Usability Study of the AESKU SARS-CoV-2 Antigen Rapid Test

Purpose of the Study

The objective of this usability study is to evaluate the usability of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001) and to provide data to demonstrate that the product can be used safely by professional and laypersons.

Product Information

Manufacturer	AESKU.DIAGNOSTICS GmbH & Co. KG Mikroforum Ring 2 55234 Wendelsheim Germany Tel.: +49 6734 9622 0, info@aesku.com, www.aesku.com
Test Name	AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001)
Detection Method	Immunochromatographic Test using a colored polymer-labeled novel coronavirus monoclonal antibody
Intended Use	Qualitative Detection of the N protein antigen from SARS-CoV-2 in human nasal swab specimen
Specimen	human nasal swab
Content of Testkit	AESKU.RAPID SARS-CoV-2 antigen test cassette Specimen processing tube Specimen sampling swab
Storage Condition	4-30°C
Lot number	P202010005
Expiration Date	09.04.2022

Study Management

Questionnaire

A questionnaire for the usability evaluation of the AESKU.RAPID SARS-CoV-2 Antigen test was developed by ESfEQA GmbH, Siemensstr. 38, 69123 Heidelberg, Germany

Study Coordinator

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Timelines

The Study was performed in November 2020

Study Design

Test persons

Professionals experienced in IvD testing as well as laypersons were involved in this study.

Items provided to the test persons

- AESKU.RAPID SARS-CoV-2 Antigen test, consisting of AESKU.RAPID SARS-CoV-2 antigen test cassette, specimen processing tube and specimen sampling swabs
- Gebrauchsanweisung AESKU.RAPID SARS-CoV-2 Rapid Test (in German language), Version 001 (Draft)
- Illustration of sample collection and test procedure (see annex)
- Questionnaire 'Fragebogen zum Usability-Test AESKU.Rapid SARS-CoV-2 Rapid Test' (in German language), Version 1, November 2020 (see annex)

Results

Eleven individuals of the age between 16 and 84 years (5 female, 6 male) were selected for this usability study. The participants represent a wide range of age groups. Among them were 3 persons trained for performing in-vitro-diagnostic test. All participants were German-native speakers or at least fluent in German language.

The questionnaire addresses questions about the comprehension of the test procedure as well as the practical application of the test device. The individual questions (17 in total) could be answered in 5 different grades from very easy/perfect to very difficult/need of improvement.

All questions of the questionnaire were answered predominantly by the two highest grades (very easy/easy and perfect/almost perfect). The illustrations in the Instruction for Use ('Gebrauchs-anweisung') and the description for the interpretation of test results were rated once as 'rather difficult'.

Several participants of this study (laypersons) missed the description of the sample collection in the chapter 'test execution' since they regard the sample collection as part of it. Instead, the sample collection is described in the IFU in the separate chapter 'sample material'. The separation of the description of the sample collection and testing procedure in the 1st version of the IFU may be reconsidered.

One participant of the study missed instructions in the IFU for the interpretation of a faint test line.

Conclusion

The usability of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001) was evaluated in this study. The participants of this study, professionals in IvD testing as well as laypersons, have rated the comprehensibility as well as the practical test procedure predominantly as very easy to easy. Participants recommended to reconsider the separation of sample collection and test execution in two separate chapters in the IFU.

In conclusion, based on the predominantly positive feedback of the participants, the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit is evaluated as easy to use.

Approval

Usability study of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit, Version 001 November 2020