AESKU.RAPID SARS-CoV-2

CE 0483 IVD

INSTRUCTIONS FOR USE

REF 840001E (20 pcs) REF 840003E (5 pcs) REF 840005E (2 pcs) REF 840007E (1 pcs) REF 840003K (5 pcs) REF 840005K (2 pcs) REF 840007K (1 pcs)

INTENDED USE

The ***AESKU**.RAPID* SARS-CoV-2 rapid antigen test is an immunological process that uses SARS-CoV-2-specific antibodies to provide qualitative evidence of coronavirus components in human nasal swab samples. The test is optimized for self-administration and is designed to provide evidence of SARS-CoV-2 antigens that can be identified during the acute phase of an infection. The test itself is quick and easy to use for people of all ages.

PERFORMANCE DATA (EVIDENCE OF THE NUCLEOCAPSID PROTEIN)

***AESKU**.RAPID* SARS-CoV-2	RT-PCR		
	Positive	Negative	Total
Positive	173	2	175
Negative	16	299	315
Total	189	301	490

The performance of the test was assessed in a study using 140 positive (Ct ≤ 32) and 301 negative samples. The specificity of the ***AESKU**.RAPID* SARS-CoV-2 is 99.3% (95% CI: 97.6-99.8); the sensitivity was determined as 100% in the critical range (Ct < 30). This means that a false positive result was produced once in 100 samples and no false negative results occurred. A false negative result means that the test is negative, although you have COVID-19. A false positive result means the test provides a positive result for someone who has not yet had any contact with the virus. The comparison qRT-PCR was carried out using the same nasal swab sample as the one used for the assessment of the ***AESKU**.RAPID* SARS-CoV-2.

C_t value	Number of samples	Number of *true-positive* rapid test results	Number of *false-negative* rapid test results	Sensitivity (95% CI)
≤ 30	119	119	0	100% (96.9–100)
≤ 32	140	138	2	98.6% (94.9–99.6)
≤ 34	168	162	6	96.4% (92.4–98.4)
≤ 36	189	173	16	91.5% (86.7–94.7)

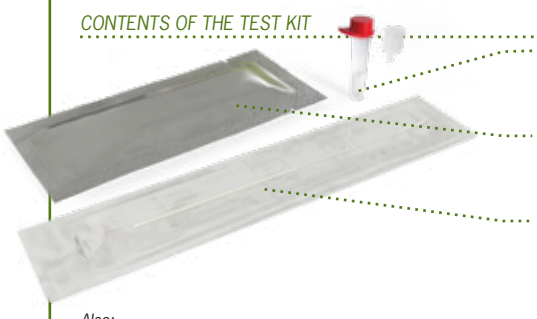
Cross-reactivities

The following inactivated viruses and bacteria were tested three times using the ***AESKU**.RAPID* SARS-CoV-2 rapid test:

Cross reactant/ interference analyte	Strain	Result
Coronavirus	OC43	negative
Coronavirus	229E	negative
Coronavirus	NL63	negative
Coronavirus	HKU1	negative
MERS-CoV	Florida/USA-2_Saudi Arabia_2014	negative
Influenza A H3N2	HK/8/68	negative
Influenza A H1N1	Brisbane/59/07	negative
Influenza A H1N1 pdm	Canada/6294/09	negative
Influenza B	Washington/02/19	negative
Influenza B	Texas/6/11	negative
Influenza B	Alabama/2/17	negative
Respiratory syncytial virus Type A (RSV)	Isolate: 2006	negative
Prot. A pos. Staph. Au.	DSM346	negative

None of the analytes tested showed cross-reactivity with the ***AESKU**.RAPID* SARS-CoV-2.

CONTENTS OF THE TEST KIT



***Sample tubes** with dropper attachment filled with extraction buffer*

SARS-CoV-2 antigen- ***test cassette*** *(inc. desiccant)*

***Test swabs** – sterile (EO), CE0197*
(Manufacturer: Jiangsu Changfeng Medical Device Co. Ltd, EC-Rep.: Llins Service & Consulting GmbH, Heidelberg)

Also:
Instructions for use with images showing how to do the test, a holder for the sample tube (5 pack/20 pack kit) or flap with pre-punched holes (1 pack/2 pack kit)

NOTES ON THE TEST

You will need around 30 minutes the first time you read the instructions and do the test.

Please read these instructions for use carefully and in full before you start the test. Allow the reagents to warm up to **room temperature before use**. The tests should be stored at 4°C to 30°C and protected from light. Never freeze the test. Check that the test has not expired and there is no damage to the foil bag.

Expiry date: see label.

You must adhere to the steps listed on the back.

Ensure that you have a watch with a second display available to carry out the test.

Nasal swabs of the front nasal region are the only samples that can be used for this test.

The tests can only be self-administered from the age of 12. Test subjects under the age of 12 must be assisted when using the tests.

