-- CONFIDENTIAL --

Report on the evaluation of the **Spartacus Biomed COVID-19 ANTIGEN RAPID TEST** in mild symptomatic population.

Population/setting	Mild symptomatic population attending GGD/hospital testlanes for COVID-19 testing
Method	Chromatographic immunoassay
Assay	Spartacus Biomed COVID-19 ANTIGEN RAPID TEST
Company	Spartacus Biomed, distributor Tunica Trading BV
Evaluation type	Clinical prospective field- and technical lab evaluation
Evaluation period	30-11-2020 through 23-12-2020
Test locations	Hoorn, Comicro Bussum, CBSL Tergooi and GGD Gooi en Vechtstreek Urmond, MUMC and GGD Zuid Limburg
Date	24-12-2020
Authors	5.1.2e | Comicro 5.1.2e | CBSL Tergooi 5.1.2e MUMC 5.1.2e | MUMC 5.1.2e | RIVM 5.1.2e | RIVM 5.1.2e | RIVM

Introduction

The Spartacus Biomed COVID-19 ANTIGEN RAPID TEST is CE marked. The assay is a chromatographic immunoassay aimed at qualitative detection of specifically the SARS-CoV-2 antigen in the nasopharynx. The Ministry of Health Welfare and Sport (VWS) requests a validation of SARS-CoV-2 rapid antigen tests before procurement.

Method

The antigen test was clinically evaluated in a population consisting of mainly mild symptomatic cases attending testlocations in Hoorn, Bussum and Urmond, the Netherlands. Participants were informed of the evaluation on site. Informed consent was requested for a second nasopharyngeal (NP) swab for the antigen test. The swabs for the antigen test was analyzed on site according to the IFU of the assay. Technicians worked in standard personal protection equipment. The swabs for RT-PCR were analyzed for regular PCR testing.

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 manufacturer (n=3). After adding the dilution the procedure is follow as described in the IFU supplied by the manufacturer.

Clinical prospective field evaluation

Sensitivity and specificity

The assay had an overall sensitivity of 73.3 % the with PCR as reference test (Table 1). The assay had an overall specificity of 99.1 % (Figure 1). 8 samples were invalid with the evaluated test.

Table 1. *Overall sensitivity and specificity of assay with PCR as reference test*

		Reference test (PCR)		
		+	-	
Test validation (Ag)	+	77	1	78
	-	26	798	824
	Invalid	2	6	8
		105	805	910
		Sens	Spec	
		73.3	99.1	

Technical lab evaluation

Limit of detection

The assay has a lower limit of detection at dilution 10^{-4}, corresponding with TCID50/ml of 3.16E+01 and 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 Spartacus Biomed COVID-19 ANTIGEN RAPID 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)	
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)	1
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)	
Test G	(3/3)	(3/3)	(3/3)	(3/3)	(0/3)	(0/3)	(0/3)	(0/3)	2
Test H	(3/3)	(3/3)	(3/3)	(1/3)	(0/3)	(0/3)	(0/3)	(0/3)	
Spartacus Biomed COVID-19 ANTIGEN RAPID TEST	(3/3)	(3/3)	(3/3)	(3/3) ^	(0/3)	(0/3)	(0/3)	(0/3)	3
Test J	(3/3)	(3/3)	(3/3)	(0/3)	(0/3)	(0/3)	(0/3)	(0/3)	
Test K	(3/3)	(3/3)	(3/3)	(0/3)	(0/3)	(0/3)	(0/3)	(0/3)	4

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

Ease of use

The assay has, compared to other SARS-CoV-2 rapid antigen test, some disadvantages concerning ease of use. The swab in the testkit (Model 905101, Taizhou Sun Trine Biotechnology Co.) has a longer, less flexible head compared to the swab used for PCR (Type A-04, Jiangsu Hanheng Medical Technology Co) in the testlane in Bussum, causing discomfort for the participants when NP swabs were taken. The buffer is not pre-filled per tube. The material of the tubes and buffer vials are quite hard to squeeze. Tube has to be shaken for 10 seconds after attachment of the nozzle. The testkit does not contain a positive control (swab). The test is less suitable to perform high volumes of tests, as is the case for large testlanes.

Conclusion

Based on the data presented the assay is not in agreement with the criteria proposed by WHO (*1*); sensitivity ≥80% and specificity ≥97% for detection of SARS-CoV-2 infected cases with RT-PCR as a reference. The technical lab evaluation confirms the low sensitivity of the assay (sensitivity level 3).

Reference

1. https://www.who.int/publications/i/item/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19-scientific-brief