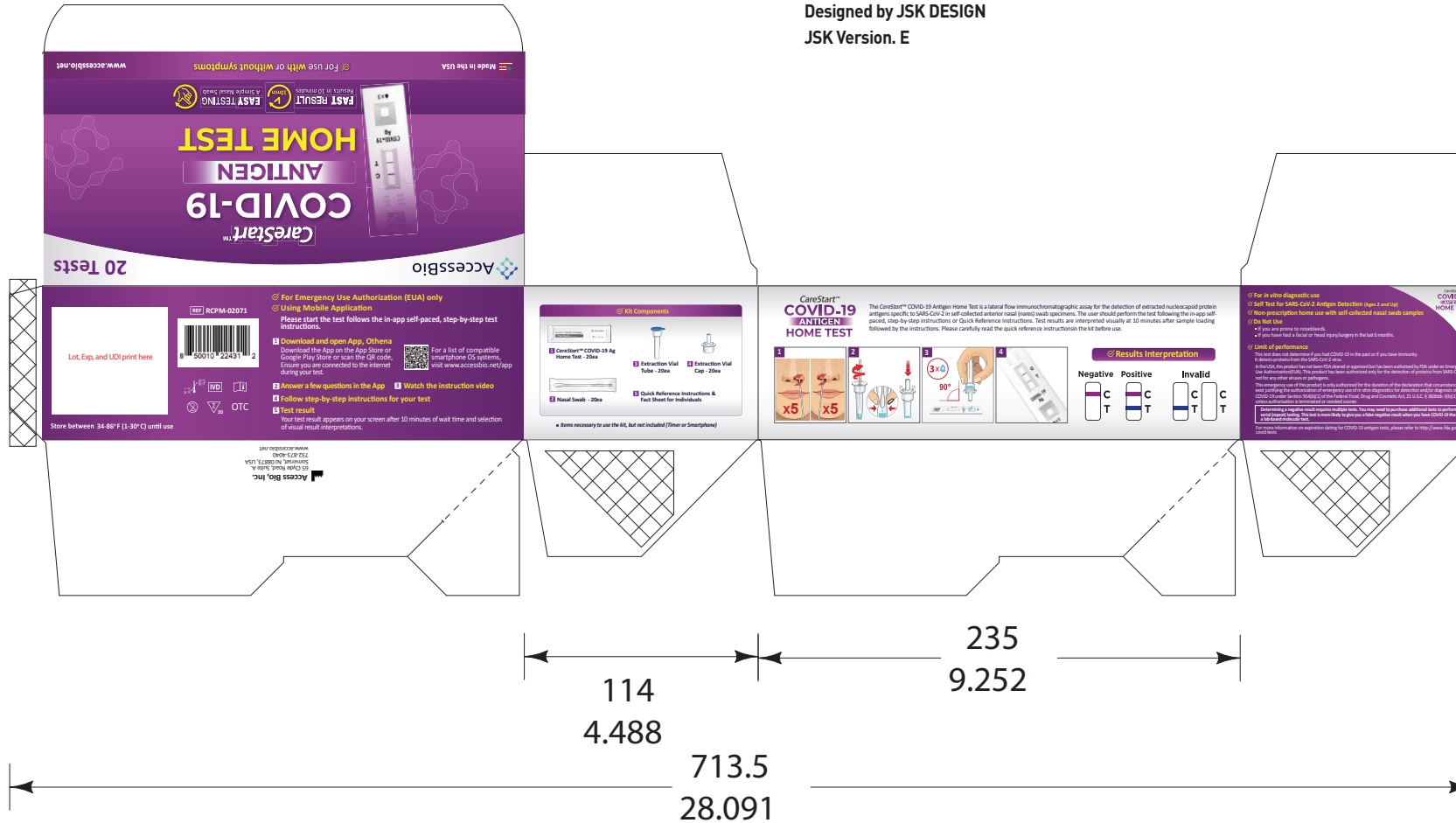
235 x 114 x 75 (9.252 x 4.488 x 2.953) exterior view
horizontal grain .018 sbs & .020 sbs

Part#PKCS0TC20C

Design Date : 01/26/23

Designed by JSK DESIGN

JSK Version. E



DIMENSIONS (FOLDED)

