ellume

COVID-19 home test

PRODUCT OVERVIEW FOR HEALTHCARE PROFESSIONALS

This test has not been FDA cleared or approved.
In USA – For use under an Emergency Use Authorization (EUA) only.

www.ellumecovidtest.com

IVD No test component to be used inside the body except the Nasal Swab as directed.

Intended Use

The Ellume COVID-19 Home Test is a rapid, lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected direct mid-turbinate nasal swab samples from individuals aged 16 years or older or adult collected mid-turbinate swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 4 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

The Ellume COVID-19 Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen which is generally detectable in mid-turbinate nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with past medical history and other diagnostic information is necessary to determine infection status.

Positive results do not rule out a bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Individuals who test positive with the Ellume COVID-19 Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measure such as isolating from others and wearing masks. Negative 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.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Test results will be reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC. Automatic test result reporting occurs via the Ellume COVID-19 Home Test software application.

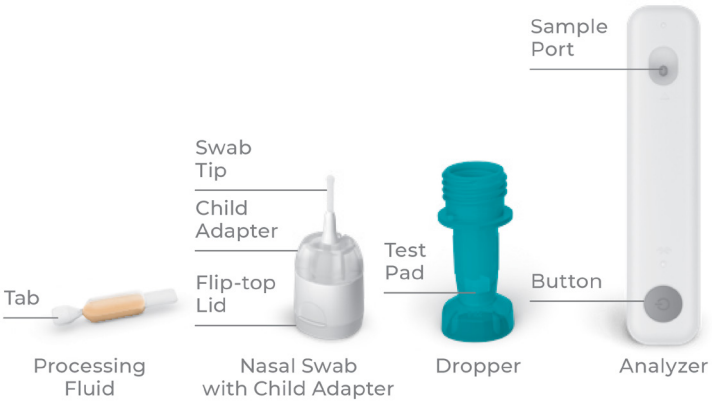
The Ellume COVID-19 Home Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The Ellume COVID-19 Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

General Description

The Ellume COVID-19 Home Test requires 3 core elements for operation:

- a smartphone (supplied by the user); see www.ellumecovidtest.com for compatible smart phones
- a single use Analyzer;
- a single use sampling and processing system that includes a sterile Nasal Swab, Processing Fluid, and a Dropper

Figure 1 – Ellume COVID-19 Home Test Contents



A Product Information Leaflet and Quick Start Guide are also included in the test kit.

To use the product, the consumer must first download the free application for iOS or Android phones using a compatible smartphone. The user follows the instructions on the Quick Start Guide. The user views the information video, connects the Analyzer to their phone, and then follows the in-app self-paced, step-by-step instructions to complete the test.

When the test has completed analyzing, the user's smartphone will generate one of the following test results:

- "Negative for COVID-19"
- "Positive for COVID-19"
- "Invalid Result"

Principle of Operation

The Ellume COVID-19 Home Test involves the pre-mixing and binding of fluorophore specific to SARS-CoV-2 with viral nucleocapsid protein present in a patient sample. First, the Processing Fluid is added into the Dropper to release the fluorophore. After collecting a mid-turbinate nasal specimen, the Nasal Swab is locked into the Dropper to release the viral antigens from the specimen, which are then bound by the fluorophore. An aliquot of the sample containing the fluorophore-labelled antigen complexes is dispensed into the Analyzer Sample Port. The deposited liquid wicks into the test strip by capillary action. The sample flows across a membrane and traverses a series of discrete capture zones, consisting of immobilized complementary antibodies to SARS-CoV-2 viral nucleoprotein. Fluorescence signals at the two test zones are detected using a sensitive single-use optoelectronics reader system, housed within the Analyzer. The tests and controls are interpreted according to thresholds set within the microprocessor contained in the Analyzer. The computed result is communicated to the smartphone application and displayed on the user's smartphone. The time from activation to result is 15 minutes.

