BIOMEX 1.1

Clinical Performance Study Report - 2022-01

AESKU.RAPID SARS-CoV-2

REF: 840001, 840003, 840005
840001E, 840003E, 840005E, 840007E
840003>K, 840005K, 840007K

Clinical Performance of Omicron variant (B.1.1.529)

(preliminary results, study is ongoing)

Sponsor:

AESKU.DIAGNOSTICS GmbH & CO.KG
Mikroforum Ring 2
55234 Wendelsheim,
Germany

AESKU.GROUP
WE TAKE CARE OF YOUR HEALTH

Content

1 Purpose of the Study

The purpose of this study is to establish the performance of the AESKU.RAPID SARS-CoV-2 Test for the SARS-CoV-2 Omicron variant, also known as lineage B.1.1.529. over a period of 8 days after onset of symptoms. The study is ongoing, as only a limited number of positive donors have been available so far.

2 Sponsor – investigation – study coordination

2.1 Sponsor

AESKU.DIAGNOSTICS GmbH & Co. KG
Mikroforum Ring 2
55234 Wendelsheim
Germany
Tel: +49-6734-9622-0
www.aesku.com
E-mail: info@aesku.com.

2.2 Investigation

Laboratories of Biomex GmbH Heidelberg
Siemensstr. 38
D-69123 Heidelberg
Germany
www.biomex.de

2.3 Study coordination

Dr. Heike Lukhaup
Principal Investigator
Siemensstr. 38
D-69123 Heidelberg
Tel.: +49 6221 4166 430
e-mail: lukhaup@biomex.de

3 Scope

3.1 Study Design type

This prospective study is an observational study which aims to demonstrate the performance of the AESKU.RAPID SARS-CoV-2 Test, CE marked for professional use and for self-testing in detecting the SARS-CoV-2 Omicron variant (lineage B.1.1.529).
A progress study was carried out with 4 freshly infected patients with confirmed Omicron infection over a period of up to 8 days after onset of symptoms.
21 more patients with confirmed Omicron infection have been tested with the AESKU.RAPID SARS-CoV-2 Test to confirm the sensitivity.
The progress study is currently ongoing with more patients.

3.2 Expected Risk & benefits

There are minimal risks to no risks attributed to the intended user. The risks related to the patients have been reduced as far as possible by providing detailed instructions for Use with the kits, at all stages of the procedure including warning and precautions for the users and known limitations of the device.

The results obtained in this evaluation study will not be used for patient care decisions.

4 Timelines

Starting date: 2022-01-07
End-date: open (ongoing study)

5 Description Device

5.1 Identification

AESKU.RAPID SARS-CoV-2 Test

5.2 Manufacturer if different from the sponsor

Not applicable.

5.3 Intended purpose

AESKU.RAPID SARS-CoV-2 rapid test that is an immunochromatographic sandwich method with two specific antibodies for the qualitative detection of the N-protein antigen in human nasal swab samples. The point-of-care test is designed to detect SARS-CoV-2 N-protein antigens detectable during the acute phase of infection.

5.4 Analyte or marker

SARS-CoV-2 antigen

5.5 Specimen Type

Anterior nasal swab

5.6 Metrological Traceability

Not applicable.

5.7 Technical and Functional Features

AESKU.RAPID SARS-CoV-2 Test is based on immunochromatographic polymer technology combined with the sandwich principle for the qualitative detection of the nucleocapsid protein antigen in human nasal swab samples. The sample is mixed with colored polymer-labeled SARS-CoV-2 monoclonal antibody 1 in the test device's sample well and chromatographed along the nitrocellulose membrane. If SARS-CoV-2 antigens are present in the sample, they will bind to SARS-CoV-2 antibody 1, and the mixture will bind to immobilized SARS-CoV-2 antibody 2 on the nitrocellulose membrane. The resulting complex of antibody 1, antigen, and antibody 2 forms the colored test line. The test device's control line is coated with secondary antibodies, resulting in a colored result during a standard test procedure.

6 Study Design

6.1 Parameters of clinical performance to be determined

The study focuses on demonstrating the performance of the AESKU.RAPID SARS-CoV-2 Test in detecting the SARS-CoV-2 Omicron variant over a period of up to 8 days after onset of symptoms.

6.2 Materials Supplied by the manufacturer.

6.2.1 Test Kits and Instructions for Use

Sufficient kits of the AESKU.RAPID SARS-CoV-2 Test including the sampling material and in addition to the IFU will be supplied free of charge to carry out the entire evaluation.

