

# SARS-CoV-2 Omicron Variant analyses for the COVID-19 Antigen Nasal Test Kit, Antigen Rapid test cassette and Antigen Saliva Test Kit by Assure Tech (Hangzhou) Co., Ltd

## **Purpose of the study**

The objective of this study is to establish the suitability of the COVID-19 Antigen Nasal Test Kit, the Antigen Rapid Test cassette and the Antigen Saliva Test Kit by Assure Tech (Hangzhou) Co., Ltd for the detection of the Corona omicron variant to demonstrate that the product is effective.

## **Materials**

For this experiment 8 samples taken in December from patients in Amsterdam were used, see table 1. Currently around 80% of the people in Amsterdam infected with corona are infected with the Omicron variant.

**Table 1**

	Date	N-gene	ORF-gene	HLA-gene
Sample 1	7-12-2021	20,52	19,78	29,9
Sample 2	1-12-2021	20,3	19,91	26,51
Sample 3	1-12-2021	24,94	23,15	33,13
Sample 4	3-12-2021	21,24	17,93	25,56
Sample 5	6-12-2021	19,15	18,49	30,48
Sample 6	2-12-2021	18,87	18,29	23,68
Sample 7	17-12-2021	21,49	20,32	27,7
Sample 8	23-12-2021	19,89	18,18	25,75

In this experiment 100 µL is used on the Rapid Antigen Tests.

## **Results**

All results were SARS-CoV-2 positive on the Antigen Nasal Test Kit, Antigen Rapid Test cassette and the Antigen Saliva Test Kit, see figure 1, 2 and 3. The intensity of the band of sample 3 was lower compared to the other samples.



Figure 1: Results Antigen Nasal Test compared to Roche



Figure 2: Antigen Rapid test compared to Roche

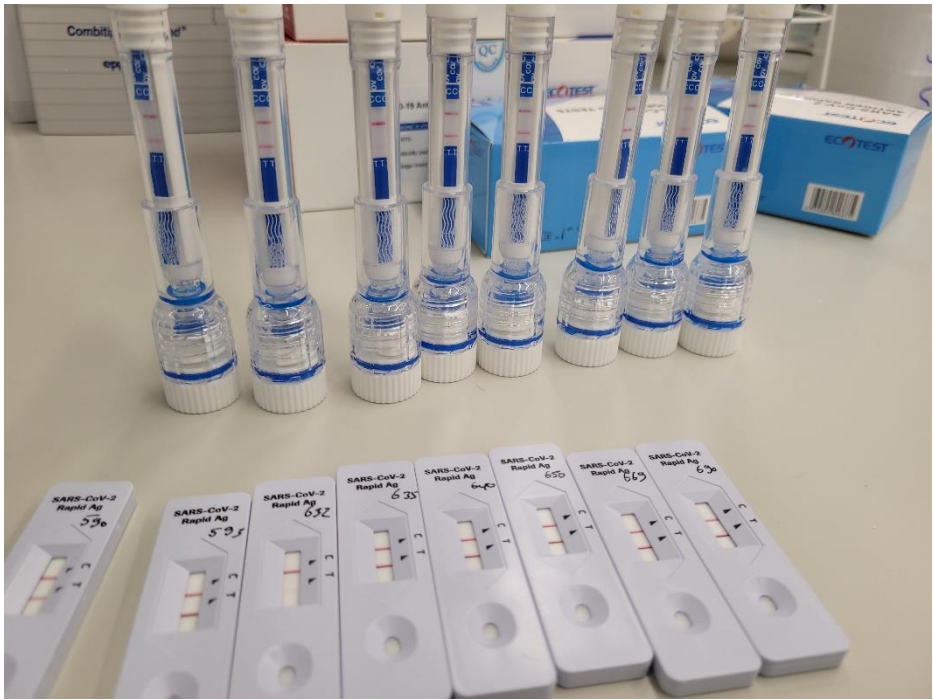


Figure 3: Results Antigen Saliva Test compared to Roche

**Conclusions**

In conclusion, the results from this study confirm indirect that the COVID-19 Antigen Nasal Test Kit, the Antigen Rapid Test Cassette and the Antigen Saliva Test Kit by Assure Tech (Hangzhou) Co., Ltd can detect the omicron SARS-CoV-2 variants.

At the Erasmus MC it was found that the Omicron and the Delta variant have the same sensitivity on multiple Rapid tests, see figure 4. The Omicron variant likely has the same sensitivity as the delta variant on the Antigen Rapid tests by Assure Tech (Hangzhou) Co., Ltd,

		x5	x25	x125	x625	x3125
<b>Omikron</b>	<b>Ct value</b>	<b>14,94</b>	<b>17,96</b>	<b>20,34</b>	<b>22,11</b>	<b>24,73</b>
SD Biosensor		++	+	(+)	+/-	-
PanBio		+	(+)	+/-	-	-
BD		(+)	+/-	-	-	-
<b>Delta</b>	<b>Ct value</b>	<b>15,38</b>	<b>18,33</b>	<b>20,63</b>	<b>23,03</b>	<b>25,37</b>
SD Biosensor		++	+	(+)	+/-	-
PanBio		+	(+)	+/-	-	-
BD		(+)	+/-	-	-	-

Figure 4: Sensitivity of Antigen rapid test of Omicron versus Delta variant

**Approval.**

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