Risk Assessment Form

Risk Assessment for: Conducting COVID-19 Asymptomatic Testing in Academy premises – January 2021 onwards.
Updated July 2021 for changes 1.9.21 onwards.

Important: Before completing read guidance overleaf.
If hazardous substances are used and/or work at height is undertaken then supplementary assessments **must** be carried out.
Where manual handling is undertaken and/or noise at work is a hazard, supplementary risk assessments are required where the hazard poses a significant risk.

Area: **Conducting COVID-19 National Testing Programme on Academy Sites – January 2021 onwards.** **Note added 12.7.21** **As per the DfE guidance from 1.9.21, all secondary aged students that have consent are to receive two supervised on site tests. All students then recommended to complete ongoing LFD tests until the end of September. Additional direction will then be given from the DfE.** **A limited on-site test facility will remain available for use when needed.**	**Activity / Task:** **General and Clinical activities associated with conducting COVID-19 Asymptomatic testing of staff and students.**	**Date of Assessment:** **06.01.2021,** **Revised 12.05.2021** **Revised 12.7,21 for implementation 1.9.21.**
Person(s) at Risk: **Staff, Students, Visitors** **N.B. for the purposes of this Risk Assessment persons being tested are referred to as 'subjects' within this document.**	**Equipment required for Activity / Task:** **Test Kits, Cleaning Equipment, Stationery, IT equipment** **Note (added 12.05.2021)** **When supply of Innova ATS Test Kits is exhausted, the Orient Gene LFD Test Kits are to be used. These test kits involve double nasal swab samples only. Only one brand of device to be used at any one time for on-site testing to minimise confusion and processing errors.**	**PPE Required for Activity / Task:** **Gloves, Aprons, Face Shields, Visors**
Hazardous Substances to be used (CoSHH): **(CoSHH Assessment Attached as Appendix 1).** **Extraction Solution** (contains the following components: NA2HPO4 (disodium hydrogen phosphate), NaH2PO4 (sodium phosphate monobasic), NaCl (Sodium Chloride))	**Manual Handling:** **Normal MH procedures apply to e.g. handling bulk deliveries.**	**Instructions / Training / Supervision – Required / Received:** **Relevant staff will undergo online training provided by the DfE / PHE.**
Work at Height: **Not applicable**	**Noise:** **Not applicable**	**Health Surveillance – Required / Provided:** **Not applicable**

Risk Assessment Form

Hazard(s):	Risk Description:	Severity x Likelihood of Occurrence = Risk Factor			Control Measure(s):	Severity x Likelihood of Occurrence = Reduced Risk Factor		
Contact between subjects increasing the risk of transmission of COVID-19	Transmission of the virus leading to ill health or potential death	4	3	12	• Asymptomatic: All subjects are to be advised in advance not to attend if they have any symptoms of COVID 19, or live with someone who is showing symptoms of COVID 19 (including a fever and/or new persistent cough) or if they have returned within 14 days from a part of the world affected by the virus or have been in close contact with someone who is displaying symptoms. Staff administering testing should wear medical face coverings. • Hand hygiene: All subjects to use hand sanitiser provided on arrival & adherence to this enforced by staff. • Social distancing: Two metre social distancing to be maintained between subjects with measured floor markings in place to ensure compliance in addition to verbal reminders if necessary from reception, queue management & sampling staff. • A one-way flow of subjects through the test area is to be initiated and maintained at all times. This will be reinforced by floor markings and/or signage. Compliance with this is to be ensured by queue management staff. • Cleaning: Regular cleaning of the site including wipe down of all potential touchpoints in accordance with PHE guidance. • Limited clutter - chairs only on request; no physical handing of documents to subjects except barcodes and PCR test kits	4	1	4
Contact between subjects and staff increasing the risk of transmission of COVID-19: Welcome and Registration	Transmission of the virus leading to ill health or potential death	4	3	12		4	1	4
Contact between subject and sampler increasing the transmission of COVID-19: Sample taking	Transmission of the virus leading to ill health or potential death	4	3	12		4	1	4
Contact between sample and test centre runner increasing the transmission 4of COVID19: Sample transport	Transmission of the virus leading to ill health or potential death	4	3	12		4	1	4
Contact between samples and sample testers increasing the transmission of COVID19: Sample processing & analysis.	Transmission of the virus leading to ill health or potential death	4	3	12		4	1	4
Contact between samples and sample testers increasing the transmission of COVID19: Sample disposal and waste disposal	Transmission of the virus leading to ill health or potential death	4	3	12		4	1	4
Incorrect result communication	Wrong samples or miscoding of results	1	3	3	• 2 identical barcodes are provided to subject at check in • The subject registers their details to a unique ID barcode before conducting the test	1	1	1

