EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
SDNA-1000 SALIVA COLLECTION DEVICE

For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only

INTENDED USE

The SDNA-1000 Saliva Collection Device (SDNA-1000) is intended for use by individuals to collect, stabilize, and maintain during transport, unprocessed saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA).[1]

The SDNA-1000 is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The SDNA-1000 Saliva Collection Device consists of a plastic 6 mL tube designed for the collection of human saliva samples, a funnel, a cap with a stem flare and a fluid chamber containing Spectrum's patented stabilizing solution. The user deposits their saliva into the collection tube with the aid of the attached funnel, the user will remove the funnel and replace it with the shipping cap. Upon twisting and closing the cap, the stabilizing solution will release into the tube to mix with the saliva.

REAGENTS AND MATERIALS

Components manufactured by Spectrum Solutions LLC, FDA registration # 3012758946 and supplied with the home collection kit include:

Kit components – SDNA 1000 Blister Pack

Name	Description	Quantity	Material Supplier
2019163	SDNA Fill Cap Assembly 1.5ml	1	Spectrum Solutions
201593	SDNA Blank Thermo Form Tray	1	Premier Plastics
2019077	IFU Insert – SDNA 1000	1	CCL

[1] While this EUA does not authorize the SDNA 1000 as a standalone self-collection kit, this device may be included as a component of an authorized or cleared self-collection kit (e.g., a kit that is authorized under its own EUA for use by an individual to collect a saliva specimen at home).

201570	Tyvek – SDNA 1000	1	Oliver Healthcare
2019094	SDNA Tube 6ml	1	Spectrum Solutions
2019076	Barcode Label SDNA 1000	1	Kala
2017115	DNA Funnel – CD	1	Spectrum Solutions

Sub-Assembly Components – 2019163 Fill Cap Assembly 1.5ml

Name	Description	Quantity	Material Supplier
2019091	SDNA Cap 2ml	1	Spectrum Solutions
2019092	SDNA Spacer Ring Flare	1	Spectrum Solutions
2019093	SDNA Valve Stem Flare	1	Spectrum Solutions
2017164	Spectrum DNA Solution – 2.1cV3	1.6ml	Spectrum Solutions

PRODUCT MANUFACTURING

The SDNA-1000 Saliva Collection Device has been validated using only the components referenced in the EUA.

1) ***Overview of Manufacturing and Distribution:***

The product will be manufactured at Spectrum Solutions LLC, FDA registration # 3012758946 by Spectrum Solutions LLC, personnel consistent with practices for the production of Saliva Collection Devices based on 21 CFR Part 820. Material manufactured by Spectrum Solutions, may be bottled and kitted by 1. EVCO Plastics 2. Technimark, and 3. UNIP Plastic Industries

The current manufacturing capabilities include the ability to manufacture approximately 1.5 million kits per week; however, in the event of a surge in demand, this could be increased to 4 million kits per week within a 90-day timeframe.

The product will be distributed by contracted distributors who purchase the SDNA-1000 in bulk.

COLLECTION DEVICE STABILITY

Initial stability claims for this device are based on previous stability studies performed for a research use only version of this device. Stability studies to support in vitro diagnostic use are being conducted as follows:

- Shelf-Life Stability- Unopened kit are currently being conducted as follows:

- 3, 6, 12, 24-month stability will be measured using the same testing matrix described in this application
- Accelerated testing is being performed in addition to real-time testing described above. Devices will be stored at accelerated aging conditions (40°C with 75% RH) for different time periods (3, 6, 12, 24 months).

PERFORMANCE EVALUATION

*1) **Sample Stability Post Collection:***

Extended sample stability at room temperature:

In order to further qualify sample stability following the addition of the SDNA-1000 preservation agent during a standard saliva collection procedure a study using ten positive and ten negative samples was conducted. Saliva samples were collected for routine analysis as per FDA EUA 200090/A001 from individuals qualified for COVID-19 testing. Immediately following clinical testing ten random positive and negative samples (in the SDNA-1000 device) were set aside in the accessioning lab at room temperature for a period of two weeks. From these samples 300 µl of saliva was used at both 7- and 14-day time points for clinical analysis. The data of the original qualitative result (w/Ct values) is compared to analysis at both 7 and 14 days below.

