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

Version 1.0

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1.0 Glossary

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

2.0 Background

In recent months, there has been growing interest in the potential for rapid antigen diagnostic tests (ADT) to aid the public health response to COVID-19. ADTs, 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 ADT is test sensitivity, which is lower than for RT-PCR, while the performance varies by assay. Currently available ADT 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 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, ADT 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 ADT, 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 Antigen Diagnostic Tests for Sars-Cov-2, the purpose of this document is to provide specific guidance and interpret operational requirements for the use of ADT 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 ADT for use in acute hospitals. This ranges from the point of sampling an individual to the performance of ADT, and the subsequent recording / reporting of results.

5.0 Target Users

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

6.0 Objective

The objective of this operational plan is to ensure correct use of ADT 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 ADT in certain scenarios should the hospital deem this appropriate and useful in the context of their current services and available resources.

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

8.0 Clinical Governance

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.

9.0 Use of ADT in Acute Hospitals

In all instances, individuals should refer to the overarching Covid-19: Operational Framework for the Deployment of Antigen diagnostic tests for Sars-Cov-2. This document outlines the standards that must be adhered to when using ADT. 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 ADT, 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 ADT Results

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

Results	Action
Detected	• 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. • All detected results should be captured and reported to the Public Health Data Processing Team (see below).
Not Detected	• Not detected ADT results should be confirmed by RT-PCR immediately. • Not-detected results will be communicated to individuals when called back for confirmatory PCR testing. • All detected results should be captured and reported to the Public Health Data Processing Team (see below).
Invalid	• The ADT 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 ADT 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 ADT completed for individuals and their corresponding result. This must be captured in the ADT result template provided which includes all the necessary data fields to allow reporting and contact tracing.
- Each hospital will be required to provide the Public Health Data Processing Team with the completed template following the below procedures:
    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. The ADT result template should be sent to central Public Health Data Processing Teams for uploading:
        a. The template must be sent to the dedicated mailbox: publichealthdataprocessing@hse.ie
        b. The subject line of the email must be **[Antigen Testing][Hospital Name][Date]**
    3. Templates must be sent once per day on the same day testing occurred. This should be done **as early as possible** to initiate contact tracing.
    4. This template must contain all the ADT results.
- It will be the responsibility of each hospital to ensure processes enable results captured during near-patient testing (using the ADT 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 ADT Results

- A central Public Health Data Processing Team is set up to specifically deal with reporting of ADT 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 Computerised Infectious Disease Reporting System (CIDR) with detected ADT 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 Alan.Brett@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 ADT assays.

9.6 Quality

- ADT 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 ADT testing and provides operators with the skills and resources on how to safely perform antigen 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 Antigen Diagnostic Tests for Sars-Cov-2, HSE, January 2021.
- Antigen diagnostic tests, HSE Website, 2021.