

## 1 **Sensitivity of SARS-CoV-2 antigen-detecting rapid tests for Omicron variant**

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25 **Keywords**

26 SARS-CoV-2; COVID19; Antigen-detecting rapid diagnostic tests; variants of concern;  
27 Omicron variant

## 28 **Abstract**

## 29 **Background**

30 The emergence of each novel SARS-CoV-2 variants of concern (VOCs) requires  
31 investigation of its potential impact on the performance of diagnostic tests in use,  
32 including Antigen-detecting rapid diagnostic tests (Ag-RDT). Although anecdotal  
33 reports have been circulating that the newly emerged Omicron variant is in principle  
34 detectable by Ag-RDTs, few data on sensitivity are available.

## 35 **Methods**

36 We have performed 1) analytical sensitivity testing with cultured virus in eight Ag-RDTs  
37 and 2) retrospective testing in duplicates with clinical samples from vaccinated  
38 individuals with Omicron (n=18) or Delta (n=17) breakthrough infection on seven Ag-  
39 RDTs.

## 40 **Findings**

41 Overall, we have found large heterogeneity between Ag-RDTs for detecting Omicron.  
42 When using cultured virus, we observed a trend towards lower sensitivity for Omicron  
43 detection compared to earlier circulating SARS-CoV-2 and the other VOCs. When  
44 comparing performance for Delta and Omicron in a comparable set of clinical samples  
45 in seven Ag-RDTs, 124/252 (49.2%) of all test performed showed a positive result for  
46 Omicron compared to 156/238 (65.6%) for Delta samples. Sensitivity for both Omicron  
47 and Delta between Ag-RDTs was highly variable. Four out of seven Ag-RDTs showed  
48 significantly lower sensitivity ( $p < 0.001$ ) to detect Omicron when compared to Delta  
49 while three had comparable sensitivity to Delta.

## 50 **Interpretation**

51 Sensitivity for detecting Omicron is highly variable between Ag-RDTs, necessitating a  
52 careful consideration when using these tests to guide infection prevention measures.  
53 While analytical and retrospective testing may be a proxy and timely solution to  
54 generate performance data, it is not a replacement for clinical evaluations which are  
55 urgently needed. Biological and technical reasons for detection failure by some Ag-  
56 RDTs need to be further investigated.

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61 alliance for diagnostics.

## 62 **Introduction**

63 The emergence of each novel SARS-CoV-2 variants of concern (VOCs) requires  
64 investigation of its potential impact on the performance of diagnostic tests in use.  
65 SARS-CoV-2 antigen-detecting rapid diagnostic tests (Ag-RDT) offer quick, cheap and  
66 laboratory-independent results at the point of care.<sup>1</sup> Although sensitivity is lower  
67 compared to the gold standard method, RT-PCR, they enable reliable detection of  
68 high viral load samples associated with infectious virus presence, making them  
69 impactful public health tools.<sup>2,3</sup> However, the majority of Ag-RDT validation studies  
70 were performed prior to the emergence of SARS-CoV-2 variants of concern (VOC).<sup>4</sup>

71 The VOC Omicron was first reported at the end of November from South Africa and is  
72 characterized by a high number of mutations compared to earlier circulating SARS-  
73 CoV-2.<sup>5</sup> The majority of mutations are located in the protein of the gene coding for the  
74 Spike protein, and, according to preliminary data, are associated with considerable  
75 escape from neutralization by both disease- and vaccine derived antibodies, and  
76 probably also associated to lower vaccine effectiveness.<sup>6,7,8,9,10</sup> Current  
77 epidemiological data show that Omicron circulation is associated with a steep increase  
78 in case numbers as well as an increased risk of reinfection.<sup>11</sup>

79 Beyond the Spike mutations, Omicron also has also mutations in the nucleocapsid,  
80 which is the target protein of almost all Ag-RDTs. Two mutations found in Omicron are  
81 R203K and G204R that have been described already before Omicron in some SARS-  
82 CoV-2 sequences. They were linked to increased sub-genomic RNA and increased  
83 viral loads.<sup>12-14</sup> In addition, a deletion (Del31-33) is found in the nucleocapsid of  
84 Omicron, as well as another mutation P13L. No information on a potential impact of  
85 these mutations on Ag-RDTs performance is available so far. Anecdotal reports  
86 showed positive detection of Omicron-confirmed patient samples by Ag-RDTs but few  
87 experimental data on Ag-RDT sensitivity for Omicron are available.

