

**Validation protocol for the
Newgene bioengineering COVID-19 Rapid Antigen Test
For the Omicron variant B.1.1.529.**



Testing laboratory:
Molecular Diagnostic Laboratory
Via Petrini 2
CH-6900 Lugano
Switzerland

Newgene Bioengineering Rapid Tests for the detection of Covid-19 infections during each phase of the disease: Reliable, fast, and cost-effective.

The **Newgene Covid-19 Rapid Antigen Test** is based upon the binding with one of the surface proteins of the virus (antigen) to an immobilized antibody and successively making this complex visible by a second antibody labeled with a colored dye. In this validation protocol we studied 56 PCR Omicron-positive samples (variant B.1.1.529.) obtained from mucous tissue by a nasopharyngeal swab. Samples were submitted to sequencing to check for the variant. In Switzerland in the last 2 months, in particular in Canton Ticino, we have practically 100% of positive samples which are positive for the Omicron variant.

Results.

N=56 Omicron positive samples were divided into three groups of N=41 with a CT<25, N=13 with a CT>25 but <30 and N=2 with a CT>=30.

The overall sensitivity on the N=56 PCR samples analyzed with CT<=30 is 100%. (see Table included).

Samples	Variant	CT value	Result for Newgene Ag test
26607689	B.1.1.529	20	Positive
26607691	B.1.1.529	19	Positive
26607693	B.1.1.529	20	Positive
26607695	B.1.1.529	20	Positive
26607711	B.1.1.529	16	Positive
26607713	B.1.1.529	20	Positive
12074728	B.1.1.529	18	Positive
12074174	B.1.1.529	19	Positive
12074629	B.1.1.529	19	Positive
12074640	B.1.1.529	19.5	Positive
12076038	B.1.1.529	20	Positive
12075671	B.1.1.529	20	Positive
12075976	B.1.1.529	20	Positive
12074160	B.1.1.529	21	Positive
12074706	B.1.1.529	21	Positive
12075056	B.1.1.529	21	Positive
12074561	B.1.1.529	21.5	Positive
12075186	B.1.1.529	21.5	Positive
12074655	B.1.1.529	22	Positive
12075619	B.1.1.529	22	Positive
12075974	B.1.1.529	22	Positive
12074450	B.1.1.529	23	Positive
12074550	B.1.1.529	23	Positive
12074953	B.1.1.529	23	Positive
12074973	B.1.1.529	23	Positive
12075270	B.1.1.529	23	Positive
12074543	B.1.1.529	23.5	Positive

12075858	B.1.1.529	23.5	Positive
12075362	B.1.1.529	23.51	Positive
12074172	B.1.1.529	24	Positive
12074152	B.1.1.529	24	Positive
12074314	B.1.1.529	24	Positive
12074017	B.1.1.529	24	Positive
12074428	B.1.1.529	24	Positive
12074409	B.1.1.529	24	Positive
12074770	B.1.1.529	24	Positive
12075205	B.1.1.529	24	Positive
12075767	B.1.1.529	24	Positive
12075936	B.1.1.529	24	Positive
12075985	B.1.1.529	24	Positive
12075145	B.1.1.529	24.39	Positive
12074089	B.1.1.529	25	Positive
12073645	B.1.1.529	25	Positive
12073684	B.1.1.529	25	Positive
12073655	B.1.1.529	25	Positive
12076247	B.1.1.529	26.3	Positive
12074031	B.1.1.529	26.5	Positive
12074225	B.1.1.529	27	Positive
12074132	B.1.1.529	27	Positive
12074006	B.1.1.529	27	Positive
12074102	B.1.1.529	27	Positive
12076274	B.1.1.529	28	Positive
12073595	B.1.1.529	28	Positive
12076229	B.1.1.529	29.48	Positive
12073652	B.1.1.529	30	Positive
12073658	B.1.1.529	30	Positive

Conclusion.

In conclusion, the Newgene antigen detection test is 100% sensitive on N=56 nasopharyngeal swab PCR Omicron variant positive samples, it is non-invasive and mimics the PCR results very closely where PCR is considered the golden standard technique.

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Dr. G. Soldati