

Title: Update on HSE plans for implementation of Antigen Detection Tests

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Action required:

- For noting
- For discussion
- For decision

Approved for future publication: YES/NO (remove as applicable)

Introduction

On 7th January 2021, NPHE approved the paper “Public Health Prioritisation of Testing in Current Epidemiological Context, 6th January”, submitted by the National Clinical Director of Health Protection. This paper describes the current status of the HSE plans for use of ADTs in acute hospitals and the community.

Updates on specific issues reported at the last update at NPHE on 21st January

1. The use of Antigen Detection Tests (ADTs) in point of care settings **has been approved by the Health and Safety Authority** as long as a written risk assessment for the use of the test in the particular setting is conducted (full text in Appendix A). In conducting the risk assessment account should be taken of [WHO guidance](#) and [HPSC public health guidance](#). When conducting the risk assessment, the risk is not based on the pathogenicity of the biological agent alone, but on the likelihood and consequence of an incident or exposure occurring. On conducting the risk assessment, it must be determined whether the risk is acceptable or not, are existing controls adequate or do additional control measures need to be introduced? If the risk is still unacceptable after the introduction of additional control measures then the point of care testing should not proceed.
2. The **new case definition** as agreed with NPHE on the 21st January, **will go live on the 27th January 2021**.
3. **An operational framework** identifying the settings for use, the criteria for ADTs and the standards for use in acute hospitals and community **settings has been finalised by HSE**, (Appendix B). The operational framework team has indicated that arrangements have been put in place to deal with the two ICT issues (reporting to COVID Care tracker and to CIDR).
4. **Guidance on use of ADTs** has been developed (Appendix C)
5. **A framework for their use in acute hospitals has been completed** (Appendix D). Within the acute hospital setting, deployment of ADTs will depend on the local laboratory capabilities for provision of large-volume batch testing, rapid PCR testing, and staffing levels. Approaches will vary by hospital location.

Within the acute hospital setting, and as advised locally, they are likely to be used in a range of settings including:

- Triage of patients in emergency departments and in ambulances arriving at department pending admission to the emergency department;
- To support early diagnosis in hospital outbreaks, including testing of symptomatic Health care workers;
- In situations where ADTs can reduce pressures on the hospital’s capability for rapid PCR testing.
- Note - Validation work on the use of ADTs for serial testing in healthcare workers is ongoing.

In the community setting, ADTs may be used as part of the response to outbreaks in symptomatic vulnerable populations and their close contacts following Public Health Risk Assessment, when there is evidence of widespread community transmission (>10% positivity in the local community). The vulnerable populations include staff and/or residents of long-

term care facilities, homeless hostels, residents of direct provision centres, prisons, Irish Travellers etc. Testing will be undertaken by the National Ambulance Service (NAS). Details of the arrangements including an assessment of their capacity to support this work are still in development. Implementation in these settings will commence once this has been completed.

6. **The local and national governance** of tests and results has been clarified. In any acute setting under the HSE where RADT is deployed, the clinical director of diagnostics will be responsible for overall clinical governance with input from clinical microbiology. During the investigation of community outbreaks, the testing is ordered by Public Health as a response to an outbreak. Governance of testing, informing patients and advising on actions based on the results is with the Medical Officer of Health, and the outbreak control team. Governance of undertaking the tests in a supervised manner, and in a quality management system rests with NAS working with the local Clinical Microbiologist.
7. **The Department of Agriculture hopes to complete validation on the use of testing in Food Business Operations (FBO) this week**, subject to sufficient positive results being achieved and the validation approved. Subject to this, HSE legal advice is that HSE can then make these tests and guidance available to FBO through the Department of Agriculture for use. The HSE will not have direct responsibility for overseeing the usage of the tests in the sector. Many of the FBO are already undertaking ADT of their staff as a precautionary measure outside the public system.

Appendix A: Health and Safety Authority response.

The Biological Agent Regulations require that a written risk assessment is carried out to identify whether there is actual or potential exposure to a biological agent such as SARS-CoV-2.

Assuming that point of care testing is not being conducted in a laboratory, then it will not fall under Regulation 17 of the Biological Agents Regulations (i.e. special measures for laboratories). If point of care testing is being carried out in a healthcare facility, then Regulation 16 will apply. However, under Regulation 16, Schedule 2 in the code of practice (i.e. the containment levels and containment measures) will only apply when point of care testing is done in an isolation facility.

So the main requirement under the Biological Agents Regulations will be to conduct a written risk assessment and in so doing, the following should be considered:

- Who's being tested – this will probably be symptomatic patients as antigen tests wouldn't be too reliable otherwise. So potential exposure to risk group 3 biological agent.
- Who's taking the samples and carrying out the tests?
- Are they competent, have they training etc.? They will need to follow the usual precautions for taking SARS-CoV-2 samples regarding PPE etc.
- What type of samples are being taken (nature of the sample)? Probably nasal but mightn't be.
- Where are the samples being taken? E.g. in a doctor's surgery, healthcare centre, hospital etc.
- Where is the test being carried out? Same location or is the sample being transported to a point of care "centre"? Is there sufficient space for the work to be carried out, can the test area be easily disinfected, is it free of material, etc.? Assume sample is being used straight away and not being stored.
- Is the sample being processed further (depends on test being used)- if not it's lower risk, is a transport medium being used, if so what volume? Is there a chance of spills, aerosol generation, skin contact etc. when handling the sample and doing the test?
- How are samples and any waste disposed of? Must have documented procedure.
- Are there other people who may be affected by the work activity e.g. pregnant employees, people handling the waste, cleaners etc.?
- Are there appropriate decontamination and disinfection procedures in place? Must have documented procedure detailing type of disinfectant, percentage, contact times etc.

In conducting the risk assessment account should be taken of [WHO guidance](#) and [HPSC](#) public health guidance. When conducting the risk assessment, the risk is not based on the pathogenicity of the biological agent alone, but on the likelihood and consequence of an incident or exposure occurring. On conducting the risk assessment, it must be determined whether the risk is acceptable or not, are existing controls adequate or do additional control measures need to be introduced? If the risk is still unacceptable after the introduction of additional control measures then the point of care testing should not proceed.



COVID-19: OPERATIONAL FRAMEWORK FOR THE DEPLOYMENT OF RAPID ANTIGEN DETECTION TESTS FOR SARS-COV-2

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Before use check the HSE webpage to verify this is the latest publication.

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1.0	DRAFT	First draft	RADT Validation Scientific Lead RADT Implementation Project Manager

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Glossary

#	Term	Description
1	RADT	Rapid Antigen Detection Tests
2	CCT	Covid Care Tracker
3	CIDR	Computerised Infectious Disease Register
4	Swiftqueue	Software for scheduling appointments
5	HPSC	Health Protection Surveillance Centre
6	LIMS	Laboratory Information Management System
7	NPT	Near-Patient Testing
8	NPHE	National Public Health Emergency Team
9	PCR	Polymerase Chain Reaction
10	PH	Public Health
11	PPE	Personal Protective Equipment
12	WHO	World Health Organisation

Background

To date, testing for SARS-CoV-2 infection has mostly relied on reverse transcription polymerase chain reaction (RT-PCR) performed on a nasopharyngeal or deep-nasal/mid-turbinate specimens. This testing method remains the gold standard for detecting SARS-CoV-2.

