The Cue COVID-19 Test, designed for the specific detection of SARS-CoV-2 virus, showed no significant combined homologies with the potential cross-reactants analyzed in silico that would predict potential Cue COVID-19 Test false results.

### Analytical Specificity – Interfering Substances

A study was performed to assess substances with the potential to interfere with the performance of the Cue COVID-19 Test. Potential interferents were tested at the highest concentration likely to be found in a nasal sample. Each interfering substance in negative clinical nasal matrix was tested in triplicate. Each interfering substance was also tested in triplicate in the presence of genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020, at 3X LoD.

The substances, concentrations, and test results are shown in the table below. None of the substances interfered in the Cue COVID-19 Test at the concentrations tested.

Cue COVID-19 Test Interfering Substances Evaluation

| Substance | Concentration | Detected/Tested | |
|---|---|---|---|
| | | Negative Nasal Matrix | Positive Nasal Matrix (SARS-CoV-2 RNA present at 3X LoD) |
| Afrin | 20% (v/v) | 0/3 | 3/3 |
| Saline Nasal Spray | 20% (v/v) | 1/9* | 3/3 |
| Zicam Allergy Relief | 15% (v/v) | 0/3 | 3/3 |
| Chloroseptic Max | 20% (v/v) | 0/3 | 3/3 |
| Neo-Synephrine | 20% (v/v) | 0/3 | 3/3 |
| Mucin | 0.5% (w/v) | 0/3 | 3/3 |
| Zanamivir (Relenza) | 0.3 mg/ml | 0/3 | 3/3 |
| Mupirocin | 10 mg/ml | 0/3 | 3/3 |
| Tamiflu (Oseltamivir phosphate) | 0.01mg/ml | 0/3 | 3/3 |
| Budesonide | 0.05 mg/ml | 0/3 | 3/3 |
| Flunisolide | 0.04 mg/ml | 0/3 | 3/3 |
| Dexamethasone | 0.5 mg/ml | 0/3 | 3/3 |
| Beclomethasone | 0.068 mg/mL | 0/3 | 3/3 |

| Substance | Concentration | Detected/Tested | |
|---|---|---|---|
| | | Negative Nasal Matrix | Positive Nasal Matrix (SARS-CoV-2 RNA present at 3X LoD) |
| Biotin | 3.5 ug/mL | 0/3 | 3/3 |
| Xofluza (baloxavir marboixil) | 0.01mg/ml | 0/3 | 3/3 |
| Nasacort/Triamcinolone | 0.04 mg/ml | 0/3 | 3/3 |
| Flonase/Fluticasone | 0.04 mg/ml | 0/3 | 3/3 |
| Mometasone | 0.04 mg/ml | 0/3 | 3/3 |
| Tobramycin | 2.5mg/ml | 0/3 | 3/3 |
| Whole Blood | 1% (v/v) | 0/3 | 3/3 |
| Chloroseptic (solid) | 20% w/v | 1/9* | 3/3 |
| Galphimia Glauca | 20% w/v | 0/3 | 3/3 |
| Rhinallergy | 20% w/v | 1/9* | 3/3 |

*A fresh dilution was prepared and the potential interferent was retested.

### Clinical Evaluation – Prospective Clinical Study in Emergency Departments

A prospective clinical study was conducted in 2 emergency departments (ED) located in an epicenter for the COVID-19 outbreak in the US. The study was IRB approved.

Patients presenting at either of two EDs with signs and/or symptoms of COVID-19 as determined by the healthcare provider were tested using the Cue COVID-19 Test at point of care. Testing was performed by untrained operators with no prior laboratory training or experience.

The Cue COVID-19 Test results were compared to the results from the healthcare institution's standard of care EUA PCR test for SARS-CoV-2. There was 100% agreement for positive cases and 92% agreement for negative cases.

| | | Institutional Standard of Care EUA SARS-CoV-2 PCR Test | |
|---|---|---|---|
| | | Positive | Negative |
| Cue COVID-19 Test | Positive | 6 | 3 |
| | Negative | 0 | 35 |

### Clinical Evaluation – Prospective Clinical Study in a Drive-Thru Testing Center

A prospective clinical study was conducted at a mid-western community drive-thru specimen collection and testing center. The study was IRB approved.

Adult outpatients were referred for testing after nurse triage based upon symptoms, exposures, or other criteria for COVID-19 testing. Patients with positive results for SARS-CoV-2 were both symptomatic and asymptomatic.

Patients were tested using the Cue COVID-19 Test at the point of care, drive-thru setting. Testing was performed by untrained operators with no prior laboratory training or experience.

The Cue COVID-19 Test results were compared to the results from the healthcare institution's standard of care EUA PCR test for SARS-CoV-2. There was 92% agreement for positive cases and 98% agreement for negative cases.

| | | Institutional Standard of Care EUA SARS-CoV-2 PCR Test | |
|---|---|---|---|
| | | Positive | Negative |
| Cue COVID-19 Test | Positive | 22 | 4 |
| | Negative | 2* | 239 |

*One patient did not have a tie-breaker SARS-CoV-2 test result available. Positive percent agreement would be 22/23 (96%) excluding that patient.

### Clinical Evaluation – Retrospective Clinical Samples and Sample Dipping

The Cue COVID-19 Test was also evaluated with 76 frozen nasal specimens in viral transport media. The samples were de-identified and the study was IRB approved.

