COVID–19
Antigen Diagnostic Testing

Training Material

V1.0

- Confidential -

Version Control

Version	Date Approved	Changes	Author
V1.0	29.01.21	First draft	ADT Validation Scientific Lead ADT Implementation Project Manager

Table of Contents

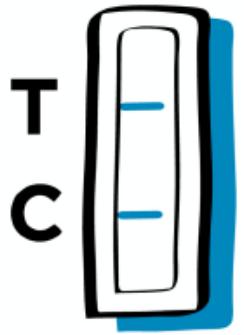
1. Introduction

Overview of ADT

SARS-CoV-2 antigen diagnostic tests (ADT) rely on direct detection of SARS-CoV-2 viral proteins (usually nucleopcapsid protein) in nasopharyngeal / nasal swabs and other respiratory secretions using a lateral flow immunoassay that provides results in up to 30 minutes.

Benefits of antigen testing:

- Enables rapid identification of positives to allow for quick isolation through fast turnaround time of results.
- Shelf life of up to 1 - 2 years without refrigeration.
- Limited / no instrumentation required when using lateral flow immunoassays and, with appropriate training, it can be performed near the patient.
- Can supplement testing capacity where PCR capacity is exceeded.



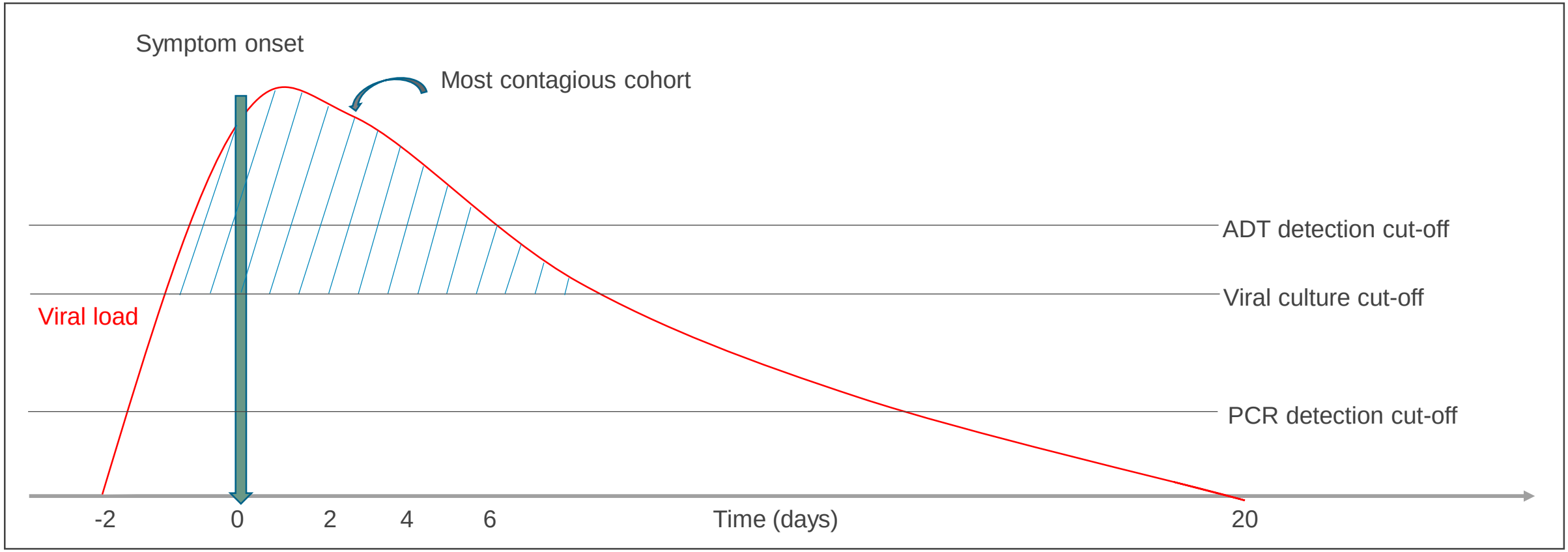
Limitations of Antigen Testing:

- Antigen testing does not have the same performance in terms of sensitivity and specificity as PCR testing.
- Most currently available ADTs show a lower sensitivity compared to the standard RT-PCR test.
- Requires strict adherence to the manufacturer's guidelines at all stages of the testing process.
- These specimens require professional sampling and the use of personal protective equipment during sampling and processing
- Visually read, ADTs is a subjective interpretation and could result in reader variation.
- Training and competency assessment of the operator is required.
- As many of the ADTs are processed individually, analysis of large volumes of specimens simultaneously is challenging.

ADT use in Symptomatic Settings

ADTs should be conducted by trained operators in strict accordance with the manufacturer's instructions early in the disease (i.e. just prior to or within the first 5–7 days after symptom onset) when viral loads are highest.

Generally, the highest viral loads have been observed at the time of symptom onset and for a few days after, with levels slowly decreasing over the next one to three weeks.



Roles and Responsibilities (1/2)

Below are the minimum roles and responsibilities required when performing ADT. These requirements may differ depending on the specific setting.

Role	Responsibilities
Clinical Director of the Laboratory / Diagnostic Service	• Professionally accountable for the quality of the results reported.
Administration	• Supports coordination of workflow at the testing site; organising test materials, paperwork, labelling, and scheduling. • Collects ADT testing information and clinical data from individuals to enable reporting (e.g. ADT batch / lot numbers, demographics, symptoms, results). • Monitors activity. • Supports the testing centre staff in carrying out the additional sampling tasks required. • Schedules the walk-in individuals as required.
Swabbing	• Explains the swabbing procedure to the individual and the details of what is required. • Collects the test samples from the individual in line with training. • Adheres to all requirements associated with assuring infection control procedures are carried out.
Testing	• Receives samples from the test operator (the 'swabber') and performs ADT. • Interprets ADT results.

Roles and Responsibilities (2/2)

Below are the minimum roles and responsibilities required when performing ADT. These requirements may differ depending on the specific setting.