## 88 **Methods**

### 89 **Virus isolates**

90 All viruses were isolated from clinical samples. Isolates were grown in Vero-E6 cells  
91 as described previously.<sup>15</sup> The Omicron variant was initially isolated on Vero-TMPRSS  
92 cells, then further passaged with a stock passage (p2) prepared on VeroE6. Vero  
93 TMPRSS were kindly received from National Institute for Biological Standards and  
94 Controls (NIBSC, Cat. Nr. 100978). The following mutations and deletion in the  
95 nucleocapsid were present in the original patients' sequence as well as in the virus  
96 isolate of the passage used in this study: R203K, G204R, P13L, Del31-33.

## 97 **Clinical specimens**

98 Nasopharyngeal swabs for diagnostics of SARS-CoV-2 by RT-PCR collected from  
99 symptomatic individuals in the outpatient testing center of the Geneva University  
100 Hospital were included in this study. Infection with SARS-CoV-2 was diagnosed by  
101 RT-PCR assay (Cobas 6800, Roche). All samples originate from the diagnostic unit of  
102 the virology laboratory of the hospital and were received for primary diagnosis of  
103 SARS-CoV-2. Remaining samples were stored at -80°C, usually on the same day or  
104 within 24h. All samples had one freeze-thaw cycle before inoculation on cell cultures  
105 for infectious virus and for viral RNA quantification, for the majority of specimens the  
106 Ag-RDT was performed at the same time. Due to logistical constraints, a subset of  
107 specimens had one additional freeze-thaw cycle for Ag-RDT testing only. All  
108 specimens were characterized by full genome sequencing for their infecting SARS-  
109 CoV-2 variant.

## 110 **Viral load quantification**

111 Viral loads in each sample were determined by quantitative real-time reverse  
112 transcription PCR (RT-qPCR) using SuperScript™ III Platinum™ One-Step qRT-PCR  
113 Kit (Invitrogen) after thawing. RT-PCR for SARS-CoV-2 E gene and quantification of  
114 genome copy number was performed as described previously.<sup>16</sup> Presence of  
115 infectious virus was determined by nucleocapsid staining for infectious foci in Vero  
116 TMPRSS 24h after inoculation with the patient sample as described previously<sup>17</sup>.

## 117 **Ag-RDT performance**

118 The 8 commercially available Ag-RDT products used in the study are summarized in  
119 **Table S1**.

### 120 *Analytical testing with cultured virus*

121 Each isolate has undergone serial dilutions at 1:2 in DMEM. For each variant, we  
122 started the dilutions with the same virus concentration at 1.72E+04 PFU/mL. All Ag-  
123 RDT assays were performed according to the manufacturers' instructions except that  
124 viral dilutions were added to the buffer instead of a swab specimen. All dilutions used  
125 for validation additionally were tested and quantified by RT-PCR assay for SARS-CoV-  
126 2 RNA copy numbers/mL. For each serial dilution of each variant, 5 µl of dilution has  
127 been applied to the proprietary buffer and then applied to the Ag-RDT using only  
128 materials provided in the kit.

### 129 *Performance testing with clinical specimens*

130 For testing with clinical specimens, 5 µl of VTM of each specimen has been directly  
131 added to the proprietary buffer, and then applied to the Ag-RDT in duplicates under

132 BSL3 conditions.<sup>18</sup> Ag-RDT buffer without virus was used as a negative control. All  
133 Ag-RDT assays were read visually in duplicate. All visible bands were considered as  
134 a positive result. The entire study was performed under BSL-3 conditions.

## 135 **Statistics**

136 We first compared whether Log<sub>10</sub> SARS-CoV-2 copies, days post symptom onset, and  
137 presence of infectious disease were significantly different between the Delta (n=18)  
138 and Omicron (n=17) patients using simple linear and logistic regressions. We then  
139 tested whether the overall sensitivities and discordances differed between Delta and  
140 Omicron using proportion tests. Finally, we compared sensitivities for Delta (n=34) and  
141 Omicron (n=36) tests separately for each Ag-RDT. To take into account that each  
142 patient had two independent tests, we used mixed-effect logistic regressions with tests  
143 nested into patients. Data were analysed using R4.1.2.