235 x 114 x 75 (9.252 x 4.488 x 2.953) exterior view

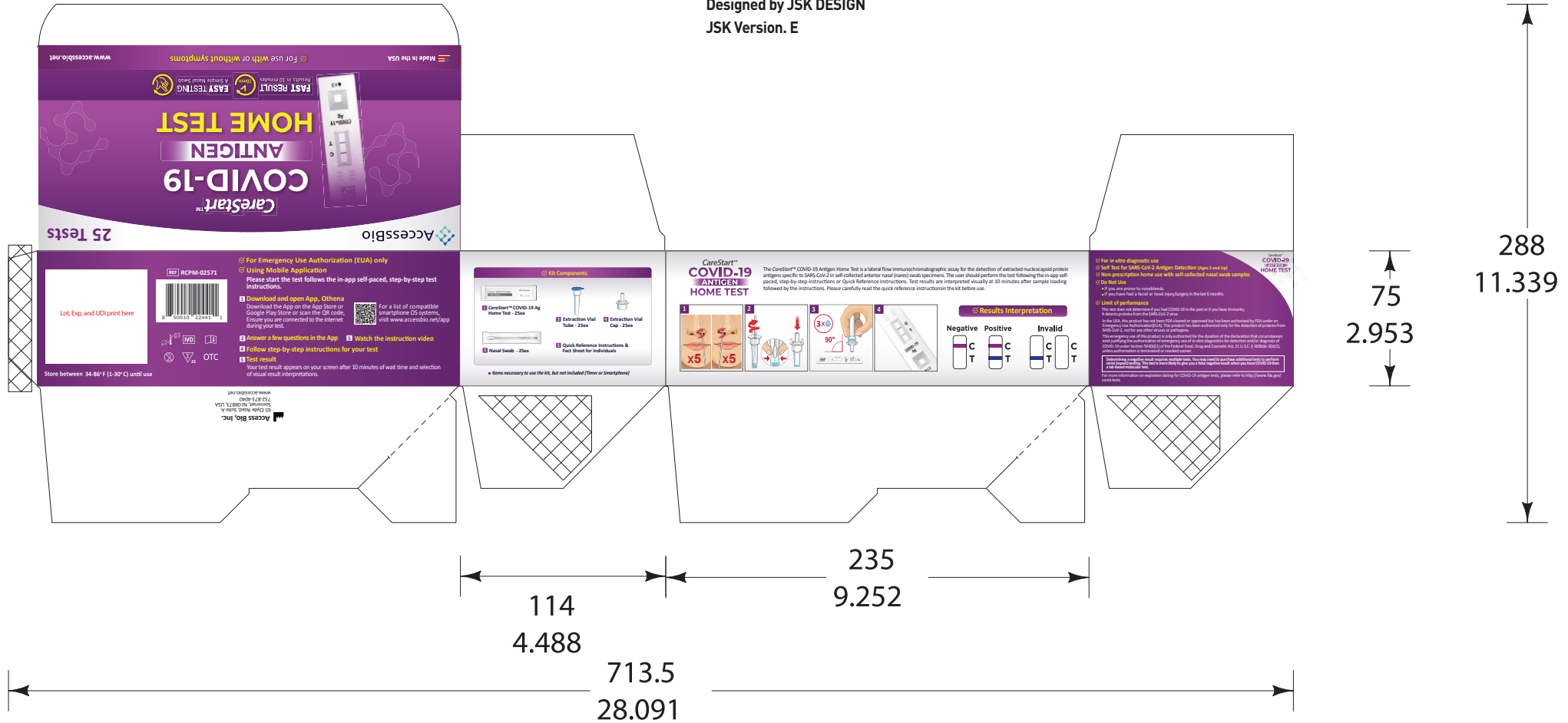
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Part# PKCS0TC25A

Design Date : 01/26/23

Designed by JSK DESIGN

JSK Version. E



DIMENSIONS (FOLDED)