Role	Responsibilities
Review and authorisation	• Undertakes the process for review of testing information captured (e.g. patient information) and authorisation of results.
Quality assurance	• Batch acceptance of reagents and traceability. • Ensures appropriate External Quality Assessment (EQA) and Internal Quality Controls (IQA) processes are implemented and maintained.
Communication of detected results	• Contacts the individual(s) with a detected (positive) ADT immediately, informing them of their result and requesting them to isolate.
Reporting	• Records results on ADT result template. • Ensures detected results are notified to the Medical Officer of Health. • Updates required systems (where necessary) with results for onward Public Health management including contact tracing and surveillance. • Ensures public health is provided with all results and testing activity.

2. Safety

Risk Assessment

Risk assessment:

In accordance with the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (S.I. No. 572 of 2013) article 16, [working with biological agents in health care setting other than diagnostic laboratories] before commencing any antigen testing, a full risk assessment should be completed. Sites should utilise their own risk assessment template when completing this step or refer to the HSE Risk Assessment Template available on the Quality Assurance and Verification Division of the HSE website (see below).

Risk assessment should consider the following:

- Who is being tested?
- Who is taking the samples and carrying out testing?
- Have they completed ADT training and passed the competency assessment?
- What type of samples are being taken (nature of the sample)?
- Where are the samples being taken?
- Where is the test being carried out (eg. live virus, ventilation)?
- How are samples and any waste disposed of?
- Are there other people who may be affected by work activity? (e.g. pregnant employees, people handling the waste, cleaners etc.)
- Are there appropriate decontamination and disinfection procedures in place?

HSE – useful materials:

- Quality Assurance and Verification Division of the HSE website: https://www.hse.ie/eng/about/qavd/
- HSE Risk Assessment Template: https://www.hse.ie/eng/about/qavd/riskmanagement/risk-management-documentation/hse%20risk%20assessment%20tool.pdf
- HSE Risk Assessment Form: https://www.hse.ie/eng/about/qavd/riskmanagement/risk-management-documentation/generic-risk-assessment-form-2018.docx

Personal Protective Equipment

Personal Protective Equipment:

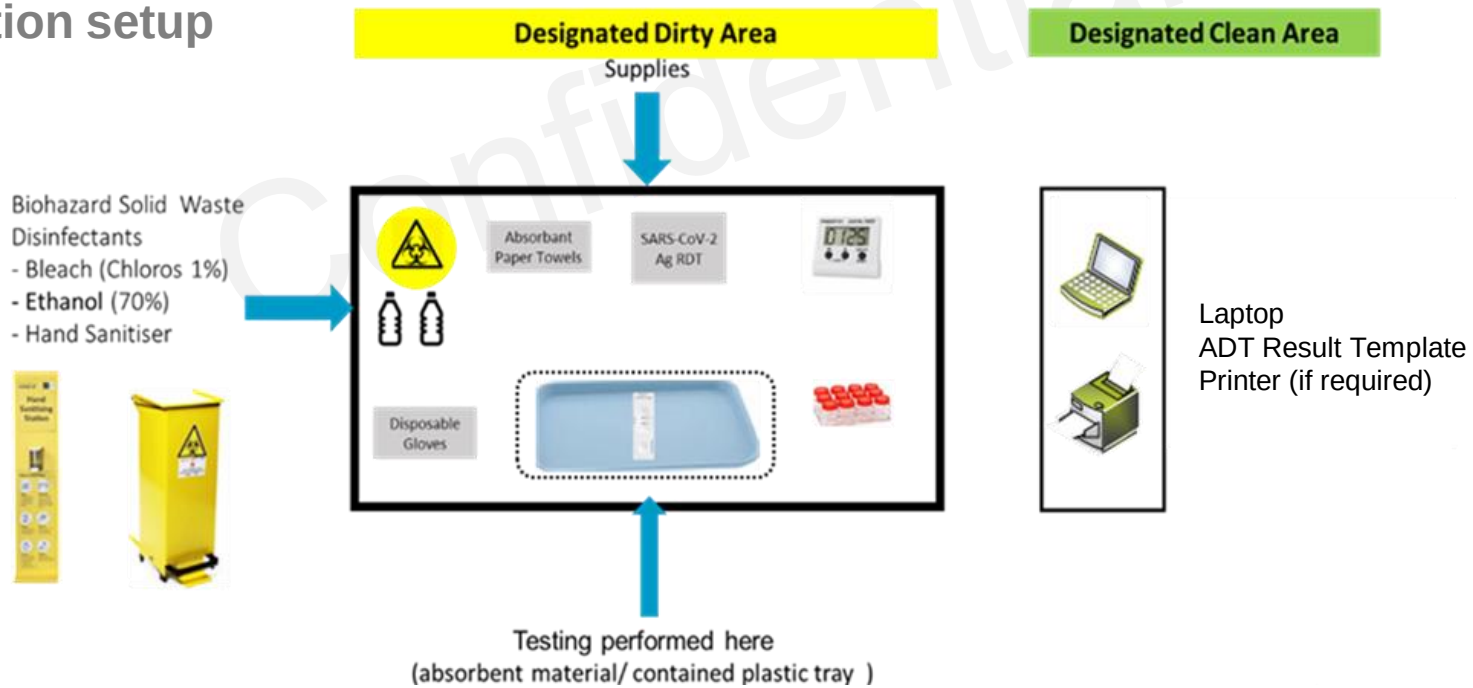
- Before commencing any sampling or antigen testing for SARS-CoV-2, the appropriate PPE must be put on.
- Please refer to table below for appropriate PPE for each part of the process.
- Please refer to HSE guidelines for donning and doffing PPE which can be found at https://healthservice.hse.ie/staff/news/coronavirus/prevent-the-spread-of-coronavirus-in-the-workplace.html

