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)