

The rapid spread of the highly transmissible omicron variant is leading to record outbreaks of coronavirus. Home antigen tests provide results in under an hour, often in under 10 minutes. At-home COVID-19 tests are more convenient for consumers as they can help avoid long wait-times and lines at testing centers.

The goal of ECRI's usability evaluation, conducted in December 2021, was to determine if there were any differences in the usability of the various tests. To our knowledge, ECRI's work is unique and adds important guidance to help our nation during a global pandemic. If and when supplies of home tests are more widely available, this report will help guide a consumer's choice based on ease of use.

When ECRI conducts its evaluations of FDA-approved medical devices, we are more likely to detect usability or safety issues than performance failures. For this reason, we decided to perform usability testing only on these at-home COVID-19 antigen tests. However, it is important to remind consumers that these devices received FDA Emergency Use Authorization (EUA), not full approval.

Test Kits Ranked by Usability

Because of the urgency in providing useful information to consumers as quickly as possible, ECRI selected the seven test kits based on retail availability. Tests are listed below in the order of their usability.

Middle Tier Kits QuickVue Score: 75.6 / Good..... page 6 BinaxNOW (tied with InteliSwab) Score: 73.3 / Good..... page 7 InteliSwab (tied with BinaxNOW) Score: 73.3 / Good..... page 8

Bottom Tier Kit

BD Veritor Score: 51.8 / OK (Marginally Acceptable) page 9

Bottom line: If you have a choice, it's better to get a higher rated test.

System Usability Scale (SUS) overview

The SUS tool was created by <u>John Brooke</u> in 1986 and offers a quick and effective way to evaluate the usability of a product and its design. SUS is a practical and reliable tool for measuring perceived ease of use, and it can be used across a broad range of products and services to help designers determine if there is an overall problem with their design solution. The SUS has become an industry standard, with references in over 1300 articles and publications.

After each product evaluation session, the user is given a questionnaire to complete. The statements are very general and the evaluator is asked score each statement with a number between 1 and 5, with the number representing how strongly the evaluator agrees or disagrees with the statement. The statements are designed to get quick and unfiltered feedback from the user and can be responded to quickly without interaction with the test leader. One of the primary benefits of using SUS is that the feedback is reliable and repeatable, and the evaluation does not require a large number of evaluators. The 10 SUS questions posed to the test kit evaluators can be viewed on page 10 of this document.

After the statement scores are collected from each evaluator, they are processed with a simple algorithm to derive an aggregate score for each product in the study. The aggregate scores range from 0 to 100, with 100 being the best possible score. The figure below provides some context for how to interpret the results.



Adapted from: Aaron Bangor, Philip T. Kortum & James T. Miller (2008) An Empirical Evaluation of the System Usability Scale, *International Journal of Human–Computer Interaction*, 24:6, 574-594, DOI: 10.1080/10447310802205776

ECRI added an additional six general questions for reviewers to answer at the conclusion of their evaluation of all seven tests. These questions and responses can be found on <u>page 11</u> of this report.

Conclusions

Based on the aggregate SUS scores, none of the COVID test kits would be judged to have **Excellent** usability. The On/Go, CareStart, Flowflex test kits we rate as **Very Good**, as the usability score for these kits falls just short of **Excellent**, as depicted in the graphic above. We rate usability of the QuickVue, BinaxNOW, and InteliSwab as **Good**, as these kits scored slightly lower than the kits rated **Very Good** and we believe these might present some usability challenges for some users. The BD Veritor kit we rated as **Marginally Acceptable** because its usability score fell well below those of the other test kits and users found some significant usability concerns.

On/Go™

This test kit includes a test cassette (small plastic enclosure into which sample solution will be deposited), extraction solution in prefilled vial, dropper tip, and nasal swab. The plastic components tray includes a well where the solution vial can be inserted and held upright while the test is running. Instructions include a QR code that links to a site with written instructions that walk the user through the test steps and includes timers for nasal swabbing and time to readout. Time to readout is 10 minutes.

