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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 (Mediaproducs 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  $\mu$ l 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.