REF: 8008466
GTIN : 03760097080084
Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test
(Colloidal Gold)

This instructions for use (IFU) must be read carefully prior to use and must be carefully followed. The reliability of the results cannot be guaranteed if there are any deviations from the instructions of use.

PACKING SPECIFICATION

This box contains 25 Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test individually packed in a sealed pouch. The Ksmart® tests must be used only with the LabPad® Evolution analyzer manufactured by the Avalun Company.

INTENDED USE

The In Vitro Medical Device Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test is an automated rapid immunochromatographic assay for use with the LabPad® Evolution. This test is intended for the in vitro semi-quantitative detection of antibodies IgG to the Spike (S) protein of SARS-COV-2 and for the qualitative detection of antibodies IgM to the Spike (S) protein of SARS-COV-2 in human serum or capillary whole blood sample collected by a trained healthcare professional.

The test is an aid in the assessment of the humoral adaptive immune response to the SARS-COV-2 antigens.

PRINCIPLE OF THE PROCEDURE

The Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test is a single used membrane-based immunoassay for the semi-quantitative detection of antibodies IgG to the Spike (S) protein of SARS-COV-2 and for the qualitative detection of antibodies IgM to the Spike (S) protein of SARS-COV-2 in human serum or capillary whole blood samples.

During testing, the sample reacts with SARS-COV-2 recombinant antigen coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the coated anti-human IgM at the first test line region. If the sample contains SARS-COV-2 IgM antibodies, a colored line will appear as a result of this. If the sample does not contain SARS-COV-2 IgM antibodies, no colored line will appear in the test line region, indicating a negative result.

Then the mixture reacts with the coated anti-human IgG antibody at the second test line region. If the sample contains SARS-COV-2 IgG antibodies, a colored line will appear as a result of this. If the sample does not contain SARS-COV-2 IgG antibodies, no colored line will appear in the test line region, indicating a negative result.

To serve as a procedural control, a control line will always appear in the control line region, indicating that the proper volume of sample has been added and membrane wicking has occurred.

The result of the Ksmart® SARS-COV-2 IgG/IgM Antibody Rapid Test is intended to be read out by the matching LabPad® Evolution analyzer which measures the optical density of the colored lines.

REAGENTS AND MATERIALS SUPPLIED

1. Main components:

- Test card in an individual foil pouch with desiccant: x25
- Dilution buffer: x1
- Instruction for use: x1
- Pipette 20 µl: x25

2. Ingredients of the test

Anti-human IgM monoclonal antibody is coated on the first test line region. Anti-human IgG monoclonal antibody is coated on the second test line region. Goat anti-rabbit IgG at the C line. Conjugate pad is coated with SARS-COV-2 recombinant antigen conjugated with gold colloidal particle.

MATERIALS REQUIRED BUT NOT PROVIDED

- LabPad® Evolution analyzer
- Timer, if to use the Endpoint mode of the analyzer.
- A lancet of gauge 21 is recommended.
- Laboratory Pipette, to control the volume of serum to be deposited on the Ksmart®. If to precisely control the volume of dilution buffer to be deposited on the Ksmart®.

STORAGE AND STABILITY

1. Store the kit at 4-30° C/ 39.2-86° F.
2. Kit materials are stable until the expiration date printed on the packaging.
3. Do not freeze the kit.
4. Test should be used within half an hour after opening.

SPECIMEN REQUIEMENTS

1. The Ksmart® can be used for serum and capillary whole blood samples.
2. Serum must be collected in a tube without anticoagulant.
3. Serum samples may be stored at 2-8°C for 3 days prior to assay. If testing is delayed more than 3 days, the sample should be frozen (-20°c or colder). Repeat freeze and thaw for nor more than 3 times.
4. For capillary whole blood samples collection:
   Prick the side of a fingertip of the patient. It is recommended to use a 21-gauge lancet. The capillary whole blood samples should be used immediately.

APPLICABLE EQUIPMENT

This product is only applicable to the LabPad® Evolution analyzer.

TEST PROCEDURE

Caution:

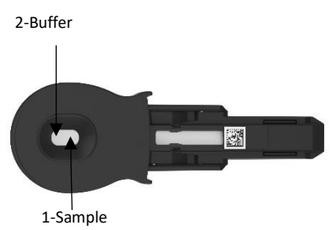
1. It is recommended to not open the pouch until you are ready to perform a test.
2. Remove the rapid test from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen.
4. Discard used test, lancet and pipette in a suitable biohazards waste container.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.

Test operation:

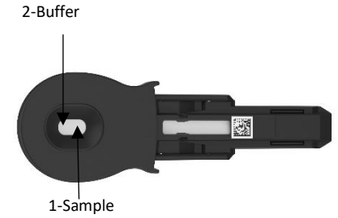
Before performing the test, you must read the instruction manual of the product and the operating manual of the LabPad® Evolution analyzer completely.

