Central Health
Solutions Ltd

Central Health Solutions Ltd (CHS) and City of Stoke-on-Trent Council Covid-19 Lateral Flow Testing Service

Service Specification 2020/21

Locally Commissioned Community Pharmacy Service

Lateral Flow Testing (LFT) is a new kind of technology that could enable us to identify and isolate more asymptomatic people who are at high likelihood of spreading coronavirus, whilst simultaneously minimising disruption for those who test negative.

The device detects a protein (antigen) produced by the virus at its most infectious stage, i.e. those with a high viral load.

The test is complete in 30 minutes, and so gives real time results. There is no time lag between testing and receiving results to aid more prompt measures to reduce the risk of transmission in positive cases and to reassure those who test negative.

The test is for the asymptomatic population, i.e. those without symptoms of Covid-19, but who may carry the virus and be able to infect others without their knowledge. Therefore, the aim of this test is to identify background cases in the population that otherwise would remain a potential risk of transmission.

If the result of the LFD is positive, the person will be asked to self-isolate for 10 days in line with normal NHS Test & Trace procedures.

It should be noted that a negative result does not rule out Covid-19 infection and there can be false negative results. If negative and it is clinically indicated, a repeat test should be undertaken using PCR to detect presence of the virus.

The use of lateral flow tests could significantly improve the detection of positive cases so that people can isolate and prevent the spread of Covid-19. Asymptomatic testing will help to protect people at high risk, find the virus and help us to back to as normal a life as possible.

This Service Specification may be reviewed if new guidance becomes available.

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1. Service Description

1.1. The agreement is for the pharmacy to provide lateral flow tests, where appropriate, to Stoke-on-Trent residents. Lateral Flow Antigen testing involves the processing of human nasal swabs, throat swabs, or sputum samples with a Lateral Flow device. The device detects a protein (antigen) produced by the virus at its most infectious stage. The test cartridge and extraction solution should be stored at ambient temperature (2-30 degrees Centigrade). The reagents and devices must be at room temperature (15-30 degrees centigrade) when used for testing.

1.2. The manufacturer's instructions for use can be found here: **Innova SARS-Cov-2 Antigen Test IFU** or as Appendix C.

1.3. Stoke-on-Trent residents will book an appointment at a participating pharmacy through the CHS website. CHS will provide access to the booking system to each individual pharmacy who will then be able to control days, times and frequency of appointments.

1.4. Testing must be be conducted on a flat surface with adequate light.

1.5. The pharmacy will record the test barcode and result on the Government Test and Trace website.

1.6. Data for each test will also be recorded on Pharmoutcomes (service: Covid-19 Testing).

1.7. Invoices will be generated and pharmacies paid monthly, by the end of the following month.

2. Duration

2.1. This agreement is for the period 8th February 2021 until 31st March 2021. It will then be reviewed.

3. Selection Criteria

3.1. The City of Stoke-on-Trent Council Covid-19 LTF service will cover the whole of Stoke-on-Trent to offer access to testing, concentrating on wards with higher infection rates.

3.2. The names and addresses of participating pharmacies will be sent to City of Stoke-on-Trent Council commissioners to promote to residents. The list plus pharmacy appointment times will also be available on a dedicated page on the CHS website.

3.3. Pharmacies will be selected to create a reasonable distribution across the Stoke-on-Trent geography, with some extended hours and weekend provision where possible.

4. Premises

4.1. In order to provide the service, pharmacies must have a consultation room or area. There must be consideration taken on the need for privacy for participants to self-administer a test.

4.2. All premises must meet all relevant legislative, certification and validation inspections and requirements including health & safety. They must be: accessible, clean, secure, suitable for the purpose for which they are being used, properly used, social distancing measures in place, properly maintained, and appropriately located for the purpose for which they are being used.

4.3. Pharmacy staff observing the test and recording results will need to wear the recommended personal protective equipment that is in line with the current advice from the government: www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe

4.4. Participating pharmacies will be identified as 'testing sites' on the national system, therefore staff will not need to isolate should a participant's test reveal a positive result.

5. The Service

5.1. Stoke-on-Trent residents will go onto the CHS website, choose a participating pharmacy of their choice and book an appointment.

5.2. The pharmacy will get an email with patient details and will also see these details on their own calendar through a system called Schedulista (https://www.schedulista.com/).

5.3. The participant will attend their appointment and be shown, by a trained pharmacy staff member, how to conduct the test. The participant will take the test themselves with the pharmacy staff member observing. Once the test has been completed the participant may leave the pharmacy.

5.4. Results will be shown on the test after 20-30 minutes. Pharmacy staff will scan the barcode of the test on to the Government site (see section 9) along with results of the test - positive, negative or void.

5.5. Pharmacy staff do not need to inform participants of their results, this will be done through the national Test and Treat system.

