

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

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23 To the Editor,

24 Coronavirus disease 2019 (COVID-19), declared a pandemic by the WHO on March
25 11th, 2020 (1), requires an early diagnosis to optimize patient management and limit further
26 transmission. Currently, the gold standard and mostly used diagnostic method in clinical
27 microbiology laboratories is real-time PCR (RT-PCR) detecting the viral RNA in
28 nasopharyngeal specimens (2). However, RT-PCR requires specialized instruments and
29 personnel. In contrast, rapid antigen detection (RAD) tests, which are widely used to detect
30 viral infections other than COVID-19, are not only rapid (15 – 30 minutes) but are less
31 laborious and require short training. However, to date, several commercialized RAD tests have
32 been evaluated and most have demonstrated a lack of sensitivity (Supplementary Table 1).

33 In the present study, we evaluated the performance of the PANBIO COVID-19 Ag rapid
34 test device (Abbott) by comparison with the VitaPCR SARS-Cov-2 assay (Credo diagnostics,
35 Singapore) on nasopharyngeal specimens. Both systems provide results within 20 minutes. The
36 former is an immunochromatographic assay detecting the SARS-CoV-2 nucleocapsid protein
37 and requiring no specialized instrument. This device is distributed worldwide except in the
38 USA where its equivalent, the BINAXNOW COVID-19 Ag card (Abbot) is FDA-approved. By
39 using tenfold dilutions of a quantified suspension of Vero E6 cell-cultured SARS-CoV-2
40 (IHUMI3 strain), as previously described (3), from 780×10^6 copies/mL at a dilution of 10^{-1} to
41 1484 copies/mL at a dilution of 10^{-6} , the RT-PCR assay was positive for all tested virus
42 dilutions, with cycle threshold (Ct) values of 16 and 34 for the most concentrated (10^{-1}) and
43 most dilute (10^{-6}) dilutions, respectively. In contrast, the RAD test was positive for all dilutions
44 except 10^{-5} and 10^{-6} . Two further replicates of this evaluation confirmed these results for both
45 assays. Then, we tested prospectively, from September 21st to October 2nd, 2020,
46 nasopharyngeal samples from 341 patients who presented at our institute for COVID-19 testing
47 using the two methods. Of these, 182 patients were symptomatic and 159 were asymptomatic

48 contacts from patients. For each patient, two nasopharyngeal samples were collected, in one
49 nostril each, with a specific swab according to the assay used. All tests were performed within
50 1 hour after specimen collection. All of the 182 symptomatic patients, but only 22 of the 159
51 asymptomatic patients were PCR-positive (median Ct values 25 and 30.5, respectively, $p < 10^{-2}$,
52 Table 1), for a total of 204 PCR positives (Supplementary Table 2). The PANBIO COVID-19
53 Ag rapid test detected 154 of the 204 PCR-positive samples (sensitivity 75.5%, 95% confidence
54 interval [95% CI], 69.5 to 81.5), including 144/182 symptomatic patients (79.1%), but only
55 10/22 asymptomatic patients (45.4%). However, the test was positive in seven of the 137 PCR-
56 negative samples, all of whom were collected from asymptomatic patients (specificity 94.9%,
57 95% CI, 91.2 to 98.6). Among individuals diagnosed ($n = 204$) or not diagnosed ($n = 137$) with
58 COVID-19, positive and negative predictive values were 95.6% (154/161) and 72.2%
59 (130/180), respectively.

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

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80 declare in relation to this research.

81 The patients gave an informed consent for this study.

82 **Authors’ contributions**

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

87 **About the Author**

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References

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98 1. WHO, Coronavirus Disease (COVID-19) Situation Report – 51, 11 March. Available from:

99 (2020) <https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200311->

100 [sitrep-51-covid-19.pdf?sfvrsn=1ba62e57810](https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200311-sitrep-51-covid-19.pdf?sfvrsn=1ba62e57810).

101 2. Corman VM, Landt O, Kaiser M, Molenkamp R, Meijer A, Chu DK, Bleicker T, Brunink S,

102 Schneider J, Schmidt ML, Mulders DG, Haagmans BL, van der Veer B, van den Brink S,

103 Wijsman L, Goderski G, Romette JL, Ellis J, Zambon M, Peiris M, Goossens H, Reusken C,

104 Koopmans MP, Drosten C. 2020. Detection of 2019 novel coronavirus (2019-nCoV) by real-

105 time RT-PCR. *EuroSurveill* 25. <https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045>.

