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Clinical Evaluation Report

'STANDARD Q COVID-19 Ag Test'

SPONSOR: SD BIOSENSOR
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INVESTIGATOR:
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Confidentially Statement

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1 Synopsis of the Study

Title	Clinical evaluation of STANDARD Q COVID-19 Ag Test
Study management	SD Biosensor Healthcare Pvt Ltd
Study site	Central Research Lab, Kempegowda Institute of Medical Sciences, Banashankari 2nd Stage, Bangalore-70
Principal Investigator	Dr. K L Ravikumar
Sample size	**Specimen types** / **Specimen information** COVID-19 Positive Nasal swab / Minimum 100 Specimen COVID-19 Negative Nasal swab / Minimum 400 Specimen
Study cohorts	Two Nasal swabs: one for Antigen test and one in VTM for RT-PCR
Study design	Minimal risk, single-visit, cross-sectional study of STANDARD Q COVID-19 Ag test compared to US FDA approved RT-PCR
Objectives	Assess diagnostic accuracy of STANDARD Q COVID-19 Ag test compared to standard comparator RT-PCR test of nasal swab specimens for detection of SARS-CoV-2
Investigational device	STANDARD Q COVID-19 Ag Test
Reference method	EURORealTime SARS-CoV-2 (FDA EUA approved)
Outcome measures	The sensitivity and specificity of STANDARD Q COVID-19 Ag Test compared to the RT-PCR test for nasal swab will be calculated

2 STUDY ADMINISTRATIVE STRUCTURE

a. Sponsor: SD Biosensor Inc.

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b. Investigation:

Address	Central Research Lab, Kempegowda Institute of Medical Sciences, Banashankari 2nd Stage, Bangalore-560070
Contact	080-26712546

c. Person in charge

Name	Designation	Role in the study	Contact detail
Dr. K L Ravikumar	Chief- Central Research Lab, Kempegowda Institute of Medical Sciences	Principal Investigator	9902240344
Dr Sudhakar H H	Professor & Head, Dept of Physiology, Kempegowda Institute of Medical Sciences	Co-Investigator	9844521274
Dr Veena Umesh	Associate. Professor, Dept of Physiology, Kempegowda Institute of Medical Sciences	Study Coordinator-Sample collection and data management	9483958875
Dr Vandana Govindan	Senior Scientific Officer, Central Research Lab, Kempegowda Institute of Medical Sciences	Study coordinator-Laboratory testing and reporting	8197863538
Lakshmi	Lab technician 1	Sample collection and rapid assay testing	
Lavanya	Lab technician 2	Sample collection and rapid assay testing	

3 Scope

3.1 Objective

- Assess diagnostic accuracy of STANDARD Q COVID-19 Ag test with nasal swab specimens compared to standard comparator RT-PCR test for detection of SARS-CoV-2

3.2 Study Design

- Prospective, point-of-care
- Blinded (test operators are unaware of the PCR result when using the antigen test)

3.3 Investigational device

- STANDARD Q COVID-19 Ag Test

3.4 Reference test

EURORealTime SARS-CoV-2

4 Timelines

- Investigation starting date: 09th November 2020
- Scheduled finish date: 14th December 2020

5 Description of Investigational Device

5.1 Investigational Device

STANDARD Q COVID-19 Ag Test (09COV31D, Lot: TQCO3120001A)

5.2 Analyte or marker

Specific antigens to SARS-CoV-2

5.3 Specimen collection

1. Insert a sterile swab into the nostril of the patient, swab over the front part of nostrils (not up to nasopharynx). Withdraw the sterile swab from the nasal cavity.
2. Repeat the same step with another nostril with same swab.
3. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
5. Press the nozzle cap tightly onto the tube.

6 Study Design

6.1 Parameters of clinical performance to be determined

- Positive percent agreement (PPA) and Negative percent agreement (NPA) of STANDARD Q COVID-19 Ag Test with reference assay for Nasal swab.

6.2 Materials Supplied by the manufacturer

6.2.1 Test Kits and Instructions for Use

- STANDARD Q COVID-19 Ag Test, EURORealTime SARS-CoV-2, VTM for swab collection for RT-PCR Test & RNA extraction Kit will be supplied free of charge to carry out the entire evaluation.