5.6. Pharmacy staff will also enter the participant's details and test results onto Pharmoutcomes in a timely manner and on the same day of the completed test.

5.7. By signing this Agreement the provider consents for their participation in the service to be shared with other providers e.g. Stoke-on-Trent Council, CHS, and other pharmacies to ensure maximum publicity within the geography.

6. Accessibility

6.1. The pharmacy contractor will inform CHS of the days and times they are able to offer this service (see appendix A), and these will be uploaded on to the CHS website.

6.2. If due to unforeseen circumstances the pharmacy is unable to provide the service, the pharmacy should either

- signpost the participant to another pharmacy who are able to provide the test. The pharmacy should ensure that the pharmacy to which the participant is being signposted is able to provide the service by phoning the pharmacy to check before the participant leaves the pharmacy, or
- arrange with the member of staff a convenient time for the participant to return to be tested

6.3. The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible participant shall be excluded or experience particular difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

7. Eligibility

7.1. The participant will be asymptomatic

7.2. The participant will consent to participation in the service (tick the consent box on Pharmacoutcomes)

7.3. The participant will consent to sharing their data with the National T & T programme

7.4. The participant will be 11 years or older

7.5. The participant will be a resident of Stoke-on-Trent city, work or study in Stoke-on-Trent or have a Stoke-on-Trent GP

7.6. The participant must wear a face covering, only removing it to take the test

8. Self swabbing sample collection procedure

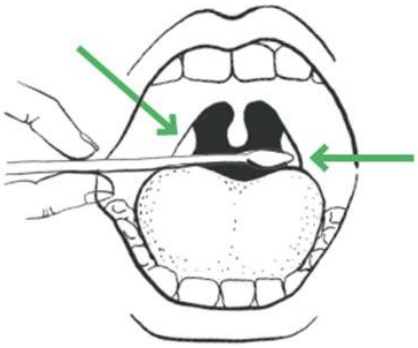
8.1. Participants will be given a sealed sterile swab

8.2. Before commencing swabbing, pharmacy staff will explain the process to the participant. The participant will also be informed that the swab may make them gag

8.3. The barcode should be placed on to the registration card and on back of the test cartridge by the pharmacy staff. The participant will then be required to remove their mask and complete hand hygiene

8.4. The participant will be required to open their mouth and visually identify

the left and right tonsils (or tonsillar pits for subjects with the previous tonsillectomy)



8.5. The participant should complete hand hygiene using alcohol based hand rub

8.6. The swab should be removed from sterile packaging by the participant. The swab must be kept dry before taking a sample from the back of the throat and therefore it must not touch any surfaces including the teeth, gums, and tongue or cheek surfaces when conducting the test.

8.7. Holding the swab in their hand, the participant should open their mouth wide, and rub the fabric tip of the swab over both tonsils (or where they would have been) at the back of the throat with good contact at least 3 times. The participant should carefully remove the swab stick from the back of their throat taking care to ensure that it does not come into contact with any other structure or surface.

8.8. The participant should then insert the same swab into one nostril. The swab tip should be inserted up to 2.5cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa of the inside of the nostril to ensure that both mucus and cells are collected.

8.9. The participant will be required to place their swab directly into the prepared extraction tube with the cotton bud end facing down. The participant will not grasp the cotton bud end, which has been in contact with the tonsils and nostril.

8.10. The participant will complete hand hygiene using alcohol based hand rub.

8.11. The participant will put back on their face covering and leave the pharmacy.

In the event that a subject vomits, testing should cease and spillage guidelines followed until the area has been cleaned adequately to allow resumption.

See Appendix B for patient information leaflet.

9. Recording of results

Results logging using website

Each pharmacy will have a site code which will be provided by CHS. Staff members providing the service will need to set themselves up as a tester, following these instructions:

9.1. Go to http://log-coronavirus-test-site-results.service.gov.uk/

9.2. Click 'I am a testing operative'

9.3. Sign up to an account

9.4. Username - add name with no spaces

9.5. Name - add full name of staff member

9.6. Password - choose a password

Once these steps have been completed CHS will approve, you will then be able to access the site and record results:

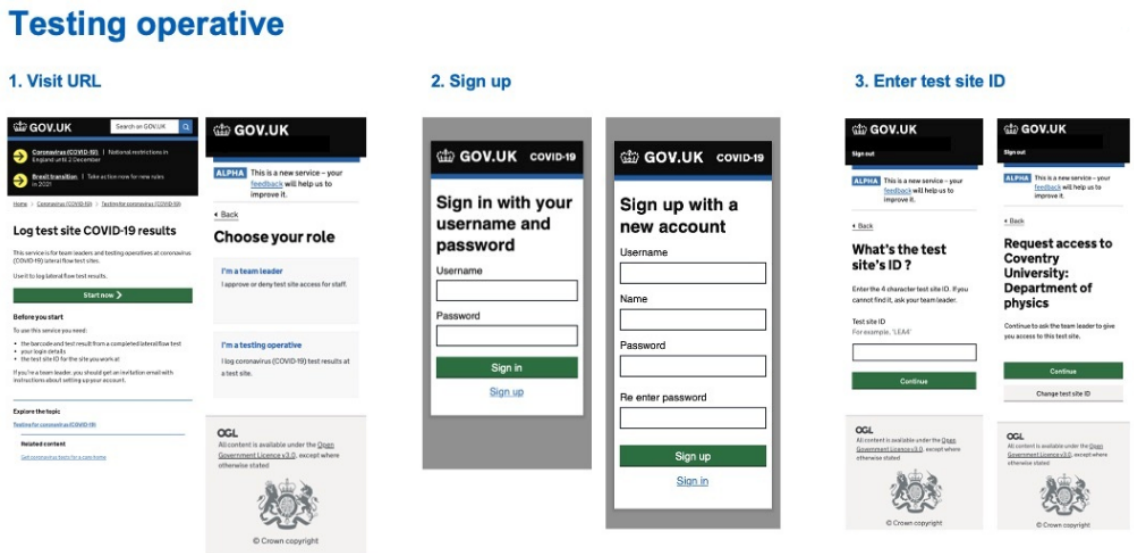
9.7. Sign in to http://log-coronavirus-test-site-results.service.gov.uk/

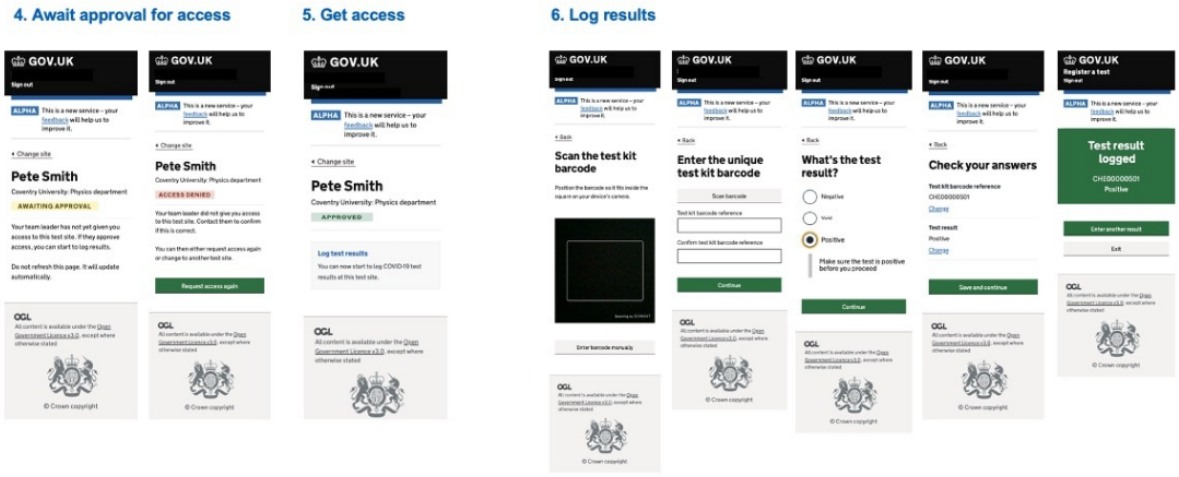
9.8. Scan the LFD barcode as per digital results recording process (Figure 4) and digitally record the result

9.9. The area where the device was situated and equipment (i.e. pen, tray, etc.) are then cleaned after each batch anti-viral wipes

9.10. Once result has been logged, the device and consumables are disposed of as per the requirements outlined in the waste management section (12.3).

Figure 1. Website Digital solution that records and captures results





Data Management:

The results are uploaded as linked to the barcode. Hence, there is no visibility or access to linking the results with the participant's identity.

Negative results

Participants who return a negative test result do not need to self-isolate (unless they are symptomatic, a contact of a positive case or otherwise indicated).

Invalid results

Participants who return an invalid/void LFT result should be retested once by LFT.

If the LFT result is invalid a second time, they should be retested with a PCR test.

If operationally more feasible it is acceptable to retest with a PCR test after the first invalid result. Participants should be directed to go to www.gov.uk/get-coronavirus-test and choose 'home testing' (do not choose a test site).

Positive results

Participants who return a positive LFT result should follow the instructions provided. They do not require a further test, and should self-isolate as government guidelines.

Contact tracing will be initiated. Until the participants gets further advice they must self-isolate immediately for 10 days and everyone in their household must self-isolate for 14 days.