The 76 samples were originally collected from patients suspected of SARS-CoV-2 infection by the healthcare provider. The samples were positive or negative by the healthcare institution's standard of care EUA test for SARS-CoV-2.

The thawed sample was applied by dipping the Cue Sample Wand into the clinical sample VTM and immediately inserting into the Cue COVID-19 Test Cartridge.

There was 100% positive (60/60) and negative (16/16) agreement of the Cue COVID-19 Test result with the institutional EUA.

### Clinical Evaluation – Prospective Clinical Study with Lay Users

Cue Health conducted prospective studies at 4 urgent care locations and at 2 Cue Health locations to evaluate use of the Cue COVID-19 Test by lay users in a simulated home use environment. All subjects successfully followed the instructions in the Cue Health App to run the Cue COVID-19 Test, start to finish without any assistance.

Adult lay users (≥18 years of age) self-collected or collected from their child (<18 years of age) a Cue Sample Wand nasal swab and ran the test.

Adult and child subjects were enrolled in an "all comers" style at the urgent care sites. Adult subjects at the Cue Health locations were enrolled to enrich inclusion of asymptomatic positive subjects by including subjects who were known positive for COVID-19. Among the total 286 subjects, 276 were adult ≥18 years of age self-swabbing and self-testing in the Cue COVID-19 Test and 10 were children <18 years of age where their parent collected the nasal sample and ran the Cue test. Thirteen (13) samples could not be included as there was no comparator assay result or Cue result available. Among the 10 unavailable Cue test results, 7 tests were cancelled, and 3 tests had invalid results. The 7 cancelled tests were 5 cartridge flow errors, 1 tilt threshold exceeded, and 1 user accidentally cancelled the test while in progress.

The rate of invalid or cancelled test results observed in this prospective clinical study was 3.7% (10/273).

Demographics for the 273 subjects included in the performance analyses are presented below.

| Age Range | N | % |
|---|---|---|
| <14 | 6 | 2.2% |
| 14-23 | 66 | 24.2% |
| 24-64 | 181 | 66.3% |
| >65 | 18 | 6.6% |
| N/A | 2 | 0.7% |

| Sex | N | % |
|---|---|---|
| Male | 133 | 48.7% |
| Female | 139 | 50.9% |
| Unknown | 1 | 0.4% |

There were 38 subjects with positive results, 233 subjects with negative results, and 2 subjects with inconclusive results by the FDA Emergency Use Authorized (EUA) molecular comparator method. Among the subjects, 10 subjects were asymptomatic positive, 123 subjects were asymptomatic negative, and 1 subject was asymptomatic inconclusive by the comparator.

| All Data | | FDA EUA Molecular Comparator | | |
|---|---|---|---|---|
| | | Positive | Negative | Inconclusive |
| Cue COVID-19 Test | Positive | 37 | 2 | 2* |
| | Negative | 1 | 231 | 0 |

*The 2 inconclusive samples by the comparator tested positive by the Cue COVID-19 Test.

Positive Percent Agreement (PPA): 97.4% (95% CI: 86.5% - 99.5%)
Negative Percent Agreement (NPA): 99.1% (95% CI 96.9% - 99.8%)

| Symptomatic Individuals | | FDA EUA Molecular Comparator | | |
|---|---|---|---|---|
| | | Positive | Negative | Inconclusive |
| Cue COVID-19 Test | Positive | 27 | 2 | 1* |
| | Negative | 1 | 108 | 108 |

*The 1 inconclusive sample by the comparator tested positive by the Cue COVID-19 Test

PPA: 96.4% (95% CI: 82.3% - 99.4%)
NPA: 98.2% (95% CI: 93.6% - 99.5%)

| Asymptomatic Individuals | | FDA EUA Molecular Comparator | | |
|---|---|---|---|---|
| | | Positive | Negative | Inconclusive |
| Cue COVID-19 Test | Positive | 10 | 0 | 1* |
| | Negative | 0 | 123 | 0 |

*The 1 inconclusive sample by the comparator tested positive by the Cue COVID-19 Test.

PPA: 100% (95% CI: 72.2% - 100%)
NPA: 100% (95% CI: 97.0% - 100%)

## Customer Support

If you have questions about this test, contact Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

You can purchase the Cue Health Monitoring System and Cue COVID-19 Test Cartridge Packs by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

## References


1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html (accessed March 23, 2021)
2. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical laboratories. http://www.cdc.gov/biosafety/publications/ (accessed March 23, 2021)
3. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline. Document M29 (refer to latest edition).


## Symbols Used on the Product Labels

The table below describes the symbols used on the Cue COVID-19 Test Cartridge Pack, the cartridge foil pouch, the Cue Sample Wand, the Cue COVID-19 Test Positive Control Swab, and the Cue Test Negative Control Swab.

| SYMBOL | DESCRIPTION |
|---|---|
|  | In Vitro Diagnostic |
|  | Consult Instructions for Use<br>eIFU available on the Cue Health Mobile Application and at www.cuehealth.com |
|  | Serial Number |
|  | Do not use if seal or packaging is broken or damaged |
|  | Storage temperature range |
|  | Catalog number |

| SYMBOL | DESCRIPTION |
|---|---|
| CONTROL + | Positive Control |
| CONTROL − | Negative Control |
|  | Manufacturer |
|  | Keep dry |
|  | Use By |




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