AESKU.RAPID SARS-CoV-2 Test is used:
Lot number: P202104001 Expiry date: 09-2022

6.2.2 Instrument

RT-PCR measurements were performed with the MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (REF: A42352; LOT: 01066648; expiration date: 17/03/2022) with the KingFisher Flex instrument and analyzed with the TaqPath™ COVID-19 CE-IVD real-time RT-PCR Kit (REF: A48067, LOT: 2107176, expiration date: 02/07/2022) with the Quant Studio 5 (ThermoFisher) analyzer. The latter is FDA and CE certified and fulfil the requirements of WHO (detecting 3 different target genes).

6.3 Study population and selection criteria

4 patients have been enrolled so far to participate in the progress study, 20 more patients with confirmed Omicron infection have been tested with the AESKU.RAPID SARS-CoV-2 Test to confirm the sensitivity.
Participants were only allowed to take part in the study after they had signed the informed consent.

6.4 Test procedure

Throughout the evaluation, all samples swabs were extracted in the AESKU.RAPID SARS-CoV-2 Test extraction buffer as described in the IFU of the rapid test. 3 drops of the treated sample were applied to the sample well of the test cassette. Results obtained with the rapid test device were visually read-out by two operators between 15 and 20 minutes after the sample had been applied onto the test cassette. Digital images were taken from used rapid test cassettes after visual read-out.

7 Results

7.1 Subjects measured in progress study

In total 27 nasal swabs from donors with known SARS-CoV-2 infection (Omicron variant) were tested with the AESKU.RAPID SARS-CoV-2 Test.

Sex, age and symptoms of the donors as well as date of onset of symptoms were known. The date of infection was presumed from indications by the donor. Date of swab collections were documented. The collection of the swabs was carried out in Germany with European subjects.

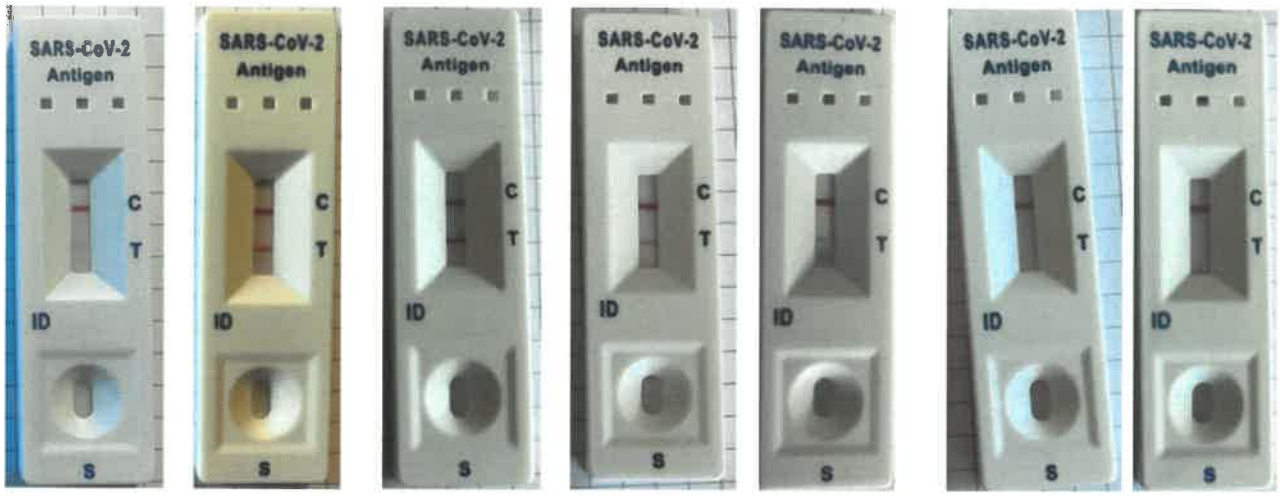
After the collection of the swab the antigen test was carried out according to the Instructions for use. All samples have been positive with the antigen test up to 12 days after onset of symptoms. One sample was negative after 9 days onset of symptoms. PCR of the samples was carried out as far as material was available. The requirements that samples should be detected positive within the first 7 days after onset of symptoms have been fulfilled for all tested samples.