10. Payment

10.1. CHS will pay a fee of £150 one off fee to each participating pharmacy.

10.2. CHS will pay a fee of £10.00 per test completed. All tests will be supplied free of charge to the pharmacy.

10.3. Payments will be made based on the information recorded on Pharmoutcomes. CHS will automatically generate a monthly payment based on total tests completed at each pharmacy, and send the remittance to participating pharmacies at the end of the following month.

10.4. Details of the testing service should be added to Pharmoutcomes within 48 hours of the completed test. Claims submitted which relate to tests over 2 months old will not be paid.

10.5. Payment will be made to participating pharmacies by CHS on a monthly basis.

11. Training

11.1. Pharmacy staff carrying out this service must access training. The link below is to the training video recommended by PHE for this test with accreditation questions provided.
All those to be involved in the test process must first undertake the training and pass the accreditation process. Clinical support is available through this process and thereafter for all trained testers.
Link: https://go.tessello.co.uk/TestDeviceTraining/Login.aspx
Access token: 3wkcVi4UTX

11.2. Pharmacy staff should also watch the COVID-19: Donning and doffing of Personal Protective Equipment in Health and Social Care Settings video

11.3. Pharmacy staff will be provided with face-to-face practical training in the pharmacy.

12. Duty of pharmacy contractors

12.1. The pharmacy contractor must have a standard operating procedure in place, which includes procedures for Infection Prevention and Control.

12.2. The pharmacy contractor must ensure that pharmacy staff providing the service are competent to do so.

12.3. The pharmacy contractor must ensure that staff are appropriately trained and made aware of the risks associated with the handling and disposal of waste and that correct procedures are used to minimise those risks.

12.4. The pharmacy contractor is required to make arrangements for the removal and safe disposal of any waste related to the provision of this service.

12.5. The pharmacy should maintain appropriate records to ensure effective ongoing service delivery and audit.

13. Governance

13.1. The pharmacy will effectively manage any complaints using the pharmacy own internal complaints procedures which must be consistent with the NHS' and Local Authority Social Services and National Health Service Complaints (England) Regulations.

13.2. The pharmacy will manage any incidents in line with the requirements of the NHS Contractual Framework for community pharmacy.

Appendix A

Participating Pharmacies

ODS Code	Pharmacy Address	Pharmacy Post Code	Days and Times service offered

Signed by ……

Print Name ……

for and on behalf of

Provider (Pharmacy) ……

Signed by ……

Print Name ……

for and on behalf of **CENTRAL HEALTH SOLUTIONS LTD**

HM Government

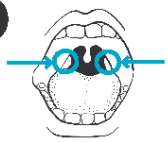
Take swab sample

Step-by-step guide

Need help?

If you have any questions or problems with this test kit, please alert a member of staff.

1



Remove your face covering.

Look inside your mouth, and find your tonsils at the back of the throat.

You can use the mirror to help.

Your tonsils or where they would have been (if they are removed) are where you will swab your sample.

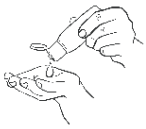
2

Gently blow your nose into a tissue

Throw the used tissue into the clinical waste bin provided.

This is so that you get rid of excess mucus.

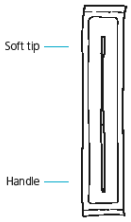
3



Use hand sanitiser to clean your hands.

This is so that you do not contaminate the test kit.

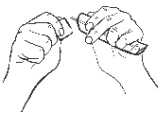
4



Check if there is a swab in a sealed pack in front of you.

Identify the soft, fabric tip of the swab.

5



Open the package and gently take out the swab.

This will be used for both throat and nose.

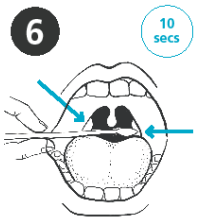
Do not touch your tongue, teeth, cheeks, gums, or any other surfaces with the fabric tip of the swab.

The swab is invalid if it touches these parts, and you will need to get a new swab. If this happens ask a member of staff to get assistance.

The swabbing may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

If there is blood or vomit on the swab sample, please alert a member of staff.

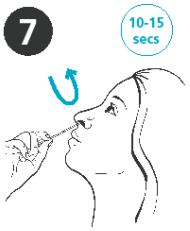
6



Holding the swab in your hand, open your mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been) at the back of the throat with good contact **at least 3 times** (use a mirror to help you do this).

Carefully remove the swab stick from the back of your throat.

7



Put the same end of the same swab gently into one nostril until you feel a slight resistance (about 2.5cm or 1 inch up your nose).

Roll the **swab 5 times** along the the inside of the nostril.

After collecting the sample hold the swab upright in your hand, do not put it down and notify one of the Testing assistants.

Be careful not to touch any surfaces with the swab.

Put on your face covering.

Follow the instructions from a member of staff on what to do next.

Use hand sanitiser after handing in your sample.

