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 SARS-CoV-2 nucleocapsid antigens from mid-turbinate nasal swabs that are self-collected by an individual aged 16 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection. The Ellume COVID-19 Home Test is authorized for non-prescription home use.

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. The antigen 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 in an asymptomatic individual are presumptive and may need to be confirmed with a molecular assay. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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 management decisions for the individual, including infection control decisions. 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.

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 only for use under the Food and Drug Administration's Emergency Use Authorization.

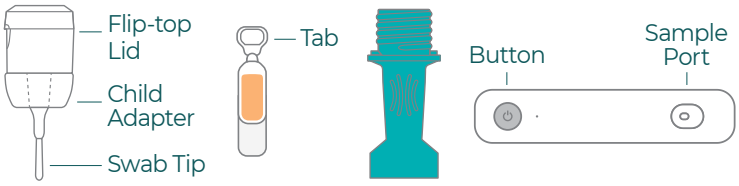
The Ellume COVID-19 Home Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Professionals and the authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

General Description

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

- a smartphone (supplied by the user);
- 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 components



Nasal Swab with Child Adapter | Processing Fluid | Dropper | Analyzer

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

The user's smartphone will generate one of the following test results:

- "Your test is negative for COVID-19"
- "Your test is positive for COVID-19"
- "A Test Error has occurred"

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 sample, 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 yet inexpensive 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 samples. A 'Test Error' 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 a 'Test Error' result rather than a false negative result to the user 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 & Failsafe Controls

The test also incorporates failure alert and failsafe controls that assure the user receives a 'Test Error' 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

- Do not use on anyone under 2 years of age.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- For in vitro diagnostic use only.
- Ensure your test is at room temperature 59-77°F (15-25°C) prior to testing.
- Do not use the test kit contents beyond the expiration date printed on the outside of the box.
- Do not reuse any used kit components.
- 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.
- Use the test within 60 minutes of opening the Analyzer and Dropper foil packaging.
- Keep the Analyzer on a flat surface until the result is available.
- Do not drop the Analyzer. Handle with care.
- Do not perform the test in direct sunlight.
- Do not perform the test within 30 feet of another Ellume COVID-19 Home Test.
- Do not close the Ellume COVID-19 Test App during processing as it will cause an error and you will need a new test kit.
- Add no less than five (5) drops into the Analyzer. False negative or invalid test results may occur.
- Keep foreign substances away from the test during the testing process. Contact with foreign substances, specifically bleach, may result in an incorrect test result.

- The reagent in the Processing Fluid contains ProClin® 300 which may cause an allergic skin reaction in some people. If the solution makes contact with the skin or eye, wash/flush with copious amounts of water. If skin irritation or rash occurs get medical advice/attention.
- To obtain accurate results, the in-app instructions should be followed.
- Inadequate or inappropriate sample collection may yield Test Error results and retesting with a new test may be required. Particular attention needs to be paid to appropriate sample collection technique, especially in asymptomatic individuals.
- When collecting a mid-turbinate nasal swab sample, use only the Nasal Swab supplied in the Kit.
- To reduce the risk of biohazard:
  - Use appropriate precautions in the collection, handling and disposal of patient samples and used kit contents.
  - Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Change gloves between patients.
  - Dispose of used specimens and test kit components in accordance with Federal, State, and Local requirements. For instructions on battery removal prior to disposal of the Analyzer refer to the Disposal section below.
  - Treat specimens and patient samples as well as used test kit components as potentially biohazardous materials.
  - Wash hands thoroughly after handling patient samples.
- Keep out of reach of children. The test contains small parts that may present a choking hazard.
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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.

Storage Conditions

Store in a dry location between 36-86°F (2-30°C).
Keep out of reach of children.

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 of the Analyzer
- 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
- Dispose of the battery according to local regulations
- Keep the battery out of reach of children
- Dispose the remainder of the test in general waste
- Do not incinerate

Limitations

- This test does not differentiate between SARS-CoV and SARS-CoV-2.
- The test detects both viable and nonviable SARS-CoV-2 viral antigens and may yield a positive result in the absence of living microorganisms.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test.
- Failure of the user to follow the test procedure correctly may adversely affect the test performance and/or invalidate the test result.
- 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 results are presumptive in asymptomatic individuals.
- Negative results are presumptive in symptomatic individuals.
- 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.
- 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.

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 samples. Healthy normal patients would not have SARS-CoV-2 viral nucleoprotein in their

mid-turbinate nasal samples 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 samples as other viruses/bacteria may cause COVID-like-illness symptoms.

Clinical Performance

A performance evaluation was 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 samples 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.

Asymptomatic subjects were defined as subjects not experiencing COVID-like illness symptoms on day of testing. Note that of the 134 subjects presenting as asymptomatic on day of testing, six (6) reported experiencing COVID-like illness symptoms in the past, with onset ranging from 4 to 18 days prior to day of site visit.

Patient Demographics

Age and gender distribution of the 198 evaluable subjects is presented in Table 1 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 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 % (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 2), for symptomatic subjects only (Table 3) and for asymptomatic subjects only (Table 4).

Table 2: Performance of the Ellume COVID-19 Home Test as compared to an FDA EUA high sensitivity molecular SARS-CoV-2 assay 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 samples, both were positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.

[b] Of the 5 false positive samples, 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 3: Performance of the Ellume COVID-19 Home Test as compared to an FDA EUA high sensitivity molecular SARS-CoV-2 assay 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 4: Performance of the Ellume COVID-19 Home Test as compared to an FDA EUA high sensitivity molecular SARS-CoV-2 assay in ASYMPTOMATIC subjects

Ellume COVID-19 Home Test	RT-PCR (Laboratory)		
	Positive	Negative	**Total**
Positive	10	5	15
Negative	1	118	119
Total	**11**	**123**	**134**

PPA: **91%** [95% CI 62% - 98%]
NPA: **96%** [95% CI 91% - 98%]

The PPA and NPA stratified by days since onset of symptoms is presented in Table 5. PPA was 100% up to six (6) days since symptom onset, after which time the PPA declined slightly to 96%.

Table 5: PPA and NPA stratified by days since onset of symptoms

Group	PPA (95% CI)	NPA (95% CI)
Asymptomatic	91% (10/11) (95% CI:62%-98%)	96% (128/134) (95% CI:91%-98%)
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%)
0 to >7 days	96% (25/26) (95% CI:81%-99%)	100% (38/38) (95% CI:91%-100%)

Invalid Test Rate

The overall invalid result rate on first test for the 209 subjects that performed testing in a clinical study in October and November 2020 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.

Analytical Sensitivity

Limit of Detection

A dilution series of heat inactivated SARS-CoV-2 virus stock (USA-WA1/2020) was prepared in natural clinical matrix (pooled nasopharyngeal swab samples eluted in VTM). 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 until the saturation of the flocked tip.

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 $10^{3.80}$ $TCID_{50}$/mL.

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 6). The microorganisms 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 6: 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 7) 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 7: 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 result, please contact our toll-free Customer Helpline on **1-888-885-6121** or visit **www.ellumecovidtest.com**

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