Table 1: Results of the AESKU.RAPID SARS-CoV-2 Test

CSP	Gender	Age	suspected date of infection	onset symptoms	positive PCR	Time between start of symptoms and test	Test Date	Result PCR	Result Antigen-test
NS	w	21	31.12.2021	02.01.2022	03.01.2022				
						5	07.01.2022	20.66	pos
						6	08.01.2022	24.19	pos
						7	09.01.2022	28.04	pos
						8	10.01.2022	t.b.d	pos
						9	11.01.2022	t.b.d	pos
						10	12.01.2022	t.b.d	neg
						11	13.01.2022	t.b.d	neg
LM	m	21	31.12.2021	02.01.2022	03.01.2022				
						5	07.01.2022	28.39	pos
						6	08.01.2022	23.12	pos
						7	09.01.2022	23.63	pos
						8	10.01.2022	t.b.d	pos
						9	11.01.2022	t.b.d	pos
						10	12.01.2022	t.b.d	pos
						11	13.01.2022	t.b.d	pos
						12	14.01.2022	t.b.d	pos
MG	m	22	31.12.2021	05.01.2022	04.01.2022				
						2	07.01.2022	17.91	pos
						3	08.01.2022	17.07	pos
						4	09.01.2022	25.81	pos
						5	10.01.2022	n.d.	pos
						6	11.01.2022	n.d.	pos
						7	12.01.2022	n.d.	pos
						8	13.01.2022	n.d.	pos
						9	14.01.2022	n.d.	neg
LU	m	21	29.12.2021	02.01.2022	04.01.2022				
						6	07.01.2022	24.03	pos
						7	08.01.2022	22.29	pos
						8	09.01.2022	25.77	pos
						9	10.01.2022	n.d.	neg

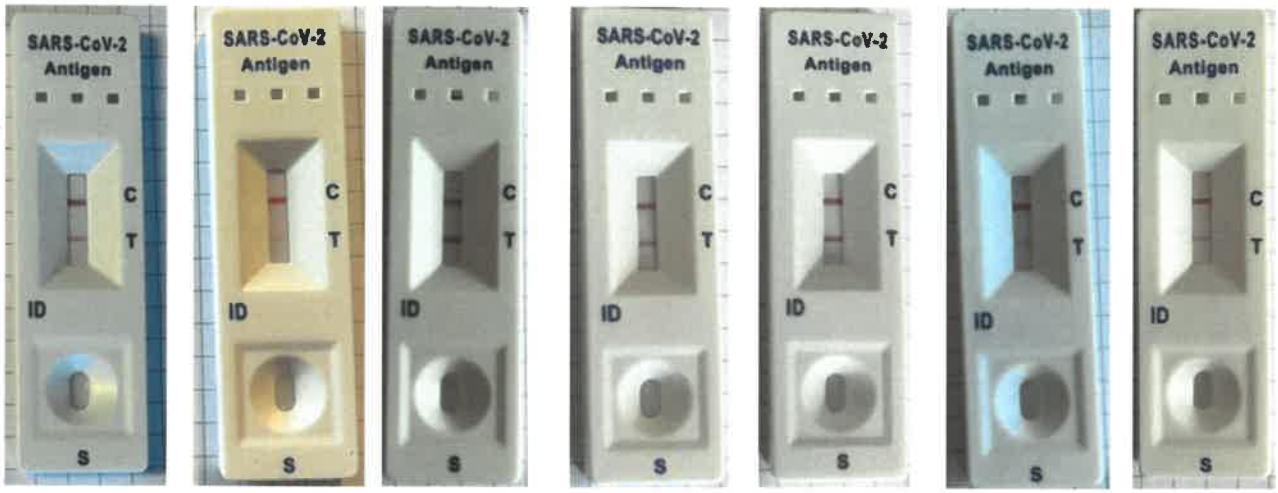
Pictures of the AESKU.RAPID SARS-CoV-2 Test tested with Omicron Variant

