(Example Optional Secondary Packaging Brand Customization)

SDNA-1000

DNA + VIRAL RNA
SALIVA COLLECTION DEVICE

PRODUCT DESCRIPTION

How you collect saliva makes a big diagnostic difference.

To incorporate the use of saliva into COVID-19 diagnostic testing protocols or implement actual real-world mass-testing in scalable scenarios, requires an authorized, proven, validated, and supported system that actually mitigates risk of exposure and a device engineered to increase testing accuracy.

The SDNA saliva collection device has been engineered to lead the saliva collection market in molecular diagnostic applications. This self-contained saliva collection system provides critical sample consistency while suspending and neutralizing viral RNA transcripts post collection for sensitive and specific analysis completely inactivating the live virus at ambient temperatures.

Spectrum's technically-superior molecular diagnostic saliva collection systems provides long-term stability and ships with verified, unique barcode serialization for biosample digital chain-of-custody. Additionally, customized secondary packaging*, kitting, and fulfillment options are available to solve any special project or testing workflow requirements.

Choosing the wrong saliva collection device can introduce and increase critical failure points. Spectrum's new and technically-superior saliva collection device is the answer your teams and projects have been waiting for.

SUPERIOR POINT-OF-COLLECTION SAMPLE PREP

ADVANTAGES

- SPECIALIZED TEST KIT DEVELOPMENT
- D_X TO R_X SOLUTIONS
- NON-INVASIVE MULTIMODAL ASSESSMENTS

SIMPLE
- Single device for DNA or viral RNA testing
- Engineered to eliminate sample self-collection errors

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

INTUITIVE
Intuitive 3-step design, reduce customer collection errors

STORAGE
- 24-month pre-collection shelf life at room temp
- 15-month post-collection DNA stability at room temp
- In-device sample storage & transport
- No temp-controlled sample storage or transport requirements

EFFICIENT
- System maintains biosample consistency. Significantly reduces costs associated with sample failures & recollection
- Improve assay repeatability and boost sensitivity
- Support in-clinic, at-home remote care, or direct-to-consumer testing solutions

SHIPPING
Shipping clearance for standard mail at ambient temps with no biohazard UN3373 designation

SOLUTION
- Patented chemistry stabilizes, preserves, & protects DNA and viral RNA transcripts
- 100% Bacteriostatic
- In-device viral neutralization at room temp
- In-device DNA amplification at point-of-collection
- Reduce effects of saliva matrix on hybridization
- Lower coefficient of variability (COV)

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
- 100% inactivation of the live virus at ambient temperature
- PCR testing that incorporates the SDNA-1000 saliva collection kit with patented preservation chemistry identifies infections at their earliest stages from as few as 200 copies/ml compared to lateral flow rapid antigen testing needing 10,000-20,000 copies/ml

SPECTRUM **MEDICAL SCIENCE**

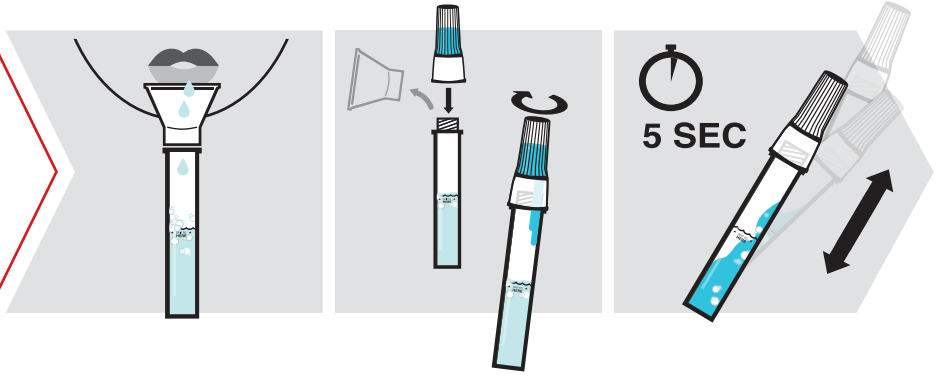
Our saliva diagnostic innovations, products, & engineering are setting new standards of care in testing, managing, and the treatment of disease. From direct-to-consumer health & wellness to point-of-care and at-home diagnostic testing.

COLLECTION PROCESS

DO NOT
eat, drink, smoke or chew gum for

30 MINUTES

before spitting in tube.



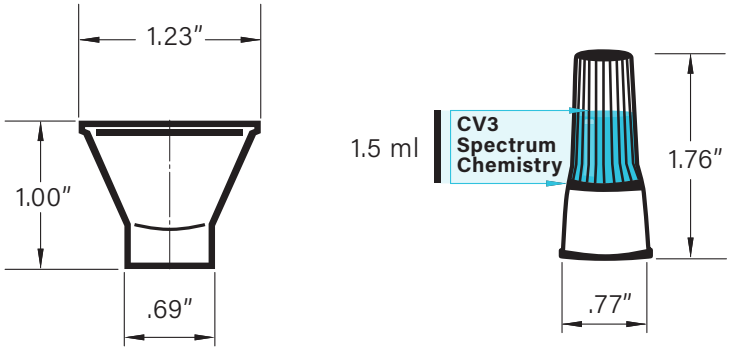
- Direct-to-Consumer
- At-Home
- Point-of-Care

Intuitive Design

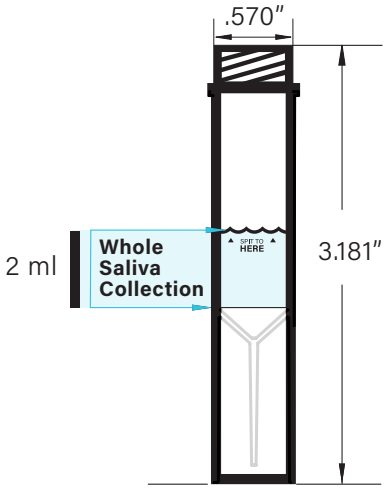
The SDNA-1000 has been engineered to resolve testing failure issues from user collection errors.

DEVICE SPECIFICATIONS

Funnel and Cap Dimensions



Tube Dimensions



FDA EUA STATEMENT

The SDNA-1000 was the first saliva collection device authorized for COVID-19 testing in March 2020 (EUA200090). FDA authorized the SDNA-1000 Saliva Collection Device for use by individuals to collect, stabilize, neutralize, and suspend biosamples post collection for and during transport at ambient temperatures. August 2020 the SDNA-1000 device was additionally authorized for unsupervised specimen self-collection by a layperson 18 years and older or for specimen collection by a healthcare worker from individuals of any age (EUA202432).

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263 using an FDA authorized in vitro diagnostic (IVD) test for the detection of SARS CoV-2 that is indicated for use with the SDNA-1000 Saliva Collection Device.

REQUEST FOR INFO

For additional information on COVID-19 saliva testing using the SDNA-1000 for sample collection, product distribution partners, and authorized processing labs visit spectrum**solution**.com/COVID-19. For product related questions or additional product information contact our Spectrum Medical Science account team or visit the SDNA product page at spectrum**solution**.com/SDNA.

MEDICAL SCIENCE | COMPOUNDING R_X | CLINICAL MANUFACTURING

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