TC

Appendix C

SARS-CoV-2 Antigen Rapid Qualitative Test

Instructions for Use

For prescription only

For in vitro diagnostic use only

Please read these instructions completely before beginning testing of specimens.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Qualitative Test is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal swabs or throat swabs 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 upper respiratory samples or lower respiratory 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. The agent detected may not be the definite cause of disease.

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 in 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.

The SARS-CoV-2 Antigen Rapid Qualitative Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures, and proper infection control procedures and individuals similarly trained in point of care settings.

SUMMARY

SARS-CoV-2 belongs to the broad family of viruses known as coronaviruses. It is a positive-sense single-stranded RNA (+ssRNA) virus. Other coronaviruses are capable of causing illnesses ranging from the common cold to more severe diseases such as Middle East respiratory syndrome(MERS). It is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and the original SARS-CoV. Protein modeling experiments on the spike (S) protein of the virus suggest that it has sufficient affinity to the angiotensin converting enzyme 2 (ACE2) receptors of human cells to use them as a mechanism of cell entry. Studies have shown that SARS-CoV-2 has a higher affinity to human ACE2 than the original SARS virus strain.

SARS-CoV-2 infections cause COVID-19 disease. People who have confirmed COVID-19 have a range of symptoms, from people with little to no symptoms to people being severely sick and dying. Symptoms can include: fever, tiredness, and dry cough.. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention.

Human-to-human transmission of the virus has been confirmed and occurs primarily via respiratory droplets from coughs and sneezes within a range of about 6 feet (1.8m). Viral RNA has also been found in stool specimens from infected patients. It is possible that the virus can be infectious even during the incubation period, but this has not been proven, and the WHO stated on 1 February 2020 that "transmission from asymptomatic cases is likely not a major driver of transmission" at this time.

The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection.3 The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, shortness of breath.

PRINCIPLES OF THE PROCEDURE

This reagent is based on colloidal gold immunochromatography assay.

During the test, specimen extracts are applied to the test cartridges. If there were SARS-CoV-2 antigen in the extract, the antigen will bind to the SARS-CoV-2 monoclonal antibody. During lateral flow, the complex will move along the nitrocellulose membrane toward the end of the absorbent paper. When passing the test line (line T, coated with another SARS-CoV-2 monoclonal antibody) the complex is captured by SARS-CoV-2 antibody on test line resulting in coloring on line T; when passing the line C, colloidal gold-labeled goat anti-rabbit IgG is captured by control line (line C, coated with rabbit IgG) resulting in coloring on line C.

REAGENTS

The following components are included in the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 kit

Materials Provided:

25-Test Kit:

1. SARS-CoV-2 Antigen Test Cartridge (25): Monoclonal anti-SARS antibodies

2.Extraction Tubes (25)

3.Extraction solution: 2 bottles/kit (enough for 25 test)

4.Instructions for use 1 copy/kit

5.QC Card (located on kit box)

Optional Materials:

1.Throat Swabs (25)

2.Nasal Swabs (25)

Materials Required but not provided:

1. Timer

2 Tube rack for specimens

3.Any necessary personal protective equipment

4.External control set (including 1negative controls and 1 positive controls).

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.

2. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

3. Do not use this kit beyond the expiration date printed on the outside carton.

4. Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.

5. Test results are meant to be visually determined.

6. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.

7. Do not reuse any kit components.

8. When collecting a nasal swab sample, use the nasal swab supplied in the kit. Use of alternative swabs may result in false negative results.

9. Proper specimen collection, storage and transport are critical to the performance of this test.

10. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.

11. The SARS-CoV-2 external positive control have been prepared from recombinant viral proteins and do not contain infectious material.

12. Dispose of used test kits as biohazardous waste in accordance with federal, state and local requirements.

13. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at bd.com.

14. Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.

STORAGE CONDITIONS & PERIOD OF VALIDITY

1. Store extraction solution at 2-30℃, the shelf life is 24 months tentatively.

2. Store the test cartridge at 2-30℃, the shelf life is 24months tentatively.

3.Test Cartridge should be used right after opening the pouch.

Reagents and devices must be at room temperature (15–30 °C) when used for testing.

SPECIMEN COLLECTION AND HANDING

Specimen Collection and Preparation

Throat Swab Specimen Collection:

Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with moderate force back and forth for at least 3 times.

Nasal Swab Specimen Collection:

1.Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril.

2.Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected

3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.

① ② ③

Specimen Transport and Storage:

Samples should be tested as soon as possible after collection. Based on data generated with influenza virus, throat swabs are stable for up to 24-hours at room temperature or 2° to 8°C.

TEST METHODS

The test should be operated at room temperature（15-30℃）.

1. Place the extraction tube with opening facing up. Press the extraction solution bottle to drip 6 drops of extract solution into the extractor tube without touching the edge of the tube.