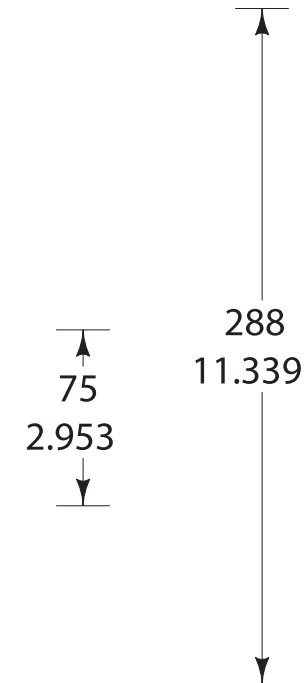
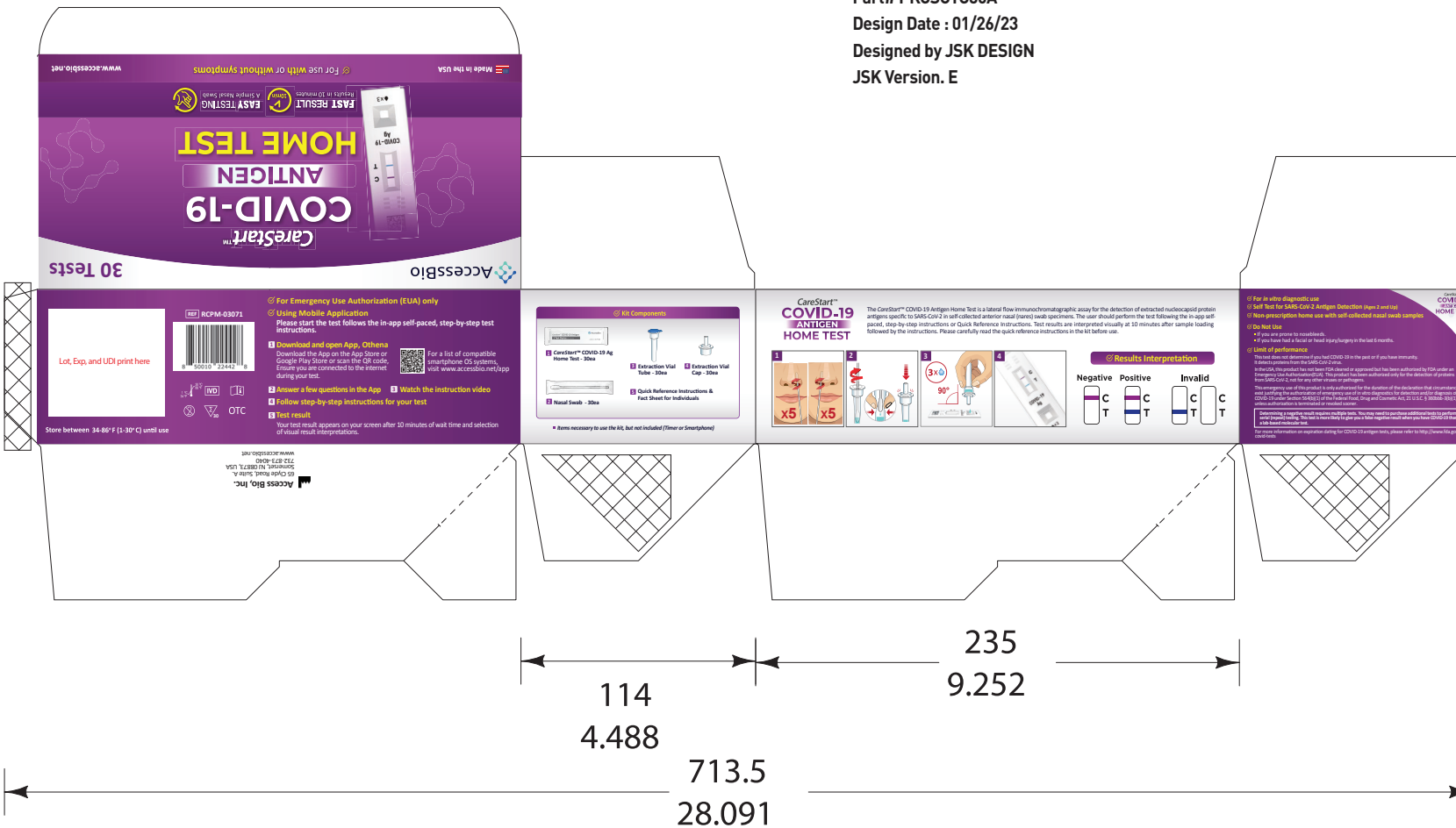
235 x 114 x 75 (9.252 x 4.488 x 2.953) exterior view
horizontal grain .018 sbs & .020 sbs

Part# PKCS0TC30A

Design Date : 01/26/23

Designed by JSK DESIGN

JSK Version. E



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