6.3 Materials Supplied by the Investigator

6.3.1 Standard laboratory reagents and disposables.

- These are supplied by the Investigator and must meet the specifications required to correctly carry out the test procedure.

6.4 Statistics & Sample Size Calculation

6.4.1 100 SARS- CoV-2 positive and 400 SARS- CoV-2 negative Nasal swab specimen

Specimen types	Specimen information	Reference Assay
COVID-19 Positive Nasal swab	100 Specimen	EURORealTime SARS-CoV-2
COVID-19 Negative Nasal swab	400 Specimen	

Essential information for the specimen were collected:
- Specimen type
- Specimen collection date
- Investigational device testing date, Reference device testing date
- Date of onset of symptom (Date of COVID-19 patient contact)
- PCR Ct value including Internal control
- Age

6.5 Study population and selection criteria

6.5.1 100 SARS- CoV-2 positive specimen

- Samples were confirmed as SARS- CoV-2 positive with reference assay EUROReal Time SARS-CoV-2 (US FDA approved RT-PCR Kit).
- Detailed Study population

	Post onset symptom date	No. of Subject required
Symptomatic	days 0-3	36
	days 4-7	61
Asymptomatic	N*	7
Total	NA	104

6.5.2 400 SARS- CoV-2 negative specimen

- Samples should be confirmed as SARS- CoV-2 negative with reference assay EUROReal Time SARS-CoV-2 (US FDA approved RT-PCR Kit).
- Detailed study population

	Post onset symptom date	No. of Subject required
Symptomatic	days 0-3	0
	days 4-7	2
Asymptomatic	N*	397
Total	NA	399

6.5.3 Exclusion criteria

- Obstruction of 1 or more nares
- Any condition that in the judgment of the investigator precludes participation because it could adversely affect subject safety or data integrity.
- Any patient who does not give consent for participation in this study

6.6 Method of trial for clinical performance

1) When COVID-19 suspected patients visiting clinics (P.O.C site) give the consent for specimen collection and provision of information, they are enrolled.

2) 2 Nasal swabs are collected from single subject by first technician.
   * Technician 1 collects the specimen and tests with STANDARD Q COVID-19 Ag Test.
3) First Nasal swab is tested with STANDARD Q COVID-19 Ag Test as soon as specimen is collected from the patients.
   * The operators performing the Ag test should not be aware of the reference assay result.
4) Second Nasal swab is stored in Viral Transport Media (VTM) and tested with reference assay (EUROReal Time SARS-CoV-2) followed by Instruction for use provided from manufacturer.
5) The Operators read Instructions for Use before conducting test.
6) The results of STADNARD Q COVID-19 Ag Test are read at 30 minutes and interpreted by testing operator and recorded the result in internal laboratory format.
7) In case of test failure, the assay should be repeated with the same lot.
8) All data from reference assay and STANDARD Q COVID-19 Ag Test are combined in the Excel database.

6.7 Interpretation of test results

6.7.1 Interpretation of test results of STANDARD Q COVID-19 Ag Test

1. Negative result: Only One visible band (”C” Control line) within the result window indicates a negative result.
2. Positive result: Two Visible bands (”C” Control line & “T” Test line) within the result window indicates a positive result.
3. Invalid result: If the control band (”C” control line) is not visible within the result window, the result is considered invalid.

• Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

• The presence of test line (T) (along with the control line), no matter how faint the test line is, the result must be considered as positive.

• Positive results should be considered in conjunction with the clinical history and other data available.

6.7.2 Interpretation of test results of reference method

In EURORealTime SARS-CoV-2, the detection of SARS-CoV-2 RNA is performed using a total of two target regions, which are both detected in the same fluorescence channel (FAM).

	SARS-CoV-2 FAM	IC VIC	Result Interpretation	Action
Patient Sample	Negative	Positive	SARS-CoV-2 RNA not Detected	Report Result
	Negative	Negative	Invalid (No amplification signal for Internal Control	Invalid Result, Specimen needs to be retested from re- extraction or re-collection from patient for test
	Positive	Negative/ Positive	SARS-CoV-2 RNA detected	Report Result

7 Discrepant Samples

Samples with discrepant results should be stored frozen and made available for any further testing. If reasonably possible, any remaining discrepancy must be resolved by appropriate data:

- by a review of the clinical status and diagnosis of the patient (if possible and useful), and
- by the testing of follow-up samples (if possible and useful).

