-- CONFIDENTIAL --

Report on the evaluation of the Sofia 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	SARS Ag Test with Sofia2 device
Company	Quidel, distributor Quidel
Evaluation type	Clinical prospective field evaluation
Evaluation period	21-10-2020 through 22-10-2020
GGD test lane	Municipal health service drive-through test location Nootdorp/GGD Haaglanden
Date	31-10-2020
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Introduction

The SARS Ag Test from Quidel 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 84.03% (95% CI 77.00% - 89.60%) (Table 1). The sensitivity was correlated to Ct values and days after first symptoms (Figure 1). The sensitivity was 90.09% with Ct values below 30 (Figure 1). Two samples were invalid (samples were tested 2x) and tested positive by PCR (Ct 18 and 27). One sample tested antigen positive with a Ct value of 34. Five antigen false negative samples had a Ct value of 18 (2x), 19 (2x) and 20 (Figure 1).

Table 1a.

		PCR		
		pos	neg	total
Antigen test	pos	121	1	122
	neg	23	588	611
	total	**144**	**589**	**733**

Table 1b

		95% CI
Sensitivity	84.03%	77.00% to 89.60%
Specificity	99.83%	99.06% to 100.00%
PPV	99.18%	94.46% to 99.88%
NPV	96.24%	94.62% to 97.38%
accuracy	96.73%	95.17% to 97.89%

Table 2a

		PCR			
		11-20	20-25	25-30	30-37
Antigen test	pos	56	43	19	3
	neg	5	3	5	10
	total	**61**	**46**	**24**	**13**
sensitivity		91.80%	93.48%	79.17%	23.08%

Table 2b

		PCR		
		<20	<25	<30
Antigen test	pos	56	99	118
	neg	5	8	13
	total	**61**	**107**	**131**
sensitivity		91.80%	92.52%	90.08%

Figure 1

Specificity

The assay had a specificity of 99.83% (Table 1). The assay yielded one false positive, as no quantitative data was yielded, the positivity (weak or strong) of this virus cannot be indicated.

Ease of use

The buffer were in powder form and needed to be dissolved on site. Samples were transferred by pipet to the cassette and analyzed in the sofia2 device. Buffers can be prepared up to 12 hours before and samples prepared up to 6 hours before enabling transfer (not frozen) to a laboratory, next to onsite testing. A total of 4 devices were used by three technicians; one technician prepared the buffers, another technician prepared the samples and cassettes and the third technician analyzed the sample in Sofia device after 15 minutes. With only 4 devices, only 4 samples could be analyzed at a time (2 min), resulting in 120 samples per hour.

Conclusion

Based on the overall data and data Ct<30 presented, the assay is in agreement with the criteria proposed by WHO (*2*); sensitivity ≥80% and specificity

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