iSWAB™-RC-EL (Extraction-Less)

Skip Viral RNA Extraction Prior to COVID-19 Molecular Testing

During the height of the COVID-19 pandemic, viral testing became the most effective tool to help bring outbreaks and surges under control. However, this comprehensive testing effort resulted in huge supply chain pressures, especially for lab consumables such as swabs and viral extraction reagents. Mawi DNA Technologies developed a modified "Extraction-Less" version of the non-invasive iSWAB™ technology.

The iSWAB™-Respiratory Tract Sample Collection Media-Extraction Less (iSWAB™-RC-EL) is designed to eliminate the RNA extraction step in the COVID-19 molecular testing workflow, allowing laboratories to perform direct RT-PCR and RT-LAMP on individual and pooled samples, eliminating or reducing the possibility of human error during long extraction protocols and the cost of extraction reagents, while increasing testing throughput. Additionally, the ambient temperature stabilization capacity of iSWAB™-RC-EL maintains the integrity of samples in cases of shipping delays/long shipping times or lab backlogs. This reduces the chances of false negatives and the need for patient re-sampling.

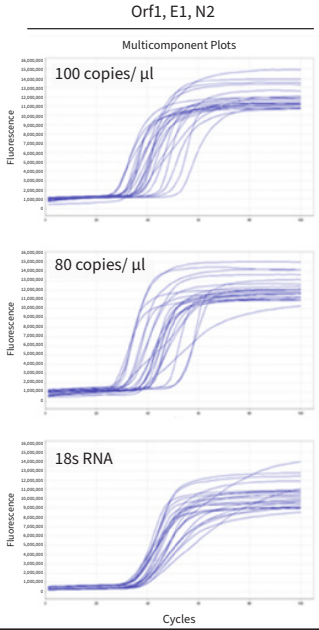
- **Effectively inactivates SARS-CoV-2**, virus and other viruses to allow safe transport and decrease the risk of infection during sample collection and processing
- **Increase throughput and operational efficiency** by reducing processing time and supply costs by eliminating the extraction step.
- **Barcoded for sample traceability and testing accuracy** especially from remote or difficult to reach areas allowing enhanced global pandemic data collection and control.
- **Swab Free transport** of samples for a concentrated, liquid sample with a minimal footprint that can be processed processed on arrival to labs
- **Long-term room-temperature stability** (15-45°C) 28 - 33 days. Viral RNA maintains sample integrity during long transit times or backlog without cold storage.
- **Interchangeable nasal and/or saliva collection compatibility** allows for continued testing even when swabs are difficult to source.

Compatible RT-PCR and LAMP Assays

Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit, Cat. #12014115 (EUA Granted) • Prime Discoveries Prime COVID-19 Extraction Less High Throughput LAMP Assay Kit (EUA Pending • SARS-CoV-2 (2019-nCoV) CDC qPCR Probe Assay 2019-nCoV RUO Kit (IDT, Cat. 10006713) & Applied Biosystems™ TaqPath™ 1-Step Multiplex Master Mix (Fisher Scientific, Cat. A28521) • SeqOnce Bio AzureSeq Direct One-Step Universal RT-qPCR Kit SARS-CoV-2, Cat. # ASD-200 (EUA-Validated, not EUA-Authorized) • 3CR Bio ProbeSure COVID-19 One Step RT-PCR Kit, Cat. # COV-1001-3 • Takara One Step PrimeScript III RT-PCR Kit, Cat. no. RR600A, RR600S, RR600B • BGI Real-Time Fluroescent RT-PCR Kit for Detecting SARS-CoV-2 Cat. # HW5105 •CDC 2019-nCoV RT-PCR Diagnostic Panel (Using IDT 2019-nCoV Kit Primers and Thermofisher TaqPath™ 1-Step RT-qPCR Master Mix, CG)

Prime's COVID-19 Extraction-Less Limit of Detection (LoD)