Noted Reviewer Comments

Positive

- One of the simpler tests to use with good printed instructions
- App, although not needed because printed instructions are good, does help and the timers it includes are useful and you can skip ahead if you know how to do the current step
- Cassette makes handling without touching the test strip easier

Negative

App allows you to photograph result, but does not give an interpretation of result so it isn't clear why the photo is needed



CareStart[™]

This test kit and the On/Go test kit are both made by AccessBio and private labeled by their respective companies. Components of the two test kits are virtually identical, with test cassette, a vial prefilled with the extraction solution, adapter tip to convert the vial into a dropper, and a nasal swab. The printed instructions for use are also virtually identical aside from the reference to the product company. The QR code links the user to the same app as the On/Go product. The plastic kit components tray includes a well where the solution vial can be inserted and held upright while the test is running. Instructions include a QR code that links to a site with written instructions that walk the user through the test steps and includes timers for nasal swabbing and time to readout. Time to readout is 10 minutes.

Noted Reviewer Comments

Positive

- One of the simpler tests to use with good printed instructions
- App, although not needed because printed instructions are good, does help and the timers it includes are useful and you can skip ahead if you know how to do the current step.
- Cassette makes handling the test device without touching the test strip easier

Negative

App allows you to photograph result, but does not give an interpretation of result so it isn't clear why the photo is needed



Flowflex[™]

This is the only kit containing a single test in the group; all of the other kits include two tests. Contents include a test cassette, a vial pre-filled with extraction buffer, an attachment on the vial to convert it into a dropper, and a nasal swab. A QR code can be scanned for video instruction, but the link actually has only written instructions and no video. Time to readout is 15 minutes.

Noted Reviewer Comments

Positive

- Instructions are very easy to read and follow
- Cassette makes handling without touching test strip easy
- Test result is easy to interpret helps with user confidence in judging readout
- Instructions had good graphics

- Attaching the dropper tip into the buffer vial is a little difficult, and might be a challenge for users with poor motor control
- Perforated hole in kit box can be used to hold the vial, but it takes a bit of force to insert the vial in the hole
- QR code for video instructions only linked to printed instructions



QuickVue[®]

This test kit includes a prefilled reagent tube (prepared tube to test for a specific chemical reaction), a paper test strip, and the nasal swab. The plastic tray that houses the components in the box includes a well where the reagent tube can be secured during testing. There is a QR code-linked video instructing the user how to do the test. Time to readout is 10 minutes.

Noted Reviewer Comments

Positive

- Printed instructions were generally clear, but a bit busy
- The QR linked instructional video is helpful, but probably not needed since the printed instructions are adequate

- The cap was difficult to remove from the reagent tube and could result in user spilling some of the reagent
- The paper test strip is more likely to be touched by the user in the test area, although the instructions do indicate which part of the strip can be safely handled
- Some packaging was difficult to open



BinaxNOW[™]

This test includes a folded test card with a readout window and two holes. When the card is unfolded the user sees two adjacent holes in the card. One hole is used to add reagent drops and the other is used to slide the swab into testing position. After the swab is inserted and an adhesive strip is uncovered, the card can be folded again to secure the swab in place until readout that requires waiting 15 minutes.

Noted Reviewer Comments

Positive

- Instructions are fairly clear and easy to follow
- Once the swab is inserted into the test card, the test seems less likely to be spilled or disturbed than other test kits
- Seems like a test that would be easy to perform if repeat testing is required

- One of the more complicated tests to perform
- Having to drip 6 small drops into tiny readout card hole takes dexterity and good vision
- Relatively small font instructions could be difficult to read for some users
- Instructions say even a very faint test line indicates a positive – leaves user with less confidence that they interpreted the test correctly
- Result window has a pinkinsh tinge which could make it difficult to interpret results



InteliSwab[™]

Test kit components include a unique test device that integrates the nasal swab and readout cassette, a prefilled reagent vial, and stand to hold vial while testing. Instructions include a QR code linking to an instructional video. Test readout is the longest of the group at 30 minutes.

