

- ✓ Direct-to-Consumer
- ✓ At-Home
- ✓ Point-of-Care



## Specimen Collection, Storage, & Transport Device

# BIOSAMPLING ADVANTAGES

### DEVICES

- **SDNA-RUO**; For Research Use Only
- **SDNA-1000 RX Only**; FDA 510k Device Clearance
- **SDNA-2000**; OTC (Over the Counter) Health Canada & CE Clearance
- **SDNA-3000 RX Only**; Health Canada & CE clearance
- **SMD-RUO**; For Research Use Only

### EFFICIENT

- Designed & engineered to eliminate sample self-collection errors
- System maintains biosample consistency significantly reducing costs associated with sample failures & recollection
- Self-contained, user-friendly saliva collection system provides critical sample quality and supports laboratory automation for high-throughput analyses
- Partner testing measured improved assay repeatability, lowering coefficient of variability, and boosted sensitivity\*
- Support in-clinic, at-home remote care, or direct-to-consumer testing solutions

### COMPATIBLE

- Compatible with automated platforms & customizable for incremental efficiency improvements
- Qualified commercial RNA extraction chemistries include Perkin Elmer, Thermo Fisher, Roche, Qiagen, & more

### SDNA BUFFER

- Patented SDNA (CV3) buffer stabilizes, preserves, & protects nucleic acid transcripts
- Single device for DNA/viral RNA nucleic acid stabilization
- Eliminates sample loss due to sample binding effect
- Bactericidal, virucidal, & microbicidal
- In-device  $\geq 99.99\%$  live virus inactivation of SARS-CoV-2, Flu A, Flu B, & RSV in 10-seconds at ambient temperatures
- In-device viral inactivation delivers direct-to-bench testing process improvement and efficiency
- Qualified commercial RNA extraction chemistries include Perkin Elmer, Thermo Fisher, Roche, Qiagen, & more
- 36-months pre-collection shelf life at ambient temperatures
- 24-months post-collection DNA stability at ambient temperatures\*
- 28-days post-collection RNA stability at ambient temperatures\*
- In-device sample storage & transport with no temperature controlled requirements
- Partner testing demonstrated DNA single amplification capability and reduced effects of saliva matrix on hybridization\*

### SMD BUFFER

- First-in-kind patent-pending solution with multi-omic capabilities stabilizes, preserves, & protects proteomic and genomic analytes at room temperature
- Preserves inflammatory markers for downstream analysis in evaluation of cytokines
- Concordance to serological biomarkers\*
- Cross-platform compatibility\* including Luminex, Olink, Somalogic, and ELISAs
- Compatibility with extractionless PCR testing\*
- 2-year shelf life at ambient temperatures
- 14 days post-collection stability for proteins at ambient temperatures\*\*\*
- Over 10-days post-collection stability for DNA at ambient temperatures\*

# Unrivaled Total Sample Collection Innovation

## Enhance Accuracy & Uphold Analyte Integrity From Anywhere Worldwide

The BioMAX family of specimen collection devices have been engineered to lead the sampling collection and analyte stabilization market for IVD molecular diagnostic applications.

In demonstration of its superior sample quality, quantity, safety, and point-of-collection innovation, the BioMAX SDNA-1000 was selected as the first EUA authorized collection device for noninvasive COVID-19 saliva-based testing. In addition, the SDNA-1000 was also awarded FDA 510k device clearance.

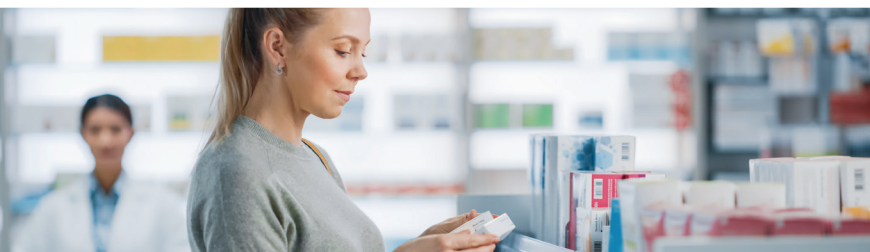
Instrumental in helping to accelerate the scientific journey, the BioMAX self-contained specimen collection device family offers RUO, OTC, and FDA cleared options delivering critical sample consistency, easy workflow integration, and direct-to-bench process efficiency for highest levels of testing sensitivity and specificity.

Spectrum offers two innovative buffer solutions that provide critical sample consistency and extended nucleic acid stability, based on application needs, at ambient temperatures, in addition to home collection and safer user sample handling.

