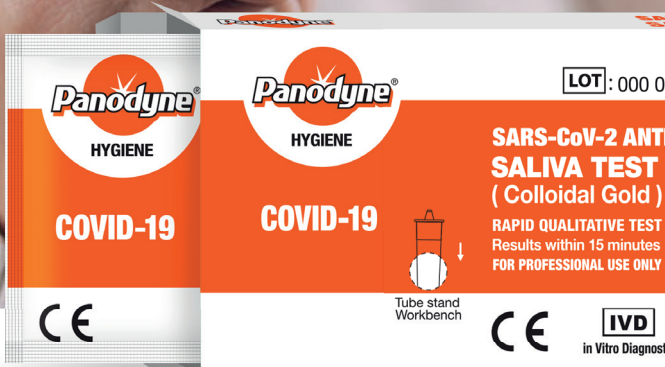




SARS-CoV-2 ANTIGEN SALIVA TEST KIT



For professional use only



SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold)

Our Panodyne Antigen Saliva Test Kit is a user-friendly and non-invasive rapid test kit that can be self-administered under supervision by trained staff, healthcare professional, company nurse or occupational health personnel. It's also more comfortable and easier to use for vulnerable people or those with a disability.



Panodyne[®]

HYGIENE

COVID-19

LOT: 000 0000 : 000 0000 : 2022-02-04

**SARS-CoV-2 ANTIGEN
SALIVA TEST KIT
(Colloidal Gold)**

RAPID QUALITATIVE TEST
Results within 15 minutes
FOR PROFESSIONAL USE ONLY

- Rapid testing for SARS-CoV-2 antigen
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- All necessary reagents provided. *Some temperature control may be required.*
- High sensitivity and specificity
- Easy to use and read.



