*Image illustrates example of optional secondary packaging

ISO 13485:2016

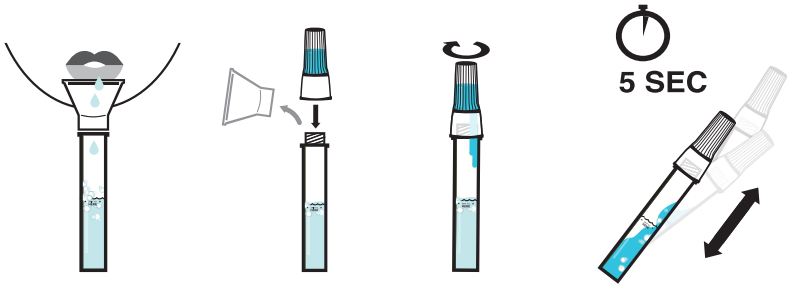
SPECTRUMDNA™

TECHNICALLY-SUPERIOR SALIVA COLLECTION

SDNA-1000
Device EUA Authorization (EUA202432) NEW

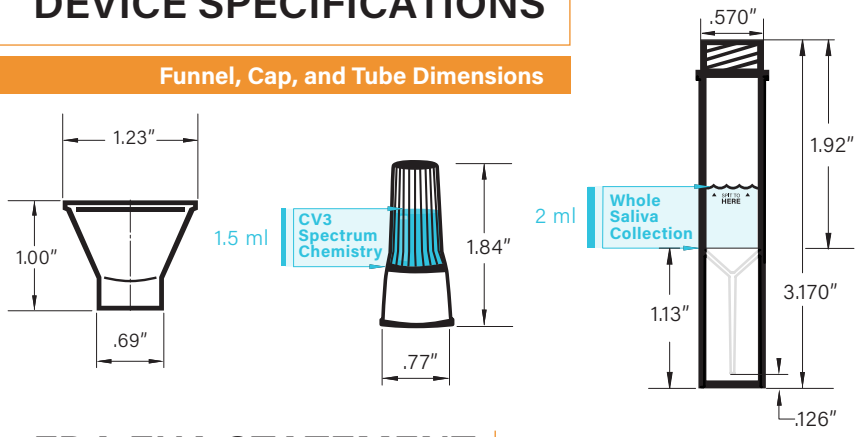
COLLECTION PROCESS

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. 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.

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 and 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

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