BIOMEX

Clinical Performance Study Report - 2022-01

AESKU SARS-CoV-2 Rapid Test

REF: 840001E, 840003E, 840005E

Clinical Performance of Omicron variant (B.1.1.529)

(preliminary results, study is ongoing)

Sponsor:

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Content

1 Purpose of the Study

The purpose of this study is to establish the performance of the Aesku SARS-CoV-2 Antigen Rapid 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

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2.2 Investigation

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2.3 Study coordination

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3 Scope

3.1 Study Design type

This prospective study is an observational study which aims to demonstrate the performance of the Aesku SARS-CoV-2 Rapid Test Kit, currently CE marked for professional use and for self-testing in detecting the SARS-CoV-2 Omicron variant (lineage B.1.1.529).
The testing was carried out with 4 freshly infected and confirmed patients over a period of up to 8 days after onset of symptoms. The study is ongoing until the results turn negative and as soon as more patients are available.

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 SARS-CoV-2 Rapid Test

5.2 Manufacturer if different from the sponsor

Not applicable.

5.3 Intended purpose

SARS-CoV-2 Rapid Test (Lateral Flow Method) is a rapid test that is used for laymen for detecting novel coronaviruses (2019-nCoV) antigen extracted from the nasal swab specimen. It is intended as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV.

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 SARS-CoV-2 Rapid Test (Lateral Flow Method) is based on the principle of Immunochromatography sandwich for determination of 2019-nCoV antigen extracted from the

anterior nasal, nasopharyngeal or oropharyngeal swab specimen. When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the 2019-nCoV antibody-dye conjugate and flows across the pre-coated membrane.

When the 2019-nCoV antigen level in the specimen is at or above the target cutoff (the detection limit of the test), the antigen bound to the antibody-dye conjugate are combined by 2019-nCoV antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the 2019-nCoV antigen level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

6 Study Design

6.1 Parameters of clinical performance to be determined

The study focuses on demonstrating the performance of the Aesku SARS-CoV-2 Rapid 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 SARS-CoV-2 Rapid Test including the sampling material and in addition to the IFU will be supplied free of charge to carry out the entire evaluation.

Aesku SARS-CoV-2 Rapid Test is used:
Lot number: P202104001 Expiry date: 09-2022

6.2.2 Instrument

Not applicable.

6.3 Study population and selection criteria

4 patients have been enrolled so far to participate in the study. 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 SARS-CoV-2 Rapid Test extraction buffer as described in the IFU of the rapid test. 2 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 10 and 15 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

In total 16 nasal swabs from donors with known SARS-CoV-2 infection (Omicron variant) were tested with the Aesku SARS-CoV-2 Rapid 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.

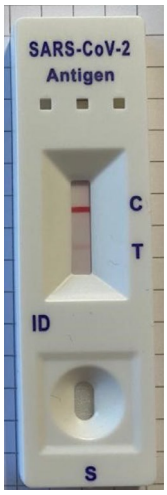
All samples have been positive with the antigen test 8 days after onset of symptoms. One sample was negative after 9 days onset of symptoms. Thus the requirements that samples should be detected positive within the first 7 days after onset of symptoms, have been fulfilled.

Table 1: Results of the Aesku SARS-CoV-2 Rapid Test

CSP	Gender	Age	suspected date of infection	onset symptoms	positive PCR	Time between start of symptoms and test	Test Date	Result Antigen-test
NS	w	21	31.12.2021	02.01.2022	03.01.2022	1		
						5	07.01.2022	pos
						6	08.01.2022	pos
						7	09.01.2022	pos
						8	10.01.2022	pos
LM	m	21	31.12.2021	02.01.2022	03.01.2022	1		
						5	07.01.2022	pos
						6	08.01.2022	pos
						7	09.01.2022	pos
						8	10.01.2022	pos
MG	m	22	31.12.2021	05.01.2022	04.01.2022	4		
						2	07.01.2022	pos
						3	08.01.2022	pos
						4	09.01.2022	pos
						5	10.01.2022	pos
LU	m	21	29.12.2022	01.01.2022	04.01.2022			pos
						6	07.01.2022	pos
						7	08.01.2022	pos
						8	09.01.2022	pos
						9	10.01.2022	neg

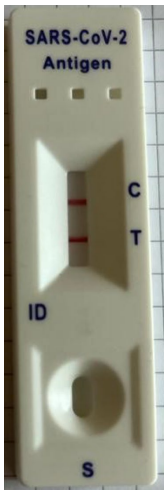
Pictures of the Aesku SARS-CoV-2 Rapid Test tested with Omicron Variant

NS



07.01.2022

08.01.2022



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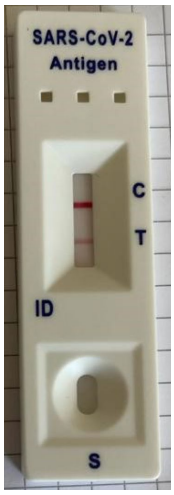
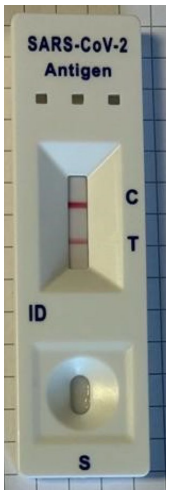
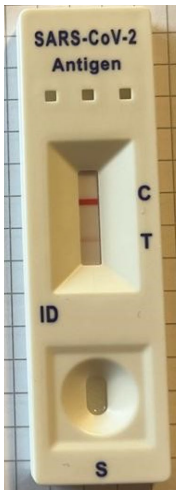


10.01.2022

LM



07.01.2022



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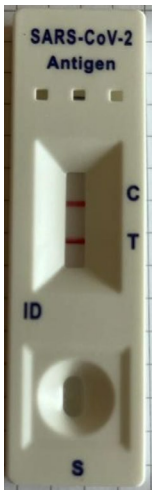
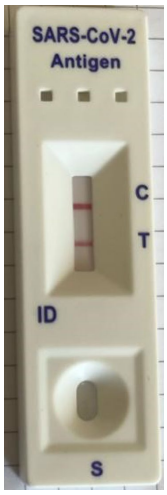


09.01.2022



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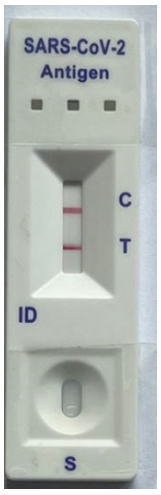
MG



07.01.2022 08.01.2022 09.01.2022 10.01.2022

LU

07.01.2022 08.01.2022 09.01.2022 10.01.2022

8 Conclusion

The sensitivity of the Aesku SARS-CoV-2 Rapid Test to detect the Omicron-Variant over a period of up to 8 days after onset of symptoms is very high.

In conclusion, the results from this study confirm that the Aesku SARS-CoV-2 Rapid 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.

9 Approval

Author

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Function:	Principal Investigator
Date:	Signature:

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