1. Allow all kit components and specimens to reach room temperature between 15°C~25°C prior to testing. Ksmart® test and dilution buffer that are not balanced to room temperature (15℃~25℃) can affect the accuracy of the results.
2. Instrument preparation: Turn on the power of the LabPad® Evolution analyzer, and check the detection mode set for SARS-COV-2 Antibody (Standard or Endpoint mode). If necessary, go to the set-up menu to switch to the desired mode (See LabPad® Evolution user manual for details).
3. Unpack the Ksmart® from the pouch and place it horizontally on a dry table.
4. Collect the specimen (see “Specimen requirements).

   a. <u>For capillary whole blood sample</u>
5. Add 20 µl of the blood sample to the right of the sample well of the Ksmart® (see picture below) with the pipette provided in the box.
6. Add two drops (or 70 µl) of dilution buffer to the left of the sample well of the Ksmart® (see picture below).
   Note Be sure to deposit only two drops of dilution buffer as more drops would hinder the rendering of results.



   b. <u>For serum sample</u>
5. With a Laboratory pipette add 10 µl of serum sample to the right of the sample well of the Ksmart® (see picture below).
6. Add two drops (or 70 µl) of dilution buffer the left of the sample well of the Ksmart® (see picture below).
   Note Be sure to deposit only two drops of dilution buffer as more drops would hinder the rendering of results.



7. Proceed to Ksmart® reading

<u>Standard Mode</u>: Insert the Ksmart® into the analyzer **as soon as the absorption of the sample is complete** and within 2 minutes after sample deposition. The reader will automatically take care of the timing of the test and the result will be displayed when 20 minutes have elapsed.
Warning: If the Ksmart® is inserted into the analyzer before the complete absorption of the sample, this may cause an incorrect migration of the sample that can lead to an error message on the LabPad®. In this case start again a new test, with a new sample.

<u>Endpoint mode</u>: Count 20 minutes with a timer before inserting the Ksmart® into the reader. Reading takes about 10 seconds until result is displayed.
Note: It is essential to insert the Ksmart® at 20 minutes.

INTERPRETATION OF TEST RESULTS

For IgM

The result is reported either positive or negative indicating a positive or negative result to SARS-COV-2 IgM antibodies.

For IgG

A negative result to SARS-COV-2 antibodies IgG is reported as “Negative”.

The reportable range is expressed as an Index with an arbitrary unit (a.u) from 2 a.u. to 100 a.u. These quantitative results are positive to SARS-COV-2 antibodies IgG.

The Index 2 a.u. corresponds to a diluted pool of SARS-COV-2 positive serum samples measured at 70 UI/ml.

The Index 100 a.u. corresponds to a diluted pool of SARS-COV-2 positive serum samples measured at 550 UI/ml.

“<2 a.u.” results are considered as low positive results to SARS-COV-2 antibodies IgG as these results are between the LOD and the LOQ of the test.

“>100 a.u.” results are considered as strong positive results to SARS-COV-2 antibodies IgG as it exceeds the upper limit of the test.

PERFORMANCE CHARACTERISTIC

1. LOD Limit of Detection- LOQ Limit of Quantification

For IgG

The LOD is equal to 3 times the standard deviation of 30 test results of samples without SARS-COV-2 antibodies IgG. The LOQ is defined as the lowest concentration of the analyte that can be accurately quantified with a CV ≤ 20 %. The LOD and the LOQ were respectively established to be 1 and 2 a.u.

2. Precision: Repeatability and reproducibility

Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test CV results are precise within <20% using whole blood and serum samples in the measurable range.

3. Linearity for IgG

SARS-COV-2 positive serum samples were pooled, then this pool was diluted to obtain a reference sample. Then this sample was diluted to obtain SARS-COV-2 Antibody IgG values over the full range of the assay. Linear regression analysis of the data indicates that the assay is linear over its entire measurable range: 2 to 100 a.u.

4. Clinical study

For IgG

The sensitivity of the reagent of the Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test was tested using 432 sera/plasma/venous whole blood samples from patients with laboratory RT-PCR-confirmed SARS-COV-2 infection and with COVID-19 symptoms over 14 days ago. The specificity was tested using 1 177 sera/plasma/venous whole blood samples from patients who were negative to RT-PCR SARS-COV-2 assay.

	Laboratory RT-PCR test		
Avalun Rapid test	Positive	Negative	Total
Positive	410	3	*413*
Negative	22	1174	*1196*
Total	*432*	*1177*	1609

Analysis of coincidence rate of the reagent of the Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test and RT-PCR test result.

