Evaluation of the Panbio Covid-19 rapid antigen detection test device for the screening of patients with Covid-19

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Abbreviations: WHO: World health organization.

To the Editor,

Coronavirus disease 2019 (COVID-19), declared a pandemic by the WHO on March 11th, 2020 (1), requires an early diagnosis to optimize patient management and limit further transmission. Currently, the gold standard and mostly used diagnostic method in clinical microbiology laboratories is real-time PCR (RT-PCR) detecting the viral RNA in nasopharyngeal specimens (2). However, RT-PCR requires specialized instruments and personnel. In contrast, rapid antigen detection (RAD) tests, which are widely used to detect viral infections other than COVID-19, are not only rapid (15 – 30 minutes) but are less laborious and require short training. However, to date, several commercialized RAD tests have been evaluated and most have demonstrated a lack of sensitivity (Supplementary Table 1).

In the present study, we evaluated the performance of the PANBIO COVID-19 Ag rapid test device (Abbott) by comparison with the VitaPCR SARS-Cov-2 assay (Credo diagnostics, Singapore) on nasopharyngeal specimens. Both systems provide results within 20 minutes. The former is an immunochromatographic assay detecting the SARS-CoV-2 nucleocapsid protein and requiring no specialized instrument. This device is distributed worldwide except in the USA where its equivalent, the BINAXNOW COVID-19 Ag card (Abbot) is FDA-approved. By using tenfold dilutions of a quantified suspension of Vero E6 cell-cultured SARS-CoV-2 (IHUMI3 strain), as previously described (3), from 780 x 10^6 copies/mL at a dilution of 10^{-1} to 1484 copies/mL at a dilution of 10^{-6}, the RT-PCR assay was positive for all tested virus dilutions, with cycle threshold (Ct) values of 16 and 34 for the most concentrated (10^{-1}) and most dilute (10^{-6}) dilutions, respectively. In contrast, the RAD test was positive for all dilutions except 10^{-5} and 10^{-6}. Two further replicates of this evaluation confirmed these results for both assays. Then, we tested prospectively, from September 21st to October 2nd, 2020, nasopharyngeal samples from 341 patients who presented at our institute for COVID-19 testing using the two methods. Of these, 182 patients were symptomatic and 159 were asymptomatic

contacts from patients. For each patient, two nasopharyngeal samples were collected, in one nostril each, with a specific swab according to the assay used. All tests were performed within 1 hour after specimen collection. All of the 182 symptomatic patients, but only 22 of the 159 asymptomatic patients were PCR-positive (median Ct values 25 and 30.5, respectively, $p < 10^{-2}$, Table 1), for a total of 204 PCR positives (Supplementary Table 2). The PANBIO COVID-19 Ag rapid test detected 154 of the 204 PCR-positive samples (sensitivity 75.5%, 95% confidence interval [95% CI], 69.5 to 81.5), including 144/182 symptomatic patients (79.1%), but only 10/22 asymptomatic patients (45.4%). However, the test was positive in seven of the 137 PCR-negative samples, all of whom were collected from asymptomatic patients (specificity 94.9%, 95% CI, 91.2 to 98. 6). Among individuals diagnosed (n = 204) or not diagnosed (n = 137) with COVID-19, positive and negative predictive values were 95.6% (154/161) and 72.2% (130/180), respectively.

We acknowledge the fact that our study population may not be representative of the general population of Marseille as symptomatic patients also came from other cities from southern France, and were thus over-represented. However, our study showed that the PANBIO COVID-19 Ag rapid test had a good specificity for SARS-CoV-2 detection in nasopharynx swab samples but a good sensitivity only for samples with Ct values lower than 25 (corresponding to viral loads higher than 10^6 copies/mL which has been proposed as threshold of transmissibility (4,5)). In our study, all 10 asymptomatic, as well as 57/144 symptomatic, patients exhibited Ct values of $\geq$ 25 (Supplementary Table 2). In this population, the PANBIO COVID-19 Ag rapid test may miss about 40 % of diagnoses. However, as the clinical performance of RAD tests largely depend on the setting in which they are used, we believe that the PANBIO COVID-19 Ag rapid test may be a useful mass screening test when RT-PCR assays are not or insufficiently available, in particular in symptomatic patients.

Transparency declaration

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Pr Raoult and Pr Drancourt are co-founders of the Pocrame startup that develops diagnostic devices for infectious diseases. The authors certify that they have no other conflict of interest to declare in relation to this research.

The patients gave an informed consent for this study.

Authors' contributions

Conceptualization, DR, PEF; formal analysis, FF, DR, PEF; investigation, AB, MB, LF, EP, HTD, MM; resources, DR, PEF; data curation, PC; writing—original draft preparation, FF, PEF; writing—review and editing, FF, MD, DR, PEF. All authors have read and agreed to the published version of the manuscript.

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Journal of Clinical Microbiology

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119 **Table 1**: Sensitivity of the PANBIO COVID-19 Ag rapid test (Abbott) according to the Ct values

	Sensitivity of the PANBIO COVID-19 Ag rapid test in the present study	
Ct range	**Numbers of positive patients**	%
<10	1	100
10-15	19	95
16-20	38	100
21-25	49	94.2
26-30	39	73.6
31-34	8	20

120

Supplementary Table 1: Comparison of rapid antigen detection tests for which evaluations have been published to date

RAD test name	Manufacturer	Test type	Number of tested specimens	Sensitivity (%)	Specificity (%)	Other characteristics	References
COVID-19 Ag Respi-strip	Coris BioConcept, Belgium	Immunochromatography	60 – 148*	30.2-57.6	99.5-100		(3,6,9)
Biocredit COVID-19 Ag test	RapiGEN, Republik of Korea	Immunochromatography	368	45.7	100		(5)
STANDARD F COVID-19 Ag FIA	SD Biosensor, Republik of Korea	Fluorescence immunoassay	359	47.1	na	Requires a fluorescence analyzer	(4)
STANDARD Q COVID-19 Ag	SD-Biosensor, Republik of Korea	Immunochromatography	330	70.6	100		(1)
SARS-CoV-2 antigen test	Bioeasy Biotechnology, China	Fluorescence immunochromatography	127	93.9	100	Requires a fluorescence analyzer	(8)
Lumipulse G SARS-COV-2 Ag	Fujirebio, Japan	Chemiluminescence enzyme immunoassay	313	55.2-91.7	97.3-99.6	Requires a fluorescence analyzer	(2,7)
PANBIO COVID-19 Ag Rapid Test Device	Abbott, USA	Immunochromatography	341	75.5	94.9		This study

RAD: rapid antigen detection; * depending on studies; na: not available; the antigen detected was a nucleocapsid protein in all tests except the Lumipulse G SARS-CoV-2 Ag for which this information is not available.

Supplementary Table 2: Results from the PANBIO COVID-19 Rapid Ag test according to the Ct values obtained by RT-PCR

	RT-PCR Ct value	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Patients	RAD result																										
Symptomatic	positive	1		1	2		5	11	9	7	5	3	14	14	8	7		19	5	9	10	5	2	2	1	2	2
	negative					1											1	2			2	5	5	5	8	5	4
Asymptomatic	positive																	1	1		1	4	2				1
	negative																			1	1			2	1	4	3

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