# Test Anywhere

**Thomas No.** 21A00F712 21A00F713

#### Description

Clip COVID Rapid Antigen Test Kit (PK/25) Clip Analyzer, Individually Wrapped Get back to normal with smartphonebased rapid testing

#### The Clip COVID Rapid Antigen Test

Mfr. No

MDL002

MDL001

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 Detected**

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 & 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 & NIH Vetted**

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

### Clip COVID RAPID ANTIGEN TEST

## Thomas Scientific

COVID-19 testing for your organization at your organization

thomassci.com

## End-to-end COVID testing solution

Handle 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.

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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 you with the testing logistics

## Things to know:

- 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)



Get more details at: MDxSupport@thomassci.com

\* 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.

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

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.



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

## Load

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.

Prepare nasal swab sample using the Extraction Tube

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

## Add

Squeeze the contents of the Extraction Tube 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 pappopriticle

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

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

605

COVID-19

O Positive

Finish

step **Z** 

step 3

step 2

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