1. SDNA (DNA/Viral RNA analyte stabilization)
2. SMD (Multi-Omic Proteomic/Genetic analyte stabilization)

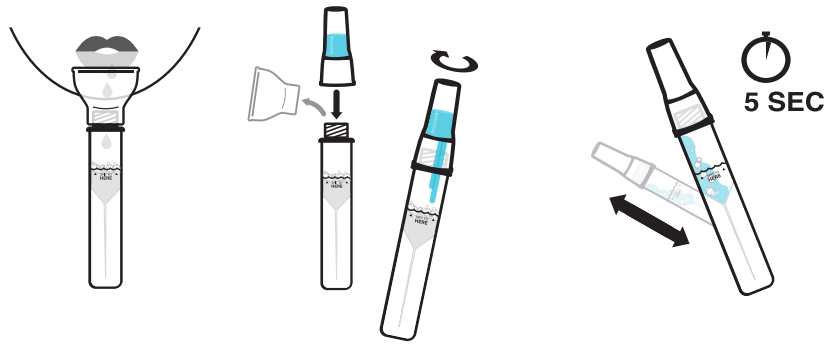
Consider pairing the BioMAX with any of our end-to-end partner solutions to innovate, advance, or support your molecular diagnostics and DTC testing applications.

- Innovative Assay Development
- Highly-Sensitive DTC, Physician-Ordered, & Reference Testing
- Test-to-Treat Digital Healthcare Partner Pharmacy
- Med-Device Product Development & Contract Manufacturing
- Clinical Kitting + Specialized Test Kit Development
- Kit Fulfillment & Warehousing
- Testing Business Support Services/Logistics



Patent Pending

# COLLECTION PROCESS

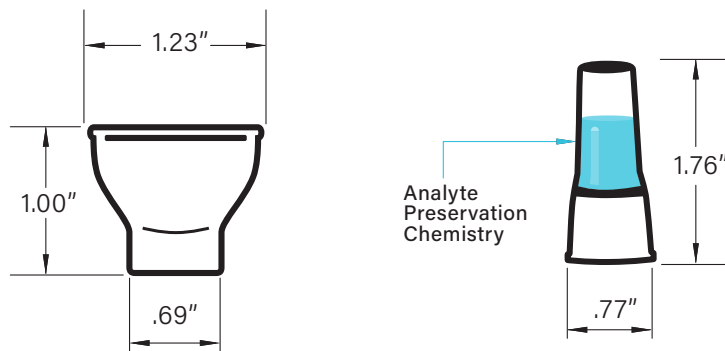


## Intuitive Design

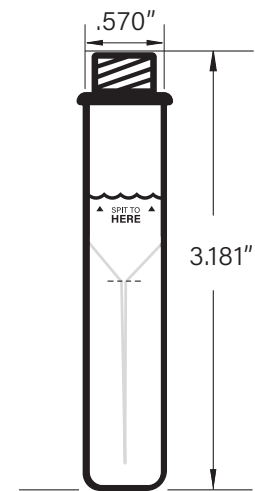
The BioMAX device family has been engineered to resolve testing failure issues from user collection errors.

# DEVICE SPECIFICATIONS

## Funnel and Cap Dimensions



## Tube Dimensions



# CONFORMITY & FDA STATEMENT

In March 2020, the FDA authorized the first saliva collection device, Spectrum's SDNA-1000 for COVID-19 diagnostic testing. In addition to noninvasively collecting, stabilizing, storing, and transporting saliva samples at ambient temperatures, the SDNA-1000 also enhanced user safety and lessened exposure risks by demonstrating a  $\geq 99.99\%$  live SARS-CoV-2 virus inactivation within 10 seconds at room temperature. The SDNA-1000 now holds FDA device 510k clearance.

- COVID-19** FDA EUA Authorization (EUA202432)
- First FDA EUA authorized device for COVID-19 saliva testing
  - First FDA EUA authorized saliva collection device for direct-to-patient at-home unsupervised sample self-collection
  - Offers earliest & asymptomatic detection of SARS-CoV-2 infection up to 4-days sooner than NP swab<sup>(1)</sup>
  - Capable of detecting a positive SARS-CoV-2 infection from as few as 200 copies/mL (lateral flow rapid antigen testing requires 10,000-20,000 copies/mL)

## REQUEST FOR INFO

For individual BioMAX product or buffer related questions contact our Spectrum sales team or visit the website [spectrumsolution.com/BioMAX](https://spectrumsolution.com/BioMAX).

LABORATORY | MANUFACTURING | COMPOUNDING Rx

© Spectrum Solutions® The information contained in this document is confidential and the sole property of Spectrum Solutions, LLC. Any reproduction without the written permission is prohibited. The components of Spectrum's specimen collection systems and stabilization chemistries are protected by issued and pending patents. Not approved for all markets. Any claims are currently intended for laboratory developed testing only.

\* Lab partner data with on-going evaluation & updates \*\* Depending on Protein  
(1) <https://pubmed.ncbi.nlm.nih.gov/34911366/>



12248 Lone Peak Parkway, Suite 106  
Draper, Utah 84020

801 569 0465

[sales@spectrumsolution.com](mailto:sales@spectrumsolution.com)

[spectrumsolution.com](https://spectrumsolution.com)