Internal Control Assays

- The test contains an internal control immunoassay that detects the presence or absence of an endogenous human marker that is ubiquitously found in nasal specimens. An 'Invalid Result' will be received by the user rather than a false negative result if no or too little sample is applied to the test.
- The test contains a second internal control immunoassay whose biological reagents will fail and will trigger an 'Invalid Result' (rather than a false negative result) if the product is exposed to extreme temperature and humidity that could be damaging to the test reagents, and therefore mitigates the user from receiving a false negative result.

Other failure alert and failsafe controls

The test also incorporates failure alert and failsafe controls that ensure the user receives an 'Invalid Result' outcome (rather than a false result), in the event of:

- The user attempting to use an expired test kit;
- The user attempting to re-use a test; or
- Technical issue encountered with the optoelectronics of the Analyzer or with sample fluid flow through the test strip.

Warnings & Precautions

- For in vitro diagnostic use only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product 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 the declaration is terminated, or authorization is revoked sooner.

- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 4 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Keep test out of reach of children and pets.
- Follow the App's instructions carefully. Failure to follow the instructions may result in inaccurate test results or technical problem.
- Do not use on anyone under 2 years of age.
- Do not use on anyone prone to nose bleeds or who has had facial or head injury/surgery in the last 6 months.
- Individuals aged 16 years and older can self-swab. Children aged 2-12 years must be swabbed with the child adapter in place.
- Children aged 2-15 years must be tested by an adult.
- Wear a safety mask or other face covering when collecting a specimen from a child or another individual.
- When collecting a mid-turbinate nasal swab specimen, use only the Nasal Swab supplied in the kit.
- Do not touch Swab Tip.
- Keep the Analyzer on a flat surface until the result is available.
- If you are operating multiple tests, connect one Analyzer to the smartphone and wait 30 secs before you connect another Analyzer to the second smartphone.
- Add exactly five (5) drops of the sample fluid into the Analyzer. Adding more or less than 5 drops of sample fluid may cause inaccurate results.
- False negative results may occur if a specimen is improperly collected or handled and retesting with a new test may be required.
- Do not use the test kit contents beyond the expiration date printed on the outside of the box.
- Do not use if the any of the test components' packaging is opened or damaged.
- All test components are single-use. Do not re-use.
- Do not use the test if it has been exposed to household cleaning products (especially bleach).
- Do not open any of the packaging until you are ready to begin your test.
- Do not perform the test in unstable (changing) light conditions.
- Avoid performing the test in a very dry environment (very low humidity).
- Do not drop the Analyzer. Handle with care.
- Test devices that contain patient specimens should be handled as though they could transmit disease. Follow universal precautions when handling specimens, this kit, and its contents. Wear appropriate personal protective equipment (PPE) including gloves when running the test and handling a patient's test device. Change gloves between tests.

Keep testing kit and kit components away from children and pets before and after use. The Processing Fluid contains a harmful chemical as shown in below table. Avoid contact of Processing Fluid with your skin, eyes, nose or mouth. Do not ingest any kit components. If contact with the Processing Fluid occurs immediately flush with copious amounts of running water. If irritation persists, please seek medical advice at: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name	GHS Codes	Concentration (%weight/weight)
mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one & 2-Methyl-4-isothiazolin-3-one (3:1) (ProClin™ 300)	H301: Toxic if swallowed H311: Toxic in contact with skin H331: Toxic if inhaled H314: Causes severe skin burns and eye damage H317: May cause an allergic skin reaction H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects	0.002 – 0.005

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Storage and Stability

- Store in a dry location between 36-86°F (2-30°C).
- Ensure the test is at room temperature 59-77°F (15-25°C) prior to testing.
- Kit components in the Ellume COVID-19 Home Test are stable until the expiration date printed on the label.
- The Test components must remain in the sealed foil pouches until use. Once the pouches have been opened, the test should be used within 60 minutes.
- Specimens should be added to the Analyzer port when instructed by the App. Do not delay, otherwise the test may produce an invalid result.