NS



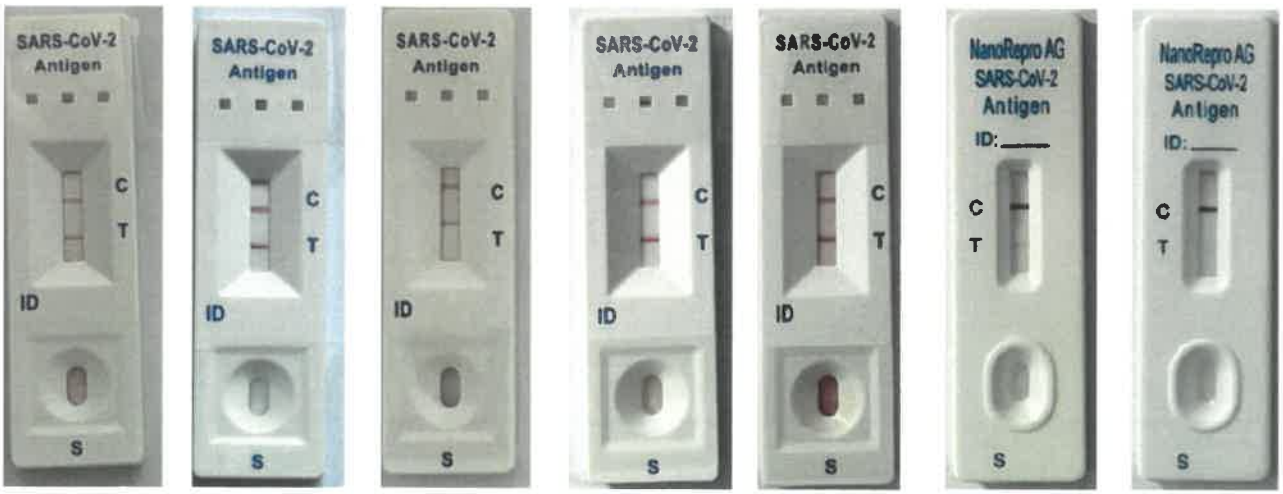
07.01.2022 08.01.2022 09.01.2022 10.01.2022 11.01.2022 12.01.2022 13.01.2022

LM



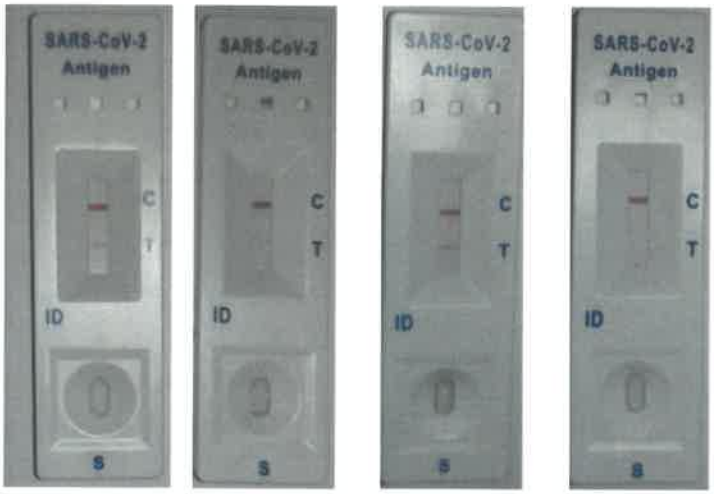
07.01.2022 08.01.2022 09.01.2022 10.01.2022 11.01.2022 12.01.2022 14.01.2022

MG



07.01.2022 08.01.2022 09.01.2022 10.01.2022 11.01.2022 13.01.2022 14.01.2022

LU



07.01.2022 08.01.2022 09.01.2022 10.01.2022

7.2 21 further Subjects with Omicrcon infection

In total 21 nasal swabs from donors with known SARS-CoV-2 infection (Omicron variant) were tested with the AESKU.RAPID SARS-CoV-2 Test.

Sex, age and symptoms of the donors as well as date of onset of symptoms were known. The date of infection was presumed from indications by the donor. Date of swab collections were documented. The collection of the swabs was carried out in Germany with European subjects.

After the collection of the swab the antigen test was carried out according to the Instructions for use. All samples have been positive with the antigen test up to 12 days after onset of symptoms. One sample was negative after 9 days onset of symptoms. PCR of the samples was carried out as far as material was available. The requirements that samples should be detected positive within the first 7 days after onset of symptoms have been fulfilled for all tested samples.

Table 2 includes the Results of all patients with confirmed Omicron infection (progress study and 21 further patients).