					• Barcodes are attached by trained staff at the sample collection bay • Barcodes are checked for congruence at the analysis station and applied to Lateral Flow Device at this station			
Damaged barcode, lost LFD, failed scan of barcode	Orphaned record on registration portal & No result communicated to individual	1	3	3	• Rule based recall of subjects who have not received a result within 1 hrs of registration • Subjects are called for a retest	1	1	1
Extraction solution which comes with the lab test kit contains the following components: NA2HPO4 (disodium hydrogen phosphate), NaH2PO4 (sodium phosphate monobasic), NaCl (Sodium Chloride)	These components do not have any hazard labels associated with them, and the manufacturer states that there are no hazards anticipated under conditions of use as described in other product literature. This is the case for exposure to: eye, skin, inhalation, ingestion, chronic toxicity, reproductive and developmental toxicity, carcinogenicity, and medical conditions aggravated by exposure.	1	3	3	• PPE: nitrile gloves which meet the Regulation (EU) 2016/425 to be used at all times when handling the extraction solution. Safety glasses with side shields which are tested and approved under appropriate government standards to be worn at all times when handling the extraction solution. Impervious clothing to be worn to protect the body from splashes or spillages. • Environmental: product will not enter drains • Spillages: wipe surfaces which the solution has been spilt on and dispose of cleaning material in line with the waste disposal procedures • Solution that has expired will not be used • Training provided in handling potentially biohazardous samples, chemicals and good lab practice. Adherence to guidelines in these training procedures to prevent improper handling. • Staff will follow procedures on the MSDS form provided by Innova to mitigate against inhalation, skin contact or ingestion of these chemicals.	1	1	1
Manual handling	Risk of injury.	2	3	3	• Bulk deliveries to be moved by site team using trolleys	2	1	2
Electrical safety / plant & equipment maintenance : Defective electrical	Risk of electric shock / electrocution. Risk of inability to perform test	3	2	6	• All electrical equipment is subject to PAT testing • Back-up equipment available	3	1	3

equipment	recording.							
Use of shared equipment	Transmission of the virus leading to ill health or potential death	4	3	12	• Use of hand sanitiser • Alcohol-based sanitiser available • Equipment cleaned with disinfectant wipes at regular intervals • All non-essential equipment removed from testing area • PPE used by all staff involved in testing	4	1	4
Incorrect result communication	Wrong samples or miscoding of results	1	3	4	• 2 identical barcodes are provided to subject at check in • The subject registers their details to a unique ID barcode before conducting the test • Barcodes are attached by trained staff at the sample collection bay Barcodes are checked for congruence at the analysis station and applied to Lateral Flow Device at this station	1	1	1
Incorrect disposal of waste	Transmission of the virus leading to ill health or potential death	3	4	12	• All waste to be bagged in black waste sacks, tied and disposed of in normal municipal mixed waste collection container for collection by contractor.	3	1	3
Accommodation	Risk of area being used for testing being unsuitable. Risk of room temperature being too cold and adversely affecting test procedure	2	2	4	• Room set up as per guidance from DfE/NHS • Temperature monitored regularly • Additional cleaning routine in place • All non-essential materials and loose furniture re-arranged or removed from test area	2	1	2

Name of person(s) carrying out this Risk Assessment:	**Signature(s):**	**Date:**
L Brown, NMAT Executive Principal **G Harris, Nunthorpe Academy Buildings and Development Manager**		

Risk Assessment Form

Completion Guidelines

1 The top section of this form should reflect the details of the activity being assessed and hazard control measures in place (at the time the assessment is carried out).

2 All 'significant' hazards in the workplace where the task is being carried out, should be recorded in the section headed 'Hazards', together with the assessor's estimate of their severity and likelihood of occurrence. Note that a narrative description is also required.

