-- CONFIDENTIAL --

Report on the evaluation of the SD Biosensor SARS-CoV-2 Rapid Antigen test at the Municipal Health service Haaglanden drive-through test location in Nootdorp.

Population/setting	Mild symptomatic population attending GGD testlane for COVID-19 testing
Method	Fluorescent immunoassay
Assay	STANDARD F COVID-19 Ag Test with F2400 device
Company	SD Biosensor, distributor Mediphos
Evaluation type	Clinical prospective field evaluation
Evaluation period	19-10-2020 through 20-10-2020
GGD test lane	Municipal health service drive-through test location Nootdorp/GGD Haaglanden
Date	31-10-2020
Authors	5.1.2e | IDS, Cib, RIVM 5.1.2e | IDS, Cib, RIVM 5.1.2e | IDS, Cib, RIVM 5.1.2e | IDS, Cib, RIVM 5.1.2e | Reinier Haga Medical Diagnostic Centre

Introduction

The STANDARD F COVID-19 Ag Test from SD biosensor is CE marked. The assay is a fluorescent immunoassay aimed at qualitative detection of specifically the SARS-CoV-2 antigen in the nasopharynx.

Method

De antigen test is evaluated in a population consisting of mainly mild symptomatic cases attending the municipal health service drive-through testlocation in Nootdorp, the Netherlands (GGD Haaglanden). Participants were informed of the evaluation on site. A participant information letter was handed out. Informed consent was requested for a second nasopharyngeal swab (NPS) for the antigen test and a clinical questionnaire was filled in by participants to obtain data on (1) reason for testing, (2) first symptoms and date symptoms started, and (3) symptoms on site.

The NPS and oropharyngeal swab (OPS) fort the RT-PCR was taken first, after which the NPS for antigen test was taken. The NPS for the antigen test was analysed on site in a mobile unit (RIVM). Technician worked in standard personal protection equipment. The swabs for RT-PCR were sent to Reinier Haga Medical Diagnostic Centre (in house PCR (E-gene) (*1*) and cobas® SARS-CoV2 test on cobas® 6800).

Evaluation on basis of clinical parameters

Sensitivity

The assay has an overall sensitivity of 77.97% (95% CI 69.41% - 85.07%) (Table 1). The sensitivity was correlated to Ct values and days after first symptoms (Figure 1). The sensitivity was 84.40% with Ct values below 30. (Figure 1). Three samples were invalid (samples were tested 2x) and tested negative by PCR. These samples were omitted from analysis. Four antigen false negative samples had a Ct value of 18 (3x) and 19 (Figure 1).

Table 1a.

		PCR		
		pos	neg	total
Antigen test	pos	92	2	94
	neg	26	508	534
	total	**118**	**510**	**628**

Table 1b

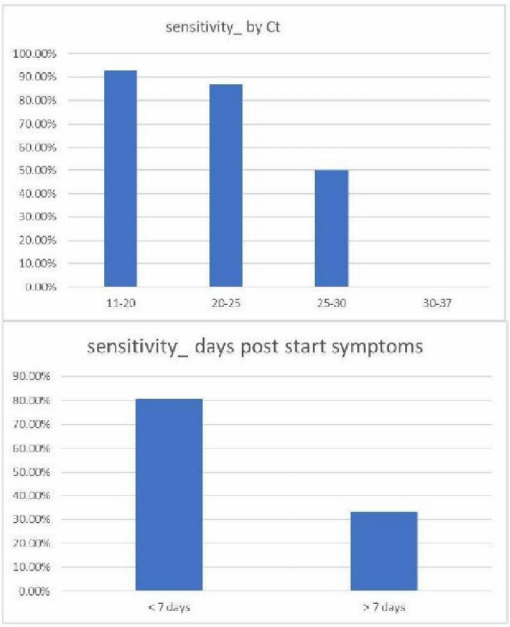
		95% CI
Sensitivity	77.97%	69.41% to 85.07%
Specificity	99.61%	98.59% to 99.95%
PPV	97.87%	92.00% to 99.46%
NPV	95.13%	93.30% to 96.48%
accuracy	95.54%	93.62% to 97.02%

Table 2a

		PCR			
		11-20	20-25	25-30	30-37
Antigen test	pos	51	33	8	0
	neg	4	5	8	9
	total	**55**	**38**	**16**	**9**
sensitivity		92.73%	86.84%	50.00%	0.00%

Table 2b

		PCR		
		<20	<25	<30
Antigen test	pos	51	84	92
	neg	4	9	17
	total	**55**	**93**	**109**
sensitivity		92.73%	90.32%	84.40%



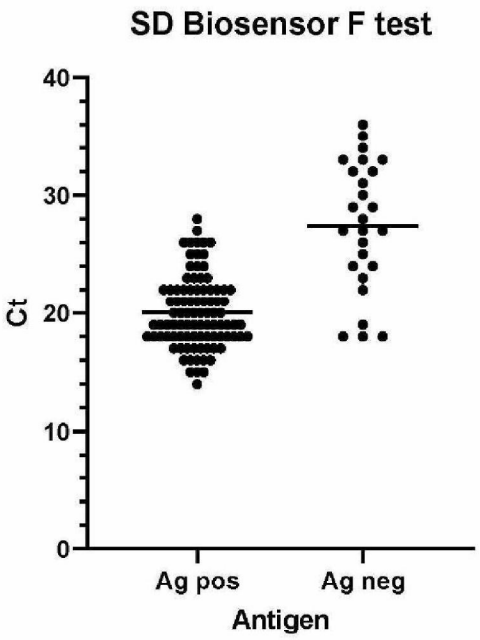


Figure 1

Specificity

The assay had a specificity of 99.61% (Table 1). The assay yielded two false positives, data from the F2400 indicated weak positive fluorescent signal.

Ease of use

The assay is read by the F2400 device with 24 slots. While analysis takes 30 minutes, the F2400 enables constant input of cassettes and once slots are available. According to SD Biosensor this should lead to 70 samples per hour after the first hour. As such the number of samples analyzed by hour is limited to a device. However samples should not be prepared in advance and should be immersed right before placement in F2400 device. This lead to a delay in analysis of samples as you

had to wait for slots to open up before samples can be prepared. As such analysis should be conducted on site. The SD biosensor does allow use of PCR buffer enabling single sampling and transport of sample (not frozen) to a laboratory. The F2400 allows coupling to LIMS as well as printable read out of the results. A single F2400 can be handled by one technician who does both sample preparation and analysis in F2400.

Conclusion

Based on the data Ct<30 presented, the assay is in agreement with the criteria proposed by WHO (*2*); sensitivity ≥80% and specificity ≥97% for detection of SARS-CoV-2 infected cases with RT-PCR as a reference.

Reference

1. Corman VM, et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020. PMID: 31992387.
2. https://www.who.int/publications/i/item/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19-scientific-brief