



VivaDiag™
SARS-CoV-2 Antigen

NOT FOR AT-HOME TESTING!
FOR PROFESSIONAL USE ONLY!

Approved by **MOH & SIMKA**

SARS-CoV-2 Ag Rapid Test

VivaDiag™ SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab, oropharyngeal swab or nasopharyngeal swab specimen. The test is for in vitro diagnostic use only.

Specification

Test Principle	Colloidal gold
Sample Type	Nasal swab or throat swab or nasopharyngeal swab
Sample Volume	60µL
Test Time	15 min
Operation Temperature	15-30 C
Storage Temperature	2-30 C
Shelf Life (Unopened)	24 months

Packing

25pcs	Test kits
25pcs	Individual packed swabs
25pcs	Butter solution capsules
25pcs	Extraction tubes
25pcs	Nozzle

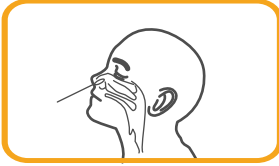
VivaDiag™ SARS-CoV-2 Ag Rapid Test	PCR		
	Positive	Negative	Total
Positive	147	0	147
Negative	7	431	438
Total	154	431	585
Sensitivity	95.45% (147/154, 95%CI, 90.92%-97.78%)		
Specificity	>99.99% (431/431, 95%CI, 99.12%-100.00%)		
Accuracy	98.80% (578/585, 95%CI, 97.55%-99.42%)		

The VivaDiag™ SARS-CoV-2 Ag Test for nasal swab specimens showed a clinical sensitivity of 95.45%.

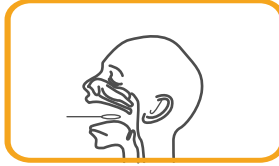
Steps for a Single Test

----Specimen Collection

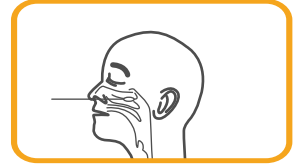
Nasal swab



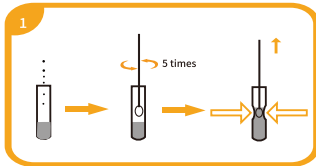
Oropharyngeal swab



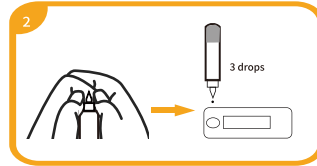
Nasopharyngeal swab



----Solution Preparation

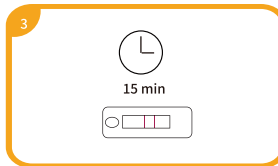


1. Prepare the specimen



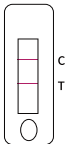
2. Apply the extracted specimen

----Detection



3. Read the test result

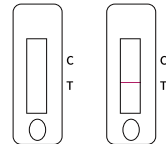
----Result Interpretation



Positive



Negative



Invalid