# High-accuracy, smartphone-based COVID-19 antigen testing.



# On-site COVID-19 testing for your organization with the Clip COVID Rapid Antigen Test

FDA authorized, 96.9% positive agreement and 100% negative agreement vs. RT-PCR for SARS-CoV-2 detection from nasal swabs in 30 minutes.\*

### Protein antigen detection

Identifies the SARS-CoV-2 nucleocapsid protein antigen detectable in nasal swab specimens during the acute phase of infection.

### **Automated reporting**

Results are automatically linkable to LIMS and EHR systems and reportable to public health authorities.

### High throughput

A single operator can run tens of tests each hour with a hands-on time of only 90 seconds per test.

### FDA and NIH vetted

Received FDA EUA in just 7 weeks and independently verified by the NIH RADx program.









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### Handle COVID testing on *your* terms:

With very little equipment you can become your own COVID lab. And with accurate results within 30 minutes, the impact on your organization can be huge.

If you're a CLIA certified setting, you can run your own tests.

or

If you're not a CLIA certified setting, we can help with your testing logistics.

### Things to know:

- Proven to detect Delta and other variants
- Highly accurate vs. RT-PCR with 100% specificity
- Smartphone-based, requiring only
  90 seconds of hands-on time per test
- Results take ~30 minutes, and are reported objectively
- Automatic data reporting and integrations available (e.g. EHRs, cloud, LIMS)
  - \*In symptomatic patients within the first 5 days of symptom onset. 31/32 (96.9%) positive agreement (95% CI 83.8%-99.9%) and 134/134 (100%) negative agreement (95% CI 97.3%-100%). Nasal swab results from Clip COVID were compared to nasopharyngeal swab results from FDA-authorized RT-PCR.

For prescription use only. This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under CLIA that meet the requirements to perform moderate, high or waived complexity tests.

Rapid antigen tests can be considered for screening asymptomatic populations when used frequently (serial testing). See https://www.fda.gov/media/146666/download

### Here's how it works:\*\*

# Load the Cartridge into the Clip Analyzer.

The Clip COVID Rapid Antigen Test employs persistent luminescence immunoassay technology in a sandwich lateral flow assay design to detect SARS-CoV-2 nucleocapsid protein from anterior nasal swab specimens.

# Prep nasal swab sample using the Extraction Tube.

Patient's nasal sample is placed in the Extraction Tube, during which the virus particles in the sample are disrupted, releasing viral nucleoproteins.



# Squeeze Extraction Tube contents into the Cartridge.

The extracted sample is dispensed into the Cartridge's sample well where it migrates through a lateral flow test strip containing various chemical environments. If SARS-CoV-2 viral antigen is present, it will be trapped and labeled by a persistent luminescent reporter nanoparticle.

## Act on the objective, rapid, accurate result for COVID-19 infection.

The Clip Analyzer measures a luminescence signal from the test strip, then method-specific algorithms are used to display objective test results (Positive, Negative, or Invalid) on the screen.



\*\*Refer to Package Insert for full instructions.



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Luminostics, Inc. dba Clip Health cliphealth.com | sales@cliphealth.com Phone 818.666.CLIP (2547)

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