Following approval by the National Public Health Emergency Team (NPHE) for the use of Rapid Antigen Detection Tests (RADT) in certain settings, RADT will be deployed to support the pandemic response.

See HPSC clinical guidance which outlines settings approved for use for RADT.

Purpose

This document is intended to provide assistance for users of RADT in the performance of testing, and to act as an overarching operational framework that should guide the use of RADT in a near-patient test (NPT) setting.

RADT users will be required to apply clinical and scientific expertise to ensure that RADT is used in each setting in ways that are safe for those who perform the testing and those who are tested, and that provide an effective quality assured service. This requires clear clinical governance and accountability that includes not only performance, but also interpretation and communication of results.

Scope

This operational framework covers all aspects of RADT. This ranges from the point of sampling an individual to the performance of RADT, and subsequent recording and reporting of detected results to the Medical Officer of Health.

As laboratory based RADT have not concluded validation, this document covers near-patient testing RADT and will be updated in due course.

Target users

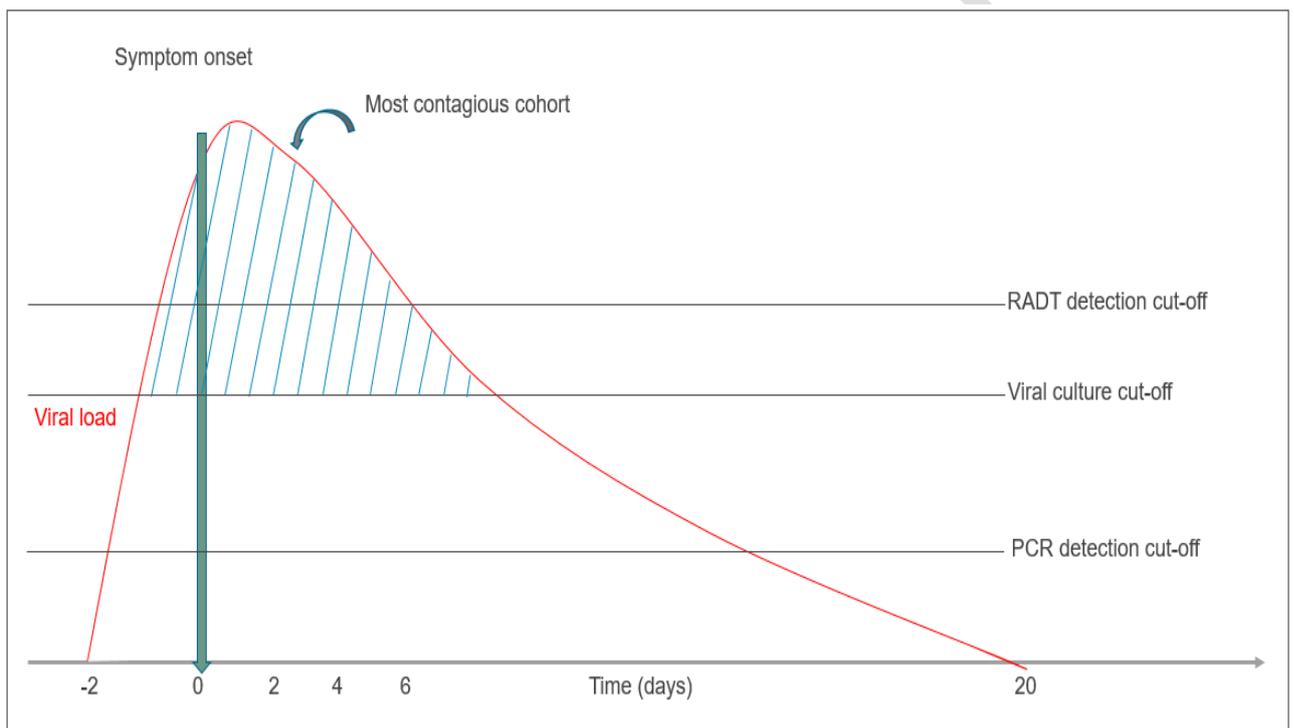
All users of RADT approved by the HSE.

Objective

The objective of this operational framework is to ensure correct use of RADT and consistency in the completion of operational requirements.

Rapid Antigen Detection Tests

RADT are comparatively easy to use and offer rapid results. Correctly applied RADT may offer benefits in comparison to RT-PCR tests for the detection of SARS-CoV-2 in certain contexts, although completion of RADT can be considered labour intensive. They have been developed as both laboratory-based tests and for NPT, and results are normally generated in 10 to 30 minutes after the start of the analysis, and at lower cost for supplies compared with RT-PCR. However, available RADT have demonstrated lower sensitivity when compared to the gold standard RT-PCR test, while their specificity is generally reported to be high. Furthermore, their intended use is in symptomatic patients within the first 5 days of symptom onset when viral loads are highest as outlined in the below graph.



Clinical Governance

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

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.

Roles and Responsibilities

The following roles and responsibilities will be required at a minimum when performing RADT. These requirements may differ depending on the specific setting.

Role	Responsibilities
Clinical Director of the Laboratory/ Diagnostic Service	<ul style="list-style-type: none">Professionally accountable for the quality of the results reported.
Administration	<ul style="list-style-type: none">Supports coordination of workflow at testing site, organising test materials, paperwork, labelling, and scheduling.Collects RADT testing information and clinical data from individuals to enable reporting (e.g. RADT 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	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Receives samples from the test operator ('the 'swabber') and performs RADT.Interprets RADT results.
Review and authorisation	<ul style="list-style-type: none">Undertakes the process for review of testing information captured (e.g. patient information) and authorisation of results.
Quality assurance	<ul style="list-style-type: none">Batch acceptance of reagents and traceability.Ensures appropriate EQA and IQC processes are implemented and maintained
Communication of positive results	<ul style="list-style-type: none">Contacts the individual(s) with a detected (positive) RADT immediately, informing them of their result and requesting them to isolate.
Reporting	<ul style="list-style-type: none">Records results on RADT result templateEnsures positive 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.

Procedures in Rapid Antigen Testing

Health and Safety Processes

The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (S.I. No. 572 of 2013) article 16, documents the special measures required for working with biological agents in health care setting other than diagnostic laboratories. Before commencing any SARS-CoV-2 RADT, 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.

The risk assessment should consider the following:

- Who is being tested?
- Who is taking the samples and carrying out testing?
- Have they completed RADT 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?
- 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?