## 144 **Ethical approval**

145 Ethical approval for samples used in this study for virus isolation was waived by the  
146 local ethics committee of the Geneva University Hospitals (HUG) that approves the  
147 usage of anonymized leftover patient samples collected for diagnostic purposes in  
148 accordance with our institutional and national regulations. The part of the study using  
149 patient specimens linked to clinical data (retrospective testing) was approved by the  
150 Cantonal ethics committee (CCER Nr. 2021-01488). For this part, all study participants  
151 and/or their legal guardians provided informed consent.

152

## 153 **Results**

### 154 *Analytical testing with cultured SARS-CoV-2 isolates*

155 We have evaluated analytical sensitivity using cultured SARS-CoV-2 Omicron variant,  
156 in comparison to previous data obtained on isolates of the other VOCs (Alpha, Beta,  
157 Gamma and Delta) and an early-pandemic (pre-VOC) SARS-CoV-2 isolate (B.1.610)  
158 in eight Ag-RDTs. Data on early pandemic SARS-CoV-2, Alpha, Beta, Gamma and  
159 Delta have been published previously but were included here for comparison to  
160 Omicron<sup>15,18</sup>.

161 Eight Ag-RDTs were used: I) Panbio COVID-19 Ag Rapid test device (Abbott); II)  
162 Standard Q COVID-19 Ag (SD Biosensor/Roche); III) Sure Status (Premier Medical  
163 Corporation); IV) 2019-nCoV Antigen test (Wondfo); V) Beijing Tigsun Diagnostics Co.  
164 Ltd (Tigsun); VI) Onsite COVID-19 Ag Rapid Test (CTK Biotech); VII) ACON biotech  
165 (Flowflex) and VIII) NowCheck Covid-19 Ag test (Bionote). This list includes all three

166 Ag-RDTs on the WHO Emergency Use Listing (WHO-EUL) and the other tests that  
167 are on the waiting list for WHO-EUL approval.

168 When assessing by infectious virus titers (PFU/mL) (**Fig 1A**), analytical sensitivity to  
169 detect Omicron was lower than for the other VOCs in most of the tests evaluated. Two  
170 tests showed a slightly higher sensitivity for Omicron than for Delta (Test V and VII),  
171 but for these tests, both Delta and Omicron showed lower detection sensitivity than  
172 the other VOCs and pre-VOC SARS-CoV-2. The same pattern of lowest sensitivity for  
173 Omicron compared to the other VOCS was confirmed when assessing RNA copy  
174 numbers (**Fig. 1B**). Significant heterogeneity was observed between different Ag-  
175 RDTs to detect Omicron.

#### 176 *Sensitivity testing in patient specimens*

177 In addition to this analytical work, we have tested seven Ag-RDTs with original patient  
178 specimens as a retrospective sensitivity study with 35 nasopharyngeal specimens of  
179 confirmed Omicron (n=18) or Delta (n=17) breakthrough infections in vaccinated  
180 individuals during the first 5 days post-symptom onset. The two sample collections of  
181 Omicron and Delta patients' specimens did not differ in RNA viral load, days post  
182 symptom onset or specimens with infectious virus presence (**Table 1**).

183 Testing with clinical specimens was done in duplicates for each specimens using  
184 seven Ag-RDTs to compare performance for Omicron and Delta infections (**Fig. 2**).  
185 When assessing overall test positivity, for Omicron 124/252 (49.2%) of tests showed  
186 a positive result compared to 156/238 (65.5%) ( $z = -3.65$ ,  $p < .001$ ). Of 126 test pairs,  
187 14 showed a discordant result for Omicron vs. 7 in 119 test pairs performed for Delta  
188 ( $z = -1.46$ ,  $p = .144$ ). When comparing sensitivity for Delta vs. Omicron for each Ag-  
189 RDT, four Ag-RDTs showed significantly lower sensitivity ( $p < 0.001$ ) while three tests  
190 showed comparable performance (**Table 1 and Fig.3**). Sensitivity in our specimens  
191 panel ranged between 22.2% and 88.9% for Omicron and 52.9% to 91.2% for Delta,  
192 confirming the high variability of sensitivity between the different tests that was  
193 observed in our testing. The three tests that performed equally well had sensitivities  
194 between 47.2 and 91.2%.

#### 195 **Discussion**

196 Newly emerging variants necessitate a rapid assessment of the performance of  
197 diagnostic tests in use. Here we have performed a comprehensive laboratory-based  
198 evaluation study of eight Ag-RDTs with cultured Omicron virus as well as a  
199 retrospective clinical validation with 35 patient specimens.