in Vitro Diagnostic



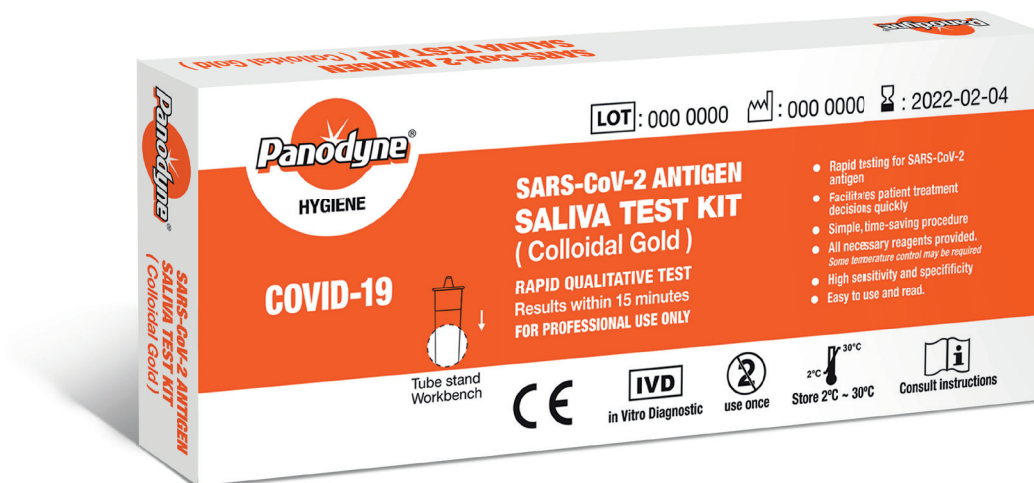
use once



Store 2°C - 30°C



Consult instructions



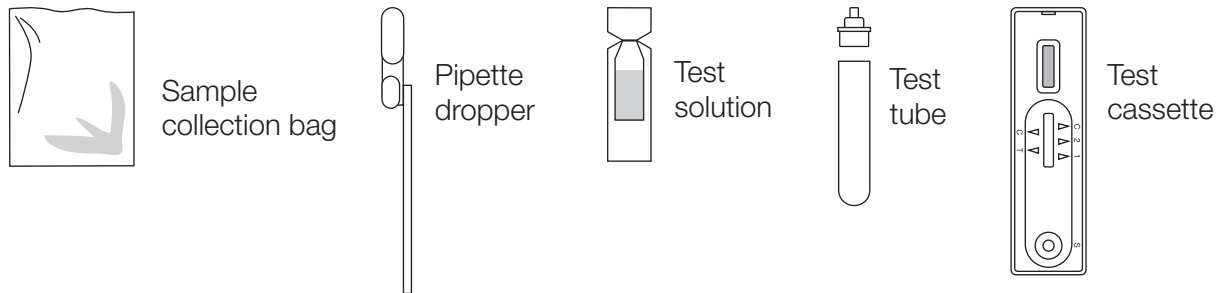
PRODUCT INFORMATION

Product Name	Panodyne SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold)
Pack Formats	1 Test/Outer of 24
Test Type	Antigen Test
Test Principle	Colloidal Gold Method
Sample Type	Saliva
Sample Volume	3 Drops of Extracted Solution (about 100µl) Each Well
Test Time	15 Mins
Storage Temperature	Room Temperature Or Refrigerated (2-30°C)
Shelf Life (Unopened)	24 Months

FEATURES

- Results ready in 15 minutes
- Non-invasive and user-friendly
- Can be self-administered
- Minimise discomfort, so easier for vulnerable and disabled people to use
- Cost-effective for regular testing in the workplace
- Quick and easy to read results
- All you need is in the pack

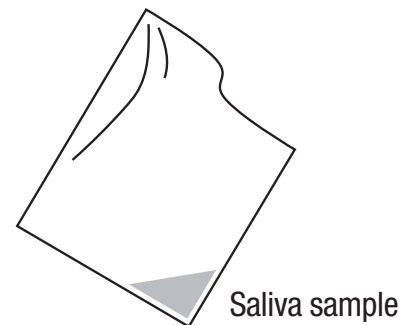
TEST KIT CONTENTS



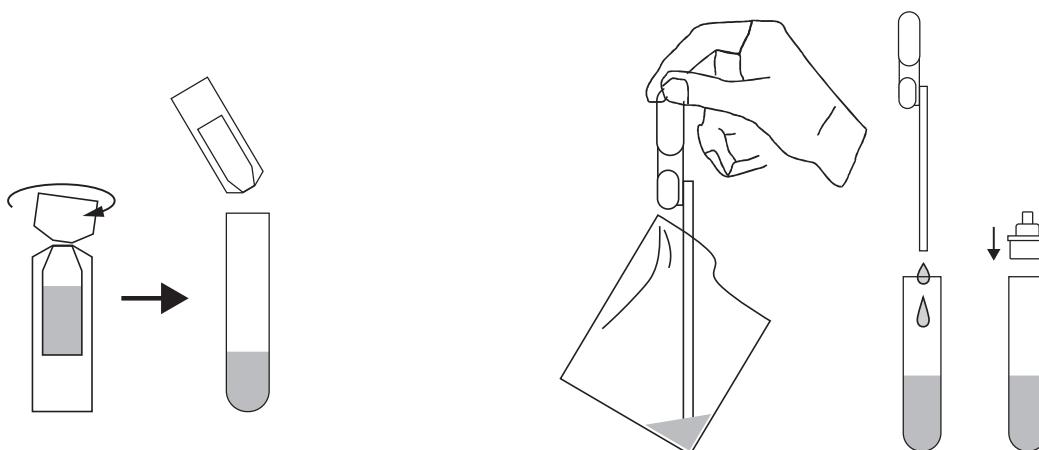
SAMPLE COLLECTION

The test subject/person must spit carefully a quantity of saliva (2ml) from deep in the throat into the sample bag provided. The purpose is to obtain a quantity of saliva and avoid spraying saliva carelessly as with sneeze. Avoid any saliva contamination of the outer surface of the container.

Optimal timing of specimen collection: after getting up and before brushing teeth, eating or drinking.