		Original Test					Day 7					Day 14				
Sample Barcode	MS2	N gene	ORF1 ab	S gene	Result	MS2	N gene	ORF1 ab	S gene	Result	MS2	N gene	ORF1 ab	S gene	Result
SD227491725888	28.31	25.57	25.14	25.40	Detected	28.43	23.42	23.97	22.22	Detected	27.54	24.23	20.97	20.22	Detected
SD228054835337	25.92	22.47	22.40	22.52	Detected	25.61	21.95	20.74	20.53	Detected	23.54	22.51	21.22	23.52	Detected
SD061024508450	27.38	26.86	26.74	26.61	Detected	24.52	19.86	18.31	18.42	Detected	24.75	20.52	19.44	19.15	Detected
SD424122556010	25.26	24.78	24.89	24.88	Detected	25.14	22.13	22.03	21.72	Detected	25.94	22.52	23.53	25.25	Detected
SD061182890627	26.32	28.32	28.68	28.36	Detected	24.20	24.18	22.74	25.62	Detected	26.32	24.63	23.15	23.27	Detected
SD061078813536	27.40	13.67	12.49	12.98	Detected	25.93	13.76	13.09	14.05	Detected	25.23	14.25	15.60	17.92	Detected
SD061211097532	28.78	24.91	25.21	24.89	Detected	24.30	22.47	23.11	22.26	Detected	23.89	22.34	21.43	23.52	Detected
SD227169138638	27.82	27.42	27.59	28.50	Detected	28.33	23.48	22.26	23.61	Detected	27.51	25.25	26.24	25.63	Detected
SD060939794835	26.71	18.24	18.36	18.38	Detected	28.46	16.45	16.63	16.80	Detected	26.42	17.42	16.23	17.51	Detected
SD213375938239	30.18	19.15	19.22	19.21	Detected	26.40	18.88	17.11	18.26	Detected	25.74	19.62	18.52	19.17	Detected
SD227804843095	27.01	Undetermined	Undetermined	Undetermined	Not Detected	27.32	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	24.52	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD226538152140	28.34	Undetermined	Undetermined	Undetermined	Not Detected	25.50	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	27.42	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD061162223537	27.67	Undetermined	Undetermined	Undetermined	Not Detected	25.42	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	25.25	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD227730722944	24.97	Undetermined	Undetermined	Undetermined	Not Detected	24.75	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	28.42	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD060913024632	27.87	Undetermined	Undetermined	Undetermined	Not Detected	25.69	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	29.52	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD061229562461	27.92	Undetermined	Undetermined	Undetermined	Not Detected	27.62	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	27.33	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD060661118008	27.37	Undetermined	Undetermined	Undetermined	Not Detected	29.21	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	25.64	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD060921039502	31.04	Undetermined	Undetermined	Undetermined	Not Detected	24.74	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	24.15	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD227877596192	26.59	Undetermined	Undetermined	Undetermined	Not Detected	30.50	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	23.64	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected
SD060700740008	25.12	Undetermined	Undetermined	Undetermined	Not Detected	25.75	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected	28.26	UNDETERMINED	UNDETERMINED	UNDETERMINED	Not Detected

Data Summary:

- 100% correlation of qualitative results across all time points
- No significant degradation of viral RNA as indicated by Ct values
- Additional studies being performed to analyze 21- and 28-day time point for sample stability

Viral inactivation as a function of sample preservation:

The SDNA-1000 preservation agent was tested to determine if the components inactivate virus rendering the clinical sample non-infectious. This would result in a mitigation of

risk associated with potential infection during the transportation and handling of primary saliva sample for analysis.

Inactivation of SARS-2 (COVID-19) viral activity (infectivity of eukaryotic cells by cytopathic effect (CPE affect) and genome replication by RT-PCR) was measured by evaluating a primary clinical sample in the context of a feeder layer of cells which simulates an environment that would support viral infection and replication in live cells. Whole replication competent SARS-2 virus was cultured and used in a BSL3 environment for these studies.

The approach used for removing any cellular toxic components in the preservation agent was demonstrated to be an effective approach to measure virus activity in buffers that are toxic to cell culture on their own.

The stock virus was diluted 1:10 in PBS to a concentration of 10^4 $TCID_{50}$/ml prior to the mixing with preservation agents. The virus was inoculated into the SDNA-1000 preservation agent to simulate a clinical saliva sample collection. Following buffer exchange the sample was serially diluted 10^0 ,10^{-1} ,10^{-2} ,10^{-3} ,10^{-4} ,10^{-5}. Each serial dilution of treated sample was used to infect 25 cm^2 flasks of 80% confluent Vero E6 cells and cultured for 3 days. Samples were analyzed for CPE and RT-PCR and passaged for an additional 3 days of culture. At the time of each passage the cells were observed for signs of CPE by viewing under a low magnification microscope and the results recorded. Samples were considered to show CPE when cells were rounded and detaching causing disruption to the cell sheet. A supernatant sample from each passage was taken for nucleic acid extraction and RT-PCR analysis for SARS-CoV-2. The goal of the study design was to determine whether complete inactivation of SARS-CoV-2 virus was attained. Inactivation of the SARS-CoV-2 infected sample was considered to be complete if no CPE was observed at any dilution for either passage and no decrease in Ct value observed by qPCR.

Triplicate samples were prepared for each sample listed below.