200 Overall, we have observed a lower sensitivity to cultured virus across different Ag-  
201 RDTs compared to earlier variants, suggesting that Omicron virus itself is detected  
202 with lower sensitivity than other variants. We have observed differences between Ag-  
203 RDTs from different manufacturers, but also between assessment for PFU and RNA  
204 copy numbers. Reasons are most likely due to different ratios between infectious  
205 particles and RNA copies among the different SARS-CoV-2 variants. Since the main  
206 public health benefit of Ag-RDTs are the detection individuals with infectious virus  
207 shedding and not just presence of viral RNA, assessment of infectious viral particles  
208 is of higher relevance in this context, and an overall tendency towards lower sensitivity  
209 was seen for both assessments. Of note, while in the analysis for infectious virus, the  
210 previous VOCs Alpha, Beta, Gamma and Delta were mainly detected with comparable  
211 or even higher sensitivity compared to pre-VOC SARS-CoV-2, and Omicron is the first  
212 VOC demonstrating a trend towards lower analytical sensitivity across assays.

213 Omicron has additional mutations in the nucleocapsid that have been previously  
214 observed in circulating SARS-CoV-2 before, although not largely present, in circulating  
215 SARS-CoV-2 before but so far their impact on Ag-RDT performance is unknown. The  
216 virus isolate used in our study carries all four of the known nucleocapsid mutations  
217 (P13L, Del31-33, R203K, G204R), confirmed from both patient specimens and virus  
218 isolate. Percentage of Omicron sequences with these mutations are 96.8% for P13L,  
219 94.9% for Del31-33xx, 98.4 for R203K, and 98.4% for G204R of currently available  
220 Omicron sequences<sup>19</sup>. As not all circulating Omicron lineages harbour all mutations,  
221 additional analysis with such isolates would be of interest, however, at the time of  
222 conducting the study, no such isolates were available. However, our isolate represents  
223 the major circulating Omicron lineages.

224 In our clinical validation, we saw large heterogeneity between Ag-RDTs, with a loss  
225 of sensitivity for four Ag-RDT specimens. Comparisons of diagnostic assay by using  
226 different patient specimen collections are not trivial, and we have aimed for similar  
227 characteristics for the main determinants for rapid test performance, which is viral load,  
228 presence of infectious virus and time since days post symptom onset.<sup>20,21</sup>  
229 Furthermore, we had access to detailed clinical data, and all specimens were from  
230 previously mRNA vaccinated individuals, followed by a Delta or Omicron breakthrough  
231 infection. At least in most high-income countries with high vaccination rates, this group  
232 of individuals is comprising the majority of Omicron infections observed, therefore our  
233 results are of immediate public health interest.

234 Few data are available so far on Ag-RDT performance for Omicron case detection. A  
235 small number of heterogeneous studies are available, but with little assessment for  
236 sensitivity and with conflicting results. A recent report from the U.S. Food & Drug

237 Agency (FDA) announced that early data suggest reduced sensitivity for Omicron, in  
238 line with our findings, although no primary data are given.<sup>22</sup> A study performed by  
239 Public Health England (PHE) with cultured isolated of Omicron and wild-type SARS-  
240 CoV-2 across dilutions ranging from 12.5 to 1250 focus forming units/mL and 30.000  
241 to 4.070.000 viral copy numbers did not find a loss in sensitivity for five Ag-RDTs<sup>23</sup>.  
242 Only one of the Ag-RDTs validated here, the Flowflex Ag-RDT, was also validated in  
243 our study. In our analytical testing, reduced sensitivity was seen for Omicron compared  
244 to wild-type SARS-CoV-2 in this test, but we did not see a difference in the clinical  
245 testing when compared to Delta. Overall, in both our assessments, this was the most  
246 sensitive Ag-RDT for most variants including Omicron. Another study used two nasal  
247 swab samples each from Omicron and Delta-infected individuals and validated the  
248 Abbott Binax Now Ag-RDT, a test that was not included in our study<sup>24</sup> They conclude  
249 that Omicron can be detected by this test, although no extensive validation for  
250 sensitivity was performed. For the same test, data from a single clinical validation  
251 study are available from an outpatient testing Centre in the US using nasal swabs.<sup>25</sup>  
252 Sensitivity of a single antigen test was 95.2% for individuals with a cycle threshold  
253 value of the RT-PCR < 30, indicating good sensitivity with high viral load. A high failure  
254 rate was observed when oral specimens (cheek swabs) were used.