Procedure	PPE Required
Sample collection	• Alcohol hand rub • Non-sterile gloves; single-use only • Gown; long-sleeved, fluid repellent • Eye protection (safety glasses or goggles, face-shields [visors]) if there is a risk of splash • Surgical mask (use of a respirator mask may be considered instead of a surgical mask based on risk assessment)
Sample receipt and accession	• Alcohol hand rub • Non-sterile gloves; single-use only • Gown; long sleeved fluid repellent • Surgical mask (use of a respirator mask may be considered instead of a surgical mask based on risk assessment)
SARS-CoV-2 ADT sample analysis	• Alcohol hand rub • Non-sterile gloves; single-use only • Gown; long sleeved, fluid repellent • Eye protection (safety glasses or goggles, face-shields [visors]) • Respirator. e.g. N95, FFP2

Set up Requirements on Workstations

- ADT must be performed in a dedicated well-ventilated space, separate from the sample collection area and other areas where patients have access.
- The work area should be marked with a biohazard sign and accessible only to staff who have been trained and are conducting the testing.
- The workstation must be set up with dirty and clean areas, ensuring adequate space on both.
- All contaminated materials (such as sample containers, transfer pipettes, tubes and cassettes) must be disposed of in a yellow biohazard bin.
- Waste disposal bins must have sufficient absorbent material in the base to absorb all liquid – it's best to assume that all contents leak, and to act accordingly to ensure there is enough material to absorb any and all liquid.

Example of a workstation setup



Working with ADTs

When working with ADTs you must:

- Change gowns and gloves if they become soiled or contaminated.
- Remove gowns and gloves before leaving the work area and between testing samples.
- Discard disposable gowns after single use.
- Always perform hand hygiene after working with samples and removing gloves.
- Ensure all new batches of tests are verified before commencing testing.

Preparing and use of disinfectants:

- Disinfect the workstation before and after use and immediately after a spill occurs.
- Contact time, dilution and shelf life of the working disinfectant solution (after dilution) are all critical for effective disinfection.
- Always leave disinfectants in contact with surfaces or spills for the recommended time, usually 10-15 minutes.
- Prepare working solution of sodium hypochlorite (bleach) daily by diluting from the concentrated disinfectant solution, as diluted sodium hypochlorite degrades rapidly losing efficacy.
- Mark the date of dilution on the bottle and only use on the day of preparation.
- 70% alcohol can also be used as an alternative disinfectant.

What you should do after testing:

- All components of ADTs are single-use and must not be reused.
- Place all contaminated materials (such as used sample containers, transfer pipettes and used test cassettes) in biohazard bins.
- At the end of the day, seal the biohazard bin, and follow your facility's guidelines for biohazardous waste disposal (autoclave and incinerate).

Spill and Waste Management

Managing a spill:

Wearing gloves, a mask, a visor and a fluid repellent gown:

- Flood the spill area with 1% bleach.
- Cover the spill and disinfectant with paper towel.
- Leave for at least 10 minutes.
- Wipe up the spill and disinfectant with paper towel and discard in the biohazard waste container.
- Disinfect the area with 1% bleach or 70% alcohol and dry with paper towel.
- Discard the paper towel in the biohazard waste container.

Managing waste:

- Handle all waste from sample collection and ADT testing as biohazardous.
- Disposal of SARS-CoV-2 ADT used cassettes:
  - Read manufacturer's specific instructions
  - Read Material Safety Data Sheets
  - Follow national, local regulations for disposal of biohazard waste
- All components of SARS-CoV-2 ADTs are single-use and must not be re-used.
- All contaminated materials (such as sample containers, transfer pipettes, tubes and cassettes) must be disposed off in a yellow biohazard bin.
- Waste disposal bins must have sufficient absorbent material in the base to absorb all liquid – it's best to assume that all contents leak, and to act accordingly to ensure there is enough material to absorb any and all liquid.
- At the end of the day, seal the biohazard bin, and follow the HSE guidelines for biohazardous waste disposal.

Testing in the Community

Guidelines for waste management with community testing (e.g. outbreak scenarios):

- Take enough biohazard bins when going to perform testing in the community.
- Place all contaminated materials (such as used sample containers, transfer pipettes and used test cassettes) in a biohazard bin and seal.
- Use a new (unused) biohazard bin for waste disposal at different locations in the community.
- Waste disposal bins must have sufficient absorbent material in the base to absorb all liquid – it's best to assume that all contents leak, and to act accordingly to ensure there is enough material to absorb any and all liquid.
- Return the sealed biohazard bin to the health facility for appropriate disposal.

3. ADT Sampling and Analysis

SARS-CoV-2 ADT Sampling (1/4)

ADT sample collection requirements:

- Samples must be collected by trained individuals (refer to HSE guidelines / training for swabbers).
- Use new (unopened) individually wrapped sterile nasopharyngeal or nasal swabs (use swabs provided in the ADT kit unless specified otherwise in the manufacturer's Instructions for Use).
- Use the primary receptacle (e.g. tube with extraction buffer). Note this may need to be pre-prepared in advance of sample collection. Refer to specific Manufacturer's Instructions for Use for the kit in question.
- Antigen testing MUST be performed immediately in accordance with the manufacturer's guidance (e.g. Immediately after sample collection or within a designated time frame after sample collection).
- Use only the materials and reagents (e.g. extraction buffer) the manufacturer supplied with the test.
- If testing cannot be performed immediately after sample collection, follow the manufacturer's recommendations for storage.

