SD BIOSENSOR

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Issue number: BA200-20220221-MKTQ-1

21st February, 2022

Subject: Declaration of PEI evaluation

Dear valued customers,

We, SD Biosensor Inc., as the manufacturer of "Standard Q Covid-19 Ag (AT-No. AT023/20 and AT394/21)", hereby in response to the report "Comparative evaluation of the sensitivities of SARSCoV-2 antigen rapid tests" published by PEI on 12 January, 2022, make the following statement:

We acknowledge the evaluation protocol and the results performed by Paul-Ehrlich-Institut (PEI), an authoritative and professional inspection agency in Germany to respond to the COVID-19 pandemic situation. As a manufacturer, we would like to provide the following information to help you better understand the product.

1. In the study, PEI used the stored swabs in universal transport medium (UTM) or phosphate-buffered saline (PBS) to measure the analytical sensitivity in clinical samples with established SARS-CoV-2 viral loads. Then, applied 50μL volume of the suspension into the extraction buffer of our STANDARD Q COVID-19 Ag Test. However, according to the instructions for use, 350μL of the virus transport medium (VTM) is mentioned as the required volume to be applied in the extraction buffer tube. This inaccurate volume of VTM would cause an unpredicted impact on the test kit and its results, which may reduce the sensitivity of the product. We recommend following the test regimen specified in the instructions for use for the most accurate results of STANDARD Q COVID-19 Ag Test.

2. STANDARD Q COVID-19 Ag Test has been tested in many countries the around the world. The specific clinical evaluation data are as follows. (Extract)

Country	Study site	Sensitivity	Specificity
Italy	San Martino Policlinico Hospital, Hygiene Unit[1]	100% (95%CI 78.5% – 100%)	93.8% (95%CI 71.7% – 98.9%)
Switzerland	Clinics in Lausanne[2]	92.9% (86.4-96.9%)	100%
Thailand	Institutional Review Board of the Faculty of Medicine Siriraj Hospital, Mahidol University[3]	98.33% (59/60, 95%CI 90.8% - 98.7%)	98.73%(389/394, 95%CI 97.10% - 99.59%)
Netherlands	Drive-thru testing center[4]	84.9% (All Ct) 98.2% (Ct<30)	99.5%
Mexico	Institute of Epidemiological Diagnosis and Reference (InDRE)[5]	93.12% (149/160, 95% CI 88.03% - 96.52%)	100% (200/200, 95% CI 98.17% - 100%)

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France	Accuracy of antigen and nucleic acid amplification testing on saliva and nasopharyngeal samples for detection of SARS-CoV-2 in ambulatory care[6]	94% (95%CI 86-98)	99%(95%CI 98-99)
Switzerland	University Hospital of Geneva (FIND)[7]	Ct ≤ 25: 97.2% (95% CI 92.9% - 98.9%) Ct ≤ 33: 91.8% (95% CI 86.9% - 95%)	99.7% (95% CI 98.3, 99.9)
Brazil	Community Testing Clinic of Macae, state of Rio de Janeiro (FIND)[8]	Ct ≤ 25: 95.9% (95% CI 86.3% - 98.9%) Ct ≤ 33: 91.9% (95% CI 84.9% - 95.9%)	97.6% (95% CI 95.2% - 98.8%)

3. SARS-CoV-2 variants detection[9]

As a result of analytical sensitivity and in-silico(IT-based) analysis, STANDARD Q COVID-19 Ag Test is not affected by Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Yota, Lambda, Zeta, Mu or Omicron SARS-CoV-2 variants

Omicron: As a result of evaluating the STANDARD Q COVID-19 Ag Test with samples from Omicron variant-positive patients, the results showed a sensitivity of 96.7% and a specificity of 100%. (Reference Method: RT-PCR)

NP swab		RT-PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 Ag	Positive	29	0	29
	Negative	1	10	11
Total		30	10	40
• Sensitivity: 96.7% (29/30) [95% CI: 82.78% - 99.92%] • Specificity: 100% (10/10) [95% CI: 69.15% - 100.00%]				

Tae Young Heo
CEO

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Annex 1. WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs PUBLIC REPORT[10]

- SD Biosensor's STANDARD Q COVID-19 Ag Tests first accepted by WHO on EUL list

EUL-0563-117-00 WHO EUL Public Report January 2021, version 4.0

WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs
PUBLIC REPORT

Product: STANDARD Q COVID-19 Ag Test
EUL Number: EUL-0563-117-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents;
- Product Dossier Review: assessment of the documentary evidence of safety and performance.

