Validated By:

CE

Department of Health & Social Care

QUADRATECH DIAGNOSTICS

HEALGEN®

HEALGEN CORONAVIRUS AG RAPID NASAL TEST

Distributed by:

Quadratech

Product Code:

GCCOV-502a

Size:

20 Tests

15 min

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Department of Health & Social Care

Federal Institute for Drugs and Medical Devices

MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ

Liberté
Égalité
Fraternité

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BENEFITS

TRUSTED

- Supplier to the NHS for 25+ years
- Validated by DHSC
- Evaluated in USA
- Registered with German Federal Institute for Drugs and Medical Devices (BfArM)

QUICK & COST EFFECTIVE

- Results in just 15 minutes
- All equipment provided
- Competitively priced

ACCURATE & RELIABLE

- Market leading accuracy vs PCR Testing in clinical trials:
  * *Relative Sensitivity:* ***97.25%***
  * *Relative Specificity:* ***99.60%***
  * *Accuracy:* ***98.73%***
- CE marked for professional use
- ISO 13485 certification

STABLE

- Storage conditions 2°C - 30°C
- Shelf life up to 24 months

PRODUCT MANUAL

INTENDED USE

The mö-screen Corona Antigen Cassette is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections.

TEST PRINCIPLE

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

The Coronavirus Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidalgold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device.

When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T).

Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

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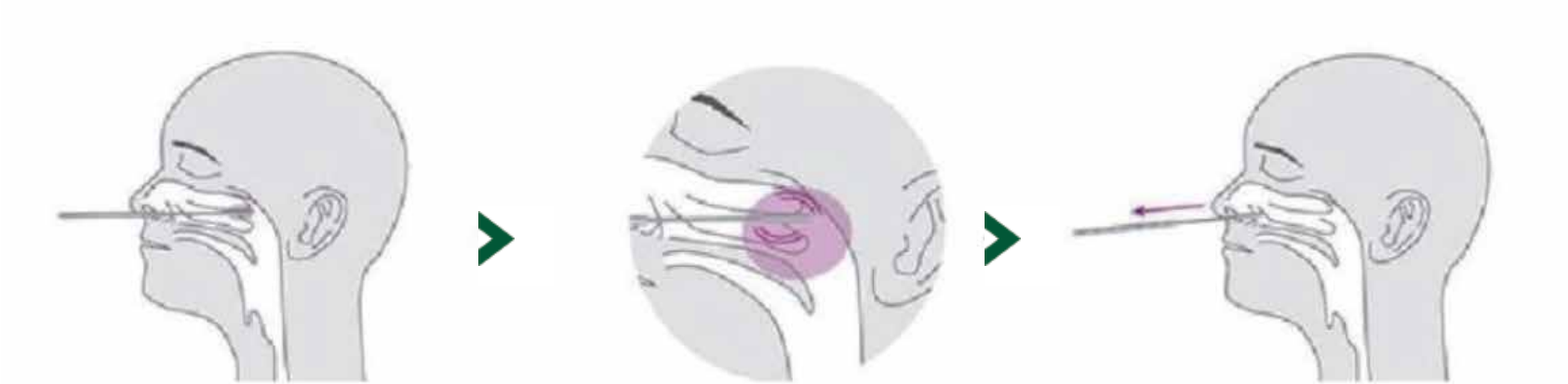
SPECIMEN COLLECTION

Use the sterile nasopharyngeal swab supplied in the kit.

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx, that presents the most secretion under visual inspection.

2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.

3. Withdraw the swab from the nasal cavity.

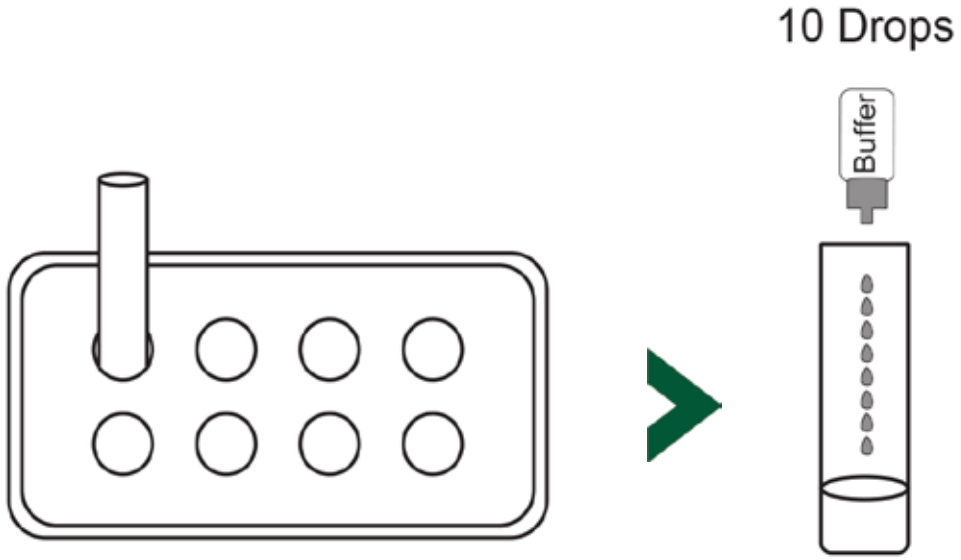


SAMPLE PREPARATION AND PROCEDURE

1. Insert the test extraction tube into the workstation. Make sure that the tube is standing firmly upright and reaches the bottom of the workstation.

2. Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.

3. Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer.