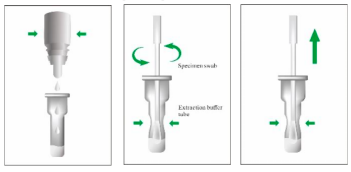
2. The extraction of specimen: Put the swab had collected specimen into the extraction tube, hold and press the swab head against the wall of tube with force while rotating the swab for about 10 seconds to release the antigen into the extraction solution from the swab head.

3. Removing swab: Squeeze the swab head while removing the swab in order to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal regulations.

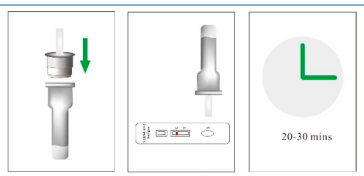
4. Install the nozzle cap onto the extraction tube.

5. Loading: drip 2 drops of extraction solution into the sample well of the test cartridge, and start the timer.

6. Read the results at 20–30 minutes. Strong positive results can be reported at 20 minutes, however, negative results must be reported after 30 minutes. If positive signal appears after 30 minutes, it should not be reported as positive.



Drip extract solution Extraction Removing swab



Install the nozzle Loading Reading

INTERPRETATION OF TEST RESULTS

Line C must be colored to have a valid test result.

Valid results:

Negative result: There is coloration on line C only showing as following picture, suggesting that there is no SARS-CoV-2 antigen in the specimen.

Positive result: There are coloration on both line C and line T showing as follow pictures, suggesting that there is SARS-CoV-2 antigen in the specimen.

Invalid result: There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.

Negative Positive Invalid

REPORTING OF RESULTS

Positive Test:

Positive for the presence of SARS-CoV-2 antigen. 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative Test :

Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management Control.

Invalid:

Do not report results. Repeat the test.

QUALITY CONTROL

The SARS CoV-2 Antigen Control Set (catalog number: 1339) is available to purchase separately from Xiamen Biotime Biotechnology Co., Ltd as external controls. The control set can be ordered through website (www.biotime.cn), telephone (+86-592-6883156) and email (baotai@biotime.cn). One negative and one positive control are included in the control set. Returning expected test results for each control in the control set indicates appropriate performance of SARS-CoV-2 Antigen Rapid Qualitative Test. If any control of the control set fail to provide the expected result, reasons that have led to failure including the test kit, the operator, the environment, the test procedure and any other causes which may affect the test result should be analyzed and corrective action taken. Clinical specimens can be run in the Biotime SARS-CoV-2 Antigen Rapid Qualitative Test. If all the control set results observed are the expected results. Please refer to the Instructions For Use of Biotime SARS-CoV-2 Antigen Control Set for expected test results as well as other information. It is recommended that the controls are tested when:

A. A new operator uses the kit;

B. A new lot of test kits is used;

C. A new shipment of kits is used;

D. The temperature used during storage of the kit falls outside of the recommended conditions;

E. The temperature of the test area falls outside of 15-30°C;

F. To verify a higher than expected frequency of positive or negative results;

G. To investigate the cause of repeated invalid results; or

H. A new test environment is used (e.g., natural light vs. artificial light).

I. As required by external quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

NOTE: Prepare kit control swabs and test using the same procedure as used for patient specimens. Failure of the external/procedural controls will generate an invalid test result.

If the kit controls do not perform as expected, do not report patient results. Contact Xiamen Biotime Biotechnology Co., Ltd Technical Services at (+86-592-6883577) and email (baotai@biotime.cn).

LIMITATIONS OF THE PROCEDURE

1.Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.

2.Users should test specimens as quickly as possible after specimen collection.

3.Positive test results do not rule out co-infections with other pathogens.

4.Results from SARS-CoV-2 Antigen Rapid Qualitative Test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

5.A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.

6.The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.

16	Haemophilus influenzae	2.0 x 10^6 TCID50/mL	NO
17	Streptococcus pneumoniae	2.0 x 10^6 TCID50/mL	NO
18	Streptococcus pyogenes	2.0 x 10^6 TCID50/mL	NO
19	Candida albicans	2.0 x 10^6 TCID50/mL	NO
20	Pooled human nasal wash – representative of normal respiratory microbial flora	2.0 x 10^6 TCID50/mL	NO
21	Bordetella pertussis	2.0 x 10^6 TCID50/mL	NO
22	Mycoplasma pneumoniae	2.0 x 10^6 TCID50/mL	NO
23	Chlamydia pneumoniae	2.0 x 10^6 TCID50/mL	NO
24	Legionella pneumophila	2.0 x 10^6 TCID50/mL	NO
25	Mycobacterium tuberculosis	2.0 x 10^6 TCID50/mL	NO
26	Pneumocystis jirovecii (PJP)	2.0 x 10^6 TCID50/mL	NO

Human nasal swab specimen matrix

The microbial interference studies for the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 was established using limiting dilutions of heat-inactivated SARS-CoV-2 (bei Resources NR-52286).

