# iSWAB™- Microbiome-EL (Extraction-Less)

## Skip Viral RNA Extraction Prior to COVID-19 Molecular Testing

During the height of the COVID-19 pandemic, testing became the most effective tool to help bring outbreaks and surges under control. However, this comprehensive testing effort resulted in massive amounts of plastic lab waste and huge supply chain pressures, especially for lab consumables such as swabs and viral extraction reagents.

Mawi DNA Technologies has developed a modified version of our non-toxic iSWAB-Microbiome collection technology, already being used by labs worldwide for COVID-19 sample collection. This product is called iSWAB-Microbiome-EL, where EL stands for "Extraction-Less". iSWAB-Microbiome-EL has been specifically designed to eliminate 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.

### By skipping the viral RNA extraction step, iSWAB-Microbiome-EL can benefit testing labs in multiple ways:

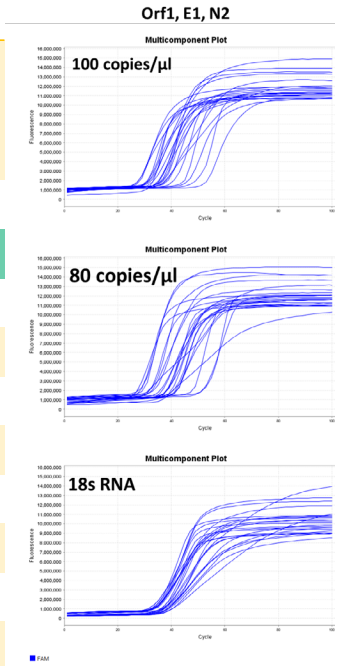
- Significantly reduce plastic waste, reducing environmental impact and overcoming consumable shortages.
- Increase throughput and operational efficiency by reducing processing time.
- Annual cost reduction of hundreds of thousands or even millions of dollars
- Long term Room temperature stability (15-45°C) of viral RNA maintains sample integrity during long transit times or lab testing backlog without the need for cold storage infrastructure.
- Increases sampling access especially from remote or difficult to reach areas allowing enhanced global pandemic data collection and control.
- 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

### Prime's COVID-19 Extraction-Less Limit of Detection

| | VTM | Mawi |
|---|---|---|
| Concentration Copies/µl in Primary Samples | A1e/E1/N2 genes (Replicates detected) | A1e/E1/N2 genes (Replicates detected) |
| 100 copy/µl | 5/24 | 24/24 |
| 80 copy/µl | 5/24 | 24/24 |
| 70 copy/µl | 4/24 | 21/24 |
| 60 copy/µl | 5/24 | 16/24 |
| 50 copy/µl | 4/24 | 17/24 |
| 40 copy/µl | 7/24 | 14/24 |
| 10 copy/µl | 5/24 | 10/24 |
| 4 copy/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 & Conclusion:

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

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Biosampling Reinvented™

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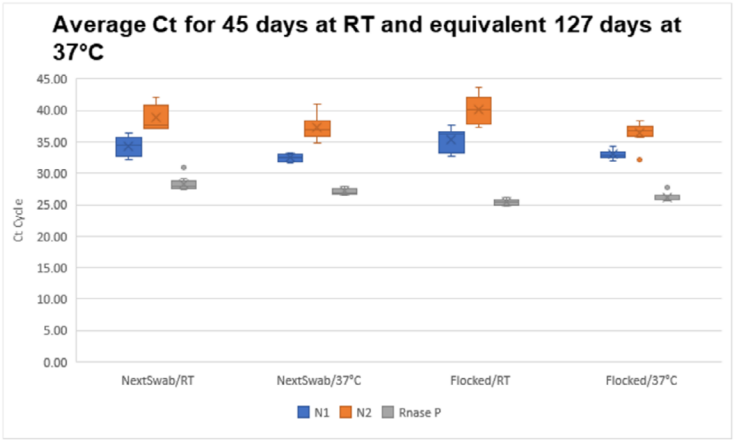
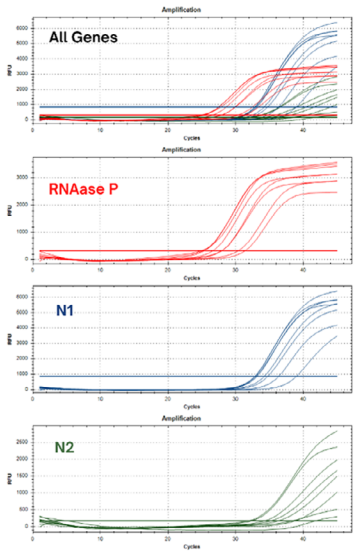
## Skip Viral RNA Extraction Prior to COVID-19 Molecular Testing

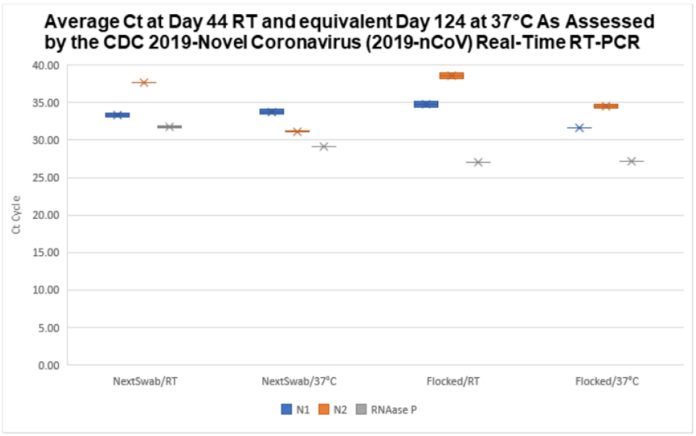
Bio-Rad's Reliance SARS-CoV-2 RT-PCR Assay Kit Performance with iSWAB-Microbiome-EL

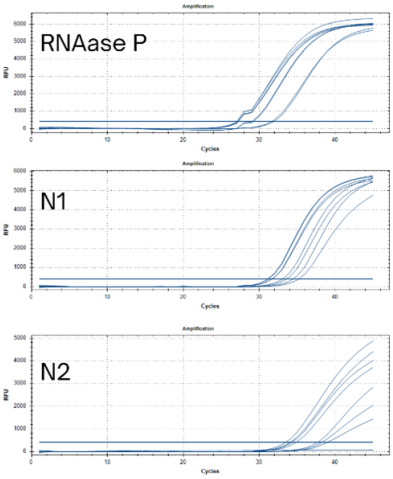



Average Ct cycle at which SARS-CoV-2 genes N1 and N2 were detected along with the Rnase P gene across 45 days in nasal samples collected either with the molded NextSwab swab or with a standard flocked swab and spiked with 110 cp/µl of heat-inactivated virus, at room temperature and at 37°C. The latter is equivalent to 127 days at ambient (room) temperature. On the right panel, 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-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 right 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, 800ul |
| NextSWAB-1 | NextSwab Universal Sterile Sampling Applicator (1 swab/pouch) |
| NextSWAB-2 | NextSwab Universal Sterile Sampling Applicator (2 swabs/pouch) |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DS-0001 MB EL datasheet v3 (Rev A)