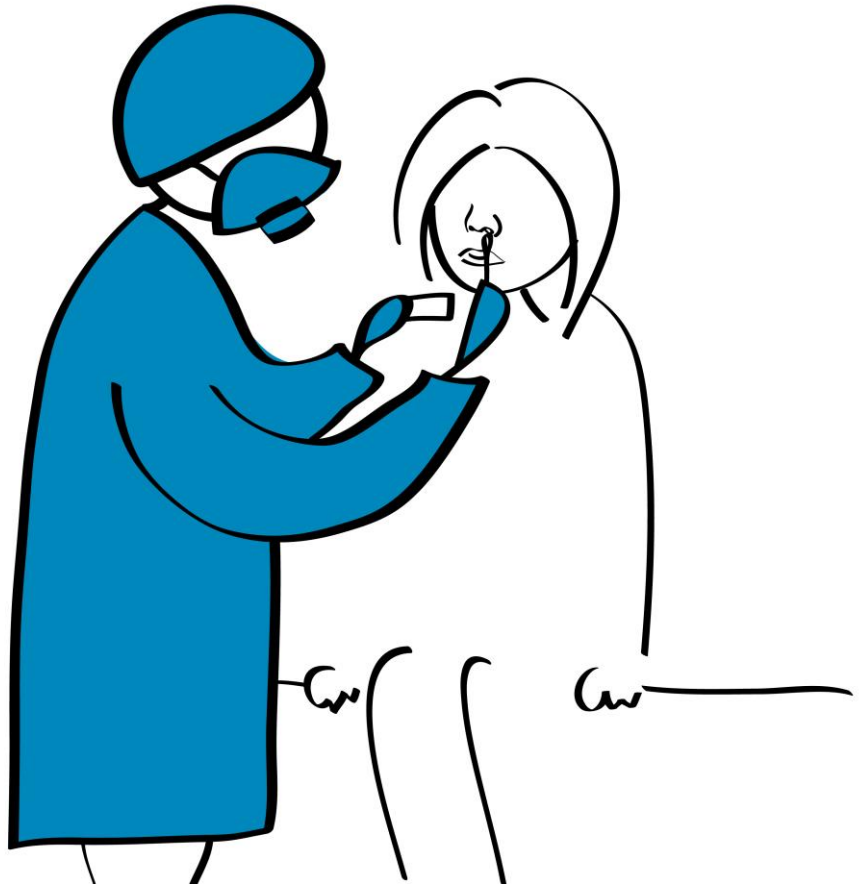
Pre-collection steps (to be performed by operator):

- Record batch number and lot number of the test kit in the result template.
- Pre-prepare the extraction buffer as indicated in manufacturer's instructions.
- Supply the pre-prepared tubes and swabs provided with test kits to swab taker prior to taking specimen.

SARS-CoV-2 ADT Sampling (2/4)

Sample collection (swabber):

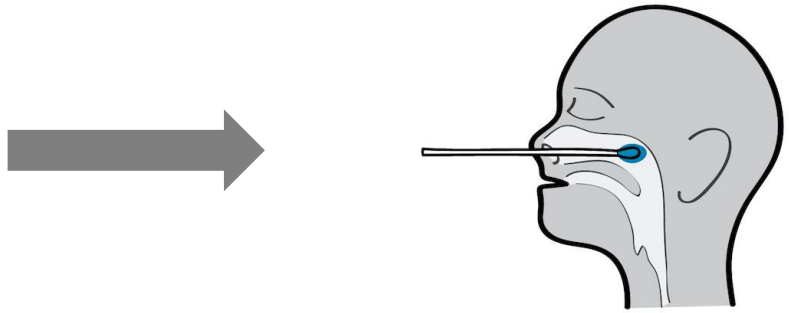
- Confirm the participant name, date of birth and mobile phone number are correct on the Swiftqueue label.
- Explain the swabbing procedure to the individual and that two swabs will be obtained (if applicable in the setting) and secure verbal consent.
- Explain that the first sample will be used for the standard PCR test and the second sample will be used for the antigen test (if dual swabbing applies).
- Print 3 additional Swiftqueue (or equivalent) ID labels for individuals. Labels will be placed on the COVID request form, ADT vial, and ADT cassette. An ADT label will clearly identify that it is related to antigen testing.
- Activity and progression of all individuals will be recorded using the result template (see section 4).



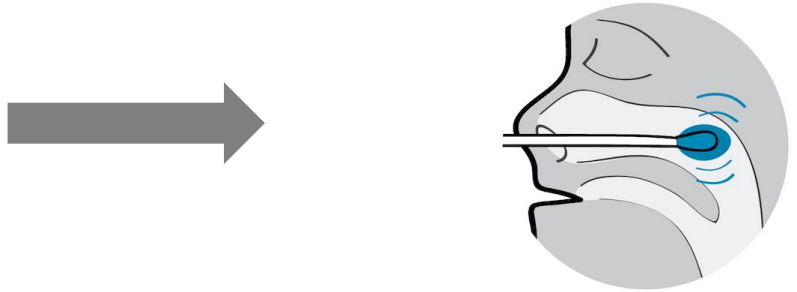
SARS-CoV-2 ADT Sampling (3/4)

Nasopharyngeal sample collection (swabber):

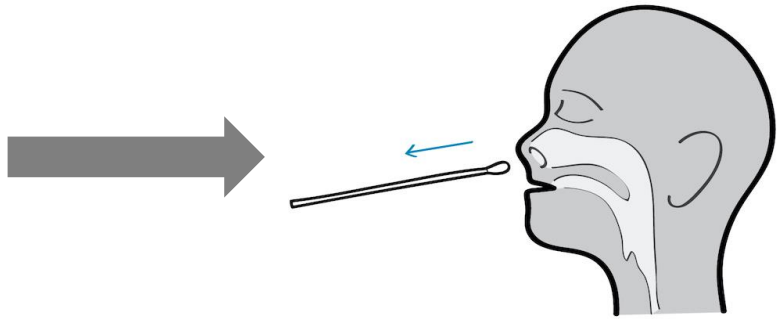
- Insert a sterile nasopharyngeal swab (provided with SARS-CoV-2 ADT kit) into the nasal cavity of the patient, reaching the surface of the posterior nasopharynx.



- Swab over the surface of the posterior nasopharynx, rotating the swab 3-4 times to ensure a good sample. Leaving the swab in the nasal cavity for a few seconds will ensure absorption of the nasal secretions.



- Withdraw the sterile swab from the nasal cavity.