In conducting the risk assessment account should be taken of WHO guidance and HPSC public health guidance.

Personal Protective Equipment

Before commencing any sampling or testing for SARS-CoV-2, the appropriate PPE must be put on (Table 1). Please refer to HSE guidelines for donning and doffing PPE.

- COVID - 19 Safe PPE – Care of Patients with respiratory symptoms/ suspected/ confirmed COVID -19 - 30/04/20
- Safe use of Masks – 26/08/20
- Putting on (donning) Personal Protective Equipment (PPE) - 19/05/20
- Taking Off (doffing) Personal Protective Equipment (PPE) - 27/07/20
- Doffing gowns in the context of COVID -19 – 06/11/20

Table 1: PPE requirements for procedures in RADT testing

Procedure	Personal Protective Equipment
Sample collection	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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)
RADT sample testing	<ul style="list-style-type: none">• 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

Waste Management

1. Handle all waste from sample collection and SARS-CoV-2 RADT testing as biohazardous.
2. Disposal of SARS-CoV-2 RADT used cassettes:
 - a. Read manufacturer's specific instructions.
 - b. Read Material Safety Data Sheets.
 - c. As per local guidelines, used cassettes should be disposed of in biohazard bins.
3. All components of SARS-CoV-2 RADTs are single-use and must not be reused.
4. Place all contaminated materials (such as used sample containers) in biohazard bins.

Procedure for cleaning up spills

The following procedure applies to RADT samples only:

1. Flood the spill area with 1% bleach.
2. Cover the spill and disinfectant with paper towel.

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

Setup of Workstation

RADT must be performed on a designated well-ventilated bench, 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 should be set up with dirty and clean areas, ensuring adequate space on both as indicated below.

All contaminated materials (such as sample containers, transfer pipettes, tubes and cassettes) must be disposed of in a yellow biohazard sharps 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.

Requirements:

Dirty Area

- Non-porous work surface, suitable for wiping down
- Hard Clinical Waste Bin (Yellow - adjustable closure)
- Clinical Waste leak proof Bag and Biohazard bin (both Yellow)
- Supply of disposable gloves (size appropriate)
- Timers
- Disinfection products
 - Surface: Chlorox 1:100; alcohol 70%
 - Hand: hand sanitiser
- Paper towels
- Absorbent pads/ a contained plastic tray
- RADT test kit
- Rack for samples
- Waterproof markers
- Instructions for Use - Laminated

Clean Area

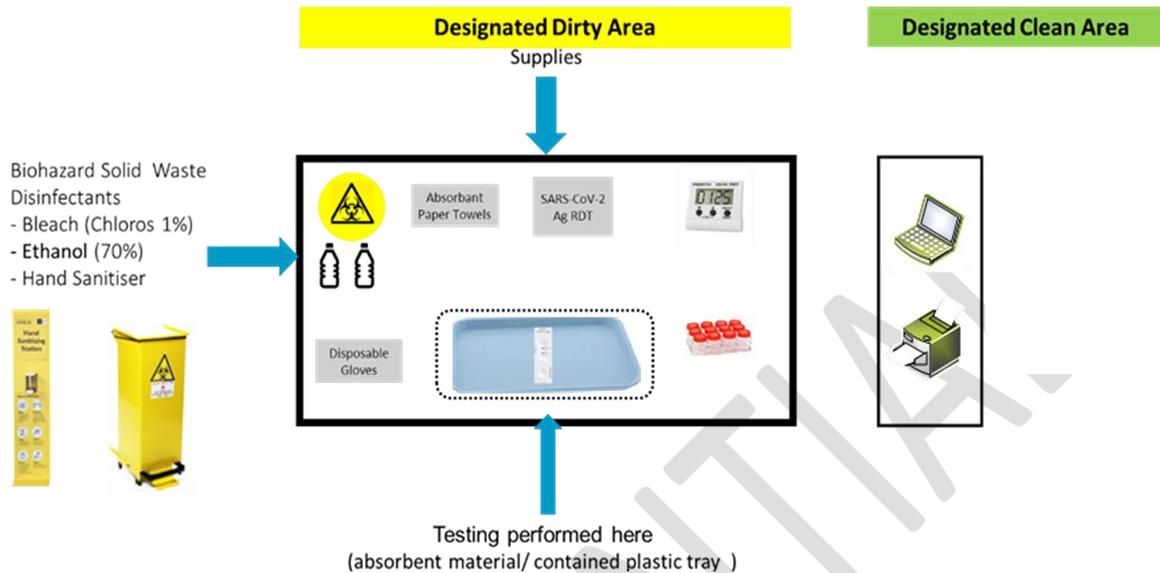
- RADT result template
- Disposable Pen

The following may be required based on the setting:

- Internet connection
- Laptop
- Printer
- Phone
- Access to the Covid Care Tracker (for reporting of detected results)

Workstation Configuration

The below diagram is an indicative setup of an RADT sampling and testing station with designated dirty and clean areas. These requirements may differ depending on the specific setting and workflows.



Preparation of workstation

1. Clean and disinfect the workstation before and after use and immediately after a spill occurs.
2. Contact time, dilution and shelf life of the working disinfectant solution (after dilution) are all critical for effective disinfection (follow manufacturer's instructions on effective and safe use).
3. Always leave disinfectants in contact with surfaces or spills for the recommended time, usually 10–15 minutes.
4. Prepare working solution of sodium hypochlorite (bleach) daily by diluting from the concentrated disinfectant solution, as diluted sodium hypochlorite degrades rapidly losing efficacy.
5. Mark the date of dilution on the bottle and only use on the day of preparation.

Sample Procedure

1. Ask the individual to confirm their name, date of birth and mobile phone number to ensure they are correct on the Swiftqueue label.
2. Individuals will be directed to the dedicated area where the RADT is being undertaken.
3. 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.
4. Print 3 additional Swiftqueue (or equivalent) ID labels for individuals. Labels will be used on the COVID request form, RADT vial, and RADT cassette. An RADT label will clearly identify that it is related to antigen testing.

5. Activity and progression of all individuals will be recorded using the appointment list (or other template).

Note: step three requirement will differ if Swiftqueue is not used as part of the referral process.

Sample Collection

Requirements:

- Samples must be collected by trained individuals (refer to HSE Guideline/training for operators/ 'swabbers').
- New (unopened) individually wrapped sterile swab (**use swabs provided in the SARS-CoV-2 RADT kit unless specified otherwise in 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 (Section 2.6 below). Refer to specific manufacturer's Instructions for Use for the kit in question.
- Antigen Testing must be performed immediately 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.
- **Note: the RADT swab type may vary based on the manufacturer (e.g. nasopharyngeal, nasal)**

Pre-collection steps

1. The batch number, lot number, and manufacturer of the test kit must be recorded in the result template.
2. Pre-prepare the extraction buffer tubes as indicated in manufacturer's instructions.
3. Provide these pre-prepared tubes and swabs provided with test kits to swab taker prior to taking specimen.