Table 2: Results of the AESKU.RAPID SARS-CoV-2 Test in comparison to PCR

Set#	Gender	Age	Swap date	Date of pos PCR	Vaccination stauts	Result Rapid-Test	Ct_N Gene	ORF1ab "swa	Ct_S "swab"	Result RT PCR
CA4821	m	20	06.01.2022	05.01.2022	once J&J	pos	13.5	11.8	neg	pos
CA5473	m	24	04.01.2022	03.01.2022	2 times Biontech	pos	14.7	12.7	neg	pos
CA4758	f	20	23.12.2021	21.12.2021	2 times Biontech	pos	15.1	13.8	neg	pos
CA5440	f	30	08.01.2022	04.01.2022	not vacc.	pos	15.2	13.8	neg	pos
CA5433	f	30	09.01.2022	04.01.2022	not vacc.	pos	15.9	13.6	neg	pos
CA5531	m	22	08.01.2022	04.01.2022	3 times Biontech	pos	17.1	14.3	neg	pos
CA5524	m	22	07.01.2022	04.01.2022	3 times Biontech	pos	17.9	15.0	neg	pos
CA4958	m	20	07.01.2022	05.01.2022	once J&J	pos	18.4	15.2	neg	pos
CA5466	m	24	05.01.2022	03.01.2022	2 times Biontech	pos	18.4	16.7	neg	pos
CA4731	m	22	24.12.2021	22.12.2021	2 times Biontech	pos	19.1	16.7	neg	pos
CA4733	m	22	25.12.2021	22.12.2021	2 times Biontech	pos	19.3	17.5	neg	pos
CA4756	f	20	24.12.2021	21.12.2021	2 times Biontech	pos	19.3	17.6	neg	pos
CA5478	m	21	03.01.2022	03.01.2022	3 times Astra/Biontech	pos	19.4	16.5	neg	pos
CA5336	m	28	09.01.2022	04.01.2022	not vacc.	pos	20.4	18.1	neg	pos
CA5529	f	21	07.01.2022	03.01.2022	3 times Biontech	pos	20.7	18.6	neg	pos
CA5168	f	23	29.12.2021	24.12.2021	2 times Biontech	pos	21.3	18.5	neg	pos
CA5013	m	21	07.01.2022	04.01.2022	3 times Biontech	pos	22.3	19.3	neg	pos
CA4823	f	22	07.01.2022	30.12.2021	2 times	pos	23.0	19.3	neg	pos
CA5453	m	21	04.01.2022	03.01.2022	3 times Astra/Biontech	pos	23.0	21.7	neg	pos
CA5508	m	21	08.01.2022	03.01.2022	3 times Biontech	pos	23.1	20.2	neg	pos
CA5500	m	21	09.01.2022	03.01.2022	3 times Biontech	pos	23.6	22.1	neg	pos
CA5166	f	23	30.12.2021	24.12.2021	2 times Biontech	pos	23.8	20.4	neg	pos
CA5003	m	21	06.01.2022	04.01.2022	3 times Biontech	pos	24.0	20.2	neg	pos
CA4759	f	20	25.12.2021	21.12.2021	2 times Biontech	pos	24.2	22.9	neg	pos
CA5509	f	21	08.01.2022	03.01.2022	3 times Biontech	pos	24.2	22.0	neg	pos
CA5333	m	28	08.01.2022	04.01.2022	not vacc.	pos	24.9	23.4	neg	pos
CA4957	m	21	07.01.2022	04.01.2022	3 times Biontech	pos	25.8	23.4	neg	pos
CA5525	m	22	09.01.2022	04.01.2022	3 times Biontech	pos	25.8	24.7	neg	pos
CA4944	f	22	08.01.2022	30.12.2021	2 times	pos	26.4	24.8	neg	pos
CA5501	f	21	09.01.2022	03.01.2022	3 times Biontech	pos	28.0	27.1	neg	pos
CA5512	m	21	07.01.2022	03.01.2022	3 times Biontech	pos	28.4	27.2	neg	pos
CA4934	m	22	07.01.2022	30.12.2021	2 times	pos	30.3	29.1	neg	pos
CA4937	m	22	08.01.2022	30.12.2021	2 times	negative	33.8	32.1	neg	pos

8 Conclusion

The sensitivity of the AESKU.RAPID SARS-CoV-2 Test to detect the Omicron-Variant over a period of up to 12 days after onset of symptoms is very high.

Also the sensitivity compared to RT PCR is very high, 1 sample out of 33 was detected negative in the AESKU.RAPID SARS-CoV-2 Test.

In conclusion, the results from this study confirm that the AESKU.RAPID SARS-CoV-2 Test can be used for the qualitative detection of antigen from SARS-CoV-2 Omicron-Variant in human anterior nasal swab with a very high sensitivity.