Sensitivity: 410/ (410+22) × 100 % = 94.91%
CI95% = [92.39 % - 96.78 %]
Specificity: 1174 / (3+1174) × 100 % = 99.75 %
CI95% = [99.26 % - 99.95 %]
Accuracy= (410+1174) / (432+1177) x 100 %= 98.45 %
CI95% = [97.71 - 98.99]

For IgM

The sensitivity of the reagent of the Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test was tested using 686 sera/plasma/venous whole blood samples from patients with laboratory RT-PCR-confirmed SARS-COV-2 infection and with COVID-19 symptoms less than 14 days ago. The specificity of the reagent was tested using 1 177 sera/plasma/venous whole blood samples from patients who were negative to RT-PCR SARS-COV-2 assay.

	Laboratory RT-PCR test		
Avalun Rapid test	Positive	Negative	Total
Positive	580	23	*603*
Negative	106	1154	*1260*
Total	*686*	*1177*	1863

Analysis of coincidence rate of the reagent of the Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test and RT-PCR test result.

Sensitivity: 580/ (580+106) × 100 % = 84.55 %
CI95% = [81.62 % - 87.17 %]
Specificity: 1154 / (23+1154) × 100 % = 98.05 %
CI95% = [97.08 % - 98.76 %]
Accuracy= (580+1154) / (686+1177) x 100 %= 93.08 %
CI95% = [91.83 - 94.19]

5. Cross reaction

Specimens tested positive with following various agent were investigated with the reagent of the Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test. The results showed no cross reactivity:

Pathogen	**Testing result**
Coronavirus Seasonal	Negative
Coronavirus 229E	Negative
Coronavirus NL63	Negative
Coronavirus HKU1	Negative
Anti-Human hepatitis C virus(HCV	Negative
anti-Helicobacter pylori(HP)	Negative
Anti-herpes simplex virus(HSV)	Negative
Toxoplasma IgM (+)	Negative
Syphilis	Negative
Influenza A	Negative
Influenza B	Negative
Respiratory Syncytial Virus (RSV).	Negative

The reagent cross reacted with WNV IgG+, mumps IgM +, Chikungunya IgM and SARS-COV-1.

6. Interference testing

The test result of the reagent of the Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test do not interfere with the following substances at the concentration:

Substance	**Concentration**
Hemoglobin	1 000 µg/dl
Bilirubin	40 g/dl
Acetaminophen	20 g/dl
Acetylsalicylic acid	65 µg/dl
Ascorbic acid	6 g/dl
Caffeine	6 g/dl
Gentesic acid	1.8 g/dl
Phenylpropanolamine	20 mg/dl
Salicylic acid	60 mg/dl
EDTA	100 µg/dl
Benzoylecgonine	10 mg/dl
Atropine	20 mg/dl
Cannabinol	10mg/dl
Ethanol	0.4 µg/dl
Morphine	50 µg/dl
Albumin	6 g/dl
Glucose	1000 mg/dl
Triglyceride	37 mmol/ml

PRECAUTIONS - LIMITATIONS

1. The reagent of the Ksmart® SARS-COV-2 Antibody IgG/IgM Rapid Test is a disposable in vitro diagnostic reagent. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing. Do not use expired or damaged products.
2. The solution and test card must be equilibrated to room temperature (15℃~25℃) before used, otherwise the results may be incorrect.
3. For the same patient, do not compare the Index result from a serum sample with a result from a whole blood capillary sample.
4. The kit should be sealed and kept away from moisture. Reagents or samples stored at low temperature should be balanced to room temperature before they can be used.
5. In order to avoid dampness to affect results, Ksmart® should be used within 30 minutes after removal from their humidity free individual pouches.
6. Do not use a Ksmart® that laid for too long or was contaminated after being removed from its individual pouch.
7. Please operate in accordance with laboratory testing procedures.
8. Results accuracy may be affected by incorrect operations mainly the amount of buffer solution, inaccurate detection time, etc.
9. Components from different batches should not be mixed.
10. There should be appropriate biosafety assurance procedures for those substances containing or suspected to contain sources of infection, especially:
11. Handle samples and reagents with gloves;
12. Do not smoke, eat, drink, make up or handle contact lenses while handling these items;
13. In case of spilled sample or reagent, immediately use a disinfectant for cleaning. Disinfect and treat all samples, reagents and potential pollutants in accordance with relevant local regulations;
14. Do not open the Ksmart®. If the Ksmart® is opened, discard the test and use another one.

MANUFACTURER
AVALUN
Add.: 7, parvis Louis Neel, 38000 Grenoble, France
Web: www.avalun.com
E-mail: contact@avalun.com

INSTRUCTIONS OF SYMBOL

	Consult instructions for use		Number of tests per kit
4°C 30°C	Store between	LOT	Lot number
	For single use	IVD	In vitro diagnostic medical device
	Manufacturer	CE	CE Mark
	Expire date		