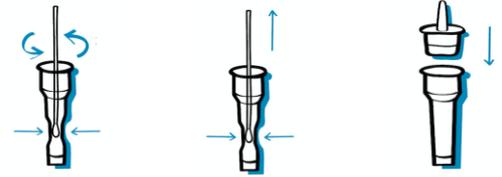
Sample collection

1. Confirm the individual name, date of birth and mobile phone number are correct on the Swiftqueue label (or equivalent).
2. Explain the swabbing procedure to the individual and that two swabs will be obtained (if applicable in the setting) and secure verbal consent.
3. After taking the first sample for the standard PCR test, proceed to obtaining the second sample for the RADT.
4. Apply Swiftqueue or equivalent ID label on the pre-prepared extraction buffer tube.

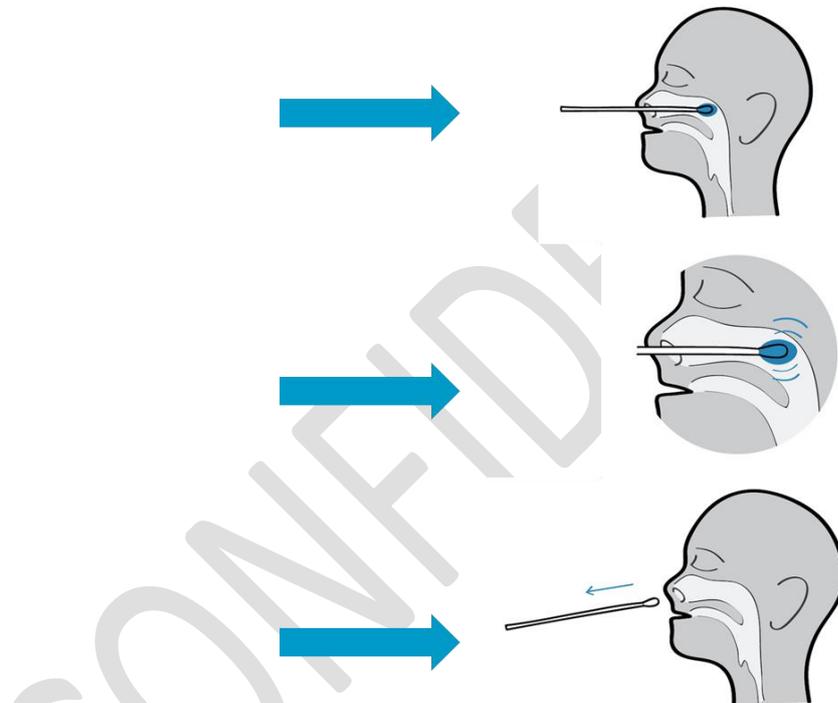
IF NASOPHARYNGEAL SWAB

5. Insert a sterile nasopharyngeal swab (provided with SARS-CoV-2 RADT kit) into the nasal cavity of the patient, reaching the surface of the posterior nasopharynx.
6. 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.
7. Withdraw the sterile swab from the nasal cavity.

8. Insert the swab into the labelled pre-prepared extraction buffer tube for the specified period of time.
9. 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.
10. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. The extracted solution will be used as test sample.
11. Press the nozzle cap tightly onto the tube.
12. Pass the tube to scientist/analysts for testing as outlined below.



Refer to [HSE video](#) on obtaining nasopharyngeal swabs for further guidance.



IF NASAL SWAB

1. To avoid viscous mucus interfering with sampling, invite the individual to blow their nose before sample collection.
2. Using the sterile nasal swab, take a bilateral nasal swab from both nostrils as follows:
3. Tilt the individuals head back 70 degrees as shown below. 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.



4. Following sample collection, immediately insert the swab directly into the labelled pre-prepared extraction buffer tube provided by the scientist. The next steps can be completed immediately by the scientists/analysts, working alongside the swabber.
5. Swirl the swab tip in the buffer fluid inside the extraction tube pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.
6. Break the swab at the break point and close the cap of the extraction tube. The extracted solution will be used as the test sample and will be added to the kits lateral flow cassette for testing.
7. Press the nozzle cap tightly onto the tube.
8. Pass the tube to scientist/analysts for testing.

Performing the SARS-CoV-2 Rapid Antigen Detection Test

Typical SARS-CoV-2 RADT kits consist of:

- Test device (individually wrapped in a foil pouch with desiccant)
- Extraction buffer tube
- Buffer
- Nozzle cap
- Paper stand for securing the extraction buffer tube
- Instructions for Use (IFU).

It is important to refer to the test-specific Instructions for Use, as reagents and procedures including incubation times may vary between different tests.

1. Check sample received against worklist form to confirm receipt of sample. This will be reconciled with RADT Result template at end of day to ensure all samples were collected, tested and resulted.
2. Label the RADT vial and RADT cassette with the Swiftqueue labels (or equivalent).
3. Apply drops of extracted specimen to the specimen well of the test device. Add the exact number of drops specified by the manufacturer.
4. 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.

5. Record the test result in the RADT Result template. See section below for interpretations. Ensure a checker confirms the result.
6. Dispose of all waste (used test kit, extraction buffer tube, swab and paper stand) in the biohazard bin.
7. Remove PPE (medical mask, gown, gloves, and eye protection or face-shield) as per doffing guidelines.
8. Perform hand hygiene.

Interpreting Results

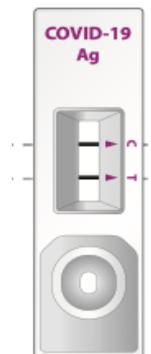
RADT results should be considered together with the patient's clinical history and other available information.

The test result **MUST** only be read within the recommended timeframe indicated by the Manufacturer.

It should be noted that the test procedures and interpretation of SARS-CoV-2 RADT results are similar for all tests. It is important to follow the test-specific Instructions for Use, as reagents and procedures including incubation times may vary between different tests.

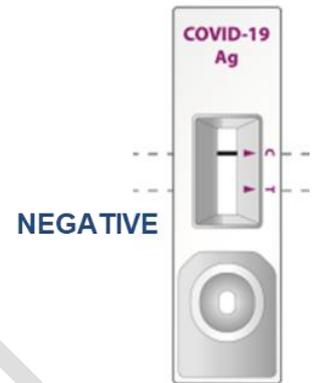
Interpreting the RADT result on the cassette:

- A coloured band will appear in the top section of the result window to show that the test is working properly. This band is the control line (C).
- Depending on the RADT 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).