SARS-CoV-2 ADT Sampling (4/4)

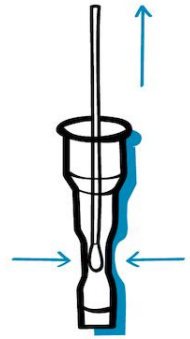
Nasal sample collection (swabber):

- To avoid viscous mucus interfering with sampling, invite the individual to blow their nose before sample collection.
- Using the sterile nasal swab, take a **bilateral nasal swab** from both nostrils as follows:
  - Tilt the individuals head back 70 degrees.
  - While gently rotating the swab, insert the swab approximately 2 cm into the nostril until resistance is met at the turbinates.
  - Rotate the swab 5 times against the nasal wall.
  - Using the same swab repeat the collection procedure with the second nostril.
  - Slowly remove the swab from the nostril each time.

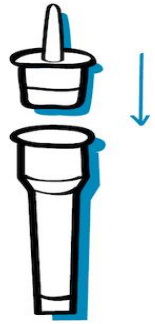
SARS-CoV-2 ADT Testing Procedure (1/3)

- Insert the swab into the labelled pre-prepared extraction buffer tube. While squeezing the buffer tube, rotate the swab gently. Please refer to the specific manufacturer's guidelines as there can be minor difference in the timing or number of rotations etc.

- Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



- Press the nozzle cap tightly onto the tube.

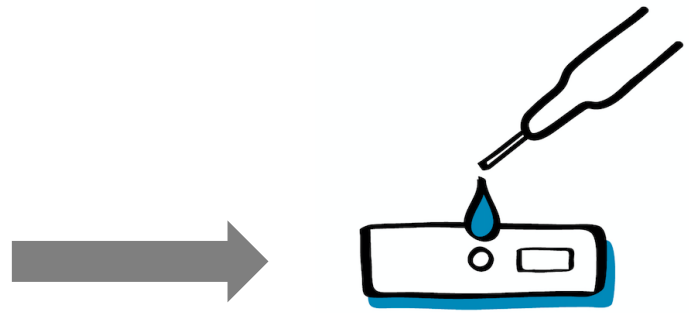


SARS-CoV-2 ADT Testing Procedure (2/3)

- Check the sample received against the worklist form to confirm receipt of sample. This will be reconciled with ADT appointment list to ensure all samples collected were tested and resulted.

- Label the ADT vial and ADT cassette with the Swiftqueue labels (or equivalent).

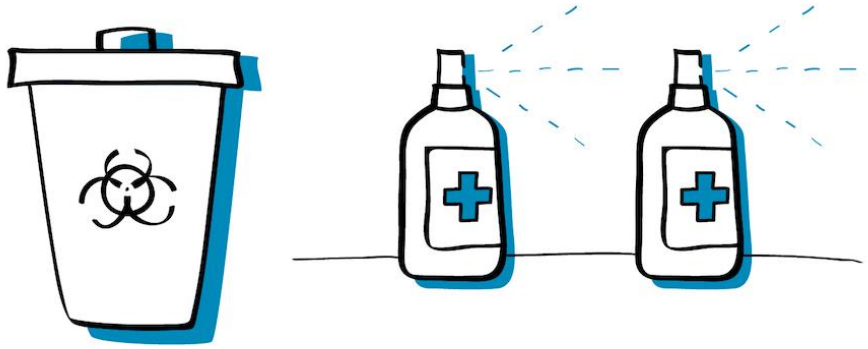
- Apply drops of extracted specimen to the specimen well of the test device. Add the exact number of drops specified by the manufacturer. **Note: failure to adhere to the exact instructions may results in incorrect test results.**



- Read and record the test result after the specified period of time, usually 15 minutes. The exact time period specified by the manufacturer should be used. **Note: all timings must be strictly adhered to.**

SARS-CoV-2 ADT Testing Procedure (3/3)

- Record the test result in the ADT result template.
- Ensure another member of the team confirms the result. This is an essential step and must be adhered to.
- If the antigen test is invalid/indeterminate, the antigen test should be immediately repeated using the same specimen collected and if it remains invalid/inconclusive the second swab sample should be sent for a confirmatory PCR result.
- Dispose of all waste (used test kit, extraction buffer tube, swab and paper stand) in the biohazard bin.
- Remove PPE (medical mask, gown, gloves, and eye protection or face-shield) as per doffing guidelines.
- Perform hand hygiene.



Interpreting SARS-CoV-2 ADT Results (1/2)

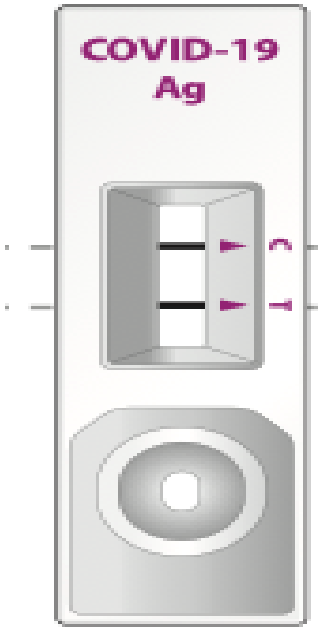
ADT results should be considered together with the patient's clinical history and other available information.

You must refer to the specific antigen test kit instructions for use, as manufactures may differ in the layout or interpretation of results.

Interpreting the ADT result on the device:

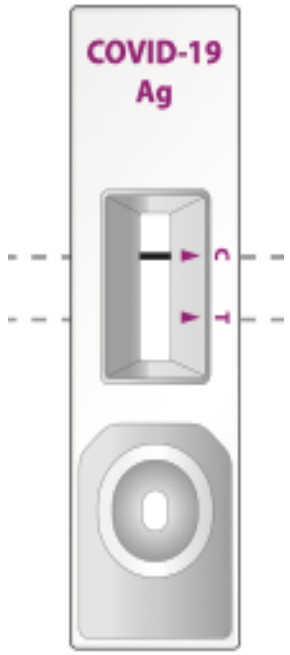
- As indicated in the figure, a coloured band will appear in the top section of the result window to show the test is working properly. This band is the control line (C).

- Depending on the ADT result, a coloured band may appear in the lower section of the result window. This band is the test line for SARS-CoV-2 antigen (T).