Sample Name	SARS-CoV-2	SDNA-1000	PBS	Amicon (filter to remove chaotropic agent)	CPE detected	RT-PCR Ct value Day 0	RT-PCR Ct value Day 3	RT-PCR Ct value passage 1
A1	+	+	n/a	+	No	25	28	29
A2	+	+	n/a	+	No	29	32	33
B1	+	n/a	+	+	+++	14	Not Done	Not Done
B2	+	n/a	+	+	+++	17	Not Done	Not Done
C	+	n/a	n/a	-	+++	N/A	N/A	N/A
D	n/a	+	+	+	No	N/A	N/A	N/A
E	+	+	n/a	-	Cell Sheet Dead **	N/A	N/A	N/A

n/a: not added.
N/A: Not Applicable

Summary:

No evidence of viral growth in the presence of SDNA-1000 lysis buffer was detected by either evaluation of CPE or RT-PCR. The complete lack of CPE in any SARS-CoV-2 positive sample mixed with SDNA-1000 lysis buffer demonstrates inactivation of viral activity in Vero cultured cells. Additionally, the lack of viral load increase (as measured by RT-PCR) across several days of cell culture indicates that there is no COVID-19 growth or infection following exposure to the SDNA preservation agent. It was confirmed that the SDNA-1000 preservation agent itself is toxic to feeder cells, so dialysis of buffer components was required to perform viral inactivation studies. PBS controls that were spiked with live virus retained both infectivity as measured by CPE and RT-PCR following the same dialysis procedure that was used to remove any cellular toxic components in the preservation agent. The data supports the inactivation of SARS-2 in the presence of SDNA1000 preservation agent.

Clinical Validation of Saliva Samples using the SDNA-1000 saliva collection device and 4 different RNA extraction platforms:

This data supports the ability of the SDNA 1000 saliva collection device to be used with multiple nucleic acid extraction chemistries and then produce appropriate results in a real time RT-PCR reaction. A total of 60 clinical samples (30 positive / 30 negative), from both symptomatic and asymptomatic patients, were collected using the SDNA-1000 device. Samples were extracted for viral RNA and subsequently analyzed using the EUA authorized TaqPath RT-PCR COVID-19 Kit for clinical testing. Clinical samples were selected from retrospectively confirmed patient samples that have concordance between nasopharyngeal and saliva samples (collected in SDNA-1000 collection device) at the time of clinical assessment. Samples used for this study have undergone one freeze thaw cycle as primary samples were stored at -80C following original clinical analysis.

Table 1 – Extraction Chemistries evaluated for SDNA 1000 collection device

Manufacturer	Chemistry	Part #	Automation Platform	# Positive Samples	# Negative Samples
Perkin Elmer*	Viral DNA/RNA 300 Kit H96	CMG-1033-S	Chemagen 360	30	30
ThermoFisher	MagMax Viral/Pathogen II NA Extraction Kit	A47814	KingFisher	30	30
Qiagen	DSP Virus/Pathogen Midi Kit	937055	QiaSymphony	30	30
Roche	Magna Pure LC Total Nucleic Acid Isolation Kit	03038505001	MagnaPure 96	30	30

**This extraction method and assay was authorized in EUA 200090/A001 to Rutgers Clinical Genomics Laboratory*

All chemistries were used as per manufactures protocol using laboratory automation validated for those specific chemistry platforms as described in Table 1.

Following extraction of 300 µl of saliva, 5 µl of each nucleic acid sample was analyzed using the ThermoFisher TaqPath RT-PCR COVID-19 Kit as described in EUA 200090/A001.

Table 2 – Performance of Extraction Chemistries Evaluated for SDNA 1000 Collection Device

Manufacturer	Chemistry	# Positive Samples Detected	# Negative Samples Not-Detected
Perkin Elmer*	Viral DNA/RNA 300 Kit H96	30/30	30/30
ThermoFisher	MagMax Viral/Pathogen II NA Extraction Kit	30/30	30/30
Qiagen	DSP Virus/Pathogen Midi Kit	29/30	30/30
Roche	Magna Pure LC Total Nucleic Acid Isolation Kit	30/30	30/30

**This extraction method and assay was authorized in EUA 200090/A001 to Rutgers Clinical Genomics Laboratory*

- 100% negative sample concordance to previously analyzed matched clinical samples from symptomatic and asymptomatic patients
- 100% chemistry concordance for Perkin Elmer kit when compared to sample results
- 100% chemistry concordance for ThermoFisher kit when compared to sample results
- 100% chemistry concordance for Roche kit when compared to original sample results
- 98% chemistry concordance for Qiagen kit when compared to original sample results

WARNINGS:

- This sample collection device has not been FDA cleared or approved;
- This sample collection device has been authorized by FDA under an EUA;
- This sample collection device has been authorized only for the collection and maintenance of saliva as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This sample collection device is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.