

PRIME VarDetect™ RAPID VARIANT DETECTION TEST



PRODUCT BROCHURE

Molecular Rapid Variant Detection tests for the detection of SARS-CoV-2 Variants of Concern (VoC)

Prime VarDetect™ targets mutations unique to the variants of concern in the Spike(S) gene in SARS-CoV-2 and can detect all known Variants of Concern of COVID including Omicron, Alpha, Beta, Gamma, Delta and Mu.

Prime VarDetect™ is simple to execute and can be run on most common RT-qPCR systems. Prime VarDetect™ test is validated with clinical samples and comparison against gold standard Next Generation Sequencing (NGS) and TaqMan assays shows VarDetect is 100% concordant to NGS and more accurate than TaqMan.

PRODUCT DESCRIPTION

Prime VarDetect™ Rapid Variant Detection Test detects SARS-CoV-2 Variants of Concern (VoC) including Omicron, Alpha, Beta, Gamma, Delta and Mu with high sensitivity and specificity.



OVERVIEW

- Go from sample to results in <60 min
- Very high analytical sensitivity and analytical specificity in detecting SARS-CoV-2 VoC
- Compatible with most RT-qPCR instruments
- Easy to use software for implementation
- Genotyping assay targets one unique mutation for each VoC

DECREASED RUN TIME

- Prime VarDetect™ PCR amplification produces results in <80 minutes and works with most extraction protocols.

HIGH ACCURACY

- Validated with clinical samples against Gold Standard NGS and TaqMan genotyping assays that show VarDetect is 100% concordant with highly sensitive NGS and superior performance to TaqMan.

SUPPORTS PCR MACHINES

- Prime VarDetect™ supports multiple qPCR instruments and has an easy to interpret genotyping software.

INCREASES REVENUE

- Prime VarDetect™ increases lab revenue with reflex testing of positive samples for variant reporting purposes.

PCR TECHNOLOGY

Prime VarDetect™ utilizes custom PCR primers and probes which target one unique mutation per Variants of Concern (VoC) in the Spike (S) gene. This lowers the numbers of targets needed per strain and simplifies the variant detection workflow.

WHO Label	PANGO Lineage	Spike Mutation	First Detected
ALPHA	B.1.1.7	A570D	Sep 2020 - UK
GAMMA	P.1	T20N	Nov 2020 - Japan / Brazil
BETA	B.1.351	D80A	May 2020 - South Africa
DELTA	B.1.617.2	T478K	Oct 2020 - India
MU	B.1.621	R346K	Jan 2021 - Colombia
OMICRON	B.1.1.529	Multiple	Nov 2021 - South Africa

1. WORKFLOW

- PCR primers and probes target one unique Spike mutation per variant and genotyping output identifies presence of Variant of Concern.
- Amplification of genetic material is rapid with our custom genotyping reagents and amplification is performed in under 60 minutes.
- Easy to understand software allows clear interpretation of genotyping results.

2. HIGH SPECIFICITY

- Prime VarDetect™ primers and probes recognize the target mutations with very high specificity.
- Prime VarDetect™ targets mutations which are unique to Variant of Concern and reduces the number of reactions needed to identify the Variant of Concern.

3. HIGH QUALITY DETECTION

- Prime VarDetect™ genotyping assay detects the mutant and wildtype alleles for the mutation.
- Strong fluorescence for high quality detection with fluorescence readers enables accurate detection of the variant.

4. TIME

- Prime VarDetect™ enables a simplified workflow which can detect the Variants of Concern in under 60 minutes.

PRODUCT PORTFOLIO AND FEATURES

1. PRODUCT OFFERINGS

- **Prime CovidDetect™**
Highly accurate, extractionless rapid RT-LAMP based COVID screening assay which requires <30 min from sample to result.
- **Prime STIDetect™**
RT-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. COMPATIBILITY

- Prime VarDetect™ 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.