



Rapid Testing in the context of the COVID-19 Pandemic

Interim Report of the Rapid Testing Expert Advisory Group



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Introduction

ESTABLISHMENT AND ROLE OF GROUP

The Expert Advisory Group on Rapid Testing (RTEAG) was appointed by the Minister of Health in July 2021. The role of the Group is outlined in the terms of reference (Appendix 2). The RTEAG's remit is to provide support and guidance to Government departments seeking to deploy Rapid Antigen Detection Tests (RADTs) in the sectors they support. Based on the terms of reference, three macro themes emerged as follows: 1) Communication with government departments on their requirements for RADTs in the sectors they support; 2) The development of tools for operational readiness to support use of RADTs as required and to support and inform the education, information and communication resources that sectors will develop themselves; 3) The rapid and real-time synthesis of the scientific evidence to guide the appropriate use of tests in areas that are important to the safe and sustainable reopening of our society.

Guidance on RADTs provided in this report is based on the current knowledge of SARS-CoV-2 infection and the disease it causes, COVID-19. Guidance may change when and if new scientific evidence is available or if there is a change in the epidemiology of the infection nationally, regionally, or globally. It is possible that expanded use of RADTs may play an important part of future testing programmes. The tools developed by this group will assist with ease of implementation if required.

The public health response to this pandemic in Ireland has been premised on the protection of a number of core priorities – limiting the direct impact of disease and protecting those most vulnerable to the severe impacts of COVID-19, protecting non-COVID health and social care, protecting education and childcare services and, more recently, the development and implementation of a comprehensive vaccination programme. The response has been risk-based and evidence-led and has sought to respond dynamically to the changing epidemiological situation over time. Central to the response has been public engagement and enormous efforts have been made across families, communities, and sectors to limit to the greatest extent possible the impact of the pandemic. These efforts, together with the very significant uptake of COVID-19 vaccines, have enabled a cautious de-escalation of public health restrictions and the gradual reopening of almost all parts of society and the economy. However, the National Public Health Emergency Team (NPHET) has noted that we cannot predict with certainty the future trajectory of the disease and we must remain ready to respond to any emerging threat. As the country continues the careful and gradual approach to reopening, it is important to continue to plan and be prepared for any changes in

circumstance. Flexibility, adaptability and scalability underpin the need for our pandemic response to be dynamic¹.

Testing for SARS-CoV-2 has been a key component in the public health response to COVID-19 in Ireland and to date has been primarily based on a substantial and agile reverse transcription polymerase chain reaction (RT-PCR, commonly referred to as PCR) capacity that has been built up by the Health Service Executive (HSE) since the outset of the pandemic. Access to timely and accurate COVID-19 testing has been essential to support the clinical management of individual cases, contact tracing, infection prevention and control, and disease surveillance.

Viral transmission is not prevented by a test alone, but rather by how, in whom, and where it is deployed and how the results of the test are interpreted and acted upon, as well as by the wider public health behaviours and actions required to prevent spread. With this knowledge from the outset of the pandemic, and taking account of the prevailing epidemiological situation, the approach to testing for SARS-CoV-2 has been kept under continuous review in order to inform the optimal approach to how tests may be most usefully deployed.

While recognising the ongoing central role of SARS-CoV-2 PCR testing in the pandemic response, RADT may have a role within specific settings as a complementary public health intervention to existing infection prevention and control measures, with the aim of identifying infectious COVID-19 cases in a timely manner and thus reduce the risk of onward transmission². Depending on the incidence of COVID-19 in the country, there may be benefits to deploying RADTs in specific settings. Substantial work has been conducted in Ireland to examine the potential utility of RADTs in the pandemic response, including by the HIQA, the HSE and the COVID-19 Rapid Testing Group³. These reports provide comprehensive background on RADTs and are a source of reference for the RTEAG. Areas where RADTs have already been deployed/approved for use or are being piloted, include outbreak response in the community, acute hospitals, meat processing plants, residential care facilities, childcare facilities and higher educational settings in addition to their use in some private sectors.

