Evaluation of the performance of the COVID-VIRO rapid test for SARS-Cov2 detection

Kit name : COVID-VIRO

Manufacturer : AAZ

Investigative laboratories:

Paule Brousse Hospital, Pr Anne-Marie Roque-Afonso (anne-marie.roque@aphp.fr)

Bicêtre Hospital, Dr Thierry Naas (thierry.naas@aphp.fr), Dr Saoussen Oueslati (oueslati.saoussen@gmail.com)

Period : September 2020

In a context of health crisis[1], where the rapid detection of patients infected with SARS-CoV-2 is crucial, the company AAZ has developed a immunochromatographic test COVID-VIRO allowing the qualitative detection of SARS-CoV-2 antigen. The principle is based on the use of monoclonal antibodies allowing the detection of the nucleocapsid protein of SARS-CoV-2 from a nasopharyngeal sample.

The performance was evaluated by sensitivity and specificity tests. These results were compared with the results of RT-PCR, the reference method, but also with those obtained with another immunochromatographic test from the company CORIS: COVID-19 Ag Respi-Strip.

Method :

The COVID-VIRO and COVID-19 Ag Respi-Strip tests were compared by evaluating the sensitivity and specificity from identical frozen specimens present in different viral transport media.

Sensitivity was assessed using 78 nasopharyngeal swabs obtained from patients infected with SARS-CoV-2, confirmed by RT-PCR, with a Ct range of 13.1 to 38.2 (Roche PCR test 6800 and Abbott Alinitym). Specificity was tested using 33 PCR negative nasopharyngeal swabs.

For this, 50µL of transport medium was mixed with 50µL of the COVID-VIRO or COVID-19 Ag Respi-Strip test buffer and then vortexed for 5 seconds. Then the entire volume (100 µL) was load on the cassette. The result was read after 15 minutes of migration.

Results :

Table 1 : Performance of the COVID-VIRO and Covid-19 Ag Respi-Strip test compared to thresholds of Ct. (%, %CI95).

	Sensitivity (n=78 COVID positive patients) % CI95%					Spécificity (n=33 COVID negative patients) % CI95%
	Global (n=78)	Ct<25 (n=29)	Ct<30 (n=46)	Ct<33 (n=71)	Ct<35 (n=74)	
Coris	**32%** 22,2-43,7%	**90%** 71.5-97.3%	**54%** 39.2-68.8%	**35%** 24.5-47.5%	**34%** 23.4-45.8%	**100%** 87-100%
AAZ	**77%** 65,8-85,4%	**100%** 85.4-100%	**93%** 81-98.3%	**83%** 71.9-90.6%	**81%** 70-88.9.6%	**100%** 87-100%

Table 2 : Percentage of sensitivity of tests according to subgroups of Ct: high viral load (Ct <20), average viral load ($20 \leqq Ct <30$) and low viral load ($30 \leqq Ct$). (%, %CI95).

	High viral load (Ct<20), n=15	Medium viral load ($20 \leqq Ct<25$), n=14	Medium viral load ($25 \leqq Ct<30$), n=17	Low viral load ($30 \leqq Ct$), n=32
Coris	**100%** 87-100%	**71%** 42-90%	**0%**	**0%**
AAZ	**100%** 87-100%	**100%** 87-100%	**82%** 55.8-95.3	**53%** 35-70.5

The results obtained show that the overall sensitivity of the COVID-VIRO test is 2.5 fold higher than that obtained with the Covid-19 Ag Respi-Strip test (Table 1). The samples with Ct lower than 33 (cut-off established by the CASFM[2]), were detected with a sensitivity equal to 83% for the AAZ test and 35% with the CORIS test. The COVID-VIRO test also has high sensitivity percentages for average viral loads: 100% ($20 \leqq Ct <25$) and 82% ($25 \leqq Ct <30$). The major point is the detection of low viral loads ($30 \leqq Ct$) with 53% sensitivity (Table 2).

The specificity for both tests is 100%, no false positives were observed.

Conclusion :

The COVID-VIRO test is a rapid diagnostic test for SARS-CoV-2 infection with 77% sensitivity and 100% specificity on our sample set (n=78). Notably, a 93% (CI95 : 81-98.3%) sensitivity was observed for samples with Cycle thresholds (Ct) values , which falls within the WHO criteria[3].

Of note, our evaluation only took into account the viral loads, estimated by Cts, and not the date on symptoms onset.

References :

1. Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU) (https://coronavirus.jhu.edu/map.html; last accessed August 20th, 2020).
2. https://www.sfm-microbiologie.org/wp-content/uploads/2020/09/Avis-SFM-valeur-Ct-excre%CC%81tion-virale-_-Version-Finale-25092020.pdf
3. *https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays)*