AESKU.RAPID
SARS-CoV-2 Rapid Test

INSTRUCTION MANUAL

CE IVD

Version 004B (2020/12/21)
REF: 840001 (20 units)
840003 (5 units)

Intended use

The AESKU.RAPID SARS-CoV-2 rapid test 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.

The test should be performed by healthcare professionals familiar with in vitro diagnostic methods and appropriate infection control procedures.

Diagnostic relevance

COVID-19 is an acute infectious disease of the respiratory tract caused by the novel coronavirus SARS-CoV-2. The primary sources of infection are symptomatic and asymptomatic infected persons. The incubation period is up to 14 days but usually lies between 5 and 6 days. The main manifestations are loss of smell and taste, fever, malaise and fatigue, and dry cough. In some cases, stuffy nose, shortness of breath, sore throat, and myalgia may occur.

Positive test results confirm the presence of viral antigens, but a clinical history is still necessary to determine the infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses.

Negative test results do not entirely rule out COVID-19 and should be considered in conjunction with recent exposure, medical history, and the presence of clinical signs and symptoms.

Test principle

The AESKU.RAPID SARS-CoV-2 rapid 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.

Components

SARS-CoV-2 Antigen Test Cassette, sample tube with specimen extraction buffer and dripper, sample swabs (sterile)

Storage and shelf life

Store at 4°C - 30°C, do not freeze, protect from light.

Shelf life: 18 months. Expiration date: see label.

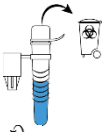
Sample material

1. Nasal swabs are useful specimens for this test.
2. Samples that are analyzed within 24 hours can be stored at 4°C. Samples that are not examined within 24 hours should be stored at -70°C or lower (if storage at -70°C is not possible, please keep at -20°C). Please do not use samples that show bacterial growth, are too old, or have been frozen and thawed several times to avoid unspecific reactions.
3. Samples must be brought to room temperature before testing.

Test procedure

1. Please read the instructions thoroughly and completely before performing the test.
2. Bring all components and samples to room temperature. Then open the foil pouch, remove the test device, and place it on the work surface. The test should be performed within one hour after removal from the foil pouch.
3. The nasal swabs are taken as follows: Insert the swab about 2.5 cm deep into one nostril. Roll the swab 5 times along the nasal mucosa to collect mucus and cells. Repeat this process in the other nostril.
4. Preparing the sample solution:

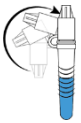
a) Remove and discard the sample tube cap.



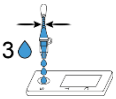
b) Insert the swab into the test tube and gently move the swab up and down in the liquid for at least 15 seconds.

c) While removing the swab, press the swab against the sample tube wall while rotating it to extract as much liquid as possible from the swab.

d) Press the attached tip firmly onto the sample tube (containing the sample). Mix thoroughly by rotating the tube or flicking it against the bottom.



5. Apply the sample: Hold the tip of the sample tube vertically downward. Add three drops of sample solution into the test device's well by pressing the tube and wait for your result.



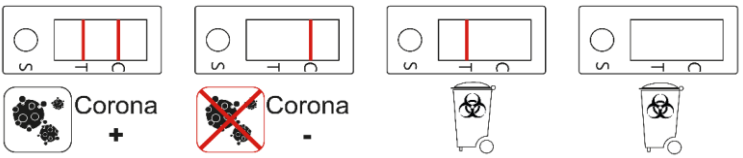
6. Assess the test result 15 minutes after sample application, within 5 minutes.

Interpretation of test results

Positive: A red line appears for both the control (C) and the test lines (T), indicating the presence of SARS-CoV-2 antigens at concentrations above the detection limit.

Negative: A red line appears only for the control (C), but not for the test line (T). Meaning that the sample does not contain SARS-CoV-2 antigens, or its concentration is below the test's detection limit.

Invalid: The test is invalid if no red line appears for the control (C).



positive negative invalid

Clinical performance

The clinical performance was evaluated in a study with 157 positive (≤7 days after onset of symptoms) and 222 negative samples (nasopharyngeal swabs) tested in both the RT-PCR (R-Biopharm RIDA Gene SARS-CoV-2 RUO real-time PCR) and the AESKU.RAPID SARS-CoV-2 rapid test.

The specificity of the AESKU.RAPID SARS-CoV-2 is 98% (95% CI: 95%-99%) and the sensitivity was determined in relation to the C_t value as follows:

C_t value	Sensitivity (%)	95% CI (%)	Number of samples
C_t value < 30	100	95-100	77
C_t value < 32	96	91-99	105
C_t value < 34	90	84-94	136
C_t value < 36	85	78-90	157

Analytical performance

Detection limit: The detection limit was determined using positive samples diluted with the sample matrix of the nasal swabs. The detection limit of AESKU.RAPID SARS-CoV-2 is **50 $TCID_{50}$/mL**.