¹ Tam, Theresa W S. "Preparing for uncertainty during public health emergencies: What Canadian health leaders can do now to optimize future emergency response." *Healthcare management forum* vol. 33,4 (2020): 174-177. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7201193/>

² Health Information and Quality Authority (HIQA). Advice to the National Public Health Emergency Team: Rapid antigen testing for screening or surveillance of asymptomatic individuals to limit transmission of SARS-CoV-2. 2021. Available from: <https://www.hiqa.ie/sites/default/files/2021-09/Advice-to-NPHET-Effectiveness-of-RADTs.pdf>

³ COVID-19 Rapid Testing Group. Safe Sustainable Re-opening: The Role of Rapid SARS-CoV-2 Testing, Report of the COVID-19 Rapid Testing Group.2021. Available from: <https://www.gov.ie/en/publication/f50f0-report-of-the-covid-19-rapid-testinggroup/>

Use of RADTs should always be considered as an additional measure of protection and not a substitution for the existing public health measures including the HSE's well-established test and trace system.

In line with the terms of reference, the role of the RTEAG is to support the implementation of RADTs as an additional measure for the public response to the ongoing pandemic. RADTs should never be considered as a replacement for existing diagnostic or public health pathways but rather an additional tool. The various education, information and communication tools developed and endorsed by this group are designed to guide and support sectors as they prepare their own, sector-specific, materials to support individual rapid testing programmes.

It is important that the benefits and limitations of all tests are communicated to the public. It should be noted that RADTs should not be used to support behavioural changes that are contrary to public health recommendations. It must also be noted that although there is limited evidence for the role of RADTs in screening and surveillance programmes⁴, some sectors may wish to consider their use as an additional measure to support ongoing public health measures⁵. Any decision to introduce such screening should consider the feasibility, logistics, and ethical issues for both larger organisations or for the individual at home, potential benefits in detecting infectious cases and establishing pathways for notifying results and confirmatory PCR testing, cost effectiveness and, where implemented, should continue to monitor and evaluate their ongoing use.

⁴ Health Information and Quality Authority (HIQA). Evidence summary for use of rapid antigen testing for screening or surveillance of asymptomatic individuals to limit transmission of SARS-CoV-2. 2021. Available from: <https://www.hiqa.ie/sites/default/files/2021-09/Evidence-summary-RADT-effectiveness.pdf>

⁵ Health Information and Quality Authority (HIQA). Advice to the National Public Health Emergency Team: Rapid antigen testing for screening or surveillance of asymptomatic individuals to limit transmission of SARS-CoV-2. 2021. Available from: <https://www.hiqa.ie/sites/default/files/2021-09/Advice-to-NPHET-Effectiveness-of-RADTs.pdf>

Governance and Stakeholder Engagement

The Minister for Health, Stephen Donnelly TD, established the Expert Advisory Group on Rapid Testing to support and advise government departments, who are responsible for progressing pilots and the rollout of RADTs in their respective sectors as required. The RTEAG membership and terms of reference are available Appendix 1 and Appendix 2 respectively.

Professor Mary Horgan chairs the RTEAG which met weekly to develop the outputs of this report. A full list of meeting dates is available in Appendix 3.

The RTEAG outlined its proposed approach to the Senior Officials' Group on COVID-19 in early August to ensure that the proposal met with departments' expectations. The Chair responded to any requests for advice on RADTs from departments. The Minister's Office in the Department of Health shared any requests received via that route to mitigate the risk of a department seeking advice for their sector being missed.

The Chair and, where appropriate, other RTEAG members met with representatives of each department seeking advice to assess their needs. Some departments required more detailed support. Representatives from these departments were invited to attend part of the RTEAG's weekly meeting to be updated on the RTEAG's progress. There is ongoing engagement between departments and the RTEAG.

The RTEAG also received a briefing from the Department of Agriculture, Food and the Marine outlining the antigen testing programme underway in meat processing plants.