Disposal

Before disposal of the Analyzer, we recommend removing the battery using the following steps:

- Locate the gap at the end (short side) close to power button.
- Place a coin in the gap
- Twist the coin to break off the bottom end of the Analyzer along the perforation in the plastic
- Remove the battery from the plastic clips of the Analyzer.
- Keep the battery out of reach of children.
- Do not incinerate
- Dispose of the battery and the remainder of the test in general waste unless otherwise indicated by local regulations

Limitations

- This test does not differentiate between SARS-CoV and SARS-CoV-2.
- Failure to follow the instructions may result in inaccurate test results.
- False positive results may occur, particularly in individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to sensitivity of the test technology. This means that there is a higher chance this test will give a negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with a low viral load.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Positive and negative predictive values are highly dependent on COVID-19 prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low activity when prevalence is moderate to low.
- The performance of this test was initially established based on the evaluation of a limited number of clinical specimens collected between October, 2020 and November, 2020. A subsequent clinical trial, which is ongoing, commenced in May 2022 when the dominant circulating strain was the Omicron variant. Clinical performance has not been established with all circulating variants, including Delta, but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

Expected Values

The Ellume COVID-19 Home Test incorporates a qualitative assay for the detection of SARS-CoV-2 viral nucleoprotein in mid-turbinate nasal specimens. Healthy normal patients would not have SARS-CoV-2 viral nucleoprotein in their mid-turbinate nasal specimens and would be expected to return a negative result.

Not all patients exhibiting COVID-like-illness symptoms will have SARS-CoV-2 viral nucleoprotein in their mid-turbinate nasal specimens as other viruses/bacteria may cause COVID-like-illness symptoms.

Interpretation of Results

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

Positive result:

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the Ellume COVID-19 Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Negative result:

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does 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 the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS- CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid result or technical problem

Retest with a new test kit.

Clinical Performance

Prospective Clinical Study 1: May 2022 – June 2022

Clinical performance of the Ellume COVID-19 Home Test was evaluated in an ongoing multi-site prospective study conducted at eight (8) geographically diverse study sites in the USA. Subjects self-sampled and self-tested using the Ellume COVID-19 Home Test in a simulated home setting utilizing only the labelling provided with the test. Symptomatic subjects over the age of 2 years, presenting to the site seeking COVID-19 testing were eligible to enroll if they met all inclusion criteria and did not meet any of the exclusion criteria.

Of the 719 subjects enrolled between 17 May 2022 to 11 June 2022, 526 subjects were considered to have valid data for interim analysis. For the evaluable subjects, days post symptom onset (DPSO) ranged from zero (0) to four (4) days. Symptomatic subjects were defined as those exhibiting at least one of the following COVID-Like-Illness (CLI) signs and symptoms on day of presentation: congestion or runny nose, headaches, fever or chills, fatigue, sore throat, cough, shortness of breath or difficulty breathing, muscle or body aches, new loss of taste or smell, diarrhea, nausea or vomiting.

Age and gender distribution of the 526 evaluable subjects is presented in Table 1 along with the positive rate per age group. The ages of subjects ranged from 2 years to 82 years.

Table 1: Age and gender distribution and positive rate (by Ellume COVID-19 Home Test) per age group (evaluable subjects)

Age Group (years)	Female	Male	Positivity Rate %
2 to 13	37	34	8.5%
14 to 24	63	56	19.3%
25 to 64	194	107	25.9%
≥65	21	14	37.1%
Total	**315**	**211**	**22.8%**

The analysis for the primary performance calculation was conducted to reflect a study population with 10% low positives. Multiple Percent Positive Agreement (PPA) are presented below for the positive samples cohort when a range of low positive samples was included (10% to 11.6%).

At 10% low positives, the PPA was 80.5% and the negative percent agreement (NPA) was 100% with 95% confidence interval bounds of 72.4% to 86.6% for PPA and 99.1% to 100% for NPA respectively. This was the basis of the authorization. A controlled analysis with low positives at Days Post Symptom Onset (DPSO) of four (4) is shown in Table 2.