Concentration (copies/ µl in primary samples)	A1e/E1/N2 genes (replicates detected)	
	with VTM	with Mawi
100 copies/ µl	5/24	24/24
80 copies/ µl	5/24	24/24
70 copies/ µl	4/24	21/24
60 copies/ µl	5/24	16/24
50 copies/ µl	4/24	17/24
40 copies/ µl	7/24	14/24
10 copies/ µl	5/24	10/24
4 copies/ µl	5/24	10/24
1 copy/ µl	4/24	10/24
0.2 copy/ µl	5/24	11/24



The LoD of Prime COVID-19 Extraction-Less High-Throughput LAMP Assay Kit (Prime Discoveries) was established using genomic RNA (from positive reference material that contain recombinant virus particle with sequence SARS-CoV-2 genome at a concentration of 1,000 copies/ml) spiked into pooled negative anterior nasopharyngeal swabs collected in Mawi's iSWAB-RC-EL. Each spiked replicate was processed using Prime's reagents / kits without RNA extraction. 24 replicates were analyzed, and samples were called negative if no amplification was detected before cycle.

SUMMARY AND CONCLUSIONS:

- The testing data from different EUA approved and LDTs COVID-19 molecular testing assays show that iSWAB-RC -EL buffer can be used directly in PCR reactions without any prior major (RNA extraction) or minor (heating or/and Proteinase K treatment) sample processing, thus providing a real extraction-less solution for the detection of SARS-CoV-2
- Mawi's molded sampling applicator, NextSWAB, performs similarly to the standard flock swabs in oral and mid-turbinate nasal sample collection.

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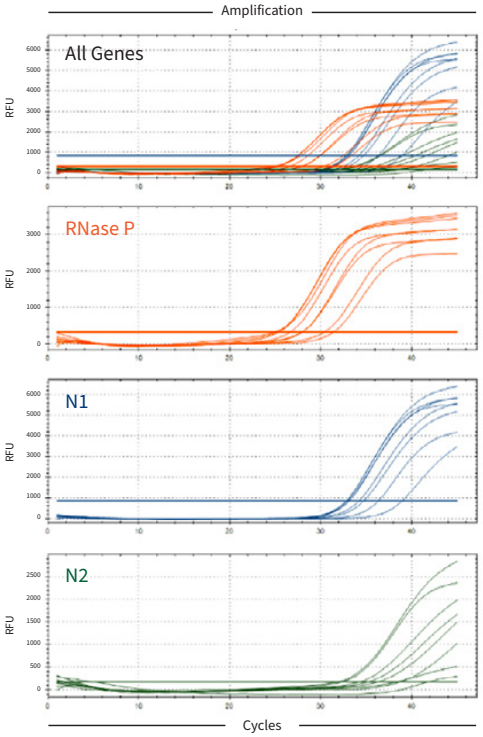
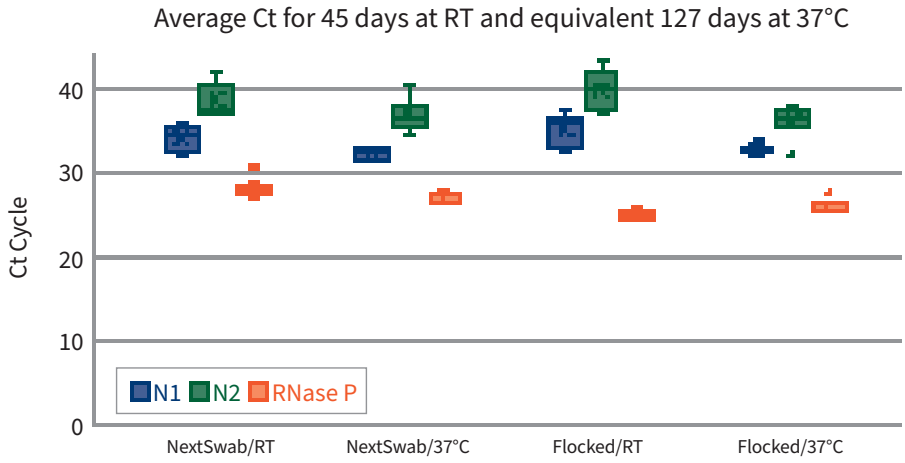
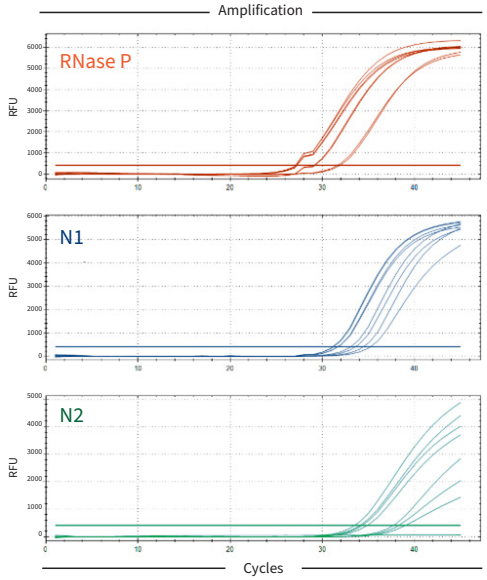
Bio-Rad's Reliance SARS-CoV-2 RT-PCR Assay Kit Performance with iSWAB™-RC-EL

