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LETTER TO THE EDITOR

Evaluation of the Panbio COVID-19 Rapid Antigen Detection Test Device for the Screening of Patients with COVID-19

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Coronavirus disease 2019 (COVID-19), declared a pandemic by the WHO on 11 March 2020 (1), requires an early diagnosis to optimize patient management and limit further transmission. Currently, the gold standard and most commonly 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 (Ag) detection (RAD) tests, which are widely used to diagnose viral diseases other than COVID-19, not only are rapid (15 to 30 min) but are less laborious and require only a comparatively short training period. However, to date, several commercialized RAD tests have been evaluated and most have demonstrated a lack of sensitivity (see Table S1 in the supplemental material).

In the present study, we evaluated the performance of the Panbio COVID-19 Ag rapid test device assay (Abbott) in comparison to that of the VitaPCR severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) assay (Credo Diagnostics, Singapore) on nasopharyngeal specimens. Both systems provide results within 20 min. The former is an immunochromatographic assay detecting the SARS-CoV-2 nucleocapsid protein and requiring no specialized instruments. This device is distributed worldwide except in the United States, where its equivalent, the BinaxNOW COVID-19 Ag card (Abbott), is FDA approved. Using 10-fold dilutions of a quantified suspension of Vero E6 cell-cultured SARS-CoV-2 (IHUMI3 strain), as previously described (3), from 780×10^6 copies/ml at a dilution of 10^{-1} to 1,484 copies/ml at a dilution of 10^{-6}, we found that the RT-PCR assay was positive for all tested virus dilutions, with cycle threshold (C_T) values of 16 and 34 for the most concentrated (10^{-1}) and most dilute (10^{-6}) solutions, 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 21 September to 2 October 2020, nasopharyngeal samples from 341 patients and subjects who presented at our institute for COVID-19 testing using the two methods. Of these, 182 were symptomatic patients and 159 were asymptomatic subjects who had had contact with patients. For each patient, two nasopharyngeal samples were collected, from one nostril each, with a specific swab according to the assay used. All tests were performed within 1 h after specimen collection. All of the 182 symptomatic patients but only 22 of the 159 asymptomatic patients were PCR positive (median C_T values, 25 and 30.5, respectively, $P < 10^{-2}$, Table 1), for a total of 204 PCR positives (Table S2). The Panbio COVID-19 Ag rapid test detected 154 of the 204 PCR-positive samples (sensitivity, 75.5%; 95% confidence

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TABLE 1 Sensitivity of the Panbio COVID-19 Ag rapid test (Abbott) according to the C_T values

	Sensitivity of the Panbio COVID-19 Ag rapid test in the present study	
C_T range	No. of positive patients	% 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

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 result was positive in 7 of the 137 PCR-negative samples, all of which had been collected from asymptomatic patients (specificity, 94.9%; 95% CI, 91.2 to 98.6). Among the 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 overrepresented. 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 C_T 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 patients, as well as 57/144 symptomatic patients, exhibited C_T values of ≥25 (Table S2). 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 depends 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 are insufficiently available, in particular, in symptomatic patients.

The patients gave informed consent for this study.

SUPPLEMENTAL MATERIAL

Supplemental material is available online only.

SUPPLEMENTAL FILE 1, PDF file, 0.1 MB.

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