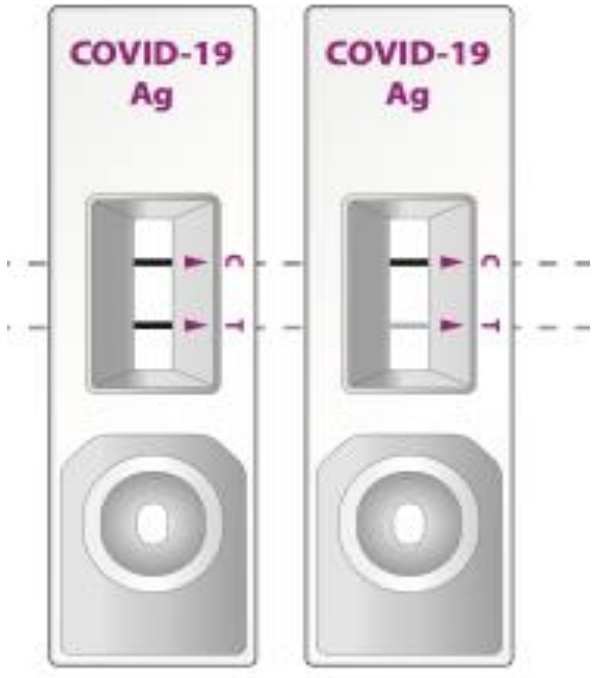


Interpreting SARS-CoV-2 ADT Results (2/2)

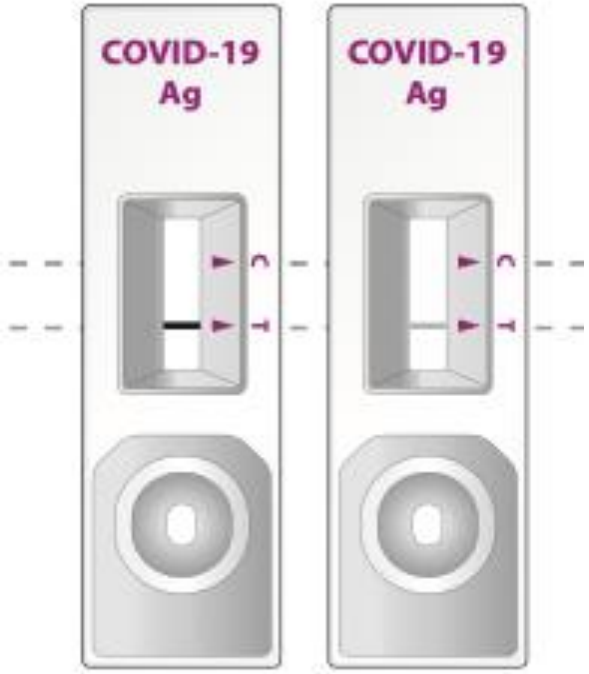
- A line in “C” and NO LINE in “T” means SARS-CoV-2 is **NOT DETECTED.**
- The result should be interpreted as a **not-detected** result.



- A line in “C” AND a line in “T” means SARS-CoV-2 is **DETECTED.**
- Even if the **control line is faint or the test line is not uniform**, the test should be considered to have been performed properly and the test result should be interpreted as a **detected** result.



- No LINE in “C” and a line or no line in “T” means the test **INVALID.**
- Repeat the test using a new (unopened) SARS-CoV-2 Antigen ADT device and a new sample.



4. Managing Results

Recording Results

Note: refer to the operational plan for your setting as reporting processes may vary for each setting (e.g. acute / community)

This process must be performed in a separate clean area. Using the ADT result template provided, two worksheets must be completed:

1. Testing information must be captured in both worksheets of the ADT result template provided. All mandatory fields (Red and Orange) must be completed, while the person in charge may choose to populate optional fields (Yellow).
2. All manual entry / recording of results must be checked and confirmed by another person.

ALL DATA MUST BE ACCURATELY CAPTURED IN THE TEMPLATE IN ORDER TO UPLOAD THE PATIENTS TO THE COVID CARE TRACKER SUCCESSFULLY. FAILURE TO PROPERLY COMPLETE THE TEMPLATE WITH REQUIRED INFORMATION WILL RESULT IN IT BEING RETURNED.

Appointment Template (Worksheet 1)

A1 : Given name

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Given name	Family name	Date of Birth	Gender	Mobile Number	Alternative N	Health Care Worker	Address 1	Address	Address 3	City/Tow	County	Country	Eircode	Dept./Ward/Area	Antigen Result	Patient/Staff Ro
2	Aoife	Adams	01/Feb/1994	Female	+353875551234		No	1 Main St.	Kilkenny			Kilkenny		A12 B345	MPH-Medical 1	Antigen-Positive	Nurse
3	Brian	Brennan	02/Feb/1994	Male	+353875551234		No	2 Main St.							GUH-ICU	Antigen-Not Detected	Patient: ABC321
4	Catherine	Casey	03/Feb/1994	Female	+353875551234		No	3 Main St.								Antigen-Indeterminate	
5	David	Doyle	04/Feb/1994	Male	+353875551234		No	4 Main St.									
6	Eileen	Edwards	05/Feb/1994	Female	+353875551234		No	5 Main St.									

Appointment Template (Worksheet 2)

	A	B
1	Test Code	Antigen
2	Test Location Name - Hospital Name	CUH
3	Test Location Area	CHO 4
4	Lot No. - list all lot no.'s that a result has been returned on.	RD-010121, RD-010221
5	Test Kit	Roche SARS-CoV 2 Rapid Antigen Test
6	Processed By	Joe Bloggs
7	Date/Time of Test (Date/time antigen testing began)	20/01/2021 08:00:00
8	Date/Time Received	20/01/2021 09:00:00

Reporting of Results

This process must be performed in a separate clean area:

1. This template should be sent to central Public Health Data Processing Teams for uploading:
   A. The template should be sent to the dedicated mailbox: publichealthdataprocessing@hse.ie
   B. The subject line of the email should be **[Antigen Testing][Hospital Name or Site (if Community)][Date]**
2. Templates must be sent once per day (at a minimum) on the same day testing occurred. This should be done as early as possible to initiate contact tracing.
3. This template must contain all the ADT results.
4. This positive result must also be input to the Computerised Infectious Disease Reporting System (CIDR) immediately (review operational plan for specific requirements).