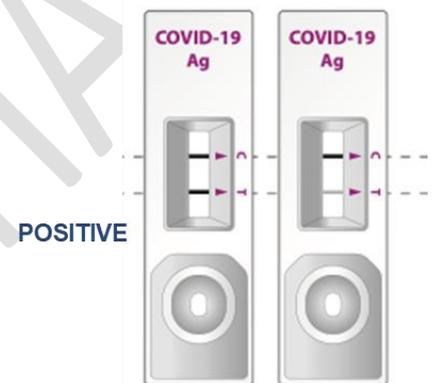
NOT DETECTED

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



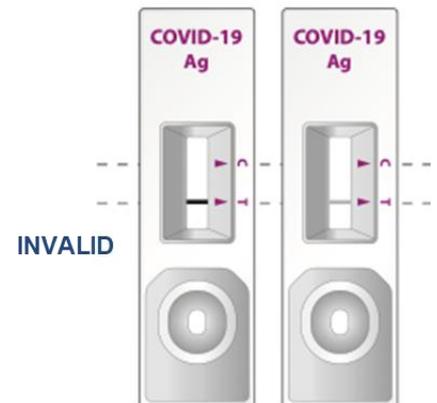
DETECTED

- 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 isn't uniform, the test should be considered to have been performed properly and the test result should be interpreted as a POSITIVE result.



INVALID

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



Managing and Recording Results

Note: a site must have a means to record results of all RADT completed. This should be captured in the RADT result template unless agreed otherwise.

This process should be performed in a separate clean area:

1. Ensure administrative individual confirms the result.
 - a. **If detected**, the result must be recorded in the RADT result template. A designated member of the team must contact the individual immediately and request them to isolate. A specific script provided by contact tracing can be used to counsel and advise individuals in each of the different settings.
 - b. **If not-detected**, the result must be recorded in the RADT result template.
 - c. **If invalid**, the result must be recorded in the RADT result template. Either repeat the antigen test immediately using the same specimen collected or request a confirmatory PCR test if required. Clinical judgement should be applied based on the setting.

Reporting of Results

Note: reporting requirements may vary dependent on the setting. All users should refer to their settings operational plan to ensure requirements are met.

This process should be performed in a separate clean area:

1. **Where detected:**
 - a. Always record each result in the RADT result template. Results must then be sent Public Health or input on the Covid Care Tracker (CCT) immediately to allow contact tracing (review operational plan for specific requirements)
 - b. This positive result must also be input to the Central Infectious Disease Register (CIDR) immediately (review operational plan for specific requirements).
2. **Where not-detected or invalid:**
 - a. Results should not be uploaded to CCT currently (review operational plan for specific requirements).
 - b. A summary update of all results must be sent to Public Health outlining the aggregate number of individuals who tested positive, negative, and invalid.

Activity Reporting

A summary report of RADT activity will be requested from sites to support planning and procurement. Sites are requested to provide aggregate data of activity upon request.

Quality Assurance

RADT 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 for safe and effective near-patient testing. Operators undertaking the sampling and testing must be documented as fully competent and trained.

This QMS 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).

Batch Acceptance

All batches of SARS-CoV-2 RADTs should be checked by lot testing, i.e. by evaluating the performance of production lots (batches) before they are deployed in the field.

- New lot testing helps to ensure that the SARS-CoV-2 RADTs delivered to the sites perform according to the manufacturer's specifications.
- 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.
- New lot testing can be conducted with QC materials.

Internal Quality Controls:

For SARS-CoV-2 RADTs, 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. positive and negative swab control) that act as positive and negative 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.
- Internal controls should be performed weekly or more frequently depending on the number of tests being performed.

External Quality Assessment:

To establish high quality and comparability of rapid antigen test results for SARS-CoV-2, EQAs suitable for rapid antigen tests (RADTs) should be used at regular intervals and performance should be reviewed under a quality management system.

Currently, there is not an EQA scheme in place for SARS-CoV-2 RADTs, however, an EQA will be put in place in due course which may include:

- Exchange of testing panels at defined intervals between testing sites using the same antigen test, to check if there is agreement in the results.
- Proficiency testing panels may become available that can be used for EQA.

Training

A training package has been developed, adopting material and guidance from the SARS-CoV-2 Antigen RDT training package v1.0 which has been designed and developed by the Foundation for Innovative New Diagnostics (FIND) and the World Health Organization (WHO). The training package addresses the theoretical and practical components of SARS-CoV-2 RADT testing and provides operators with the skills and resources on how to safely perform SARS-CoV-2 Antigen RDT testing.

It also includes competency assessment which should be carried out after the initial training to determine whether participants have understood the content of the training, can safely and accurately perform the nasopharyngeal sample collection and SARS-CoV-2 Antigen RDT(s), and can interpret and record the test result(s). The operators should be observed carrying out the entire process and should process a minimum of two SARS-CoV-2 Antigen RDTs during the training, each tester will be asked to independently perform two complete SARS-CoV-2 Antigen RDT tests in parallel.

To pass the competency assessment, trainees should obtain a passing score of 80% on the competency assessment. This must be signed off and documented.

Revision and Audit

This document will be revised and updated in line with RADT developments.

References

HSE/HPSC, COVID-19: GUIDELINES FOR USE OF RAPID ANTIGEN DETECTION TESTS FOR SARS-COV-2 IN APPROVED SCENARIOS, Version 1.0, January 2021.

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[COVID-19 Awareness and Poster Material](#)



Interim guidance on use of Antigen Detection Tests in the public health system in Ireland

Version 1.0.

26.01.2021

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Key points

- Antigen Detection Tests (ADTs) for SARS-CoV-2 detection are carried out either at the point of care, where they are known as Rapid Antigen Detection Tests (RADTs), or they can be laboratory based.
- These immunoassays detect the presence of specific antigens on the surface of the virus, and identify people who are infectious, when virus levels in the body are likely to be high
- They are less sensitive than PCR tests, but can be performed outside the laboratory and generally take less than 30 minutes to perform providing rapid information for detection management and control spread of infection.
- Before implementing ADT, ECDC has advised countries to undertake independent and setting-specific validations of RADTs before their implementation. This work is underway in Ireland, led by the HSE Antigen Project Evaluation Working Group
- Based on the results of validations to date, ADTs will be used in the acute hospital setting and in outbreaks in vulnerable populations in the community
 - In the acute hospital setting, deployment will depend on local laboratory capabilities for provision of large-volume batch testing, rapid PCR testing, and staffing levels, and approaches will vary by hospital location. They may be used in a range of settings including:
 - Triage of patients in emergency departments and in ambulances arriving at department pending admission to the emergency department;
 - To support early diagnosis in hospital outbreaks, including testing of symptomatic health care workers;
 - In identification of infectious cases in outbreaks, and also in using repeat ADTs to guide decisions on when to declare an outbreak closed.
 - In situations where ADTs can reduce pressures on the hospital's capability for rapid PCR testing.
 - In community settings they will be used for cases and close contacts in outbreaks in vulnerable populations when community transmission is high
- An operational framework which includes national and local governance arrangements, roles and responsibilities, procedures for all aspects of the testing process, as well as specifying how to report results to the individual and to public health for contact tracing and surveillance has been developed.
- The Irish case definition for SARS-CoV-2 has being updated to include notification of positive results from ADTs undertaken in the public health system

Introduction

This document provides guidance on the use of antigen detection tests (ADTs) for SARS-CoV-2 in the public health system in Ireland. The majority of ADTs are rapid tests undertaken at the point of care tests, known as Rapid Antigen Detection Tests (RADTs); antigen detection tests can also be carried out in the laboratory. This guidance was developed by the HSE Antigen Project Evaluation Working Group (membership in Appendix A), and approved by the National Public Health Emergency Team.

