philosys

Gmate® COVID-19 Ag Saliva
Viral Antigen Test Kit

- **15 minute** to get the result
- **Mutant viruses** detectable
- **Easy** sample collection

Intended Use

The Gmate® COVID-19 Ag Saliva is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 virus in human saliva from individuals who are suspected of COVID -19 by their healthcare provider within the first five days of the onset of symptoms. Results are for the identification of SARS-CoV-2 nucleocapsid antigen.

Antigen is generally detectable in human saliva samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered with the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management.

Principle

According to the gold immunochromatographic test principle, double antibody sandwich method is used to detect SARS-CoV-2 antigen in the samples. When the antigen is contained in the sample, the antigen binds with the corresponding gold labeled monoclonal antibody 1 and the coated monoclonal antibody 2 at the test line to form a compound and then condenses into a red band, indicating a positive result. When the sample does not contain antigen, complex cannot be formed at the test line, and no red band appears, indicating negative result.

Regardless of whether the SARS-CoV-2 antigen is contained in the sample, the gold labeled antibody will bind with the coated antibody at the C line to form a complex and develop color (C line).

Materials Provided

1. Test Device
2. Funnel with Cap
3. Prefilled buffer tube & Cap
4. Instruction for Use

Gmate® COVID-19 Ag Saliva
Viral Antigen Test Kit

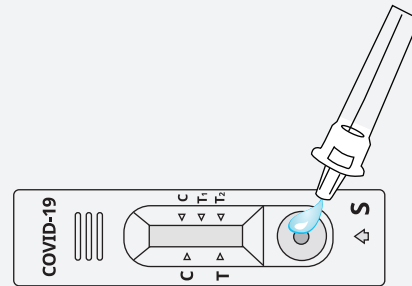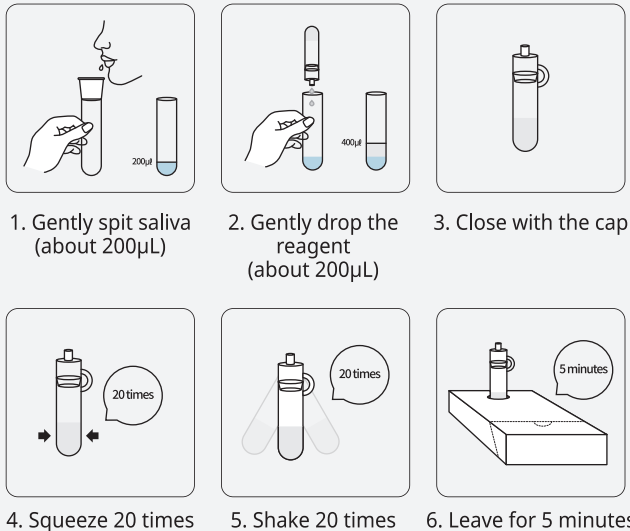| Package	Bulk: 25 test / Box Single: 1 test / Box
Storage	4-30℃
Specimen Type	Saliva
Time to result	15 minute

Bulk: 25 test / Box   Single: 1 test / Box

Sample Treatment

Rinse your mouth with water 30 minutes before sampling, and do not eat, smoke, drink alcohol or drinks after rinsing. Open sample collection kit pouch. Connect funnel to the sample collection tube. Gently spit saliva without bubble into the funnel until it reach to the lower line of the sample collection tube.(about 200μL). Make sure the collected saliva sample is free of impurities. Remove the funnel. Open reagent pouch. Remove the foil of the reagent tube and close it with the cap. Gently drop the reagent(about 200μL) into the sample collection tube until it reaches the upper line of the sample collection tube.

Close the sample collection tube with a cap. Squeeze the lower part of the sample collection tube and gently shake it 20 times. Place the sample collection tube in the hole marked on the package. Leave the sample collection tube for 5 minutes to make sure saliva is mixed well with the reagent(buffer solution).
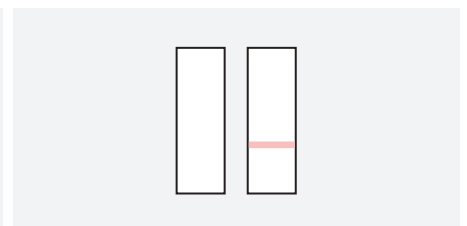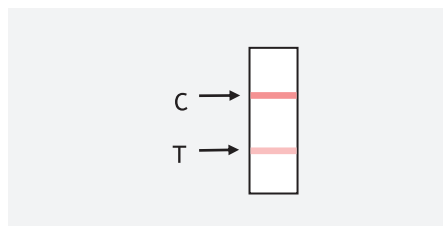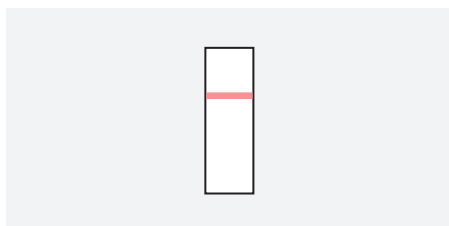
Test Procedure

Instructions must be read entirely before taking the test. Leave the reagent and sample at room temperature for 30 minutes before use. Return to room temperature. Do not open the inner packing until it is ready. Use it as soon as possible after opening the inner packing.

Open the tear hole of the aluminum foil bag, take out the test card and lay it flat. Apply 2-3 drops of the treated sample extract (60μl-80μl) vertically into the sample well of the test cassette.

The results are observed after 15 minutes and showed no clinical significance after 20 minutes.

1. Gently spit saliva (about 200μL)
2. Gently drop the reagent (about 200μL)
3. Close with the cap
4. Squeeze 20 times
5. Shake 20 times
6. Leave for 5 minutes

Interpretation of Results

Negative	Positive	Invalid
Control Region (C) → Presence of a red line Test Region (T) → Absence of a red line *Note that the negative result does not indicate the absence of analytes in the sample. It only means the level of tested analytes in the sample is below the cut-off level.	Control Region (C) → Presence of a red line Test Region (T) → Presence of a red line *Note that lines appear are distinct.	Control Region (C) → Absence of a red line Test Region (T) → Absence of a red line *Note that no colored line on control line indicates the operation error or reagent failure. Please verify the test procedure and repeat the test with a new testing device.

At 15 minutes

C

T

Do not interpret the result after 20 minutes.

Performance Characteristics

Clinical evaluation was performed to compare the results obtained by Gmate® COVID-19 Ag Saliva and PCR. The results are summarized below:

Table: Gmate® COVID-19 Ag vs. PCR

Gmate® COVID-19 Ag Saliva	PCR Results		Total
	Positive	Negative	
Positive	115	2	117
Negative	5	498	503
Total	120	500	620

Sensitivity: 95.83%   Specificity: 99.60%   Overall agreement: 98.87%

CE   IVD