STANDARD Q COVID-19 Ag Test, product code 09COV30D, CE-mark regulatory version, manufactured by SD Biosensor, Inc., C 4th and 5th, 16 Deogyeong-daero, 1556 beon-gil Suwon-si, Geonggi-do, 16690, Republic of Korea, was listed on 22 September 2020.

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the EUL product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	Addition of a warning that STANDARD COVID-19 Ag Control (product code:10COVC10) was not assessed with STANDARD Q COVID-19 Ag Test and is not part of EUL.	6-Nov-2020
3.0	Correction of the warning added in version to read as, *"STANDARD COVID-19 Ag Control (product code:10COVC10) was assessed and found not acceptable"*	18-Nov-2020
4.0	Change of the outside packaging box in the public report to align with the approved IFU.	15-Jan-2021

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Reference

1. Comparative diagnostic performance of rapid antigen detection tests for COVID-19 in a hospital setting https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8078031/)
2. Antigen rapid tests, nasopharyngeal PCR and saliva PCR to detect SARS-CoV-2: a prospective comparative clinical trial (https://www.medrxiv.org/content/10.1101/2020.11.23.20237057v1)
3. Rapid SARS-CoV-2 antigen detection assay in comparison with real-time RT-PCR assay for laboratory diagnosis of COVID-19 in Thailand (https://doi.org/10.1186/s12985-020-01452-5)
4. Clinical Evaluation of Roche SD Biosensor Rapid Antigen Test for SARS-CoV-2 in Municipal Health Service Testing Site, the Netherlands (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8084500/)
5. Preliminary comparative evaluation report. (InDRE, Mexico)
6. Accuracy of antigen and nucleic acid amplification testing on saliva and nasopharyngeal samples for detection of SARS-CoV-2 in ambulatory care (https://www.medrxiv.org/content/10.1101/2021.04.08.21255144v1)
7. FIND Evaluation of SD Biosensor, Inc. STANDARD Q COVID-19 Ag Test External Report ver 2.0 (https://www.finddx.org/wp-content/uploads/2020/11/SDQ-Ag-Public-Report_20201103-v2-0.pdf)
8. FIND Evaluation of SD Biosensor, Inc. STANDARD Q COVID-19 Ag Test External Report ver 2.0(https://www.finddx.org/wp-content/uploads/2020/11/SDQ-Ag-Public-Report_20201103-v2-0.pdf)
9. Internal evaluation - CAPITAL DIAGNOSTICS, STANDARD Q COVID-19 Ag Test ANALYTICAL METHOD VALIDATION and REPORT
10. WHO EUL Public Report for SARS-CoV-2: Product: STANDARD Q COVID-19 Ag Test EUL Number: EUL 0563-117-00 (https://www.who.int/diagnostics_laboratory/eual/201019_final_pqpr_eul_0563_117_00_standard_q_covid19_ag_test.pdf?ua=1)

Evaluation Report: Standard Q COVID-19 Ag Test

Background

FIND, in collaboration with partners, is conducting prospective diagnostic evaluation studies across multiple, independent sites to determine the accuracy of COVID-19 antigen (Ag) Rapid Diagnostic Tests (RDTs). The index tests include novel lateral flow format tests that detect recombinant SARS-CoV-2 antigens. The RDT results are compared to RT-PCR results.

Objectives

The primary objective of the studies is to determine the clinical accuracy, *i.e*. sensitivity and specificity of the tests; secondarily, the studies are determining the ease of use of each assay and the analytical sensitivity and specificity are also being determined using viral culture. The studies have a target sample size of enrolling up to 100 PCR positive participants per test. Assuming about a 10% positivity rate, interim analyses are being performed at 25% and 50% enrolment (*i.e*. 250-500 total participants) and the evaluation is stopped if tests do not meet at least 97% specificity.