The material was supplied frozen at a concentration of TCID50 of 3.40 x10^5 per mL. the starting material was spiked into a volume of pooled nasal swab specimen (the most challenging respiratory matrix) obtained from healthy donors and confirmed negative for SARS-CoV-2. Based on the LOD studies, a low (3x LoD) SARS-CoV-2 concentration of 1.02x 10^3 TCID50/mL was chosen. The specimen was confirmed positive for SARS-CoV-2 with faintly line on Line T. Furthermore, the above-mentioned specimen was divided into 30.Finally, the microorganism indicated below was respectively spiked into the divided specimen to obtain microbial interference specimens that SARS-CoV-2 is present in a specimen with one microorganism.

Each microbial interference specimen was tested individually. At each test, 50 µL samples were added to swab. The results shows that the specimen was confirmed positive for SARS-CoV-2 with faintly line on Line T. Based on the study, no appreciable interference was observed for the following substances at the spiked levels indicated below in nasal swab specimen matrix.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^5 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^5 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^5 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^5 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^5 TCID50/mL	NO
6	Human coronavirus HKU1	2.0 x 10^5 TCID50/mL	NO
7	Adenovirus C1	2.0 x 10^5 TCID50/mL	NO
8	Adenovirus 71	2.0 x 10^5 TCID50/mL	NO
9	Human Metapneumovirus (hMPV)	2.0 x 10^5 TCID50/mL	NO
10	Parainfluenza virus 1-4	2.0 x 10^5 TCID50/mL	NO
11	Influenza A	2.0 x 10^5 TCID50/mL	NO
12	Influenza B	2.0 x 10^5 TCID50/mL	NO
13	Enterovirus	2.0 x 10^5 TCID50/mL	NO
14	Respiratory syncytial virus	2.0 x 10^5 TCID50/mL	NO
15	Rhinovirus	2.0 x 10^5 TCID50/mL	NO
16	Haemophilus influenzae	2.0 x 10^6 TCID50/mL	NO
17	Streptococcus pneumoniae	2.0 x 10^6 TCID50/mL	NO
18	Streptococcus pyogenes	2.0 x 10^6 TCID50/mL	NO
19	Candida albicans	2.0 x 10^6 TCID50/mL	NO
20	Pooled human nasal wash – representative of normal respiratory microbial flora	2.0 x 10^6 TCID50/mL	NO
21	Bordetella pertussis	2.0 x 10^6 TCID50/mL	NO
22	Mycoplasma pneumoniae	2.0 x 10^6 TCID50/mL	NO
23	Chlamydia pneumoniae	2.0 x 10^6 TCID50/mL	NO
24	Legionella pneumophila	2.0 x 10^6 TCID50/mL	NO
25	Mycobacterium tuberculosis	2.0 x 10^6 TCID50/mL	NO
26	Pneumocystis jirovecii (PJP)	2.0 x 10^6 TCID50/mL	NO

Endogenous Interference Substances Studies:

Human sputum matrix

A study was performed demonstrate that eighteen (18) potentially interfering substances that may be found in the lower respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the SARS-CoV-2 Antigen Rapid Qualitative Test.

S.N	Interfering Substance	Concentration	Cross-Reactive Results	Interference Results**
1	Whole Blood	4%	Negative	Positive
2	Mucin	0.50%	Negative	Positive
3	Ricola (Menthol)	1.5 mg/mL	Negative	Positive
4	Sucrets (Dyclonin/Menthol)	1.5 mg/mL	Negative	Positive
5	Chloraseptic (Menthol/Benzocaine	1.5 mg/mL	Negative	Positive
6	Naso GEL (NeilMed)	5% v/v	Negative	Positive
7	CVS Nasal Drops (Phenylephrine)	15% v/v	Negative	Positive
8	Afrin (Oxymetazoline)	15% v/v	Negative	Positive
9	CVS Nasal Spray (Cromolyn)	15% v/v	Negative	Positive
10	Nasal Gel (Oxymetazoline)	10% v/v	Negative	Positive
11	Zicam	5% v/v	Negative	Positive
12	Homeopathic (Alkalol)	1:10 dilution	Negative	Positive
13	Fisherman's Friend	1.5 mg/mL	Negative	Positive
14	ore Throat Phenol Spray	15% v/v	Negative	Positive
15	Tobramycin	4µg/mL	Negative	Positive

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16	Mupirocin	10 mg/mL	Negative	Positive
17	Fluticasone Propionate	5% v/v	Negative	Positive
18	Tamiflu (Oseltamivir Phosphate)	5mg/mL	Negative	Positive

Based on the data generated by this study, the substances tested SARS-CoV-2 Antigen Rapid Qualitative Test do not cross-react or interfere.

Human nasal swab specimen matrix

A study was performed demonstrate that eighteen (18) potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the SARS-CoV-2 Antigen Rapid Qualitative Test.