Communicating Results

Communicating issues promptly with the clinical team:

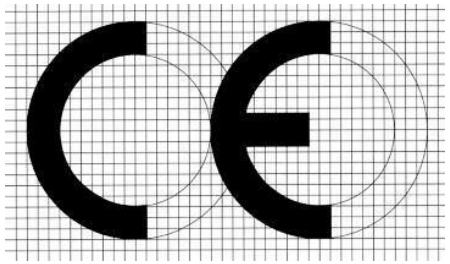
- **Detected:** The primary benefit of ADT testing is the quick turnaround time of results. Detected ADT results will be communicated immediately to the individual on site by the team (a record of all phone calls must be held). This phone call must be made to the individual immediately after the detected result is received to allow them to commence their isolation period.
- **Not detected:** Individuals must be informed that in the case of a not detected ADT result, a confirmatory PCR test will be required. The individual's sample will be sent to a laboratory for confirmatory PCR testing and the individual will ultimately receive an SMS with their PCR test result.

5. Quality Assurance

The CE Mark

The tests used for COVID-19 are classified as *in-vitro* diagnostic medical devices (IVDs) that is, they analyse a sample *in-vitro* (outside the body) for the presence of either the virus (e.g. RNA or antigen) or the body's immune response to the virus.

Currently tests for COVID-19 are regulated under the European *In-Vitro* Diagnostics Directive (IVDD, Directive 98/79/EC) and must be CE-marked and used as outlined in the accompanying product literature called instructions for use (IFU).



Elements of Quality Assurance for Antigen Testing

Elements of quality assurance:

Antigen testing should be conducted under the specific clinical guidance and governance as outlined in clinical governance section. A quality management system (for point of care/near-patient testing) should be implemented in line with national guidelines.

This should take into account the following:

- Training and ongoing competency assessment of the operator.
- Record keeping and maintenance of documentation.
- Performance and documentation of appropriate internal quality control.
- Correct patient identification.
- Obtaining a satisfactory sample and sample integrity.
- Performance of the test in accordance with the manufacturer's instruction.
- Recording of the test result in the patient record.
- Correct interpretation of the result and appropriate action taken.
- Recording of non-conformances, and corrective and preventive actions.
- Performance of quality indicators (IQC and EQA).

Source: Guidelines for safe and effective near-patient testing (NPT) [Soft Release (Beta) Version 5.7, released April 20, 2020. Valid until April 20, 2021].

Record Keeping and Maintenance of Documentation

Points to consider:

- Ensure that all information is recorded every time a procedure is performed.
- Ensure that the minimal critical information required is recorded:
  - Patient information
  - Test kit name, lot number, expiry date
  - Individual and final test results
  - Name of person performing the analysis
  - Name of person checking analysis
- The information should be documented the same way every time.
- Records of test results must be stored securely and confidentially and must be available for inspection in line with Royal College of Pathologists guidance (Retention and Storage of Pathological Specimens and Records).

Quality Assurance during the different stages of the Analytical Process

Stage	Actions
Pre-analytical	**Mitigating actions**
Correct labelling of specimen	• Cross-check labelling of the sample cassette, specimen tube, and the sample request form.
Correct handling of sample before testing	• Test the sample immediately after sample collection. • Where samples have to be stored or transported from the collection to the testing site, follow the manufacturer's instructions on maximum time and temperature of storage.
Batch acceptance	• All new batches / lot number need to be verified and accepted before use. This involves testing batch with control material.
Storage of test kits / reagents and used within expiry date	• Follow the manufacturer's instructions on storage conditions. • Monitor the temperature of the storage room and testing site. • Check expiry dates of kits and use kits with the shortest expiry first. • Do not use kits that are past their expiry date.
Analytical	**Mitigating actions**
Correct labelling of test cassette	• Cross-check labelling of the sample cassette, specimen tube, and the sample request form.
Correct interpretation and recording of results	• Review test quality controls (internal quality control and, if applicable, test detected and not-detected controls). • Only report results if the test have passed the embedded quality control.
Post analytical	**Mitigating actions**
Ensure result is reported	• A system of double checking / audit is in place.
Ensure result is reported to the correct patient	• Cross-check labelling of the sample cassette, specimen tube with the sample request form, result recorded and identifier on the result report to ensure they are the same.

Quality Indicators

Which Quality Indicators (QIs) should be used to monitor antigen testing?:

The QIs listed below are collected from the daily, and then weekly, totals captured.

Audits should be conducted regularly to monitor the following QIs:

- Number and proportion of specimens tested by specimen type, by batch/lot, by tester.
- Number and proportion of detected, not detected and unsuccessful (invalid) SARS-CoV-2 Antigen ADT results.
- Concordance of SARS-CoV-2 ADT result with PCR result where both tests are performed.
- Number and proportion of spoilt tests (damaged packages, etc.).

Addressing Issues

The following approaches should be taken to addressing quality issues:

- Conduct further investigation to determine the reason why QIs fall outside of an acceptable range or have unusual trends.
- Sites should seek help if there are difficulties in identifying problems and corrective actions.
- Breaking down errors by tester or batch may help to identify root causes due to operator error (e.g. errors occurring with new or untrained staff) or batch issues.
- Undertake and document actions to correct errors and note what measures are put in place to prevent them from re-occurring (preventive actions).
- Monitor the effectiveness of actions in terms of improving QIs.
- Track the QI data over time (monthly and quarterly) for longer term trends that may not be apparent from weekly reports.
- Where appropriate, issues should be communicated, for example the microbiologist overseeing community ADT, so that potential issues can be communicated to other sites and experience can be collated.

QC of Controls on an ADT Device (1/2)

Batch acceptance:

All batches of SARS-CoV-2 ADTs should be checked by lot testing, i.e. by evaluating the performance of production lots (batches) before it is used.