Device under investigation

STANDARD Q COVID-19 Ag Test

Manufacturer

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Manufacturing site

74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
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Intended use

STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx. This test is for administration by

healthcare workers and labs only, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test result. This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required[1].

Kit contents

1. Test device (individually in a foil pouch with desiccant)
2. Extraction buffer tube
3. Nozzle cap
4. Sterile swab
5. Instructions for use

Kit storage and stability

Store the kit at 2-30°C / 36-86°F out of direct sunlight. Kit materials are stable
until the expiration date printed on the outer box. The kit material should not be frozen.

Methodology

This was a prospective study that had ethics approval (IRB) from the respective institutions.
Testing procedures for the product under evaluation followed the instructions for use as provided by the manufacture. A dedicated respiratory swab was collected prospectively utilizing the swab provided by the manufacturer for study purposes. Results were compared to routine, RT-PCR test results used for diagnostic purposes on another swab. Both swabs were collected at the same time.

The **STANDARD Q COVID-19 Ag test** (SD Biosensor, Inc. Product Code: Q-NCOV-01G) was evaluated in collaboration with three institutions in two countries: (i) University Hospital Heidelberg (HD) and (ii) Charité – Universitätsmedizin Berlin in Germany; and (iii) Universidade Federal do Rio de Janeiro, Brazil.

Testing sites: Germany

Adults presenting to temporary testing locations around Heidelberg, Germany or Berlin, Germany for COVID-19 screening, who gave written consent to participate in this study were included. Criteria to define suspect COVID-19 cases were determined by the Department of Public Health. At the time of initiation of the study, the criteria for eligible persons for COVID-19 screening included all people with symptoms suggestive of COVID-19, independent of travel history.

Testing site: Brazil

Participants were recruited consecutively from a COVID-19 Testing Clinic in Macaé, Rio de Janeiro State. All participants were suspected to have COVID-19 according to national guidance and gave written consent to participant in the study. In addition, some health care workers were routinely tested following any possible COVID-19 exposure, irrespective of symptoms, were also included.

Information on the study design and the study cohorts are summarized in **Table 1**.

Table 1: Summary of site characteristics and study cohorts of enrolment to date.

Country	**Germany**		**Brazil**	
Study Design				
Total enrolled	n= 1238		n= 376	
Study Period	HD: 20 July to 31 July	Berlin: 03 June to 31 July	13 to 30 July (closed)	
Population	Adults in community meeting national suspect definition, generally with mild - moderate symptoms Adults characterized as first contact to a positive individual		Adults in community meeting national suspect definition, generally with mild - moderate symptoms Health care workers with documented exposure	
Testing site	Drive-In Testing Site		Health Center	
User	Medical Students, Doctors and trained laboratory personnel		Nurse	
Comparator	4 commercial PCR kits		In house PCR, using CDC method	
Study Cohort				
Age [Avg (min-max)]	37 (18-80)		38 (3-94)	
Sex (n, % F)(n, % missing)	612, 50.2%	20, 1.6%	226, 60.1%	1, 0.5%
Overweight (BMI > 25) n, %)	450, 37.6%		221, 58.8%	
Presence of co-morbidities (n, %)	414, 33.4%		95, 25.2%	
Time of testing from symptom Onset [Avg (min-max)]	3 (0 to 65)		5 (-4 to 24)	
Positivity Rate	3.6%		26.6%	

Results

A. Preliminary Results of the FIND Clinical Evaluation:

The pooled sensitivity across both testing sites in Germany was 76.6% (62.8-86.4%) and pooled specificity was99.2% (98.6-99.6%). The sensitivity observed in the testing clinic in Brazil was higher at 91% (95% CI: 83.8-95.2%), but with slightly decreased specificity (Table 2). Further details on the PCR Positive samples included in the Brazil study (n = 100) are shown in **Figure 1.** Additional analysis of Standard Q COVID 19 antigen RDT performance according to the PCR cycle threshold (Ct), indicates that the sensitivity of the assay is lower with increased Ct /lower viral loads (sensitivity of 70.6% when Ct value ≥ 30); and is considerably higher at lower Ct values (96.4% when Ct is < 30, Table 3).