Rapid Antigen Detection Tests (RADTs)

OVERVIEW

Rapid antigen detection tests (RADTs) may be used for the detection of SARS-CoV-2, the virus causing COVID-19. From the outset it is important to state that PCR tests are the most sensitive method for detecting SARS-CoV-2 and are the gold standard test for diagnosing the infection. Based on current guidance, people with symptoms of COVID-19 should always undergo a PCR test which can be booked at <https://covid19test.healthservice.ie/hse-self-referral/>. In comparison to PCR, RADTs are cheaper, easy to use and offer rapid results in under 30 minutes⁶. They may be performed either as near-patient tests by an experienced trained professional or may be performed as a self-test.

Currently available RADTs have, to date, demonstrated lower overall sensitivity to detect all cases of SARS-CoV-2 when compared to PCR testing, and should not be considered a replacement for the currently recommended PCR testing for individuals with symptoms of COVID-19, public health guidance or infection control measures. However, a positive RADT test result is highly suggestive of the presence of viable virus and therefore the potential for transmission of infection. As prevalence of COVID-19 in the community decreases, there is a higher likelihood that a positive RADT result may be a false positive which means that PCR testing should be used to confirm the positive RADT result⁷.

Test performance may vary based on sample quality, where and how they are used and whether the test is self-administered or supervised (i.e., conducted or overseen by a trained professional). In addition, CE marking of RADTs is based upon manufacturer “self-assessment”, and therefore there is the potential that the test performance of some commercially available RADT devices may not have been independently verified, which could introduce significant variation in test performance between commercially available RADTs.

There is significant evidence that RADTs are more likely to identify current infection in asymptomatic individuals with higher viral loads who may be infectious and therefore more

⁶ Crozier A, Rajan S, Buchan I, McKee M. Put to the test: use of rapid testing technologies for covid-19. *BMJ*. 2021;372. n208. Available from: <https://doi.org/10.1136/bmj.n208>

⁷ Dinnes J, Deeks JJ, Berhane S, Taylor M, Adriano A, Davenport C, et al. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. *Cochrane Database of Systematic Reviews*. 2021 (Issue 3). Available from: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013705.pub2/full#>

likely to transmit the infection to others⁸. However, a negative RADT result should not be used as a “green light” for an individual to ignore or bypass current public health advice. In addition, in those with symptoms, current guidance states that a PCR test should be used to diagnose infection. It is also possible that RADTs may miss some early infections in individuals who have been very recently infected. Therefore, in high-risk environments such as meat processing plants, serial testing has been recommended. Within current public health guidelines in Ireland, RADTs have been identified to have a role in supporting the public health response by detecting infectious, asymptomatic cases as part of well-designed screening programmes, where testing may not otherwise have been indicated.

TEST TYPE, AVAILABILITY AND APPLICATION

There are a number of commercially available RADTs in Ireland, ranging from those supplied by the HSE to those RADTs sold in retail outlets. The common factor is that all RADTs sold in Ireland must have a CE mark, which denotes that the product is compliant with EU legislative requirements. Once the product is CE marked there are no restrictions regarding the availability of the device throughout all EU countries.

However, the current European in-vitro Diagnostics Directive (IVDD; 98/79/EC) categorises all SARS-CoV-2 tests in the “general category” which means that the performance of the RADT is self-assessed by the manufacturer prior to their release into the market. Therefore, this means that there is no “independent” performance assessment of the product to determine the accuracy of the device prior to the device becoming CE marked.

To address this constraint, independent verifications have been performed to compare the accuracy of a number of commercially available RADT using respiratory samples previously tested using PCR. Many of the studies utilise WHO and ECDC acceptance criteria. There is ongoing debate regarding the applicability of comparing RADT assay performance to SARS-CoV-2 RNA detection, as RADTs detect viral proteins, which reflects the presence of viable virus, while PCR detects SARS-CoV-2 RNA. Low levels of SARS-CoV-2 RNA can be detectable in individuals who have resolved the infection and are no longer infectious. Conversely low levels of RNA may also be detectable in early acute infection when the individual could be infectious but where levels of viral protein may be too low to detect on RADTs. Although such patients may not be identified using the RADT at that point in time, RADTs do detect most cases with high viral loads. Test performance may also vary based on how the test is administered – e.g., self-swabbing (self-test) versus swabbing performed or supervised by a trained healthcare professional (supervised test).