255 Strength of our study is that we have validated eight and seven Ag-RDT side-by-side  
256 for analytical and retrospective clinical sensitivity, respectively. Our selection of Ag-  
257 RDTs cover all of the three Ag-RDTs on the WHO-EUL, and three others that are on  
258 the WHO-EUL waiting list for approval, thus of high global public health relevance.<sup>26,27</sup>  
259 If the lower sensitivity towards Omicron that we observed here is confirmed by findings  
260 from clinical validations at the point of care, the use of Ag-RDTs in the early  
261 symptomatic period of an Omicron infection or in asymptomatic patients could be less  
262 reliable, with possibly important implications for public health measures. However, all  
263 Ag-RDTs were able to detect Omicron infections and so far, there is no reason to  
264 change advice on how to implement RDTs to support testing and COVID response  
265 strategies. As our evaluation here was rather focused at the lower end of detection,  
266 results might be of higher relevance to testing in an asymptomatic population or in the  
267 very early infection phase, but not necessarily to the acute symptomatic infection  
268 phase when peak viral loads are reached.

269 Our study has several limitations. For cultured virus, the ratio between infectious virus,  
270 viral protein and RNA copies might differ considerably to original human specimens.  
271 The retrospective testing is done with only a low number of patients swab samples  
272 that have been submerged in viral transport medium, whereas the recommended  
273 sample type for Ag-RDT use is fresh swabs. This has introduced an extra dilution  
274 factor as well as an additional freeze/thaw cycle. Although we tried to reduce the



275 number of freeze-thaw cycles to a minimum, we cannot exclude loss of RNA, protein  
276 or infectious virus, thus not reflecting fully the characteristics of a fresh patient  
277 specimen. To correct for loss of RNA after the first freeze-thaw cycle, we have re-  
278 tested viral RNA loads by RT-PCR and have used these values for comparison.  
279 Another limitation is that to compare across assays we have used the same approach  
280 as we did for analytical testing, with only 5  $\mu$ L of the original patient VTM added to the  
281 buffer of each kit to be able to use the same specimens for testing with a high number  
282 of tests in parallel. The volume of viral transport medium added to the buffer was lower  
283 than what was recommended by some manufacturers, and for some Ag-RDTs there  
284 was no recommendation on the use of swab samples in VTM. Therefore, viral loads  
285 of the original sample and sensitivities observed in our sample collection cannot be  
286 compared to results obtained from clinical validations performed on fresh samples and  
287 our results should be interpreted as a comparison between Ag-RDTs and not as  
288 sensitivity thresholds for absolute viral loads and/or presence of infectious virus.  
289 Rather, we have investigated the lower end of sensitivity in the Ag-RDTs tested.  
290 Therefore, a reduced sensitivity in some tests, but not complete failure to detect  
291 Omicron could be of higher relevance in the beginning of the infection, when viral loads  
292 are still on the rise, and of less relevance once peak viral loads are reached.

293 Lower sensitivity observed in this study could be due to a variant-specific impact on  
294 Ag-RDT performance. However, since many Omicron infections are currently  
295 observed in vaccinated individuals, it remains unclear if virus shedding and test  
296 performance differs between unvaccinated and vaccinated individuals, and no studies  
297 are available investigating Ag-RDT performance in unvaccinated vs. vaccinated  
298 individuals are available yet. To date, most validation studies of Ag-RDTs were done  
299 in the first year of the pandemic, before circulation of VOCs and in mostly immune-  
300 naïve individuals experiencing their primary SARS-CoV-2 infection. Other factors,  
301 such as *in vivo* shedding of infectious virus and overall viral can be one reason for  
302 differences in test performance. However, we have shown recently that neither RNA  
303 viral loads nor infectious titers differ significantly between Omicron and Delta  
304 breakthrough infections, thus differences in viral load are unlikely the reason for lower  
305 sensitivity in Omicron in some tests.<sup>17</sup>

306 Importantly, while analytical and retrospective testing may be a proxy for clinical  
307 sensitivity, is not a replacement for clinical evaluations at the point of care. The  
308 discrepancies in our results between testing with cultured virus and retrospective  
309 patient samples highlights the need for proper clinical studies in well-defined patient  
310 cohorts. Therefore, further studies on diagnostic accuracy of Ag-RDTs performed at  
311 the point of care for the newly emerged VOC Omicron are urgently needed to guide  
312 public health responses.