3 The 'Hazard Severity' should be assessed on a scale of 1-5 as follows:

5 Very High - Causing multiple deaths or widespread destruction
4 High - Causing death or serious injury
3 Moderate - Causing injury or disease – off work 3 days or more
2 Slight - Causing minor injury – first aid treatment, return to work
1 Nil - No risk of injury or disease

4 The 'Likelihood of Occurrence' should be assessed on a scale of 1-5 as follows:

5 Very likely - If corrective measures are not taken
4 Likely - Probable, only requires additional factor (e.g. carelessness, bad weather etc.)
3 Quite Possible - Additional factors could precipitate an occurrence but unlikely without such factors
2 Possible - Probability low and Risk minimal
1 Not likely - No risk present

5 In the section headed 'Control Measures' it is important to specify the recommended corrective action. (Note that this may include, in extreme circumstances, the instruction to stop the activity until certain corrective actions have been carried out. In other cases, the timescale for undertaking corrective action shall be specified). The 'Reduced Risk Factor' numerical value shall be entered to show the effect of taking the recommended corrective action for each 'significant' hazard identified.

6 Once all corrective actions are complete, the Risk Assessment should be signed off by the appropriate manager. It is important to stress that the person signing off the risk assessment must take an action upon themselves to check that ALL corrective actions have been carried out and they are effective. (Note: the Risk Assessment must not be 'signed off' until ALL corrective actions have been completed).

Name of person confirming that ALL corrective actions are complete and effective:	**Signature:**	**Date:**
Name of person 'signing off' this Risk Assessment as complete:	**Signature(s):**	**Date:**

Date Risk Assessment to be reviewed: _____ (annually or following any incident or change in national advice from the DfE and/or Public Health England.)

Nunthorpe Multi Academy Trust

COSHH ASSESSMENT FORM

To be completed with Materials Safety Data Sheet **Attached** ✓

Substance Information	
Substance / Material:	SARS-CoV-2 Antigen Rapid Qualitative Test Extraction Solution
Trade Name(s):	N/A
Manufacturer:	Xiamen Biotime Biotechnology Co. Ltd.
What is the substance used for?	Qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal / throat swabs.
What are the hazardous ingredients/chemicals in the substance?	Extraction solution which comes with the lab test kit contains the following components: NA2HPO4 (disodium hydrogen phosphate), NaH2PO4 (sodium phosphate monobasic), NaCl (Sodium Chloride). **The solution is not described as hazardous when used for its intended purpose.**
Do any of the chemicals have a Workplace Exposure Limit?	No

Is the substance: (check for CLP symbol on Data Sheet or packaging)								
	Explosive			Corrosive			Harmful to Health	
	Flammable			Toxic			Serious Health Hazard	
	Oxidising			Harmful to the environment			Gas under pressure	

Is the substance hazardous to health when:					
In contact with skin	No	Breathed In	No	Swallowed	No
Injected (via needlestick/high pressure)	No	In contact with eyes	No	Other (specify below) Biohazardous waste product after use for intended purpose.	Yes

Use of the substance	
How should the substance be used? (e.g. diluted with water, applied with brush, sprayed etc.)	6 drops of the extract solution should be dripped into the extractor tube without touching the edge of the tube.
How much is used every week? (State quantity in litres or kilograms as appropriate)	Minimal amounts – the solution is packaged in bottles containing enough solution for approx. 25 tests.
Who is exposed to the substance? (e.g. those using it, employees, students, service users)	Employees, Students

Control Measures	
Can a less hazardous substance be used to do the same job? Yes ☐ No ☑	
What controls are required for this substance, other than Personal Protective Equipment (PPE)?	Store between 2 and 30°C Dispose of safely – see below
Is any Personal Protective Equipment (PPE) required when using this substance? Please state type required:  Overalls / Clothing? ✓ Disposable Polythene Apron  Gloves? ✓ Disposable Nitrile Gloves  Eye Protection? ✓ Visor  Mask / Respirator? ✓ Face Mask and Visor  Other?	

How should the substance be stored? (e.g. locked cupboard, away from other substances etc.)	Store extraction solution at 2-30°C, the shelf life is 24 months tentatively. Reagents and devices must be at room temperature 15-30° when used for testing.
Other Precautions and Emergency Procedures	
Spillages How should accidental release/spillage of this substance be dealt with?	Any spilled fluids should be mopped up with disposable wipes which should then be disposed of as per below.
First Aid What actions should be taken if the substance is:	
Ingested (swallowed) Seek medical advice	In contact with eyes Irrigate thoroughly and seek medical advice
Absorbed (in contact with skin) Wash thoroughly under running water.	Inhaled (breathed in)
Other (please specify)	
Fire Precautions What actions should be taken in the event of fires involving this substance?	N/A
Chemical Reaction Is there any other substance that this substance must not come into contact with?	None stated by manufacturer
Disposal How should the substance be disposed of (or not disposed of)?	Used product and test equipment should be placed in black waste sacks, sealed and placed in general/municipal mixed waste container to be collected by contractor. It should not be placed recycling containers.
Health Surveillance Do staff using this substance require any health surveillance?	No