⁸ European Centre for Disease Prevention and Control. Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK Key messages. 2020. Available from: <https://www.ecdc.europa.eu/sites/default/files/documents/Options-use-of-rapid-antigen-tests-for-COVID19-19-11-2020.pdf>

In addition to a wealth of published literature, results of validation experiments conducted by the HSE are available on the link:

<https://www.hse.ie/eng/services/publications/healthprotection/hse-covid-19-antigen-test-validation-report-june-2021.pdf>

Based upon the results of this report, several RADTs tested were found to meet the minimum requirements set out by the WHO (in terms of sensitivity and specificity) for use for testing of symptomatic individuals. It is the case that some CE marked RADTs are currently available for purchase and are being used where their performance has not been independently assessed.

However, there is an EU initiative through the EU Health Security Committee to produce a document “A common list of COVID-19 rapid antigen tests and a common standardized set of data to be included in the COVID-19 test result certificates” and these RADT are listed in an Annex available on the link below. This Annex is updated periodically.

https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_addendum_en.pdf

The data presented is not a direct comparison of different RADTs, however the information supplied includes:

- Clinical Performance data (data supplied by manufacturer)
- FIND (global Alliance for diagnostics) evaluation studies
- A list of the EU member states using the device
- Completed validation studies

In addition to the “Common List” above, the Health Products Regulatory Authority (HPRA) provides information on the Field Safety Notices (FSN) issued regarding RADTs. FSN are issued when there are concerns regarding the use or performance of RADTs.

The RTEAG does not recommend specific RADTs for use but there will be links to the resources listed above in addition to links to the FSN issued by the HPRA. It is not clear which RADTs are available commercially in Ireland at any particular point in time, but once a product is CE marked there are no restrictions regarding the possible availability of that RADT device, should the company wish to make it commercially available in Ireland. Any programme involving CE marked RADTs should, therefore, ensure that there is robust ongoing monitoring and evaluation of the performance of the test.

Education and Training

The following training materials have been prepared to support Departments and the sectors they support considering the introduction of RADTs.

GUIDANCE FOR THE IMPLEMENTATION OF A RAPID ANTIGEN TEST PROGRAMME IN A SERVICE OR FACILITIES.

This is presented in both a detailed guidance document format and in a slide deck on PowerPoint.

Details include:

- An overview of the programme.
- A Guidance document, including a process map.
- Instructions how to carry out an antigen test including preparing the test and reading the result.
- Guidance on how to prepare for an antigen-testing programme, including a site preparation checklist and risk assessment advice.
- Information on logistics – ordering, distributing and tracking of test kits.
- Recording and reporting usage guidance and templates.
- Advice on getting feedback from participants.

A QUICK GUIDE EXPLAINING HOW TO DO AN ANTIGEN TEST

This is a short two-page document outlining in a process map the steps required when conducting an antigen self-test. It also simply explains what to do if the test is negative, positive or invalid.

A VIDEO DEMONSTRATING THE COMPLETE PROCESS OF PREPARING THE ANTIGEN TEST, DOING THE TEST AND READING THE RESULTS

This video is the one provided by Siemens to demonstrate how to use their Clinitest antigen test. The HSE is in the process of providing a voice-over to explain the steps.

