iSWAB™-Microbiome-EL (Extraction-Less)

Skip Viral RNA Extraction Prior to COVID-19 Molecular Testing

Mawi DNA Technologies has developed a modified version of our non-toxic iSWAB-Microbiome collection technology, already used by labs worldwide for COVID-19 sample collection, that significantly reduces lab waste and supply chain pressure.

This new product, iSWAB-Microbiome-EL (Extraction-Less), eliminates the RNA extraction step in the COVID-19 molecular testing workflow, allowing researchers to perform direct RT-PCR on individual and pooled samples, especially when our 100% plastic NextSWAB is used as replacement for flocked swabs. iSWAB-Microbiome-EL is compatible with both nasal swab and saliva collection.

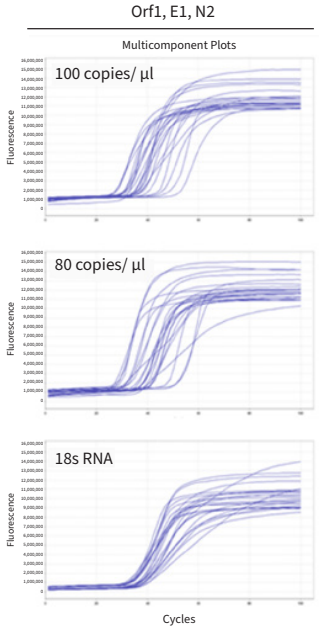
- **Significantly reduce plastic waste**, reducing environmental impact and overcoming consumable shortages.
- **Increase throughput and operational efficiency** by reducing processing time.
- **Increases sampling access** especially from remote or difficult to reach areas allowing enhanced global pandemic data collection and control.
- **Annual cost reduction** of hundreds of thousands to millions of dollars
- **Long-term room-temperature stability** (15-45°C) of 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

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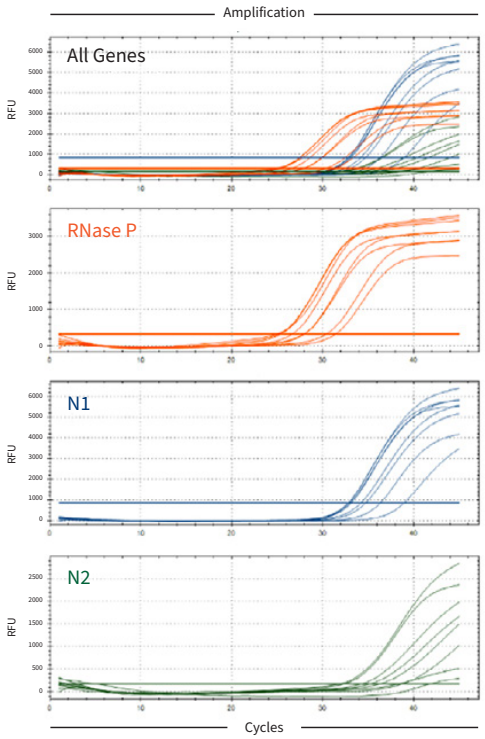
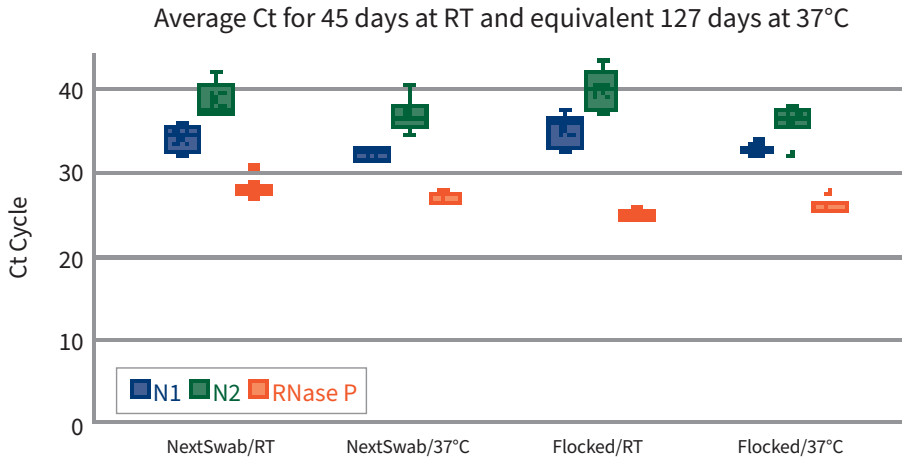
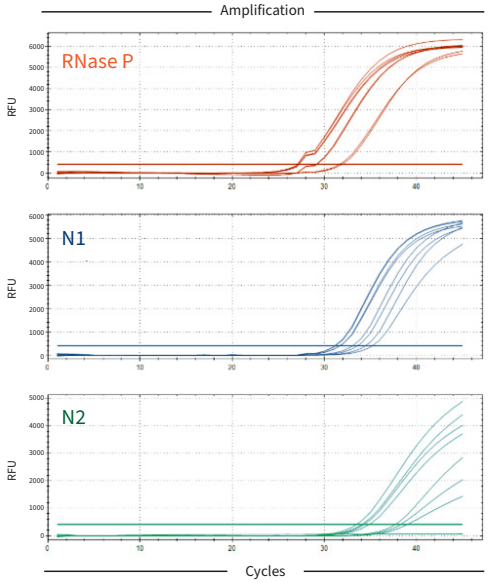
Bio-Rad's Reliance SARS-CoV-2 RT-PCR Assay Kit Performance with iSWAB-Microbiome-EL

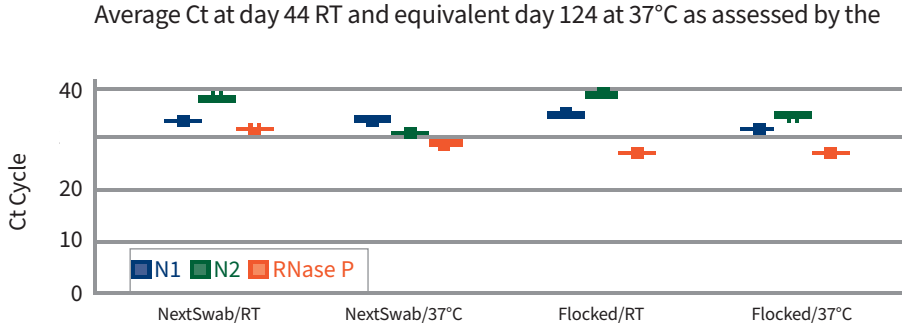




Average Ct cycle at which SARS-CoV-2 genes N1 and N2 were detected along with the RNase P gene across 45 days in nasal samples collected either with the molded NextSwab swab or with a standard flocked swab and spiked with 110 cp/µl of heat-inactivated virus, at room temperature and at 37°C. The latter is equivalent to 127 days at ambient (room) temperature. The left panel shows amplification plots of all three genes, of SARSCoV-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-Microbiome-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-Microbiome-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 44 days.

Catalog No.	Description
ISM-T-EL	iSWAB-Microbiome-EL collection tube, 800µl
ISM-T-EL-R	iSWAB-Microbiome-EL collection tube rack , 800µl x 50
NextSWAB-1	NextSwab Universal Sterile Sampling Applicator (1 swab/pouch)
NextSWAB-2	NextSwab Universal Sterile Sampling Applicator (2 swabs/pouch)
iSPIT	iSPIT Spit Funnel (1 unit)

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