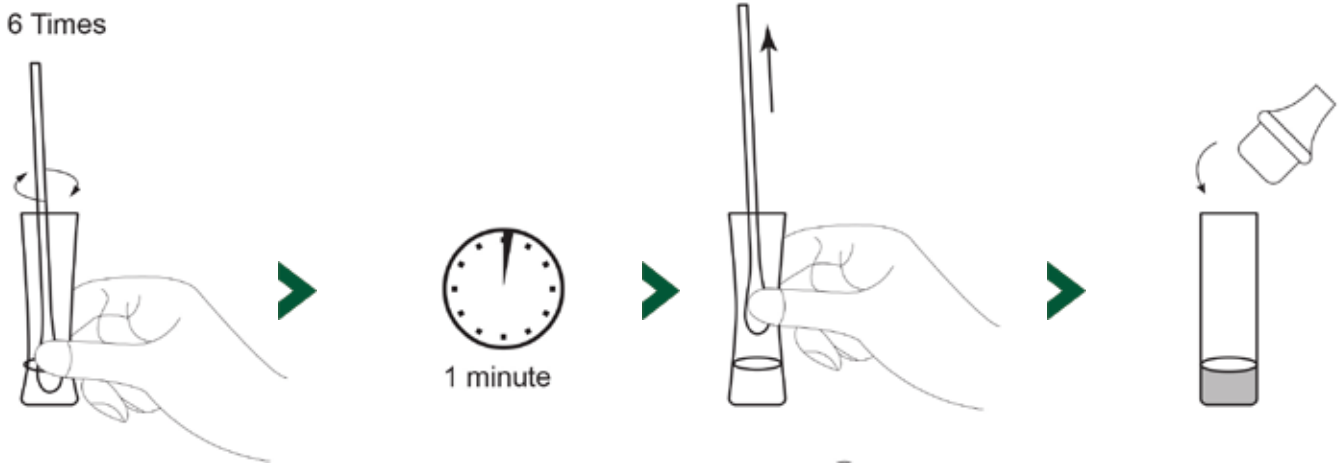
Continued...

SAMPLE PREPARATION AND PROCEDURE

4. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.

5. Leave the swab in the extraction tube for 1 minute.

6. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. Insert a nozzle with filter into the sample extraction tube tightly. The extracted solution will be used as test sample.



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TEST PROCEDURE

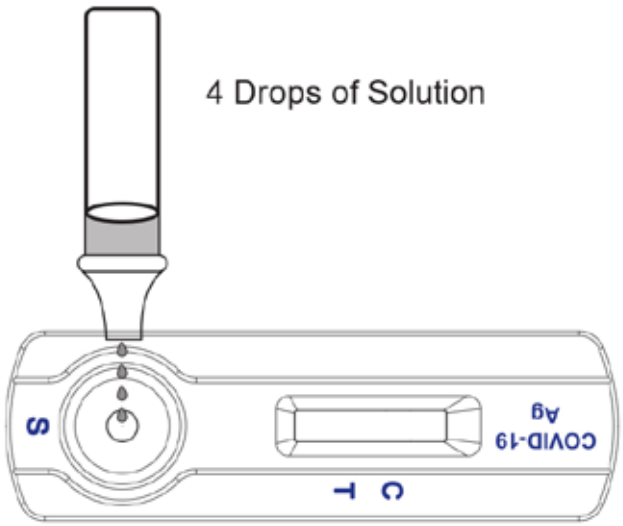
Allow the test device, test sample and buffer to equilibrate to room temperature (15 - 30°C) prior to testing.

1. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.

2. Ensure that the nozzle with filter is inserted into the sample extraction tube tightly.

3. Hold the sample extraction tube vertically and add 4 drops (approx. 100 µL) of test sample by squeezing the extracted solution tube into the sample well.

4. Start your timer. Wait for the colored band(s) to appear. The result should be read at 15 minutes. **Do not interpret the result after 20 minutes.**



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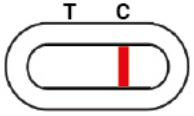
INTERPRETATION OF RESULTS

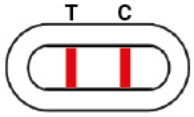
The result should be read at 15 minutes. **Do not interpret the result after 20 minutes.**



NEGATIVE

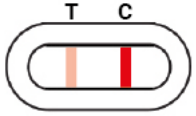
A coloured line appears in control area C.

No coloured line appears in test area T.

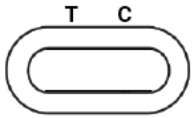


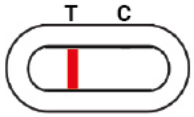
POSITIVE

Two coloured lines appear, one in control area C and one in test area T.



The intensity of the test line T may vary depending on the concentration of the antigen in the sample. Any sign of a line should be considered a positive result.





INVALID

In the control area C, a red line must always appear when the test is performed. If this line does not appear, the test is invalid in any case. Please repeat the test with a new test cassette.

CERTIFICATION AUTHORITY

CE MARKED FOR PROFESSIONAL USE

As per Directive 98/79/EC Of the European Parliament an of the council of 27 October 1998 on in-vitro Diagnostika.

Federal Institute for Drugs and Medical Devices

GERMAN GOVERNMENT REGISTRATION

Registered with German equivalent of MHRA: Federal Institute for Drugs and Medical Devices (BfArM).

ISO MANUFACTURING QUALITY MANAGEMENT

MöLab manufacture in accordance to their ISO13485 Quality Management accreditation.

Department of Health & Social Care

UK GOVERNMENT VALIDATION

Independent evaluation performed by DHSC and PHE at Porton Down has approved tests for use in community settings.

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CONTACT US

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