S.N	Interfering Substance	Concentration	Cross-Reactive Results	Interference Results**
1	Whole Blood	4%	Negative	Positive
2	Mucin	0.50%	Negative	Positive
3	Ricola (Menthol)	1.5 mg/mL	Negative	Positive
4	Sucrets (Dyclonin/Menthol)	1.5 mg/mL	Negative	Positive
5	Chloraseptic (Menthol/Benzocaine	1.5 mg/mL	Negative	Positive
6	Naso GEL (NeilMed)	5% v/v	Negative	Positive
7	CVS Nasal Drops (Phenylephrine)	15% v/v	Negative	Positive
8	Afrin (Oxymetazoline)	15% v/v	Negative	Positive
9	CVS Nasal Spray (Cromolyn)	15% v/v	Negative	Positive
10	Nasal Gel (Oxymetazoline)	10% v/v	Negative	Positive
11	Zicam	5% v/v	Negative	Positive
12	Homeopathic (Alkalol)	1:10 dilution	Negative	Positive
13	Fisherman' s Friend	1.5 mg/mL	Negative	Positive
14	ore Throat Phenol Spray	15% v/v	Negative	Positive
15	Tobramycin	4 µ g/mL	Negative	Positive

16	Mupirocin	10 mg/mL	Negative	Positive
17	Fluticasone Propionate	5% v/v	Negative	Positive
18	Tamiflu (Oseltamivir Phosphate)	5mg/mL	Negative	Positive

Based on the data generated by this study, the substances tested SARS-CoV-2 Antigen Rapid Qualitative Test do not cross-react or interfere.

HIGH DOSE HOOK EFFECT

As part of the LoD study the highest concentration of heat-inactivated SARS-CoV-2 stock available (TCID50 of 3.40 x10^5 per mL) was tested. There was no Hook effect detected.

INDEX OF SYMBOLS

Symbol	Description	Symbol	Description
IVD	In vitro diagnostic medical device		Do not re-use
	Expiry date		Consult instructions for use
	Warning, please refer to the instruction		Manufacturer
	Store at 2-30℃	LOT	Lot number
	Keep away from sunlight		Keep dry
EC REP	European authorized representative		Don't use the product when the package is damaged
	Date of manufacture		Biological risks
Rx ONLY	For Prescription Only	CE	CE mark
STERILE EO	Sterilized using ethylene oxide		

IN VITRO DIAGNOSTIC MEDICAL DEVICE TECHNICAL ASSISTANCE

For technical assistance, call Biotime Technical Services at +86-592-688-3577, email baotai@biotime.cn, or visit Biotime website at http:// www.biotime.cn.

GENERAL INFORMATION

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Manufactured for: **Innova Medical Group Inc.**

INNOVA

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Public Health England

Putting on personal protective equipment (PPE)

Standard Infection Control Precautions

Please see donning and doffing video to support this guidance: https://youtu.be/-GncQ_ed-9w

Pre-donning instructions:

- **Ensure healthcare worker hydrated**
- **Tie hair back**
- **Remove jewellery**
- **Check PPE in the correct size is available**

1 Perform hand hygiene before putting on PPE.

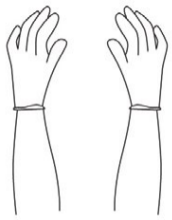
2 Put on apron and tie at waist.

3 Put on facemask – position upper straps on the crown of your head, lower strap at nape of neck.

4 With both hands, mould the metal strap over the bridge of your nose.

5 Don eye protection if required.

6 Put on gloves.



Public Health England

Taking off personal protective equipment (PPE)

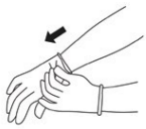
Standard Infection Control Precautions

Please see donning and doffing video to support this guidance: https://youtu.be/-GncQ_ed-9w

- **PPE should be removed in an order that minimises the risk of self-contamination**
- **Gloves, aprons (and eye protection if used) should be taken off in the patient's room or cohort area**

1 Remove gloves. Grasp the outside of glove with the opposite gloved hand; peel off.

Hold the removed glove in the remaining gloved hand.



Slide the fingers of the un-gloved hand under the remaining glove at the wrist.

Peel the remaining glove off over the first glove and discard.

2 Clean hands.

3 Apron.

Unfasten or break apron ties at the neck and let the apron fold down on itself.

Break ties at waist and fold apron in on itself – do not touch the outside – **this will be contaminated**. Discard.

4 Remove eye protection if worn.

Use both hands to handle the straps by pulling away from face and discard.

5 Clean hands.

6 Remove facemask once your clinical work is completed.

Untie or break bottom ties, followed by top ties or elastic, and remove by handling the ties only. Lean forward slightly. Discard. DO NOT reuse once removed.

7 Clean hands with soap and water.