Assessment of Risk				
Are all the controls detailed above currently in place?	Yes	✓	No	
If these are not in place, or additional controls are required, state action to be taken. Note – COSHH substances must **not** be used if adequate control measures are not in place.				
Remedial actions required:	Date for completion:			
Are hazards to health adequately controlled with all measures in place?	Yes	✓	No	

Assessor(s) Name: L Brown G Harris	Assessor(s) Signature:	Date: 06.01.2021, revised 12.05.2021 Revised for 1.9.21
The Line Manager should sign below to show that the assessment is a correct and reasonable reflection of the hazards and of the control measures and actions required.		
Line Manager's Name:	Line Manager's Signature:	Date:
Remedial Actions Complete: (Date)	Line Manager's Signature:	Reviewed On: (Date)
This COSHH Assessment should be reviewed at least annually or following any incident or accident involving the substance to which this assessment relates.		

SARS-CoV-2 Antigen Rapid Qualitative Test

Instructions for Use

CatalogNo.BT1309

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, throat swabs, and sputum 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. 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.

Specification and Component

Specification / Component	10Tests/Kit	25Tests/Kit	Note
SARS-CoV-2 Antigen Test Cartridge	10	25	Materials Provided
Extraction Tube	10	25	Materials Provided
Extraction solution	1 bottle/kit	2 bottles/kit	Materials Provided
Instructions for use	1 copy/kit	1 copy/kit	Materials Provided
Qualification Certificate	1 copy/kit	1 copy/kit	Materials Provided
Throat Swab	10	25	Optional Materials (Scheme A)
Nasal Swab	10	25	Optional Materials (Scheme B)
Screw-cap collection cup	10	25	Optional Materials (Scheme C)
Transfer Pipette	10	25	

Note: Our customers and agents can chose one of the three Schemes mentioned-above respectively.

Materials Required but not provided:

1. Timer

2. Tube rack for specimens

3.Any necessary personal protective equipment

4.External control set .

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,handing and disposal of the components within this kit,please refer to the Safety Data Sheet (SDS).

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:

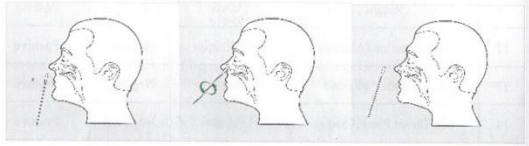
Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with moderate force back and forth for at least 3 times.

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

Sputum Specimen Collection:

1. Rinse the mouth with water.

2.Expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup.

Specimen Transport and Storage:

Samples should be tested as soon as possible after collection. Based on data generated with influenza virus, Specimen 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℃）.

For Nasal Swab Specimen/ Throat Swab Specimen

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.

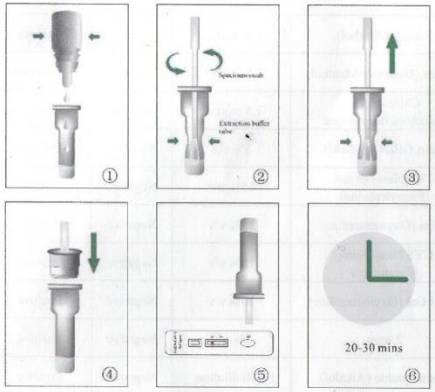
2. The extraction of specimen: Put the swab had collected specimen into the extraction tube, hold and press the swab head against the wall of tube with force while rotating the swab for about 10 seconds to release the antigen into the extraction solution from the swab head.

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. If positive signal appears after 30 minutes, it should not be reported as positive.



For Sputum Specimen

1. Place the extraction tube with opening facing up. Press the extraction solution bottle to drip 10 drops of extract solution into the extractor tube without touching the edge of the tube.

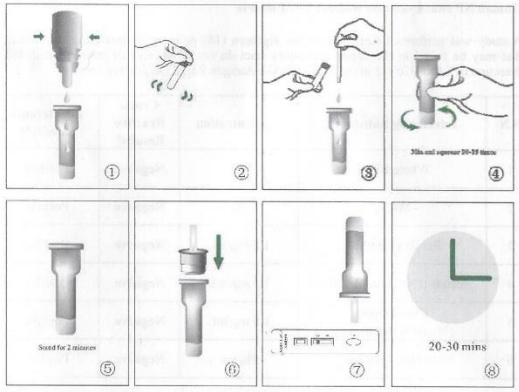
2 Vortex or thoroughly mix Sputum specimen. Do not centrifuge.