Table 2: Controlled analysis of Ellume COVID-19 Home Test low positive and NPA with DPSO 4

Controlled Analysis of Ellume COVID-19 Home Test low positive results versus molecular comparator results		
	10% Low Positive	11.6% Low Positive (All Data)
High positive samples	106	106
Low positive samples	12	14
Total Comparator Positive for PPA calculation	118	120
Total Test Positives for PPA calculation	95	95
PPA	80.5%	79.2%
95% CI	72.4% - 86.6%	71.1% - 85.5%
NPA for Ellume COVID-19 Home Test versus molecular comparator results		
NPA	100% (406/406)	
95% CI	99.1% - 100%	

Invalid Test Rate

A total of seven-hundred and nineteen (719) tests were performed. Forty (40) Invalid Results were recorded. Overall Invalid Result rate was therefore 5.6%.

Prospective Clinical Study 2: October 2020 – November 2020

The initial authorization of this test to support the original intended use (i.e., DPSO 7) was based on the following prospective study conducted from 29 October 2020 to 17 November 2020 at five (5) geographically diverse study sites in the USA. Subjects self-sampled and self-tested using the Ellume COVID-19 Home Test in a simulated home setting utilizing only the labelling provided with the test. The study was designed as an all-comers study where subjects (both symptomatic and asymptomatic) over the age of 2 years, presenting to the site seeking COVID-19 testing for any reason, were eligible to enroll if they met all inclusion criteria and did not meet any of the exclusion criteria.

All subjects also had a nasal swab sample collected by clinical study site staff for testing at a reference laboratory with an EUA high sensitivity molecular SARS-CoV-2 assay. Any specimens for which the Ellume COVID-19 Home Test result and the EUA high sensitivity molecular SARS-CoV-2 assay result did not agree were tested with a second, high sensitivity molecular SARS-CoV-2 assay.

A total of 198 subjects were evaluated in this study. Sixty-four (64) were symptomatic and one-hundred and thirty-four (134) were asymptomatic at time of presentation. Symptomatic subjects were defined as those exhibiting at least one of the following signs and symptoms on day of presentation: Fever, cough, shortness of breath, difficulty breathing, muscle pain, headache, sore throat, chills, repeated shaking with chills, new loss of taste or smell, congestion or runny nose, diarrhea, nausea, or vomiting.

Patient Demographics

Age and gender distribution of the 198 evaluable subjects is presented in Table 3 along with the positive rate per age group. Overall positive rate for the study was 20.2%. Ages of subjects ranged from 2 years to 82 years.

Table 3 Age and gender distribution and positive rate (by Ellume COVID-19 Home Test) per age group (evaluable subjects)

Age Group (years)	Female	Male	Positivity Rate % (total positive/total tested)
2 to 13	12	16	10.7% (3/28)
14 to 24	20	16	22.2% (8/36)
25 to 64	87	36	22.0% (27/123)
≥65	6	5	18.2% (2/11)
Total	**125**	**73**	**20.2% (40/198)**

The following tables summarize the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the Ellume COVID-19 Home Test when compared with an FDA EUA high sensitivity molecular SARS-CoV-2 assay, for all subjects (Table 4) and for symptomatic subjects only (Table 5).

Table 4: Performance of the Ellume COVID-19 Home Test in ALL subjects

Ellume COVID-19 Home Test	RT-PCR (Laboratory)		
	Positive	Negative	Total
Positive	35	5[b]	40
Negative	2[a]	156	158
Total	**37**	**161**	**198**

[a] Of the 2 false negative specimens, both were positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.

[b] Of the 5 false positive specimens, all were negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.

PPA: **95%** [95% CI 82% - 99%]

NPA: **97%** [95% CI 93% - 99%]

CI = Confidence Interval

Table 5: Performance of the Ellume COVID-19 Home Test in SYMPTOMATIC subjects

Ellume COVID-19 Home Test	RT-PCR (Laboratory)		
	Positive	Negative	Total
Positive	25	0	25
Negative	1	38	39
Total	**26**	**38**	**64**

PPA: 96% [95% CI 81% - 99%]

NPA: 100% [95% CI 91% - 100%]

