

PRIME CovidDetect™ RAPID ASSAY



PRODUCT BROCHURE

Prime CovidDetect™ Rapid Assay for the detection of SARS-CoV-2

Prime CovidDetect™ targets Orf1, Nucleocapsid(N) and Envelope (E) viral genes in SARS-CoV-2 and can detect all known strains of COVID including Alpha, Beta, Gamma, Delta and Mu.

Extractionless isothermal amplification is massively scalable and can be fully automated for laboratories. Prime CovidDetect™ test is validated across multiple labs locally and internationally.

PRODUCT DESCRIPTION

Prime CovidDetect™ rapid SARS-CoV-2 test detects SARS-CoV-2 with high analytical sensitivity and analytical specificity.

Prime CovidDetect™ works with MawiDNA iSwab-EL extraction-less sample collection medium and does not require nucleic acid extraction when samples are placed in the iSwab-EL medium.



OVERVIEW

- Go from sample to result results in <45 min
- Very high analytical sensitivity and analytical specificity in detecting SARS-CoV-2
- Very high throughput capable of running >3,000 samples per technician per machine on a 8 hour shift (* assuming thermal cycler with 4 x 384 capacity)
- Isothermal and extractionless protocol is easier to set up for screening

DECREASED RUN TIME

- Extractionless isothermal amplification produces results in <45 minutes compared to ~120 minutes for PCR.

HIGH ACCURACY

- Externally validated by NYU on several hundred clinical samples (+200) with high analytical sensitivity and specificity (>99%).

SUPPORTS PCR MACHINES

- Supports multiple qPCR instruments and thermal cyclers / plate readers.

INCREASES REVENUE

- Increases lab throughput as high as 4x and increases billable revenue.

RT-LAMP TECHNOLOGY

Prime CovidDetect™ test utilizes Reverse-Transcription Loop-mediated isothermal amplification (RT-LAMP) and eliminates the need for RNA extraction.

1. ANALYSIS

- RT-LAMP analyzes genetic material faster than PCR and can be detected by fluorescence output.
- Amplification of genetic material is rapid under isothermal conditions, which eliminates need for alternate heating and cooling like PCR.

2. HIGH SPECIFICITY

- RT-LAMP recognizes the target genes using six target sequences compared to just 2 target sequences in PCR.
- Prime CovidDetect™ targets three viral genes (18 target sequences), which leads to high specificity.

3. HIGH QUALITY DETECTION

- Prime CovidDetect™ recognizes the three target viral genes emitting strong fluorescence for high quality detection with fluorescence readers.

4. TIME

- Prime CovidDetect™ does not require RNA extraction or thermal cycling, which allows for rapid amplification.
- PCR can require >2 hours while Prime CovidDetect™ produces results from sample in <30 minutes.

PRODUCT PORTFOLIO AND FEATURES

1. PRODUCT OFFERINGS

- **Prime VarDetect**
Highly accurate, rapid PCR based COVID variant detection assay for Alpha, Beta, Gamma, Delta and Mu variants.
- **Prime STIDetect**
LAMP and PCR based detection assay for STIs (Herpes, Hepatitis B/C, Chlamydia, Gonorrhea, *Candida Albicans*, Trichomonas, Syphilis, etc.).
- **Prime RespDetect**
LAMP and PCR based detection assay for respiratory infections including Influenza A/B, RSV A/B, etc.
- **Prime VarDetectNGS**
A rapid Illumina NGS assay for full genome SARS-CoV-2 sequencing supporting rapid turnaround times and small batch sizes up to 25 samples.

2. PRIME'S ADVANTAGES

High Innovation:

- Highly innovative Rapid LAMP and PCR assays for multiple microbes.
- Our team works with you to design and develop novel assays within 3-4 weeks.

Customization:

- Highly reliable assays that can be customized to your lab workflows.
- Our specialists work with your team during the entire process for successful execution of the assays.

3. PARTNERSHIPS

- Partners with academic institutions including NYU, UPenn and University of Alaska.
- Test kits have been validated in multiple labs in NY, CA, New Orleans, NC and PA.
- Partners with multiple labs including Summer Bio, VeroDx, HookDx, Unilab, Biolabs, SepsisMD, and DNA Healthcare Solutions.

4. PCR COMPATIBILITY

- Prime CovidDetect™ has been validated with multiple qPCR instruments including Applied Biosystems 7500 Fast Real-time PCR instrument with SDS Software version 1.4, QuantStudio version 3, 5, and 6/7 Flex Systems.

5. US SUPPLY CHAIN

- Partners with US ISO certified CMOs and has multiple reagent suppliers.
- Can accommodate turnaround time of less than two weeks.
- One day shipping is available in US based on reagent availability.
- Bulk reagent supply ready to order.