- New lot testing is usually carried out in the laboratory, following standardized procedures and using QC materials (detected and not-detected controls).
- At least five samples (three detected and two not-detected) should be tested for each new lot. This can be conducted with QC materials or detected and not-detected samples.

Internal Quality Controls (IQC):

For SARS-CoV-2 ADTs, the controls come in the form of:

- In-built internal procedural controls that validate the test sample has travelled through the intended reaction area (often in lateral flow designs).
- IQC can also involve the use of quality control materials (some manufacturers provide these as part of the assay e.g. detected and not-detected swab control) that act as detected and not-detected controls.
- Alternatively, use third party quality control materials such as proficiency testing panels as they become available, or patients' samples already tested with results known from a verified method / assay.
- The operators performing the tests must ensure that IQC is performed correctly and consistently.

QC of Controls on an ADT Device (2/2)

External Quality Assessment (EQA):

- EQA is a means of determining how a particular diagnostic test is performing in comparison to a similar diagnostic test at different sites and to other manufacturers' tests or other laboratory analysers.
- To establish high quality and comparability of ADT results for SARS-CoV-2, EQAs suitable for antigen tests should be used at regular intervals and performance should be reviewed under a quality management system.

- Currently, there are two EQA schemes for SARS-CoV-2 ADTs, which are due to commence shortly
  - INSTAND EQA Scheme Virus Antigen Detection SARS-CoV-2 antigen – March 2021 (410)
  - Lab quality, 5681 SARS-CoV-2, antigen detection EQA scheme .
  - Proficiency testing panels may become available

Clinical Governance

Clinical and managerial governance of NPT within the acute hospital settings:

All NPT in hospital settings should ideally be accredited to ISO 15189/22870 standards and meet the requirements as described in the Guidelines for safe and effective near-patient testing (NPT) (April, 2020).

- In any acute setting under the HSE where ADT is deployed, the clinical director of diagnostics will be responsible for overall clinical governance with input from clinical microbiology.

Clinical and managerial governance of NPT outside of acute hospital settings:

It is important that primary and community care settings have a clearly defined and well-structured approach to NPT to ensure that it is performed in a safe and effective manner and that results generated are accurate, reliable and recorded.

- In the community, the testing is ordered by Public Health, as a response to an outbreak, and governance of who is to be tested, informing patients, and advising on actions based on the results rests with Public Health and the outbreak control team. Governance of undertaking the tests in a supervised manner, and in a quality management system rests with the NAS working with the local Clinical Microbiologist.

It is acknowledged that many NPT services are not accredited today, even in the hospital sector. However, progress has been made in all sectors since the first edition of the NPT guidelines, released in 2007, and all sectors have embarked on a journey where full accreditation is the ultimate goal to optimise clinical outcomes and patient safety.

Stock Management

When to order:

- Each site should maintain one month's worth of stock.
- Each site should ensure they have the capacity to safely and appropriately store stock.

Placing stock orders:

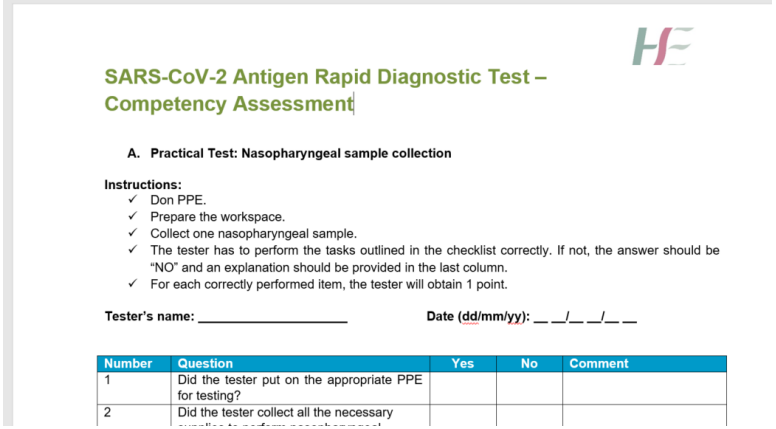
- A stock of SARS-CoV-2 Antigen ADT tests is being maintained centrally by the HSE.
- Each hospital can request one month's supply at a time for all requirements within your site by contacting declan.coffey@hse.ie or ellen.white2@hse.ie indicating the quantities required, and the point of contact for the delivery of tests.
- Deliveries can only be facilitated from Monday to Friday.

6. Training & Competency Assessment

Training Requirements

To achieve competency in the use of antigen tests, all users must ensure the following:

- ❑ Completion of training is mandatory for all staff performing testing.
- ❑ All operators being trained must complete an attendance log.
- ❑ All operators being trained must demonstrate adherence to Health and Safety and Biohazard guidance.
- ❑ All operators being trained must demonstrate the correct set up of the work station and correctly wearing personal protective equipment (PPE).
- ❑ All operators being trained must read the manufacturers instructions and any locally produced SOPs.
- ❑ All operators being trained must complete a minimum of 2 observed tests and show test results and devices to the instructor.
- ❑ All operators being trained must identify a series of results correctly (paper exercise). Operators are required to obtain >80% for each component of the assessment.
- ❑ All operators being trained must complete a competency assessment.
- ❑ A register of certified testing staff and their competency assessment must be maintained.



SARS-CoV-2 Antigen Rapid Diagnostic Test – Competency Assessment

A. Practical Test: Nasopharyngeal sample collection

Instructions:
- ✓ Don PPE.
- ✓ Prepare the workspace.
- ✓ Collect one nasopharyngeal sample.
- ✓ The tester has to perform the tasks outlined in the checklist correctly. If not, the answer should be "NO" and an explanation should be provided in the last column.
- ✓ For each correctly performed item, the tester will obtain 1 point.

Tester's name: _____ Date (dd/mm/yy): __ __/__ __/__ __

Number	Question	Yes	No	Comment
1	Did the tester put on the appropriate PPE for testing?			
2	Did the tester collect all the necessary			

- Confidential -