** TBC: to be confirmed.*

Table 2: Preliminary clinical performance results

Country	Germany		Brazil	
Results				
Sensitivity [% (95% CI)]|n/N	76.6% (62.8-86.4%)	36 / 47	91% (83.8-95.2%)	91 / 100
Specificity [% (95% CI)]|n/N	99.2% (98.6-99.6%)	1182/ 1191	97.8% (95.3-99.0%)	270 / 276
Ct values for Ag POS/PCR POS [Avg (min-max)]	23.84 (15.75 – 32.35)		N1: 25.3 (14.9-36.7) N2: 26.8 (15.2-37.9)	
Ct values for Ag NEG/PCR POS [Avg (min-max)]	33.37 (27.44 – 37.60)		N1: 30.6 (22.2-37.8) N2: 32.2 (23.7-39.2)	

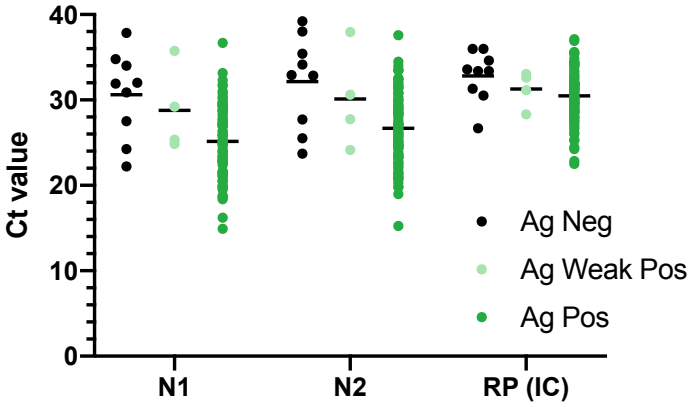

Figure 1: Cycle threshold values for all RT-PCR positive samples tested in Brazil according to Ag RDT results: Negative (black), Weak positive (light green), Positive (green)

Table 3: Sensitivity in Brazil according to different Ct value thresholds:

Sensitivity according to Ct value (N1 gene)			
Group	**Sensitivity**	**95% CI**	**n/N**
Ct ≥ 30	70.6%	[46.9-86.7%]	(12/17)
Ct < 30	96.4%	[89.9-98.8%]	(80/83)
Ct ≥ 25	86.8%	[75.2-93.5%]	(46/53)
Ct < 25	96.4%	[89.9-98.8%]	(45/47)

B. Summary Results of additional studies:

The Standard Q COVID-19 Ag Test has also been evaluated in a number of studies, summarised here are 14 data sets, including the two studies coordinated by FIND, (Table 3, next page). Results from eleven of the studies demonstrate that the sensitivity of the test is sufficient to meet the WHO Target Product Profile (≥ 70%) and twelve studies demonstrate that the specificity is sufficient to mee the WHO Target Procure Profile (≥ 97%).

Table 4: Consolidated data sets from FIND coordinated studies, other external evaluations, including those sponsored by the manufacturer.