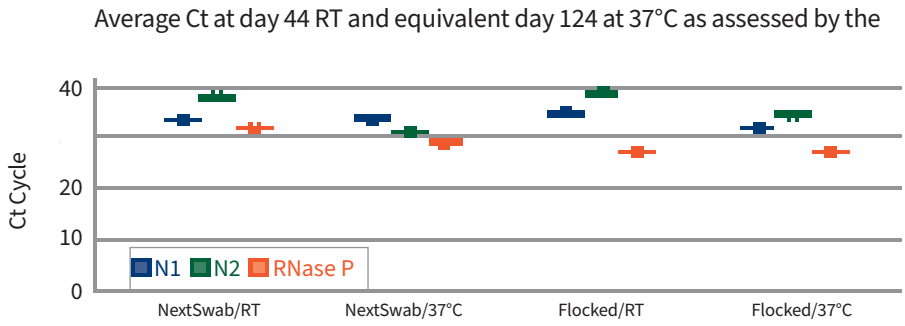




Averag
days in
spiked
days at ambient (room) temperature. The left panel shows amplification plots of all three genes, of SARS-CoV-2 gene N1 (FAM channel), of SARS-CoV-2 gene N2 (HEX channel), and of human RNase P gene (Texas Red Channel), at Day 45 after sample collection. SARS-CoV-2 was consistently detected (Ct values ≤40 for SARS-CoV-2 specific genes N1 and N2) across 45 days at room temperature and at 37°C directly from iSWAB-RC-EL stabilization buffer, without the need of laborious RNA extraction and in the presence of background human RNA. No PCR inhibition was observed for all conditions tested, as assessed by amplifying the human RNase P gene, whose Ct value remained stable for 45 days.

CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Assay using Applied Biosystems™ TaqPath™ 1-Step Multiplex Master Mix Performance with iSWAB-Microbiome-EL





Average Ct cycle at which SARS-CoV-2 genes N1 and N2 were detected along with the Rnase P gene at days 44 in nasal samples collected either with the molded NextSwab swab or with a standard flocked swab and spiked with 110 cp/µl of heat-inactivated virus, at room temperature and at 37°C. The latter is equivalent to 124 days at ambient (room) temperature. The left panel shows amplification plots of all three genes assessed by the panel including: SARS-CoV-2 gene N1 (FAM channel), of SARS-CoV-2 gene N2 (FAM channel), and of human Rnase P gene (Fam Channel) at Day 44 after sample collection. SARS-CoV-2 was consistently detected (Ct values ≤40 for SARS-CoV-2 specific genes N1 and N2) across 44 days at room temperature and at 37°C directly from iSWAB-RC-EL stabilization buffer, without the need of laborious RNA extraction and in the presence of background human RNA. No PCR inhibition was observed for all conditions tested, as assessed by amplifying the human RNase P gene,

Catalog No.	Description	Stabilizing Buffer Volume
IRC-T-EL	iSWAB-RC-EL Collection Device,	800µl x 500 units
IRC-T-EL-R	iSWAB-RC-EL Collection Device Rack ,	800µl x 50 Units

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