Noted Reviewer Comments

Positive

- Test does not require dripping the reagent into tester so may be easier for those with poor motor control
- Test result is easy to interpret
- QR linked instructional video is easy to follow
- Flange on nasal swab portion of test device helps user gauge how much of the swab to insert into the nose

- 30 minute test readout is too long to wait
- Removing the cap from the reagent vial is a little tricky and may lead to spilling some reagent
- The test device is inserted into the reagent vial to start test readout, but the test device is a bit top heavy and could lead to the vial toppling out of the vial stand
- Tapered flat swab part of test device is uncomfortable to use in the nasal swabbing step and the 15 nasal swirls required are way more than the 5 required by most other tests



BD Veritor[™]

This app-guided test includes a special card that identifies your test for the app and is used to read out the result after waiting 15 minutes. Readout results cannot be interpreted without the app. The app judges whether ambient lighting is adequate for readout. The test app requires that you watch separate videos for each step of the test. You must register with BD and are required to provide some personal information before the app can be downloaded. Some users may have privacy concerns with the information requested.

Noted Reviewer Comments

Positive

- App video guidance helpful
- App includes timer for test readout
- App allows you to forward test result to other parties

- No written instructions to follow for test must use app and follow videos for each step of test – with repeated tests this would be frustrating and makes test take longer than necessary
- The app does not permit you to go back and review the video if you have a question about how to perform a step. You cannot fast-forward the videos.
- There is no picture of what a positive or negative test looks like – must rely on app's interpretation
- Product information leaflet and quick start guide have very small font and could be difficult for some users to read
- Test strip unique in that it has 2 lines while waiting for readout – since the other test kits typically have only one line showing, this can raise anxiety



The System Usability Scale

The reviewers were asked to score the following 10 items with one of five responses that range from Strongly Agree to Strongly disagree:

- 1. I think that I would like to use this system frequently.
- 2. I found the system unnecessarily complex.
- 3. I thought the system was easy to use.
- 4. I think that I would need the support of a technical person to be able to use this system.
- 5. I found the various functions in this system were well integrated.
- 6. I thought there was too much inconsistency in this system.
- 7. I would imagine that most people would learn to use this system very quickly.
- 8. I found the system very cumbersome to use.
- 9. I felt very confident using the system.
- 10. I needed to learn a lot of things before I could get going with this system.

General Questions Applying to All Kits Evaluated

Twelve volunteers were asked to score the SUS tool statements after finishing each COVID test. Seven COVID tests were evaluated. Volunteers were made up of individuals with engineering, clinical, or graphic arts backgrounds. Test kits were presented to volunteers in a randomized order. After they had tried all the test kits volunteers were asked the following general questions:

1. Have you used any of these home COVID tests before, and if so, which one(s)?

Three of the 12 volunteers (25%) had previously used a home rapid COVID test (BinaxNOW, QuickVue)

2. Indicate which test, if any, stood out as hardest to use.

67% Found the BD Veritor to be most difficult to use

22% Found the BinaxNOW to be the most difficult to use

11% Found the InteliSwab hardest to use

3. What did you find difficult with this test?

BD Veritor:

Time consuming due to need to use app

Concerns about having the right lighting

BinaxNOW:

Test seemed to have the most steps

Some steps (adding drops, inserting swab into test card) seemed tricky to do correctly

InteliSwab:

Swab shape made swabbing nose uncomfortable

4. If one test left you with lower confidence in the result, which one was that?

Most volunteers thought that all of the tests seem to give you a clear result, but a few commented that:

BD Veritor test because you have to rely on the app to give you the result and the reminders about having proper lighting raised concerns about whether the readout was correct QuickVue because it can be hard to see the readout lines

5. If you had poor vision, which test(s) might be most difficult to use?

QuickVue - readout lines are difficult to see to begin with

Flowflex - instructions are a bit busy

BD Veritor, QuickVue, because they have small font print

6. If you had poor motor control, which test(s) might be most difficult to use?

All of the tests require good dexterity and hand control. Those tests that require user to remove a vial cap (Flowflex, CareStart, On/Go, InteliSwab) and to add drops to the test device (BinaxNOW, BD Veritor) would be challenging for someone with a tremor or challenged with poor hand control.

Learn more: **www.ecri.org**

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