3. Transfer 300 μL of specimen into the extractor tube using transfer pipette.

4. Mix well and squeeze 10-15 times. Stand for 2 minutes. 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, If positive signal appears after 30 minutes, it should not be reported as positive.



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.

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 Innova Medical Group, Inc. as external controls. The control set can be ordered through website (www.innovamedgroup.com), telephone (+1-6262390025) and email (info@innovamedgroup.com). 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 Innova 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 Innova 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;

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 Innova Medical Group, Inc. Technical Services at (+1-6262390025) and email (info@inpovamedgroup.com).

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.

7.Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

8.The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from throat or nasal swab specimens only.

9.The kits for rapid detection of SARS-Cov-2 can detect both viable and non-viable SARS-CoV-2 material. The SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.

10.Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.

11.Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.

12.This device has been evaluated for use with human specimen material only.

13.Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.

14.The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.

15.Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.

16.The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.

17.Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within one hour after specimen collection.

18.The validity of SARS-CoV-2 Antigen Rapid Qualitative Test has not been proven for dentification/confirmation of tissue culture isolates and should not be used in this capacity.

CLINICAL PERFORMANCE

The performance of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 was established with 295 direct nasal swab or throat swab prospectively collected and enrolled from individual symptomatic patients (within 5 days of onset) who were selected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases. For each type, four kinds of samples from the same person were tested by Company's Kit. We selected 25 positive and 25 negative sample. P1-P25 of samples are from infected people, and NI-N25 are from uninfected people. P21-P25 are weekly positive.

Method		PCR Test		Total Results
	Results	positive	Negative	
Innova Results	positive	72	0	72
	Negative	3	220	223
Total Results		75	220	295

*** 95% Confidence Interval**

Relative Sensitivity:	72/75	96.00% (88.75%~99.17%)
Relative Specificity:	220/220	100.00% (98.34%~100.00%)
Accuracy:	292/295	98.98% (97.06%~99.79%)

ANALYTICAL PERFORMANCE

CROSS REACTIVITY (ANALYTICAL SPECIFICITY)

Human sputum matrix

Cross-reactivity of the SARS-CoV-2 Antigen Rapid Qualitative Test for Rapid Detection of SARS-CoV-2 was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid Detection of SARS-CoV-2. Each organism and virus spiked into negative sputum specimen was wet-tested in triplicate. The final concentration of each organism is documented in the following table.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO
7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO
10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Nomal nasal flush fluid	/	NO

Note :1 TCID50/mL≈0.7CFU/ml

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

Human NP swabs samples without VTM matrix

Cross-reactivity of the SARS-CoV-2 Antigen Rapid Qualitative Test for Rapid Detection of SARS-CoV-2 was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid Detection of SARS-CoV-2. Each organism and virus spiked into negative NP swabs samples without VTM was wet-tested in triplicate. The final concentration of each organism is documented in the following table.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO
7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO
10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Nomal nasal flush fluid	/	NO

Note :1 TCID50/mL≈0.7CFU/ml

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

MICROBIAL INTERFERENCE STUDIES

Human sputum matrix

The starting material was spiked into a volume of pooled human sputum (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 matrix contrived sputum sample 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, 75 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 sputum matrix.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO
7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO
10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Nomal nasal flush fluid	/	NO

Human NP swabs samples without VTM matrix

The starting material was spiked into a volume of pooled NP swabs samples without VTM (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 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 samples that SARS-CoV-2 is present in a specimen with one microorganism.

Each microbial interference specimen was tested individually. At each test, 75 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 NP swabs samples without VTM matrix.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO

7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO
10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Nomal nasal flush fluid	/	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
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.
* The negative matrix was chose for the Cross-Reactive Study.
* * The positive matrix was chose for the Interference Study.

Human NP swabs samples without VTM 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.
* The negative matrix was chose for the Cross-Reactive Study.
* * The positive matrix was chose for the Interference Study.

HIGH DOSE HOOK EFFECT

As part of the LoD study the highest concentration (or titer) of heat-inactivated SARS-CoV-2 samples available (6000xLOD) 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
2℃ 30℃	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 Innova Technical Services at +1-6262390025, email info@innovamedgroup.com, or visit Innova website at http:// www.innovamedgroup.com.

GENERAL INFORMATION

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Tried&Tested www.triedandtested.tech

Manufacturer

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