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325

326 **Conflicts of Interest**

327 The authors declare no competing interests.

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375 [o=Zeta&gene=N&threshold=70&nthresh=1&sub=false&dark=true](https://outbreak.info/compare-lineages?pango=Delta&pango=Omicron&pango=Alpha&pango=Beta&pango=Gamma&pango=Zeta&gene=N&threshold=70&nthresh=1&sub=false&dark=true) (accessed 13.01.2022).

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395

396 **Tables**

	Omicron (n=18)	Delta (n=17)	p <sup>1</sup>
Log <sub>10</sub> SARS-CoV-2 copies, mean (SD)	7.9 (0.7)	8.0 (0.7)	.510
DPOS, mean (SD)	2.0 (1.2)	1.9 (1.3)	.892
Presence of infectious virus, n (%)	14/18 (77.8%)	14/17 (82.4%)	.613

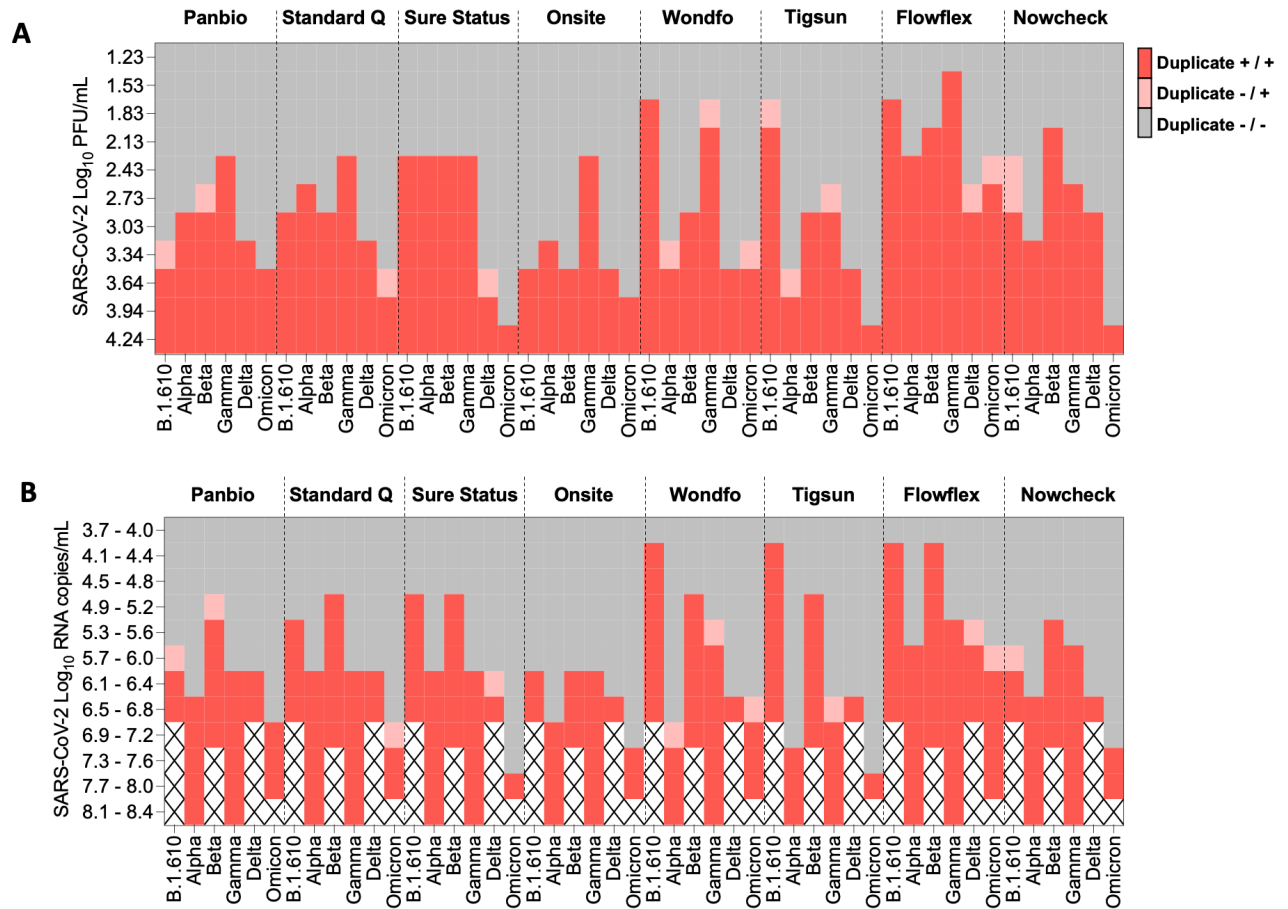
397 **Table 1.** Characteristics of clinical specimens. <sup>1</sup>p-values for simple linear regressions  
398 (Log<sub>10</sub> SARS-CoV-2 copies, DPOS) and simple logistic regression (Presence of  
399 infectious virus) are reported.

