

December 9, 2020

Subject : Statement letter of clinical performance for STANDARD™ Q COVID-19 Ag Test

Dear Sir,

Clinical performance of the STANDARD™ Q COVID-19 Ag Test was evaluated in Brazil/Germany, Switzerland and Italy. The following table shows the clinical performance of the STANDARD™ Q COVID-19 Ag Test in all RT-PCR-positive and negative samples.

#	Site	Sample size	Sensitivity (95% CI), Ct < n	Specificity
1	Brazil and Germany, FIND	1659	97.14% (90.1-99.65) Ct < 25	98.94% (98.23-99.39)
2	Switzerland, HUG	529	98% (n.a.) Ct < 22	99.7% (98.36-99.99)
3	Italy, Ospedale Amedeo di Savoia	330	100% (n.a.) Ct < 28	100% (98.36-100)

Attached

1. [No.1] Clinical evaluation report in Brazil and Germany
2. [No.2] Clinical evaluation report in Switzerland
3. [No.3] Clinical evaluation report in Italy

Sincerely,



Hyo-keun LEE
CEO
SD Biosensor, Inc.