The test should be carried out **immediately** after the test strip is removed from the aluminum pack.

Mutations: This test provides evidence of the highly conserved nucleocapsid protein. The previous functional mutations all occurred in the spike protein and its receptor binding areas. The ability to detect delta and omicron could be demonstrated in studies.

PRECAUTIONS AND WARNINGS

The pack contains components that are classified according to EC Regulation 1272/2008. The following warnings, preventative measures, and response notes relate to the pure substances (e.g., citric acid) that are used to manufacture the extraction buffer.

The buffer itself is a mixture of low concentrations of substances with different biochemical properties, all of which are under their respective GHS limit:

Warning: H317: May cause an allergic skin reaction.

Prevention: P280: Wear protective gloves/protective clothing/face protection.

Response: P333+P313: If skin irritation or rash occurs: Get medical advice/attention; P362+P364: Take off contaminated clothing and wash it before reuse.

Avoid it getting into the environment, sewer system, or water.

Do not use any of the test components other than the included test swabs in your body.

Please clean the work surface with a disinfectant or cleaning agent after carrying out the test.

All components are for single use.

Please rinse your skin or eyes if they come into contact with the extraction buffer.

PREPARATION OF THE TESTS

Please blow your nose and wash your hands before you start.

Firstly, open the aluminum pack containing the test strip. Take the test strip out and dispose of the desiccant in the pack. Ensure that the aluminum pack is not damaged.

Prepare the enclosed sample tube holder, or fold up the tab with the prepunched holes.

Take the sample tube and carefully remove the lid. Place the sample tube into the holder.

Take the test swab pack out and open where it says "OPEN" or "PEEL". *Please open the pack here only, as the other sterile end will be inserted into the nose later.*

Take the test swab out. Hold the test swab as shown in the figure on the reverse (*step 1*).

CARRYING OUT THE TESTS

You can find the full explanation of the test with pictures on the reverse.

WHAT TO DO NEXT

A positive test result needs to be confirmed with a PCR test. Contact your primary care physician by phone to arrange this. No medically important decisions should be made without consulting a doctor. The possibility of returning a false positive or false negative result can never be ruled out.

If you have a negative result but you still have symptoms such as coughing, fever, or a cold, we recommend that you contact your primary care physician.

Even if you have no symptoms and test negative, you should still continue to comply with social distancing rules, restrictions on contact, and hygiene measures.

RESTRICTIONS OF THE TEST

A positive result does not rule out simultaneous infection with other pathogens.

A negative result does not rule out infections with other pathogens.

Cross-reactions with SARS-CoV-1 were not able to be ruled out on the basis of the current data.

NOTE ON DISPOSAL

Ensure that you comply with the applicable regulations when disposing of items. Dispose of the components in their respective packaging. Throw this into household waste.

LITERATURE

Lindner AK et al., Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with self-collected anterior nasal swab versus professional-collected nasopharyngeal swab. Eur Respir J 2020. doi: 10.1183/13993003.03961-2020

https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

Rozand, C. (2013). Paper-based analytical devices for point-of-care infectious disease testing. European Journal of Clinical Microbiology & Infectious Diseases, 33(2), 147–156. doi:10.1007/s10096-013-1945-2

THE SARS-COV-2 SERVICE TEAM LOOKS AFTER YOU

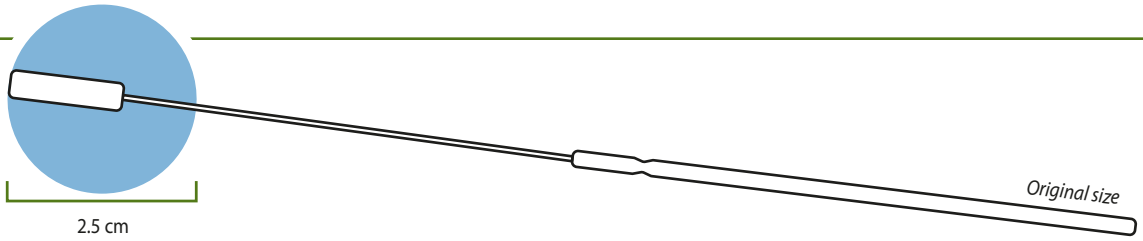
Please do not hesitate to contact us if you have any questions: **+49 6734 9622 6666**