Given rapidly emerging information about their use in supporting public health response, ongoing validation work, and also the pace of innovation in diagnostics, it is likely that this guidance will need to be adapted and amended over time.

Background

Antigen Detection Tests (ADTs) for SARS-CoV-2 are carried out either at the point of care, where they are known as Rapid Antigen Detection Tests (RADTs), or they can be laboratory based. ADTs are immunoassays that detect the presence or absence of specific antigens on the surface of the virus, and can identify people who are at the peak of infection, when virus levels in the body are likely to be high. ADTs need a sample to contain thousands of virus particles per microlitre to produce a positive result whereas RT-PCR tests can detect very small amounts of viral RNA. ADTs are less sensitive in detecting SARS-CoV-2 infection, so, if a person has low amounts of virus in their body, the test can give a false-negative result. Antigen tests are currently designed to be performed on nasopharyngeal or nasal swab specimens placed directly into the assay's extraction buffer or reagent. Tests take between 15 and 30 minutes to perform and provide a result, and need to be carried out by trained personnel.

Benefits of ADTs

There is growing interest in the potential for ADTs to aid the public health response to COVID-19. The main potential benefits identified are shorter turnaround times, and lower reagent costs, particularly in cases with high viral loads i.e. pre-symptomatic cases shortly before symptoms develop in and symptomatic cases within 5 days of onset of symptoms. Used in this way, ADTs can help reduce further transmission through early detection of highly infectious cases, enabling isolation of cases, contact tracing and restriction of movements of contacts to start quickly.

When community prevalence is high, and when there may be pressures on laboratory capacity for PCR testing, ADTs have a role in detection of symptomatic cases, particularly in settings where there is swabbing capacity on site, such as in acute hospitals. In these circumstances RADTs as well as laboratory-based ADTs might be used.

The fact that RADTs can be performed outside the laboratory can be an advantage, but they need to be performed by trained personnel and each test takes time. There are significant logistical issues to consider in introducing RADTs, including limitations in their capacity to scale up to test large volumes of patients, and the need for large numbers of trained staff to undertake higher volumes of testing.

Laboratory based antigen detection tests (ADTs) are also becoming an option as availability increases. ADTs offer greater scalability, as they avoid the need to recruit large numbers of staff required to perform antigen testing at the point of care to a significant extent. Additionally, these tests are more sensitive than RADTs.

On 20th January 2021, the European [“Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU”](#) set out several recommendations regarding ADTs. These include the following:

- Consider using RADTs where there is limited capacity for RT-PCR, or prolonged testing turnaround times
- Ensure that ADT is conducted by trained healthcare personnel or other trained operators where appropriate and in line with national specifications, as well as in strict accordance with manufacturer’s instructions, with appropriate biosafety measures in place, and subject to quality control.
- Invest in training and, if appropriate, certification of healthcare personnel and other operators to carry out sampling and testing, thereby ensuring adequate capacities as well as safeguarding the collection of good quality samples.
- Ensure that the results of rapid antigen testing are registered in the respective national data collection and reporting systems, where feasible.
- Consider their use among symptomatic cases regardless of the setting, for asymptomatic close contacts, and in outbreaks. For screening in high risk areas and closed settings, if used, they need to be repeated every 2 to 4 days if possible. ECDC will soon publish guidance on the advantages and disadvantages of population wide testing using ADTs.
- Continue to invest in conducting independent and setting-specific validation studies of rapid antigen tests, with the aim of assessing their performance against RT-PCR assays. They recommend that the Member States agree on, maintain and share with the ECDC and the Commission, a common and updated list of COVID-19 rapid antigen tests that are considered appropriate for use in the situations described above, following validation.

Work of the HSE Antigen Evaluation Working Group

On November 19th 2020 ECDC recommended that EU Member States perform independent and setting-specific validations of RADTs before their implementation¹. Sensitivity and specificity depend on the performance characteristics of individual assays, and on the circumstances in which they are used. The Irish Antigen Project Evaluation Working Group was established to perform independent and site-specific validations in Ireland. It has undertaken desktop evaluations to identify assays suitable for further evaluation, and site-specific evaluations in acute hospitals, in meat plants and in the community. Some of these evaluations are still ongoing.

Validations undertaken to date by the HSE Antigen Project Evaluation Working Group have shown sensitivity above 80% and specificity >97% for some RADT assays when used in symptomatic patients. Results in asymptomatic patients however have shown significantly lower sensitivity, well below the minimum performance requirements set by WHO of $\geq 80\%$ sensitivity. Evaluations of laboratory-based antigen detection tests (ADTs) are also underway.

The ADT evaluation process is still underway. One test has been verified for use with nasopharyngeal swabs in symptomatic individuals. Verification of a second test, for use with nasal swabs, will conclude within the next few days, and a third assay verification, using viral transport medium (the

¹ ECDC Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK https://www.ecdc.europa.eu/sites/default/files/documents/Options-use-of-rapid-antigen-tests-for-COVID-19_0.pdf

same sample could be used for antigen and PCR) is underway and will conclude in approximately 2 weeks.

The ADT assays approved for use within the HSE public health system following the validation process will be available when the tender processes are complete by contacting the HSE Antigen Project Evaluation Working Group.

Operational framework for implementation

An operational framework for implementing RADT within the HSE has been developed. This includes national and local governance arrangements, roles and responsibilities, procedures for all aspects of the testing process, as well as specifying how to report results to the individual and to public health for contact tracing and surveillance.

The Irish case definition for SARS-CoV-2 is being updated to include notification of positive results from ADTs undertaken in the public health system, see Appendix B.

Interim recommendations for use of ADTs in Ireland

ADTs are proposed for use in the following circumstances and settings:

1. Use in community outbreak response and control in vulnerable populations

The procedure for NAS deployment in outbreaks is yet to be finalised. There is an agreement in principle and, pending process finalisation and training, the use of ADT in outbreak settings is as follows:

On notification of a potential outbreak in the community (PCR tests not yet carried out), **OR** in the early stages of management of a PCR confirmed COVID-19 outbreak, as part of the Public Health Risk Assessment, RADTs can be considered for use as part of the response if the following 3 criteria are met:

1. There is evidence of widespread community transmission (>10% positivity in the local community)
2. There are symptomatic person(s) on site
3. The outbreak involves a vulnerable population, including among staff and/or residents of long-term care facilities, homeless hostels, residents of direct provision centres, prisons, Irish Travellers etc

If these criteria are met, then

FOR CASES

- (a) Ask the National Ambulance Service (NAS) to use RADTs to test all persons with symptoms suggestive of COVID-19 with onset within the last 5 days. Persons with symptom onset more than 5 days ago should be tested with PCR tests. If numbers of symptomatic cases are large, RADTs may be undertaken on a subset of cases, as advised by the Outbreak Control Team. In this instance, all those with similar symptoms but who have not been tested will be presumed to be COVID-19 positive.