400

	Sensitivity (%)		p <sup>1</sup>
	Delta (n=34)	Omicron (n=36)	
Panbio	67.7	36.1	<.001
Standard Q	52.9	22.2	<.001
Sure Status	52.9	27.8	<.001
Onsite	64.7	47.2	<.001
Wondfo	76.5	75.0	.984
Tigsun	52.9	47.2	.634
Flowflex	91.2	88.9	.918

401 **Table 2.** Detailed sensitivity for the seven Ag-RDTs tested with clinical samples. <sup>1</sup> p-  
402 values for logistic mixed-effect models (with tests nested into patients) are reported.

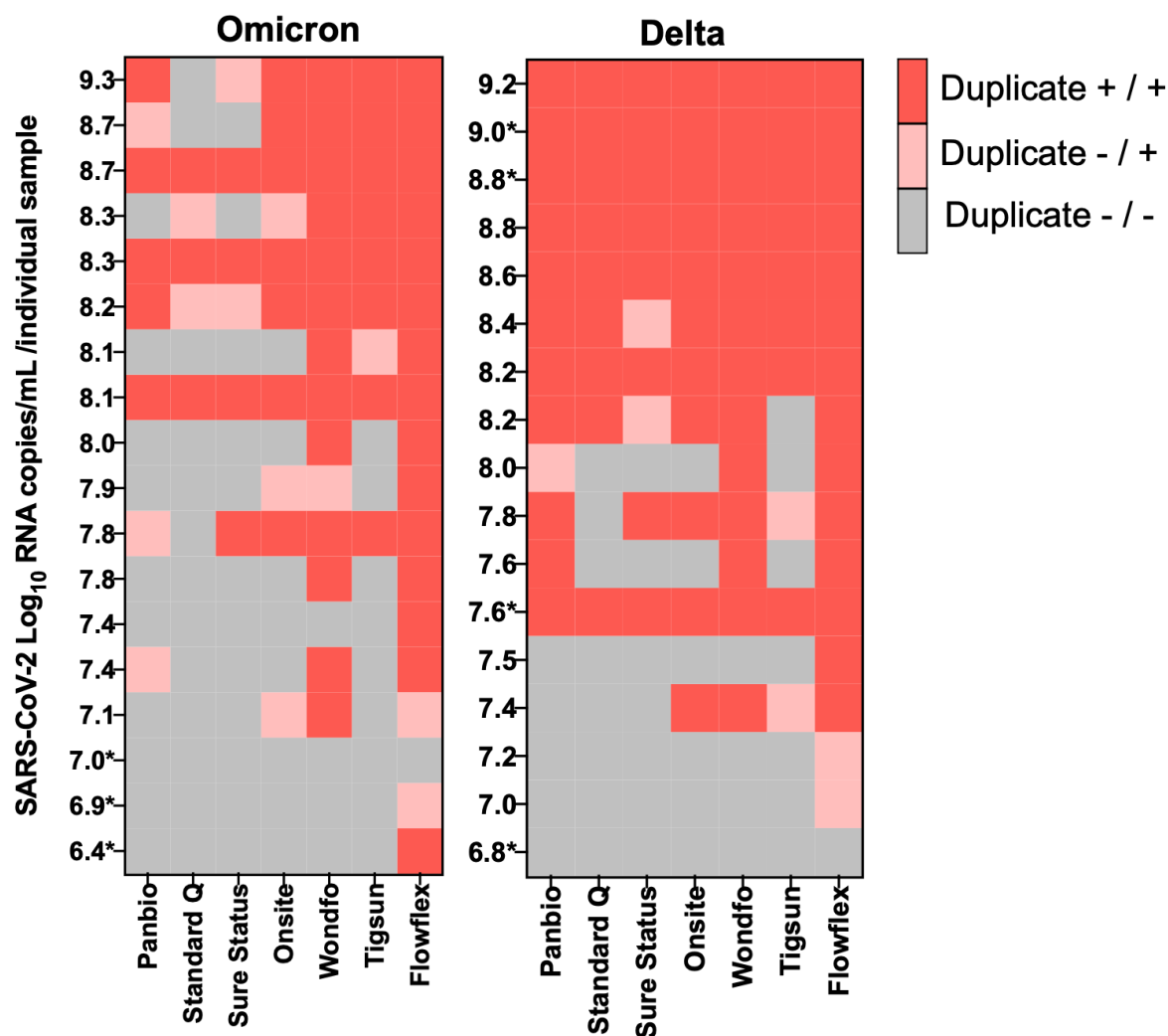
403 **Figures**



404

405 **Figure 1.** Heatmap based on Log<sub>10</sub> PFU/mL (**Fig 1A**) and on RNA viral load ranges  
 406 (**Fig 1B**) for analytical sensitivity of eight Ag-RDTs assays with an early-pandemic  
 407 SARS-CoV-2 isolate (B.1.610), the VOCs Alpha, Beta, Gamma and Delta in  
 408 comparison Omicron.

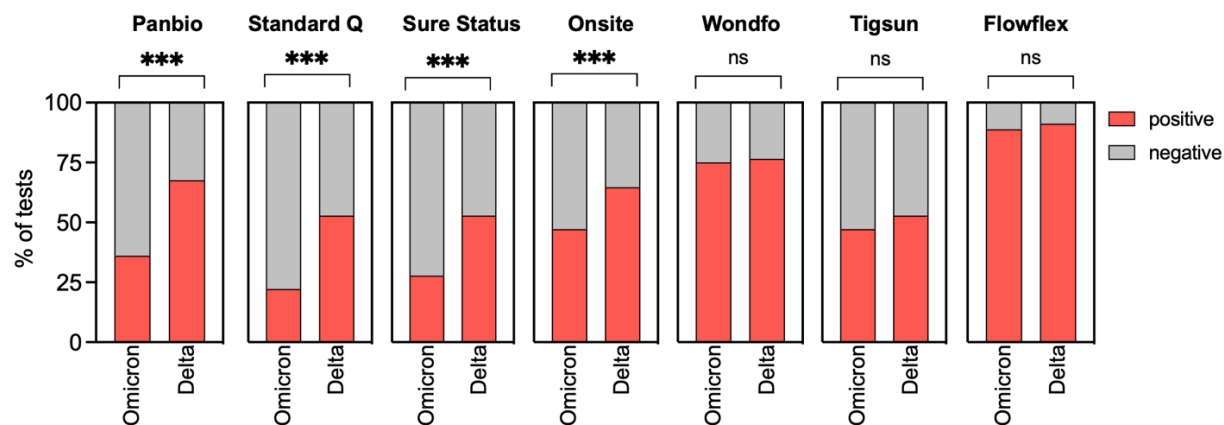
409 Note: Analytical sensitivity for early-pandemic SARS-CoV-2 B.1.610, Alpha, Beta,  
 410 Gamma and Delta have already been published before but were added here for  
 411 consistency reasons and better interpretability of the data on Omicron.<sup>15,16</sup>



412

413 **Figure 2.** Heatmap of retrospective testing of original nasopharyngeal patient swab  