A KEY MESSAGES DOCUMENT

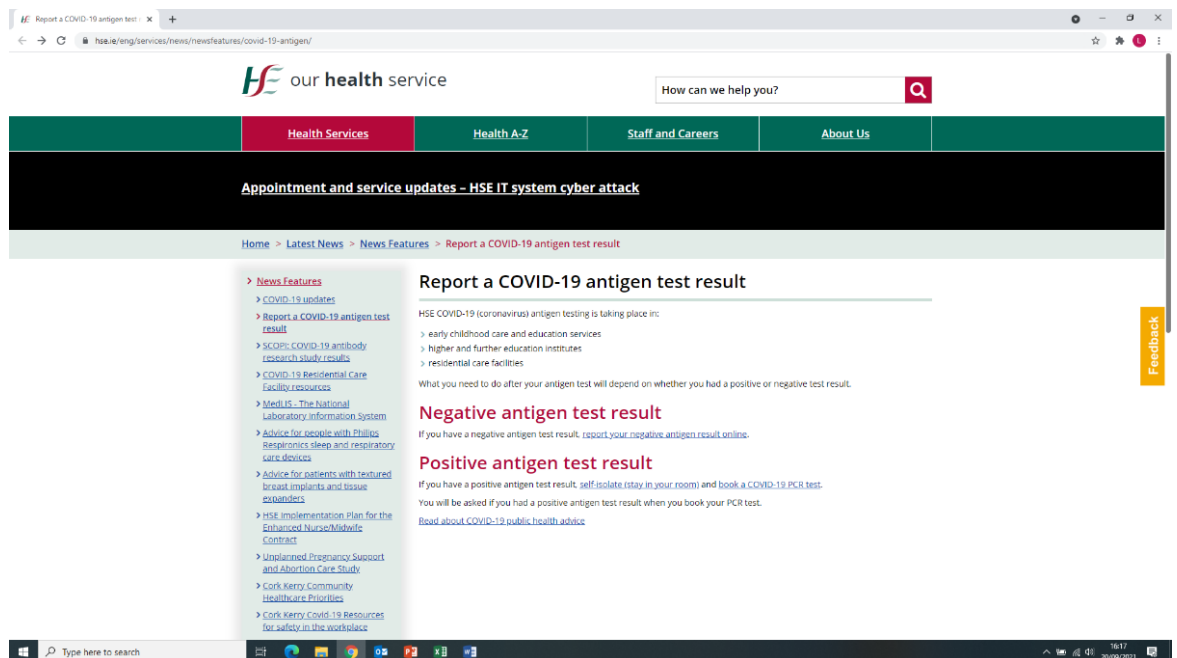
This explains the COVID-19 testing programme to date in place in Ireland. It summarises what is currently known about the differences between RADT and PCR testing and provides links to online information and resources available in other countries. A copy of this document is available in Appendix 5.

A FREQUENTLY ASKED QUESTIONS DOCUMENT

A short document providing answers to most likely questions that will be raised including what to do if the antigen test is positive, negative or invalid and where to get further information. A copy of this document is available in Appendix 6.

IT Platform

The HSE has developed an online pathway for RADT users to report test results. This web-based system went 'live' on 16th September 2021. The pathway consists of a landing page which can be accessed at hse.ie/reportantigenresult; this page contains some basic information about the RADT programmes currently in place, and has 2 separate links for users – one to report a negative test and one to report a positive test.



On each of the pathways, the user is asked to identify the reason for using RADT – they can select from a dropdown list of current RADT programmes (e.g., Further and Higher Education, Early learning and Childcare, Residential Care Facilities) or select 'Other'. Additional fields can be added or removed from this list as antigen programmes are stepped up or stepped down. The user is also asked about their vaccination status and whether or not they have symptoms of COVID-19.