Table 6: PPA and NPA stratified by days since onset of symptoms

Group	PPA (95% CI)	NPA (95% CI)
0 to 1 day	100% (7/7) (95% CI:65%-100%)	100% (9/9) (95% CI:70%-100%)
0 to 2 days	100% (13/13) (95% CI:77%-100%)	100% (17/17) (95% CI:82%-100%)
0 to 3 days	100% (18/18) (95% CI:82%-100%)	100% (26/26) (95% CI:87%-100%)
0 to 4 days	100% (21/21) (95% CI:85%-100%)	100% (29/29) (95% CI:88%-100%)
0 to 5 days	100% (22/22) (95% CI:85%-100%)	100% (32/32) (95% CI:89%-100%)
0 to 6 days	100% (25/25) (95% CI:87%-100%)	100% (33/33) (95% CI:90%-100%)
0 to 7 days	96% (25/26) (95% CI:81%-99%)	100% (34/34) (95% CI:90%-100%)

Invalid Test Rate

The overall invalid result rate on first test for the 209 subjects that performed testing was 8% (17/209). Nine (9) of the seventeen (17) invalid results recorded were generated by the Analyzer as a failsafe control to indicate to the user that insufficient sample had been collected for the test to give a valid result. All 9 were generated by asymptomatic subjects. It is therefore very important that a user with no symptoms pays close attention to sampling technique to avoid having to retest with a new test.

Prospective Clinical Study 3: January 2021 – May 2022

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in Table 7.

Table 7: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

Days after first PCR positive test result	Asymptomatic on first day of testing			Symptomatic on first day of testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Analytical Performance

Analytical Sensitivity

Limit of Detection (LoD)

A dilution series of heat inactivated SARS-CoV-2 virus stock (USA-WA1/2020) was prepared in natural clinical matrix. Five (5) replicates were tested per dilution. The testing was performed as per the recommended instructions for use, with the virus in clinical matrix applied directly onto the swab.

The estimated LoD concentration for verification was selected as the concentration in between the dilution factor that returned 5/5 positive test outcomes (100%) and the next dilution factor that returned 0/5 positive (0%) based on the qualitative result. The quantitative signal value between these points, displayed by the firmware algorithm was also used to inform an estimated C95 (95% detection rate) concentration. The C95 was then verified by testing 20 replicates of virus, prepared at the estimated LoD concentration in natural clinical matrix.

The concentration of virus at which 19/20 replicates produced positive results (the LoD) was 6,309 $TCID_{50}$/mL.

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of heat-inactivated clinical specimens which were positive for the Omicron variant (Table 8). This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Compared to an EUA authorized RT-PCR method, the Ellume COVID-19 Home Test detected 100% of live-virus Omicron samples at a Ct-value of 23.6 (n=5). Testing was also compared to two additional EUA-authorized antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 23.6) were not detected by the Ellume COVID-19 Home Test in this study.

Table 8: Detection of an Omicron clinical sample pool by Ellume COVID-19 Home Test compared with two other EUA-authorized OTC antigen tests

Omicron Pool 2 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	Ellume COVID-19 Home Test Percent Positive (n=5)
Omicron-Dilution 1	19.8	100	100	100
Omicron-Dilution 2	20.8	100	100	100
Omicron-Dilution 3	21.5	100	100	100
Omicron-Dilution 4	22.7	100	100	100
Omicron-Dilution 5	23.6	100	0	100
Omicron-Dilution 6	24.0	60	0	40
Omicron-Dilution 7	24.8	0	0	0
Omicron-Dilution 8	25.8	0	0	0
Omicron-Dilution 9	27.4	0	0	0
Omicron-Dilution 10	28.1	0	0	0
Omicron-Dilution 11	29.1	0	0	0

Hook Effect

No high dose hook effect was observed when the Ellume COVID-19 Home Test was tested with up to a concentration of $10^{6.43}$ $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus (USA-WA1/2020 Isolate).

Analytical Specificity

Microbial Cross Reactivity and Interference

The Ellume COVID-19 Home Test was tested with 16 non-SARS-CoV-2 viral isolates at a concentration of $1x10_5$ $TCID_{50}$/mL, 12 bacterial microorganisms at a concentration of $1x10_6$ CFU/mL and pooled human nasal wash at a concentration of 10% v/v (Table 9). The micro-organisms and pooled nasal wash were evaluated in the absence of SARS-CoV-2 virus to assess potential cross-reactivity and also in the presence of SARS-CoV-2 virus at 3xLoD concentration to assess potential interference with the detection of SARS-CoV-2. No cross-reactivity was observed with the viral and bacterial pathogens tested nor with the pooled nasal wash.

