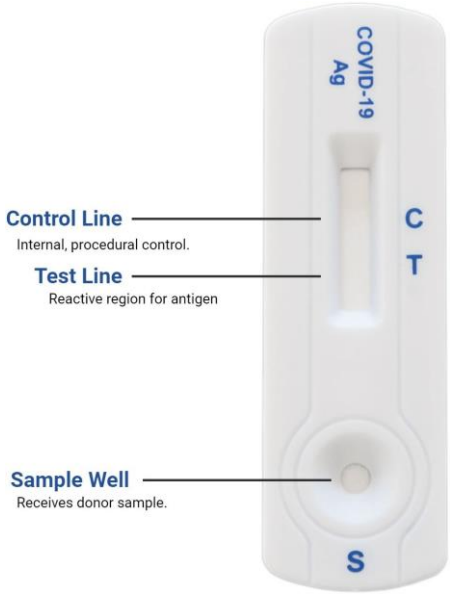
Rapid COVID-19 Antigen Test

The Rapid COVID-19 Antigen Test is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections.



Specifications

Information	Details
Time to result	15 minutes
Storage	2-30°C
Shelf life	24 months
Specimen type	Nasopharyngeal swab

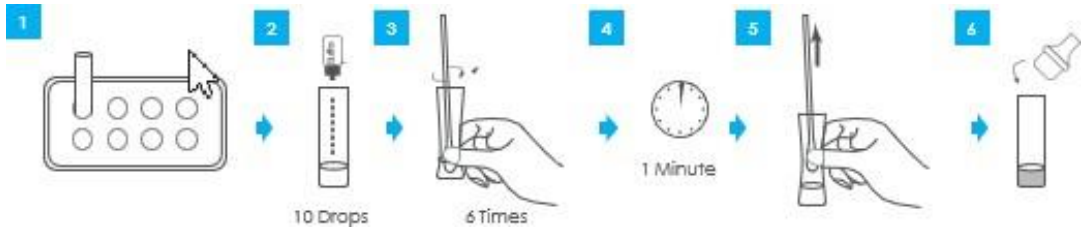
Benefits

- Rapid testing for SARS-CoV-2 antigen within 15 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

Rapid COVID-19 Antigen Test – Test Procedure

Specimen Collection

1. Use the nasopharyngeal swab supplied in the kit.
2. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion under visual inspection.
3. Swab over the surface of the posterior nasopharynx.
4. Rotate the swab several times. Withdraw the swab from the nasal cavity.



Sample Preparation

1. Allow the test device, test sample and buffer to equilibrate to room temperature prior to testing
2. Insert the test extraction tube into the workstation
3. Make sure that the tube is standing firm and reaches the bottom of the workstation
4. Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.
5. Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube. Leave the swab in the extraction tube for 1 minute.
6. Squeeze the tube several times with fingers from outside of the to immerse the swab
7. Fit the dropper tip with filter on top the extraction tube tightly
8. Remove the swab. The extracted solution will be used as test sample.

Rapid COVID-19 Antigen Test – Test Procedure

Testing Sample

1. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2. Ensure the nozzle with filter is fitted on to the sample extraction tube tightly.
3. Reverse the sample extraction tube and add 4 drops (about 100 µL) of test sample by squeezing the extracted solution tube into the sample window.
4. Wait for the colored band(s) to appear. The result should be read in 15 minutes.
5. Do not interpret the result after 20 minutes.

Results Analysis

POSITIVE

The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.

NEGATIVE

The presence of only control line (C) within the result window indicates a negative result.

INVALID

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

Rapid COVID-19 Antigen Test - Technical Specifications

Contents

All necessary items are provided & no extra equipment is needed

- 20 Test cassettes
- 20 Sterile swabs
- 20 Extraction tubes and dropper tip
- 1 Workstation
- 2 Buffers
- 1 Package insert
- 20 sealable poly bags

Performance Characteristics

- The Healgen Covid-19 Antigen Test (Swab) has been evaluated with specimens obtained from patients.
- The results show that the Healgen Covid-19 Antigen Test (Swab) has a high overall relative accuracy
- Relative Sensitivity: 96.72%
- Relative Specificity: 99.22%
- Accuracy: 98.74%

Regulatory/Certification

IVD CE notification p109656 Edmacode 1504 80 19(2020-03-11-medical device safety service)

International Organization for Standardization (ISO 13485:2016)

MHRA CTK Biotech branded COVID-19 IgG/IgM Rapid Test Device) product can be placed on the UK market for professional use

World Health Organisation CTK Biotech are currently recognised supplier by the WHO

Approved for use in the UK by the MHRA