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Report on the technical lab evaluation of the SD Biosensor Standard-F-Covid-19 Ag Test

Assay	SD Biosensor Standard-F-Covid-19 Ag test with F2400 device
Method	Fluorescent immunoassay
Company	Mediphos
Evaluation type	Technical lab evaluation
Date	27-01-2021
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Introduction

The SD Biosensor Standard F-Covid-19 Ag Test is CE marked. The assay is Fluorescent immunoassay aimed at qualitative detection of specifically the SARS-CoV-2 antigen in the nasopharynx. The test can be read with F2400 device.

Method

The antigen test was technically evaluated by diluting SARS-CoV-2 stock provided by Erasmus MC in 10-fold series (10^{-1} to 10^{-8}) viral transport medium (Mediaproducts B.V., Groningen, The Netherlands) with an end volume of 9 ml. The 10-fold series are vortex for 1 minute at room temperature. For each SARS-CoV-2 Rapid-Ag test, 350 µl from each dilution is added to the buffer supplied by the manufacture (n=3). After adding the dilution the procedure is follow as described in the prescription supplied by the manufacture.

Technical lab evaluation

Limit of detection

The assay gives an inconsistent signal at LLOD dilution 10^{-4}, corresponding with 4.98E+03 E-gene Copies/ml (Table 2). The technical lab evaluation shows 4 levels of sensitivity, based on lower limit of detection and the signal strength of the test result (weak signals are indicated by ^). The sensitivity of the SD Biosensor Standard F-Covid-19 Ag Test is low (sensitivity level 3) compared to other SARS-CoV-2 Rapid antigen tests.

Table 2. *Results of the diluted SARS-CoV-2 stock read out. The dilution is done in triplicate in each SARS-CoV-2 Rapid-Ag test. Colored boxes show the categorization of the SARS-CoV-2 Rapid-Ag test in sensitivity levels.*

Dilution	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}	Sensitivity level:
TCID50/ml	3.16E+04	3.16E+03	3.16E+02	3.16E+01	3.16E+00	3.16E-01	3.16E-02	3.16E-03	
E-gene Copies/ml	4.98E+06	4.98E+05	4.98E+04	4.98E+03	4.98E+02	4.98E+01	4.98E+00	4.98E-01	
Ct-value E-gene qRT-PCR	10.86	14.43	17.77	20.97	24.02	27.34	30.18	34.29	
Test A	(3/3)	(3/3)	(3/3)	(3/3)	(3/3) ^	(0/3)	(0/3)	(0/3)	1
Test B	(3/3)	(3/3)	(3/3)	(3/3)	(3/3) ^	(0/3)	(0/3)	(0/3)	
Test C	(3/3)	(3/3)	(3/3)	(3/3)	(3/3) ^	(0/3)	(0/3)	(0/3)	
Test D	(3/3)	(3/3)	(3/3)	(3/3)	(3/3) ^	(0/3)	(0/3)	(0/3)	
Test E	(3/3)	(3/3)	(3/3)	(3/3)	(3/3) ^	(0/3)	(0/3)	(0/3)	
Test F	(3/3)	(3/3)	(3/3)	(3/3)	(0/3)	(0/3)	(0/3)	(0/3)	2
Test G	(3/3)	(3/3)	(3/3)	(3/3)	(0/3)	(0/3)	(0/3)	(0/3)	
SD Biosensor Standard F-Covid-19 Ag	(3/3)	(3/3)	(3/3)	(1/3)	(0/3)	(0/3)	(0/3)	(0/3)	3
Test I	(3/3)	(3/3)	(3/3)	(3/3) ^	(0/3)	(0/3)	(0/3)	(0/3)	
Test J	(3/3)	(3/3)	(3/3)	(0/3)	(0/3)	(0/3)	(0/3)	(0/3)	4
Test K	(3/3)	(3/3)	(3/3)	(0/3)	(0/3)	(0/3)	(0/3)	(0/3)	

^ *These SARS-CoV-2 Rapid-Ag tests have a weak signal.*

Conclusion

The technical lab evaluation shows low sensitivity of the assay compared to other SARS-CoV-2 Rapid antigen tests.