Cross-Reactivity: The cross-reactivity of the test was tested against several microorganisms and viruses. No cross-reactivity could be determined for the following viruses and microorganisms for the specified concentrations:

Virus / Microorganism	Concentration	Cross-Reactivity (yes/no)
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL	No
	1.41×10^4 $TCID_{50}$/mL	No
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	4.68×10^3 $TCID_{50}$/mL	No
MERS	1.17×10^4 $TCID_{50}$/mL	No
Influenza A H1N1	1.0×10^5 $TCID_{50}$/mL	No
	1.15×10^6 $TCID_{50}$/mL	No
Influenza A H3N2	1.0×10^5 $TCID_{50}$/mL	No
Influenza B Victoria	2.5×10^5 $TCID_{50}$/mL	No
	1.70×10^4 $TCID_{50}$/mL	No
Influenza B Yamagata	2.5×10^5 $TCID_{50}$/mL	No
	5.62×10^3 $TCID_{50}$/mL	No
RSV-A	5.01×10^4 $TCID_{50}$/mL	No
RSV-B	1.55×10^3 $TCID_{50}$/mL	No
Avian influenza H7N9	1.7×10^5 $TCID_{50}$/mL	No
Avian influenza H5N1	1.7×10^5 $TCID_{50}$/mL	No
Rhinovirus	1.4×10^5 $TCID_{50}$/mL	No
Adenovirus	1.1×10^5 $TCID_{50}$/mL	No
Measels Virus	1.0×10^6 $TCID_{50}$/mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No

Hook Effect: Even in samples with high virus doses (3.6×10^5 $TCID_{50}$/mL) no hook effect was detectable.

Limits of the detection method

1. The contents of this kit are for the qualitative detection of SARS antigens from nasal swabs.
2. A negative test result may occur if the antigen level in a sample is below the test's detection limit or if the sample has not been correctly collected or stored.
3. Mistakes in the test procedure may affect the test performance and/or invalidate the test result.
4. Test results must be evaluated in conjunction with other clinical data available to the physician.
5. Positive test results do not exclude co-infections with other pathogens.
6. Negative test results do not rule out other viral or bacterial infections.
7. Negative results should be considered a possibility and should be confirmed with a clinical molecular assay, including infection control, as appropriate.
8. Clinical performance was evaluated with frozen specimens and may vary with fresh samples.
9. Specimen stability recommendations are based on stability data from influenza testing, and performance may vary for SARS-CoV-2. Users should test samples as soon as possible after collection.
10. If the differentiation of specific SARS viruses and strains is necessary, additional tests are required.
11. This IVD has been evaluated for use with human specimen material only.
12. Performance may vary for asymptomatic individuals.
13. It has been shown that the sensitivity of the test decreases after the first five days after the onset of symptoms compared to an RT-PCR SARS-CoV-2 assay.
14. The validity of the AESKU.RAPID SARS-CoV-2 rapid test has not been demonstrated to identify/confirm tissue culture isolates and should not be used in this function.

Safety information

1. For use in human in-vitro diagnostics only.
2. Please read the complete instructions for use before performing the test.
3. Do not use any reagents after the expiration date.
4. Take appropriate precautions when collecting, handling, storing, and disposing of samples and used kit contents and wear proper protective equipment and gloves.
5. If the sample extraction solution touches the skin or eye, rinse with plenty of water.
6. All components are intended for single use.
7. Ensure that the test device's foil pouch is undamaged and do not use a damaged or dropped test device.
8. Insufficient or inappropriate specimen collection, storage, and transport may result in erroneous test results.
9. Opened and exposed test cassettes should not be used under a laminar flow hood or in highly ventilated areas.
10. Do not use visually bloody or excessively viscous samples.
11. Use the swab provided in the kit to collect the nasal swabs. The use of alternative swabs may lead to incorrect results.
12. Pathogenic microorganisms, including hepatitis viruses and the human immunodeficiency virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed when handling, storing, and disposing of all samples and any items contaminated with blood or other body fluids.
13. Your test results are not valid if the precautions are not followed.

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MatchPHARM

Used Symbols

	Follow instructions for use		Usable until	REF	Catalogue number
IVD	In Vitro Diagnostic	LOT	Batch designation		Store dry
	Store at room temperature		Manufactured by		Attention
	Number of determinations		Do not reuse	CE	Conformité Européenne
STERILE EO	Sterilization with ethylene oxide		Protect from exposure to light		