Source	Country	Sample size	RT-PCR positive	Sensitivity %(n)	Specificity %(n)	§ WHO TTP - Sensitivity	* WHO TTP - Specificity	Population	Comparator	Epidemic description
FIND indepdendent evaluation	Brazil	376	26.6% (100/376)	91% (90/100)	98% (270/276)	++	+	Symptomatic ambulatory patients	In-house PCR, CDC	High positivity rate, accelerating epidemic
ICMR independent evaluation	India	(120)		75% (45/60)	100% (60/60)	+	++	Hospitalized patients previously testing positive on RT-PCR; subgroup with high VL (CT<30)	BGI RT-PCR	
AIIMS evaluation	India	231	37.7% (87/231)	84% (73/87)	99% (1/144)	++	++	TBD	Not stated	
Asl 5 Liguria - La Spezia	Italy	60	50% (30/60)	86.7% (26/30)	90% (27/30)	++	++	COVID-19 suspects	Seegene Allplex nCov2019	
FIND indepdendent evaluation	Germany	1238	3.5% (35/990)	74%(26/35)	99%(949/955)	+	++	Symptomatic ambulatory patients	Commercial PCR	Low positivity rate, declining epidemic
ICMR evaluation	India	142	62.7% (89/142)	51%(89/142)	99%(143/144)	-	++	Hospitalized patients previously testing positive on RT-PCR; subgroup with mixed VL	BGI RT-PCR	
CAPSULA Saude E Medicina Laboratorial Pliclinica Piquet Carneiro (PPC/UERJ)	Brazil	24	20.8% (5/24)	91.70%	99%	++	++	Patients at Policlinica Piquet Carneiro/UERJ	Not stated	High positivity rate, accelerating epidemic
Uganda Virus Research Institute	Uganda	227	30.8% (70/227)	78.6% (55/70)	91.7% (144/157)	+	-	COVID-19 PCR confirmed and non-exposed healthy volunteers	Berlin protocol	
Institute for Medical Research Kualu Lumput	Malaysia	100	50% (50/100)	90% (45/50)	100% (50/50)	++	++	Not stated	IMR in-house	
Mahidol University, Bangkok	Thailand	454	13.22% (60/454)	98.3% (59/60)	98.7% (389/394)	++	+	COVID-19 suspects (contacts)	Seegene Allplex nCov2019	
Laboratório i9med FCMMG	Brazil	27	22.2% (6/27)	100% (6/6)	100% (21/21)	++	++	COVID-19 positive and negative confirmed	Sansure BioTech Novel Coronavirus (2019-nCov) Nucleic Acid Diagnostic Kit	High positivity rate, accelerating epidemic
ANNAR Health Technologies	Colombia	135	28.1% (38/135)	65.8% (25/38)	96.9% (94/97)	-	+	COVID-19 positive and negative confirmed	Seegene Allplex nCov2019	
Instituto Naciona De Salud	Colombia	300	10% (30/300)	83.3% (25/30)	100% (270/270)	++	++	COVID-19 positive and negative confirmed	Real-time RTPCR Charité Virology, Berlin, Germany	
Instituto Naciona De Salud	Colombia	183	33.8% (47/136)	63.8% (30/47)	96.3% (131/136)	-	-	COVID-19 positive and negative confirmed	Seegene Allplex nCov2019	

Footnote: WHO TTP considers § Sensitivity Acceptable >= 70% (+) and Desirable >=80% (++); * Specificity Acceptable >= 97% (+) and Desirable >=99% (=+); Does not meet threshold (-)

Conclusions

The performance evaluation of STANDARD Q COVID-19 Ag test coordinated by FIND with collaborators in Germany and Brazil with a total number of enrolled individuals of 1614, yielded a sensitivity of 76.6% (62.8-86.4%) and 91.0% (83.8-95.2%) respectively, and a specificity of 99.2% (98.6-99.6%) and 97.8% (95.3-99.0%), respectively compared to the site-specific RT-PCR method.

The report presents data sets generated by independent organisations, such as FIND and the Indian Council of Medical Research, as well as nine studies supported by the manufacturer with a total sample size of 3497 tests performed in nine countries covering three regions, Africa, Asia and Latin America. The vast majority of these studies met the recently released WHO Target Product Profile specifications[2].

There is an indication that the sensitivity of the assay is superior at lower cycle thresholds or higher viral loads which are observed in the early phase of SARS CoV2 infection. This is consistent with published studies on other Antigen RDTs and support the intended use of this test*, i.e.* "*as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with SARS-CoV-2 infection.*"

References:

1. SD Biosensor, Instructions for Use for STANDARD Q COVID-19 Ag, reference Q-NCOV-01G L23COV3ML4R2. Issue date: 2020.07
2. WHO, Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.0.1 05 August 2020 (https://www.who.int/publications/m/item/covid-19-target-product-profiles-for-priority-diagnostics-to-support-response-to-the-covid-19-pandemic-v.0.1)