BIOMEX

Clinical Performance Study Report - 2021-25

AESKU SARS-CoV-2 Rapid Test

REF: 840001E, 840003E, 840005E

Clinical Performance of Delta variant (B.1.617.2)

Sponsor:

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Content

1 Purpose of the Study

The purpose of this study was to establish the performance of the Aesku SARS-CoV-2 Antigen Rapid Test for the SARS-CoV-2 Delta variant, also known as lineage B.1.617.2. over a period of 9 days after onset of symptoms.

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 was 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 Delta variant (lineage B.1.617.2).
The testing was carried out with 4 freshly infected and confirmed patients over a period of up to 9 days after onset of symptoms.

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: 2021-07-10
End-date: 2021-07-29

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 focused on demonstrating the performance of the Aesku SARS-CoV-2 Rapid Test in detecting the SARS-CoV-2 Delta variant over a period of up to 9 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 Materials Supplied by the Investigator

6.3.1 Standard laboratory reagents and disposables.

These have been supplied by the Investigator and must meet the specifications required to correctly carry out the test procedure.

6.3.2 Equipment/Instrumentation

Nucleic acid extraction will be performed with the R-Biopharm RIDA Xtract (REF: PGZ001) and analyzed with the R-Biopharm RIDA Gene SARS-CoV-2 real-time PCR kit (REF: PG6815), with the CFX96 Touch Real-Time PCR Detection System from Bio-Rad Laboratories (Hercules, USA).

R-Biopharm RIDA Xtract Kit used:
Lot number: QL210010 Expiry date: 2022-07

R-Biopharm RIDA Gene SARS-CoV-2 real-time PCR kit used:
Lot number: 212001Z Expiry date: 2023-05

6.4 Study population and selection criteria

4 patients have been enrolled to participate in the study. Participants were only allowed to take part in the study after they had signed the informed consent.

6.5 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.

Total RNA was extracted from 200 µL of the remaining liquid using the R-Biopharm RIDA Xtract (REF: PGZ001), and analyzed with the R-Biopharm RIDA Gene SARS-CoV-2 real time PCR kit (REF:PG6815).

According to a validation of different extraction volumes of 50 µl, 200 µl and 400 µl an average value of 2.27 Ct was calculated as difference between the used 200 µl and the requested 400 µl. Therefore, a Ct-value of 2.27 was subtracted from the PCR results received with 200 µl for each sample.

Real-time RT-PCR analysis was performed in single determination for all samples that were collected from infected donors and conducted using a CFX96 Touch Real-Time PCR Detection System from Bio-Rad Laboratories (Hercules, USA). The real-time RT-PCR results were obtained as Ct-values. Samples with a Ct-value of 36 (mean of the two replicates) or below were included in the calculation of the sensitivity of the Aesku SARS-CoV-2 Rapid Test.

7 Results

7.1 Subjects

In total 26 nasal swabs from donors with known SARS-CoV-2 infection 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 (see annex "SRF Delta Variant Aesku"). 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. The residual volume of the extraction buffer was immediately frozen at -20° and stored until the PCR was carried out.

The correlation between the PCR results of the analyzed samples and the Aesku SARS-CoV-2 Rapid Test is very good. All samples up to Ct-values of 36.15 have been positive with the antigen test. Even samples which have been negative in the PCR gave still faint bands with the antigen test in some cases. Thus the requirements stipulated in the "Minimum criteria for Rapid SARS-CoV-2 Antigen Tests of the Paul-Ehrlich-Institut (PEI)" that samples within the first 7 days after onset of symptoms should be detected positive, have been fulfilled.

Furthermore the sensitivity of the antigen tests is very high as even samples with Ct-values > 36 have been detected positive with the Aesku SARS-CoV-2 Rapid Test.

Table 1: Results of the Aesku SARS-CoV-2 Rapid Test compared to RT-PCR

Donor	Gender	Age	suspected date of infection	onset symptoms	positive PCR	Time between start of symptoms and test	Test Date	Result PCR	Result Antigen-test
CSP151	w	27	07.07.2021	11.07.2021	12.07.2021	1			
						2	13.07.	30.88	pos
						3	14.07.	34.70	pos
						4	15.07.	36.15	pos
						5	16.07.	35.93	weak pos
						6	17.07.	neg	weak pos
						7	18.07.	neg	neg
CSP152	w	28	05.07.2021	07.07.2021		2			
						3	10.07.	33.93	pos
						4	11.07.	32.38	pos
						5	12.07.	33.10	pos
						6	13.07.	neg	pos
						7	14.07.	35.35	pos
						8	15.07.	neg	neg
						9	16.07.	neg	neg
CSP155	w	30	10.07.2021	15.07.2021	15.07.2021	0			
						1	16.07.	33.78	pos
						2	17.07.	31.92	pos
						3	18.07.	26.03	pos
						4	19.07.	34.68	pos
						5	20.07.	neg	neg
						6	21.07.	neg	neg
CSP148	w	23	06.07.2021	10.07.2021	09.07.2021	0			
						1	11.07.	33.89	pos
						2	12.07.	neg	pos
						3	13.07.	33.21	pos
						4	14.07.	neg	pos
						5	15.07.	32.73	pos
						6	16.07.	35.49	weak pos
						7	17.07.	neg	neg

8 Conclusion

The sensitivity of the Aesku SARS-CoV-2 Rapid Test compared to the reference method RT PCR was very high, as all samples, which have been detected positive in the PCR have also been positive with the antigen rapid test. The antigen test is able to detect the Delta-Variant over a period of up to 7 days after onset of symptoms and was as sensitive the RT-PCR.

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 Delta-Variant in human anterior nasal swab with a very high sensitivity.

9 Annex

Annex I SRF Main Evaluation EDGC™ COVID-19 Ag Test
Annex II Pictures of positive samples