- (b) If the RADT result is positive, treat the person as having confirmed COVID-19.
- (c) If the RADT result is “not detected”, and the pre-test probability of infection is high in this instance (i.e. symptomatic person and high community prevalence), take a second sample for PCR testing and continue with infection control precautions until the second result comes back as “not detected”.
- (d) At least one person in the outbreak should be tested using PCR to confirm that this is a PCR confirmed COVID-19 outbreak. This can be done in parallel with RADT testing.
- (e) Positive RADTs are to be reported to the COVID Care Tracker so that close contacts outside the vulnerable setting can be identified to the Contact Management Programme and contact traced.
- (f) All cases detected during the outbreak either by RADT or PCR need to be notified to the Medical Officer for Health through CIDR

FOR CLOSE CONTACTS

- (g) Test asymptomatic close contacts using RADTs
- (h) If the RADT is “not detected” in the close contact, repeat the test using PCR
- (i) If the RADT is positive, then treat as a confirmed case, report to the COVID care tracker to identify and manage close contacts outside the outbreak setting and notify to CIDR

Clinical governance of this testing: In this instance, 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.

2. In the acute hospital setting

Within the acute hospital setting, deployment of ADTs will depend on the local laboratory capabilities for provision of large-volume batch testing, rapid PCR testing, and staffing levels. Approaches will vary by hospital location. The clinical director of diagnostics will be responsible for overall clinical governance with input from clinical microbiology.

Within the acute hospital setting, and as advised locally, they can be used in a range of settings including:

- Triage of patients in emergency departments and in ambulances arriving at department pending admission to the emergency department;
- To support early diagnosis in hospital outbreaks, including testing of symptomatic health care workers;
- In identification of infectious cases in outbreaks, and also in using repeat ADTs to guide decisions on when to declare an outbreak closed.

- In situations where ADTs can reduce pressures on the hospital's capability for rapid PCR testing.

Many acute hospitals have sufficient rapid PCR testing capacity and may decide for operational reasons not to use ADTs, but ADTs have a role in preserving capacity if PCR testing is under pressure or overwhelmed.

Use in other HSE settings:

Validation work on the use of ADTs for serial testing in healthcare workers is ongoing, and guidance will be updated in this area when results are available.

Validation work is ongoing in relation to the use of RADT in symptomatic people and asymptomatic close contacts in the community who are tested in community testing centres. Guidance will be updated when this work has been completed.

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Appendix A to Appendix C Members of the HSE Antigen Project Evaluation Working Group

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Appendix B to Appendix C: Case definition

Clinical criteria

- A patient with acute respiratory infection (sudden onset of at least one of the following; cough, fever¹, shortness of breath)

OR

- Sudden onset of anosmia², ageusia³ or dysgeusia⁴

OR

A patient with severe acute respiratory infection (fever and at least one sign/symptom of respiratory disease (e.g. cough, fever, shortness of breath)) **AND** requiring hospitalisation (SARI) **AND** with no other aetiology that fully explains the clinical presentation.

Clinical judgement should be applied in application of these criteria to determine who requires testing.

Epidemiological criteria

At least one of the following two epidemiological links:

- close contact⁵ with a confirmed COVID-19 case in the last 14 days prior to onset of symptoms
- having been a resident or staff member, in the 14 days prior to onset of symptoms, in a residential institution for vulnerable people, where ongoing COVID-19 transmission has been confirmed

Diagnostic imaging criteria

Radiological evidence showing lesions compatible with COVID-19

Laboratory criteria

Detection of SARS-CoV-2 nucleic acid or antigen in a clinical specimen⁶

Case classification

Possible case:

Any person meeting the clinical criteria

Probable case:

Any person meeting the clinical criteria with an epidemiological link

OR

Any person meeting the diagnostic imaging criteria

Confirmed case:

Any person meeting the laboratory criteria

[1] Fever may be subjective or confirmed by healthcare worker ($\geq 38^{\circ}\text{C}$).

[2] Loss of sense of smell

[3] Loss of sense of taste

[4] Distortion of sense of taste

[5] Close Contact: <2 metres face-to-face contact for greater than 15 minutes.

[6] Rapid Antigen Tests should be performed within 5 days of onset of symptoms or within 7 days from time of last exposure to a case. As the sensitivity and specificity of antigen tests depend on the test used, the personnel carrying out the test and the clinical indication or setting in which they are used, at present antigen testing undertaken outside the governance of the public laboratory service is not recognised for the purpose of notification of SARS-CoV-2/COVID-19.

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**COVID-19: OPERATIONAL PLAN FOR THE DEPLOYMENT OF
RAPID ANTIGEN DETECTION TESTS FOR SARS-COV-2 IN
ACUTE SETTINGS**

Version 1.0

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Version	Date Approved	Changes	Author
1.0	DRAFT	DRAFT	Acute Operatons RADT Validation Scientific Lead RADT Implementation Project Manager

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1.0 Glossary

#	Term	Description
1	RADT	Rapid Antigen Detection Tests
2	CCT	Covid Care Tracker
3	CIDR	Computerised Infectious Disease Register
4	Swiftqueue	Software for scheduling appointments
5	HPSC	Health Protection Surveillance Centre
6	LIMS	Laboratory Information Management System
7	NPT	Near Patient Testing
8	NPHE	National Public Health Emergency Team
9	PCR	Polymerase Chain Reaction
10	PH	Public Health
11	PPE	Personal Protective Equipment
12	WHO	World Health Organisation

2.0 Background

In recent months, there has been growing interest in the potential for rapid antigen diagnostic tests (RADT) to aid the public health response to COVID-19. RADTs, normally directed against the nucleoprotein of SARS-CoV-2, involve lateral flow assays that facilitate fast delivery of results outside of the laboratory setting. They can be read visually or by the utilisation of a specific reader. The main potential benefits identified are early detection of infection, particularly in cases with high viral loads i.e. symptomatic cases within 5 days of onset of symptoms. A key limitation of RADT is test sensitivity, which is lower than for RT-PCR, while the performance varies by assay. Currently available RADT have an intended use for symptomatic populations within 5 days of onset of symptoms. Use among asymptomatic populations is outside the CE mark and there is very limited data on antigen test (RADT) performance in asymptomatic persons. However, currently available data suggests the sensitivity of antigen testing is considerably lower in asymptomatic individuals compared with symptomatic individuals.

