SDNA-1000

DNA + VIRAL RNA

SALIVA COLLECTION DEVICE

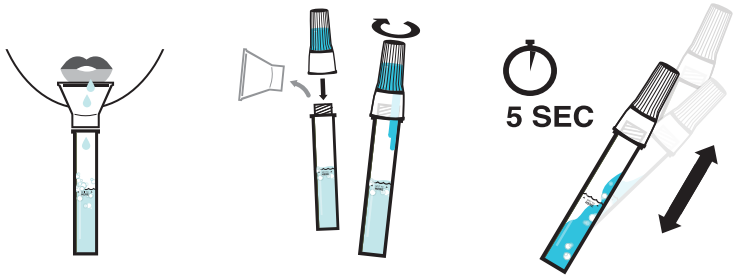
- SPECIALIZED TEST KIT DEVELOPMENT
- D_X TO R_X SOLUTIONS
- NON-INVASIVE MULTIMODAL ASSESSMENTS

(Example Optional Secondary Packaging Brand Customization)

COLLECTION PROCESS

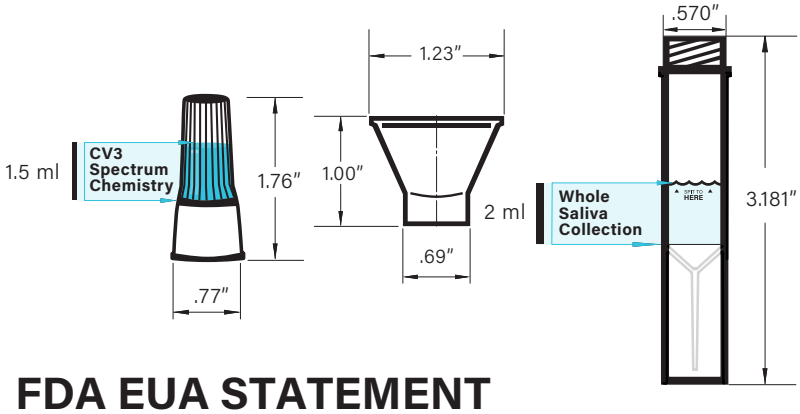
- ☑ Direct-to-Consumer
- ☑ At-Home
- ☑ Point-of-Care

No food, drink, chewing gum, or smoking for 30 Minutes before spitting.



DEVICE SPECIFICATIONS

Funnel, Cap, and 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.

SUPERIOR POINT-OF-COLLECTION SAMPLE PREP

ADVANTAGES

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

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