8 Data management

Data management entails the planning for the creation, identification, verification, storage, transfer and archiving of data pertinent to the study, by means of the format of the study records, as well as associated responsibilities.

8.1 Data and results recording

The persons performing the assay recorded the screening ID, result obtained with the STANDARD Q COVID-19 Ag Test on laboratory internal record. The Record was filed in an electronic archive. These files were considered as the source data of the study. Subsequently, the data obtained with the STANDARD Q COVID-19 Ag Test, subject information and reference assay result were combined in an excel file (Annexure 1). Upon completion of the excel file, the Principal or Co-investigator reviews the recorded data for completeness, accuracy and legibility.

The raw data of this evaluation study is attached as Annexure 1 in form of excel sheet. The sheet contains the following information:

- Specimen type
- Specimen collection date
- Investigational device and Reference device testing date
- Date of onset of symptom (Date of COVID-19 patient contact)
- PCR Ct value including Internal control
- Age
- Gender

8.2 Data and results management plan

The Investigators allow SD Biosensor to audit the test laboratory during the experimental procedure and/or until 1 year after the end of the study.

All data will be filed by Principal Investigator. Data will be stored for at least 5 years. All laboratory results are strictly confidential. STANDARD Q COVID-19 Ag Test results are for performance evaluation only and must not be used for diagnostic purposes.

8.3 Data analysis

Positive percent agreement (PPA), Negative percent agreement (NPA)

The clinical overall percent agreement, positive percent agreement, negative percent agreement of investigational devices, was calculated after integrating the test result in the raw data sheet with samples from subjects confirmed to be infected or not with real-time PCR.

The findings of the evaluation are listed below in the table:

Table 1: Summary of study cohorts

Study cohorts		Bangalore
Total No. of population		503
No. of Invalid subject (Excluded from population)		0
No. of SARS-CoV-2 Positive Subject		104
No. of SARS-CoV-2 Negative Subject		399
Positivity Rate		26.1%
Symptomatic subject		99
	• Days 0 ~ 3 (n, %):	36
	• Days 4 ~ 7 (n, %):	63
Asymptomatic subject		404
PCR	PCR Ct [mean (min-max)]:	25.7 (15.2 – 34.4)
	• Ct ≥ 30 (n, %):	12 (11.54%)
	• Ct < 30 (n, %):	92 (88.46%)

Table 2: Entire Clinical performance results

Type of Sample		EURO Real Time SARS-CoV-2		
		Positive	Negative	Total
Standard Q Covid-19 Ag	Positive	101	0	101
	Negative	3	399	402
	Total	104	399	503

(1) PPA (Positive Percent Agreement) = **97.12%** (95% CI 91.86% to 99.01%)

(2) NPA (Negative Percent Agreement) = **100.00%** (95% CI 99.05% to 100.00%)

Table 3: Detailed analysis of Clinical performance

Category		Positive agreement
Post-onset symptom date	0~ 3	97.22% (95% CI 85.83 – 99.51%)
		35/36
	4 ~ 7	96.83% (95% CI 89.14 – 99.13%)
		61/63
Ct value	Ct ≥ 30 (n, %):	83.33% (95% CI 55.20 – 95.30%)
		10/12
	Ct < 30 (n, %):	98.91% (95% CI 94.10 – 99.81%)
		91/92

The Investigation device- Standard Q Covid-19 Ag Test is a rapid test to detect the presence of antigen in human nasal or nasopharyngeal sample . In this study, the kit performance was evaluated using the nasal sample following the guidelines mentioned in the IFU.

The Positive Predictive agreement of the STANDARD Q COVID-19 Ag Test using nasal swab as specimen and RT- PCR Test as reference assay is 97.12% and the negative percent agreement is 100%. There were no Invalid Test results while using Standard Q Covid-19 Ag Test.

9 Conclusion

The study results suggest that use of nasal swab samples for sample collection was much easier and convenient for performing Rapid Antigen Test. The STANDARD Q COVID-19 Ag Test Device performed well as a POC test for early diagnosis of COVID-19 with fast high sensitivity and specificity, turnaround-time and ease-of-use.

10 Approval

Principal Investigator: DR. K. L. RAVIKUMAR Co- Investigator: DR. SUDHAKAR HH

Signature: Signature:

Date: 15/12/20 Date: 15/12/20

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