



SPECTRUMDNA™

## TECHNICALLY-SUPERIOR SALIVA COLLECTION

SDNA-1000

Device EUA Authorization (EUA202432)

NEW

### SDNA 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.

### ADVANTAGE

- ✓ SIMPLE ..... Single device for DNA/viral RNA biosample collection, transportation, & storage
- ✓ 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, proven to reduce customer collection errors
- ✓ STORAGE ..... 24-month shelf life at room temperature
- ✓ EFFICIENT ..... System maintains biosample consistency. Significantly reduces costs associated with sample failures & recollection
- ✓ SHIPPING ..... Standard mail at ambient temperatures. In device viral neutralization delivers shipping clearance with no biohazard UN3373 designation
- ✓ SOLUTION ..... Innovative, patented chemistry that preserves & protects both DNA/viral RNA transcripts, manages bacteria & mitigates any risk of infection throughout the testing process
- ✓ COVID-19 .....
  - First FDA EUA authorized saliva collection device for COVID-19 testing
  - First FDA EUA authorized device for direct- to-patient at-home sample self-collection
  - Delivers 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

## COLLECTION PROCESS

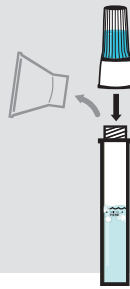
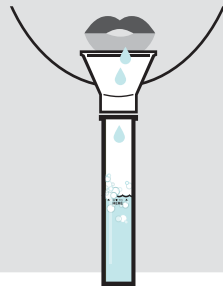
### Intuitive Design

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

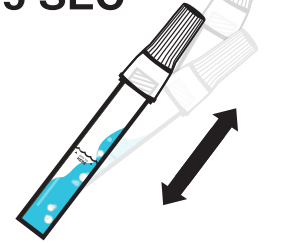
**DO NOT**  
eat, drink, smoke or  
chew gum for

**30**  
MINUTES

before spitting in tube.

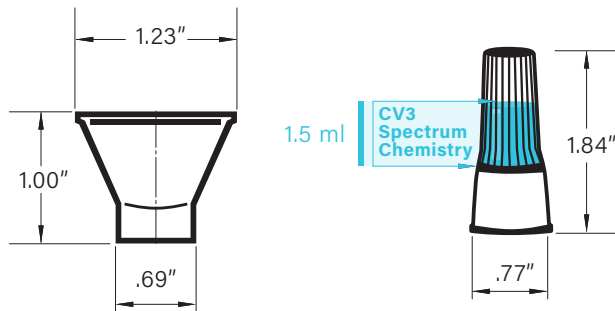


  
**5 SEC**

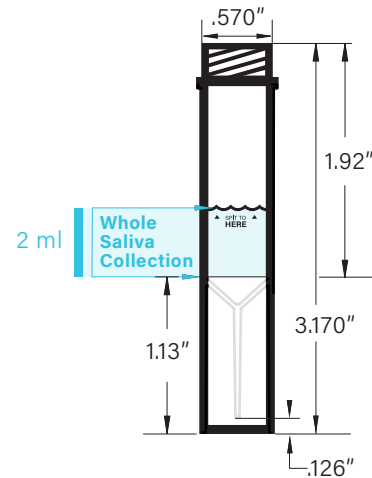


## DEVICE SPECIFICATIONS

### 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. October 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 INFORMATION OR QUOTATION

Visit [spectrumsolution.com/COVID-19](https://spectrumsolution.com/COVID-19) for additional information, authorized labs processing COVID-19 tests using the SDNA-1000 saliva collection device, partners selling direct at-home and corporate testing options, or

product distribution partners. For product related questions or additional product information contact our Spectrum DNA account team or visit the SDNA product page at [spectrumsolution.com/SDNA](https://spectrumsolution.com/SDNA).



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