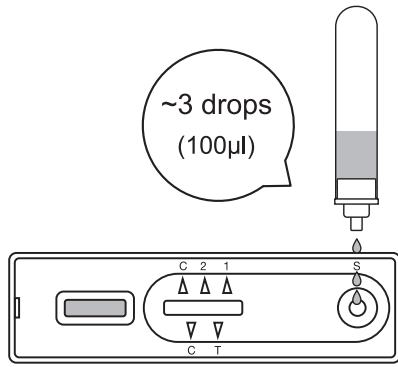


TEST PROCEDURE



Open the test solution bottle, which has a twist off top. Pour the solution into the test tube provided.

Use the pipette to take a sample of saliva and transfer this saliva sample to the test tube containing the test solution. Then place the test tube cap onto the test tube. Shake and mix completely.

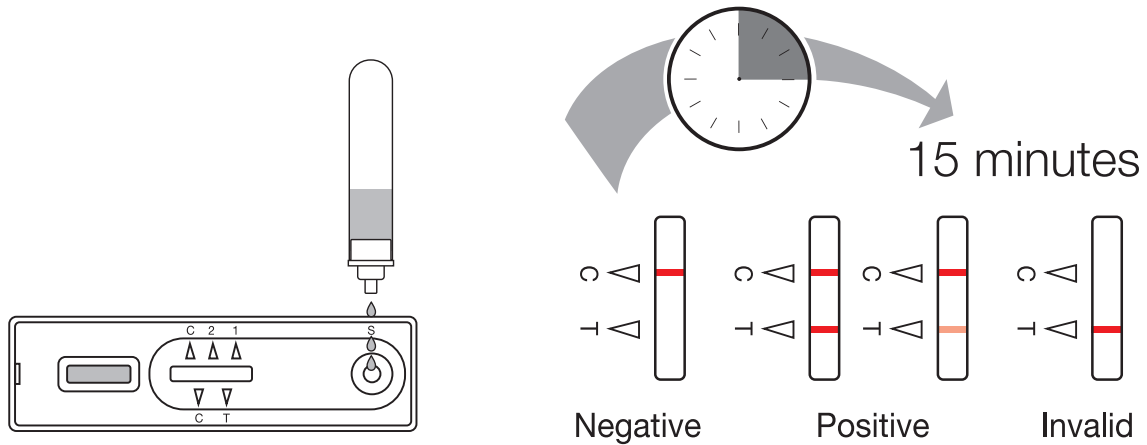


Carefully add 3 drops of the test sample liquid into the test cassette well marked “S”.

Wait for 15 minutes for the test result to develop in the cassette.

If left unread for 20 minutes or more the results are invalid and a repeat test is recommended.

INTERPRETATION OF RESULT



PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity: the COVID-19 Antigen Test Cassette was compared with a commercial PCR and the results show a high sensitivity and specificity.

Method		PCR		Total Results
		Positive	Negative	
COVID-19 Antigen Test Cassette	Results			
	Positive	54	0	0
	Negative	6	30	30
Total Result		60	30	30

Relative Sensitivity: 90.00% (95%CI: 79.49%~96.24%)

Relative Specificity: 100.00% (95%CI: 88.43%~100.00%)

Accuracy: 93.33% (95%CI: 86.05%~97.51%)

LIMITATIONS

1. This test detects both viable (live) and non-viable, SARS-CoV and COVID-19. Test performance depends on the amount of virus (antigen) in the sample and may or may not be correlated with viral culture results performed on the same sample.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. The performance of COVID-19 Antigen Test Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. False negative results may occur if a specimen is improperly collected, transported, or handled.
5. If the test is performed more than 1 hour after the specimen is collected, false results may occur. The specimen should be tested as soon as possible after specimen collection.
6. Positive test results do not rule out co-infections with other pathogens.
7. Positive test results do not differentiate between SARS-CoV and COVID-19.
8. Negative test results are not intended to rule out other non-SARS viral or bacterial infections.
9. Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.
10. If the differentiation of specific COVID-19 viruses and strains was needed, additional testing, in consultation with state or local public health departments is required.



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