No interference was observed in the detection of SARS-CoV-2 virus with the viral and bacterial respiratory pathogens tested, nor with the pooled nasal wash.

Table 9: Microorganisms tested for cross reactivity in, and interference with, the Ellume COVID-19 Home Test (wet testing)

Viruses	Bacteria
Human coronavirus 229E	Haemophilus influenzae
Human coronavirus OC43	Streptococcus pneumoniae
Human coronavirus NL63	Streptococcus pyogenes
Adenovirus C1/71	Staphylococcus aureus
Human metapneumovirus (hMPV)	Staphylococcus epidermidis
Parainfluenza 1	Candida albicans
Parainfluenza 2	Bordetella pertussis
Parainfluenza 3	Mycoplasma pneumoniae
Parainfluenza 4	Chlamydia pneumoniae
Influenza A/Perth/16/2009	Legionella pneumophila
Influenza B/Phuket/3073/2013	Mycobacterium tuberculosis
Enterovirus	Pneumocystis jirovecii (PJP)
Respiratory syncytial virus A	
Respiratory syncytial virus B	
Rhinovirus	
MERS-Coronavirus	

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for Human Coronavirus HKU1 and SARS-CoV-1. Human Coronavirus HKU1 showed 37% homology across 82% of the nucleocapsid sequence, which is relatively low. Cross-reactivity is unlikely but possible. For SARS-CoV-1 there was 91% homology across 100% of the nucleocapsid sequence and therefore cross-reactivity is likely.

Interference

The effect of 17 substances commonly found in nasal aspirates, including blood and a selection of the active ingredients of over-the-counter (OTC) products and 6 common household chemicals (Table 10) were evaluated on the Ellume COVID-19 Home Test. The potentially interfering substances were evaluated in the absence of SARS-CoV-2 virus to assess potential cross-reactivity, and also in the presence of SARS-CoV-2 virus at 3xLoD concentration to assess potential interference with the detection of SARS-CoV-2.

Table 10: Potentially interfering substances tested on Ellume COVID-19 Home Test

Substance	Concentration
Whole Blood	4% v/v
Ricola (Menthol)	1.5mg/mL
Sucrets (Dyclonin/Menthol)	1.5mg/mL
Chloraseptic (Menthol/Benzocaine)	1.5mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nose Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15%v/v
NasalCrom (Cromolyn)	15%v/v
Zicam (with Oxymetazoline)	5% v/v
Homeopathic (Alkalol)	10% v/v
Fishermans Friend	1.5mg/mL
Sore Throat Phenol Spray	15% v/v
Mucin	0.5% v/v
Tobramycin	4µg/mL
Mupirocin	10mg/mL
Tamiflu (Oseltamivir Phosphate)	5mg/mL
Fluticasone Propionate	2.5mg/mL
Hand Sanitizer (Ethyl alcohol)	1% v/v
Hand Soap (Benzalkonium chloride)	1% v/v
Laundry Detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% v/v
Surface Sanitizer (Citric Acid)	1% v/v
Dish-washing Liquid (Sodium lauryl sulfate)	1% v/v
Bleach (Sodium Hypochlorite)	1%v/v

There was no interference of SARS-CoV-2 detection observed from any of the substances tested except for bleach which was shown to interfere at the initial concentration of 1% v/v tested. Further testing indicated that the highest bleach level the test system could tolerate was 0.2% v/v.

Customer Helpline

If you have any questions about the Ellume COVID-19 Home Test or your patient's results, please contact Ellume's toll-free Customer Helpline on **1-888-885-6121** or visit **www.ellumecovidtest.com**

Manufactured by Ellume Limited
57 Didsbury St, East Brisbane, Qld 4169, Australia

01/2023
D1012929 G