 414 specimens from Omicron (n=18) and Delta (n=17) breakthrough infections in seven  
 415 Ag-RDT assays per SARS-CoV-2 log<sub>10</sub> RNA copies/mL, performed in duplicates.  
 416 Infectious virus was detected from all patient specimens unless marked with \* (\* = no  
 417 infectious virus isolated).

418



419

420 **Figure 3.** Percentage of positive/negative results for Omicron and Delta vaccine  
421 breakthrough infections per number of tests performed (Omicron n=36, Delta n=34).  
422 \*\*\* p<0.001, n.s., non-significant.

423



424 **Supplementary material**

425 **Tables**

426 **Table S1.** Overview of Ag-RDTs kits evaluated in the study.

427

	<b>Name of kit</b>	<b>Manufacturer</b>	<b>Target protein</b>
I	Panbio, COVID-19 Ag Rapid test device	Abbott	Nucleocapsid
II	Standard Q COVID-19 Ag	SD BIOSENSOR (Roche)	Nucleocapsid
III	Sure Status	Premier Medical Corporation	Nucleocapsid
IV	2019-nCoV Antigen test	Wondfo	Nucleocapsid
V	Beijing Tigsun Diagnostics Co. Ltd	Tigsun	Nucleocapsid
VI	CTK biotech	Onsite	Nucleocapsid
VII	ACON biotech	Flowflex	Nucleocapsid
VIII	NowCheck Covid- 19 Ag test	Bionote	Nucleocapsid

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