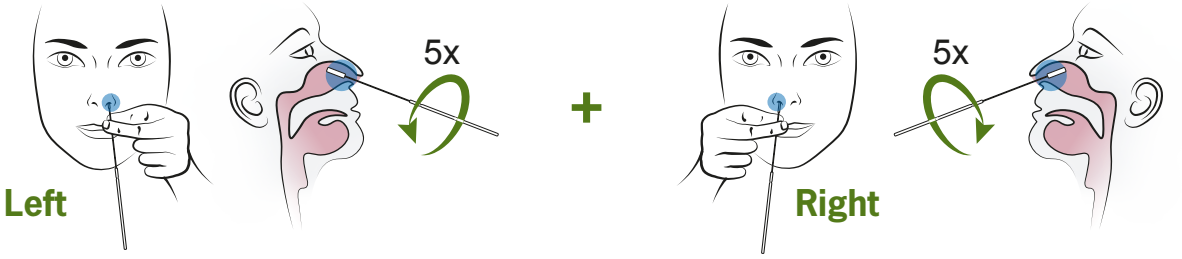
	Comply with the instructions for use	STERILE EO	Sterilization with ethylene oxide		Do not reuse		Warning
IVD	In-vitro diagnostics		Use by		Protect from light		The Green Dot
	Storage at room temperature	LOT	Batch designation	REF	Order number	CE	Conformité Européenne
Σ	Number of tests		Manufactured by		Store in a dry place		

Test for self-administration

Version 011A_LAIE_CE: 2022-08-18-EN

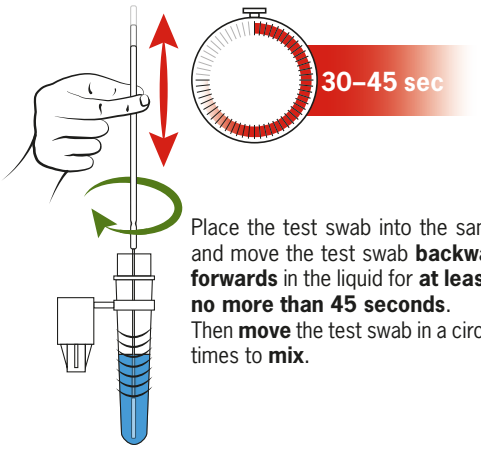
1



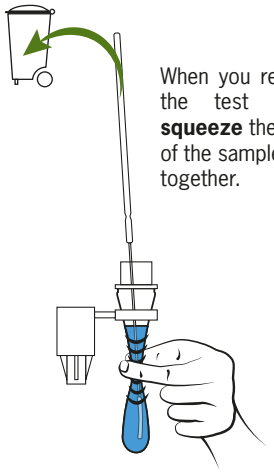


Carefully insert the test swab around **2.5 cm into your nostril** – for children/adolescents, only insert it until you feel a slight resistance. **Roll** the test swab around the walls of the nostril **5 times**. **Repeat** this process with the same test swab in **the other nostril**.

2

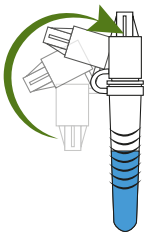


Place the test swab into the sample tube and move the test swab **backwards and forwards** in the liquid for **at least 30 and no more than 45 seconds**.
Then **move** the test swab in a circle several times to **mix**.

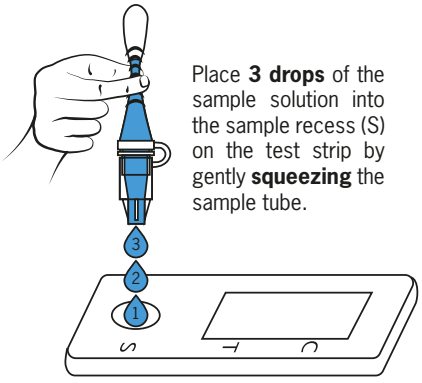


When you remove the test swab, **squeeze** the walls of the sample tube together.

Push the attached dropper firmly onto the sample tube.



3

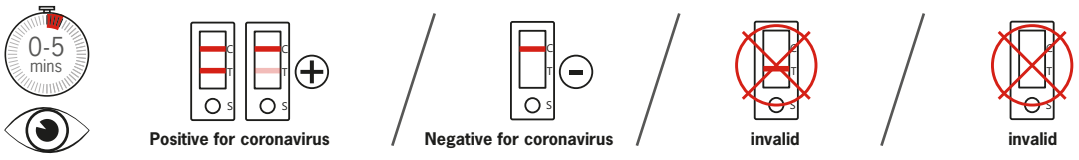


Place **3 drops** of the sample solution into the sample recess (S) on the test strip by gently **squeezing** the sample tube.

Wait 15 minutes after applying the sample for the result.
Please leave the test strip alone during this period.

4

Check the test result **within 5 minutes** of the end of the 15-minute **waiting period**.
If you read the test result after more than 20 minutes, it may be distorted.



Positive for coronavirus / **Negative for coronavirus** / **invalid** / **invalid**

Strength of the test line
Both darker and lighter lines should be considered valid, provided they can clearly be identified.

If your test result is invalid
If you get an invalid test result, please repeat the test with a new test kit.

If your test result is positive
Positive results must be reported to the relevant health authority immediately in line with local guidelines. The positive test result must always be confirmed by a PCR test carried out by a registered doctor as quickly as possible. You and your household should isolate yourselves according to the guidelines until the result of this test is known.

Test for self-administration

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