106 3. La Scola B, Le Bideau M, Andreani J, Hoang VT, Grimaldier C, Colson P, Gautret P, Raoult

107 D. 2020. Viral DNA as determined by cell culture as a management tool for discharge of

108 SARS-CoV-2 patients from infectious disease wards. *Eur J Clin Microbiol Infect Dis* 39:1059-

109 61. <https://doi.org/10.1007/s10096-020-03913-9>

110 4. He D, Zhao S, Lin Q, Zhuang Z, Cao P, Wang MH, Yang L. 2020. The relative

111 transmissibility of asymptomatic COVID-19 infections among close contacts. *Int J Infect Dis*

112 94:145-7. <https://doi.org/10.1016/j.ijid.2020.04.034>.

113 5. Wölfel R, Corman VM, Guggemos W, Seilmaier M, Zange S, Müller MA, Niemeyer D,

114 Jones TC, Vollmar P, Rothe C, Hoelscher M, Bleicker T, Brünink S, Schneider J, Ehmann R,

115 Zwirgmaier K, Drosten C, Wendtner C. 2020. Virological assessment of hospitalized patients

116 with COVID-2019. *Nature* 581:465-9. <https://doi.org/10.1038/s41586-020-2196-x>

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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

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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

Patients	RAD result	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						
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					

References

1. Cerrutti F, Burdino E, Milia MG, Alice T, Gregori, G, Bruzzone B, Ghisetti V. 2020. Urgent need of rapid tests for SARS-CoV-2 antigen detection: evaluation of the SD-Biosensor antigen test for SARS-Cov-2. *J Clin Virol* 132:104654. <https://doi.org/10.1016/j.jcv.2020.104654>
2. Hirotsu Y, Maejima M, Shibusawa M, Nagakubo Y, Hosaka K, Amemiya K, Sueki H, Hayakawa M, Mochizuki H, Tsutsui T, Kakizaki Y, Miyashita Y, Yagi S, Kojima S, Omata M. 2020. Comparison of automated SARS-CoV-2 antigen test for COVID-19 infection with quantitative RT-PCR using 313 nasopharyngeal swabs, including from seven serially followed patients. *Int J Infect Dis* 99:397-402. <https://doi.org/10.1016/j.ijid.2020.08.029>
3. Lambert-Niclot S, Cuffel A, Le Pape S, Vauloup-Fellous C, Morand-Joubert L, Roque-Afonso AM, Le Goff J, Delaugerre C. 2020. Evaluation of a Rapid Diagnostic Assay for Detection of SARS-CoV-2 Antigen in Nasopharyngeal Swabs. *J Clin Microbiol* 58:e00977-20. <https://doi.org/10.1128/JCM.00977-20>
4. Liotti FM, Menchinelli G, Lalle E, Palucci I, Marchetti S, Colavita F, La Sorda F, Sberna G, Bordi L, Sanguinetti M, Cattani P, Capobianchi MR, Posteraro B. 2020. Performance of a novel diagnostic assay for rapid SARS-CoV-2 antigen detection in nasopharynx samples. *Clin Microbiol Infect* epub. <https://doi.org/10.1016/j.cmi.2020.09.030>
5. Mak GC, Cheng PL, Lau SS, Wong KK, Lau CS, Lam ET, Chan RC, Tsang DN. 2020. Evaluation of rapid antigen test for detection of SARS-CoV-2 virus. *J Clin Virol* 129:104500. <https://doi.org/10.1016/j.jcv.2020.104500>
6. Mertens P, De Vos N, Martiny D, Jassoy C, Mirazimi A, Cuypers L, Van den Wijngaert S, Monteil V, Melin P, Stoffels K, Yin N, Mileto D, Delaunoy S, Magein H, Lagrou K, Bouzet J, Serrano G, Wautier M, Leclipteux T, Van Ranst M, Vandenberg O. 2020. Development and potential usefulness of the COVID-19 Ag Respi-Strip Diagnostic assay in a pandemic context. *Front Med (Lausanne)* 7:225. <https://doi.org/10.3389/fmed.2020.00225>
7. Ogawa T, Fukumori T, Nishihara Y, Sekine T, Okuda N, Nishimura T, Fujikura H, Hirai N, Imakita N, Kasahara K. 2020. Another false-positive problem for a SARS-CoV-2 antigen test in Japan. *J Clin Virol* 131:104612. <https://doi.org/10.1016/j.jcv.2020.104612>
8. Porte L, Legarraga P, Vollrath V, Aguilera X, Munita JM, Araos R, Pizarro G, Vial P, Iruetagoiena M, Dittrich S, Weitzel T. 2020. Evaluation of a novel antigen-based rapid detection test for the diagnosis of SARS-CoV-2 in respiratory samples. *Int J Infect Dis* 99:328-333. <https://doi.org/10.1016/j.ijid.2020.05.098>
9. Scohy A, Anantharajah A, Bodeus M, Kabamba-Mukadi B, Verroken A, Rodriguez-Villalobos H. 2020. Low performance of rapid antigen detection test as frontline testing for COVID-19 diagnosis. *J Clin Virol* 129:104455. <https://doi.org/10.1016/j.jcv.2020.104455>