In the acute hospital setting, depending on current services and resources, RADT can be useful for the rapid triage of symptomatic patients at the time of admission and to test symptomatic patients or staff for early detection of cases. Results of testing can guide timely isolation and the type of personal protective equipment (PPE) required. However, due to the poor sensitivity of RADT, negative results will require confirmatory PCR testing.

3.0 Purpose

Notwithstanding the guidance set out in the overarching Covid-19: Operational Framework for the Deployment of Rapid Antigen Detection Tests for Sars-Cov-2, the purpose of this document is to provide specific guidance and interpret operational requirements for the use of RADT in acute hospitals. This document should be read in conjunction with the wider operational framework.

4.0 Scope

This operational plan covers all aspects of RADT for use in acute hospitals. This ranges from the point of sampling an individual to the performance of RADT, and the subsequent recording / reporting of results.

5.0 Target Users

All users of RADT in acute hospitals approved by the HSE.

6.0 Objective

The objective of this operational plan is to ensure correct use of RADT and consistency in the completion of operational requirements in acute hospital settings.

7.0 Scenarios for Use

Within the acute hospital setting, deployment of ADTs will depend on the local laboratory capabilities for provision of large-volume batch testing, rapid PCR testing, and staffing levels. Approaches will vary by hospital location. Within the acute hospital setting, and as advised locally, they can be used in a range of settings including:

- Triage of patients in emergency departments and in ambulances arriving at department pending admission to the emergency department;
- To support early diagnosis in hospital outbreaks, including testing of symptomatic health care workers;
- In identification of infectious cases in outbreaks, and also in using repeat ADTs to guide decisions on when to declare an outbreak closed.
- In situations where ADTs can reduce pressures on the hospital's capability for rapid PCR testing.

Negative results will require confirmatory PCR testing.

Many acute hospitals have sufficient rapid PCR testing capacity and may decide for operational reasons not to use ADTs, but ADTs have a role in preserving capacity if PCR testing is under pressure or overwhelmed.

Consideration can be given to the use of Covid-19 RADT in certain scenarios should the hospital deem this appropriate and useful in the context of their current services and available resources.

To note, RADTs have also been validated for use in maternity and paediatric hospitals.

8.0 Clinical Governance

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

9.0 Use of RADT in Acute Hospitals

In all instances, individuals should refer to the overarching Covid-19: Operational Framework for the Deployment of Rapid Antigen Detection Tests for Sars-Cov-2. This document outlines the standards that must be adhered to when using RADT. In addition, users must also refer to Guidelines for safe and effective near-patient testing (NPT) by National Near-Patient Testing Consultative Group, April 2020 for further guidance.

9.1 Procedures for Use

- Before commencing any RADT, 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. All risks should be mitigated or closed prior to launch.

9.2 Managing RADT Results

- It is the responsibility of local clinicians to exercise judgement should RADT be used outside prescribed settings. Clinicians must also ensure appropriate notification of results to individuals. The following actions must be taken when managing RADT results.

Results	Action
Detected	<ul style="list-style-type: none"> • Accepted as a true detected result. • Detected result communicated as soon as possible via local clinician. • Detected individuals should be isolated immediately, and in the case of HCWs removed from the workplace.

	<ul style="list-style-type: none"> All detected results should be captured and reported to the Public Health Data Processing Team (see below).
Not Detected	<ul style="list-style-type: none"> Not detected RADT results should be confirmed by RT-PCR immediately. Not-detected results will be communicated on a call backs for confirmatory PCR testing. All detected results should be captured and reported to the Public Health Data Processing Team (see below).
Invalid	<ul style="list-style-type: none"> The RADT sample and test should be repeated. All detected results should be captured and reported to the Public Health Data Processing Team (see below).

9.3 Recording RADT Results

- Hospitals may utilise local diagnostic test ordering systems to label and manage test samples. The use of local ordering systems will necessitate the local recording of all tests (for healthcare record, quality and audit purposes).
- Each hospital is required to record all RADT completed for individuals and their corresponding result. This must be captured in the RADT result template provided which includes all the necessary data fields to allow reporting and contact tracing. The minimum data set is also outlined in appendix A.
- Each hospital will be required to provide the Public Health Data Processing Team with the completed template following the below procedures:
 - Testing information must be captured in both worksheets of the RADT result template provided. All mandatory fields (Red and Orange) must be completed, while the person in charge may choose to populate optional fields (Yellow).
 - The RADT result template should be sent to central Public Health Data Processing Teams for uploading:
 - The template must be sent to the dedicated mailbox: publichealthdataprocessing@hse.ie
 - The subject line of the email must be **[Antigen Testing][Hospital Name][Date]**
 - 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.
 - This template must contain all the RADT results.
- It will be the responsibility of each hospital to ensure processes enable results captured during near-patient testing (using the RADT result template) are transmitted to the Laboratory Surveillance Scientist (or other designated individual) for quality review and sending to the Public Health Data Processing Team.

9.4 Reporting RADT Results

- A central Public Health Data Processing Team is set up to specifically deal with reporting of RADT results into the Covid Care Tracker (CCT), which will enable case management and contact tracing.
- It will be the responsibility of each acute hospital to update the Central Infectious Disease Register (CIDR) with detected RADT results.

9.5 Distribution

- A stock of antigen tests is being maintained centrally on behalf of the HSE. Each hospital should request one month's supply at a time, for all requirements within their hospital.
- Acute hospitals are advised to be conservative in their estimated quantities to ensure sufficient stock is obtained.
- Orders can be placed by contacting declan.coffey@hse.ie or Ellen.white2@hse.ie indicating the quantities required and the point of contact for delivery of the tests. Deliveries can only be facilitated Monday to Friday.
- Procurement will provide more information on validated RADT assays.

9.6 Quality

- RADT should be conducted under the specific clinical guidance and governance as outlined in the clinical governance section. A quality management system (for point of care/near-patient testing) should be implemented in line with national guidelines for safe and effective near-patient testing. Operators undertaking sampling and testing must be documented as fully competent and trained. Refer to the operational framework for more information.

9.7 Training

- A training package has been developed which addresses the theoretical and practical components of SARS-CoV-2 RADT testing and provides operators with the skills and resources on how to safely perform SARS-CoV-2 Antigen RDT testing. It also includes a competency assessment that should be carried out after the initial training to determine whether participants have understood the content of the training, can safely and accurately complete sample collection, perform testing, and interpret and record results.

10.0 References

- Guidelines for safe and effective near-patient testing (NPT) by National Near-Patient Testing Consultative Group, April 2020.
- Covid-19: Operational Framework for the Deployment of Rapid Antigen Detection Tests for Sars-Cov-2, HSE, January 2021.
- Rapid Antigen Detection Tests, HSE Website, 2021.

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