NEGATIVE RESULTS

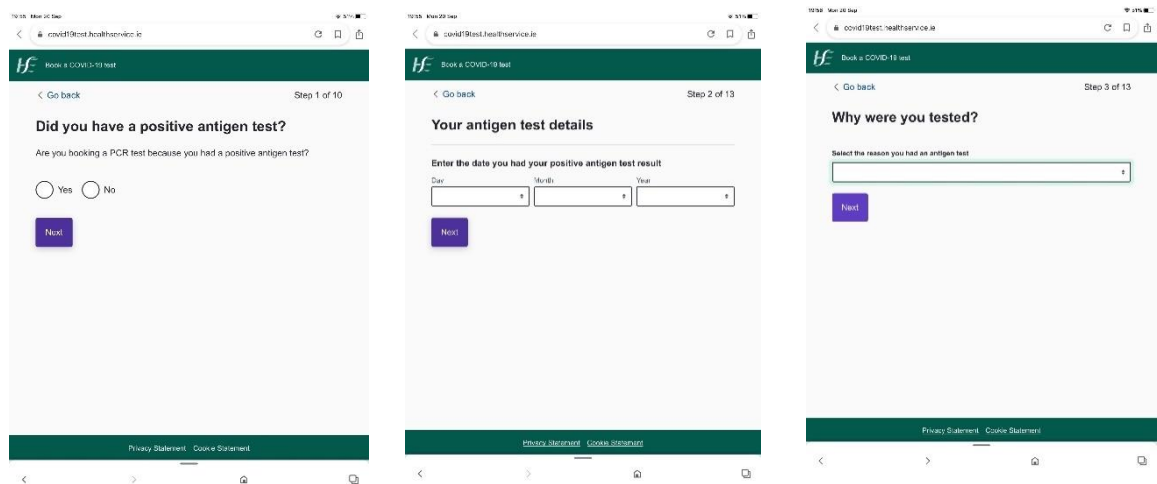
The negative results pathway also captures some basic demographic information i.e., age bracket and county. Anyone with symptoms is advised to book a PCR test regardless of a negative antigen test result.



The screenshot shows a web browser window displaying the 'Report a negative antigen test result' form. The form is titled 'Report a negative antigen test result' and includes instructions: 'Use this online form to report a negative antigen test result as part of the antigen programme from the HSE.' Below the title, there are three paragraphs of text: 'Only complete this form if you have had a negative antigen test result.', 'If you had a positive antigen test, book a COVID-19 PCR test.', and 'If you have symptoms, self-isolate (stay in your room) and book a COVID-19 PCR test.' The form contains several fields: 'Age *' (a dropdown menu), 'County *' (a dropdown menu), 'Date of your antigen test (DD/MM/YYYY) *' (a text input field), and 'Why you were tested *' (a radio button selection with four options: 'I am part of an antigen pilot in further or higher education', 'I am part of an antigen pilot in an early learning or childcare service', 'I am part of an antigen pilot in a residential care facility', and 'Other'). There is also a section for 'Residential care facility details' with a text input field for the facility ID. A 'Feedback' button is visible on the right side of the form.

POSITIVE RESULTS

The positive results pathway is integrated with the online booking system for PCR testing, so as well as reporting their RADT result the user is brought through to book a PCR test in a test centre of their choice.



The three screenshots show the mobile app interface for reporting a positive antigen test result. The first screenshot is 'Step 1 of 10' and asks 'Did you have a positive antigen test?' with 'Yes' and 'No' radio buttons and a 'Next' button. The second screenshot is 'Step 2 of 13' and asks 'Your antigen test details' with a date input field (Day, Month, Year) and a 'Next' button. The third screenshot is 'Step 3 of 13' and asks 'Why were you tested?' with a dropdown menu and a 'Next' button. All screenshots show the HSE logo and navigation options like 'Go back' and 'Privacy Statement'.

The online system is currently aimed primarily for users within specified RADT programmes; however, there are no restrictions on any user entering their RADT result.

It is important to note that all information entered on the online system is self-reported and is not subject to independent validation, so the data extracted from this system must always be interpreted in this context. Reports from other jurisdictions would indicate that the rate of reporting of negative results is much lower than positive results; the positive pathway has a tangible outcome for the user i.e., a PCR test booking, and is likely to only be required once, whereas there is no outcome for the user in reporting a negative result and may be required twice a week for those involved in ongoing serial RADT programmes.

The HSE will continue to enhance the system based on feedback and learning.

Developing a risk assessment model to assist in appropriate use of RADTs

RISK ASSESSMENT AND EVIDENCE SYNTHESIS

Screening asymptomatic populations using rapid antigen detection tests (RADTs) could be useful in limiting transmission of SARS-CoV-2 in certain circumstances. The utility of RADTs is context and activity specific and varies depending on a number of key factors, including

- The age demographic of individuals participating in a specific activity, with the consequences of onward SARS-CoV-2 transmission and COVID-19 outbreaks regarded as more severe in older populations.
- The prevalence of SARS-CoV-2 infection within populations participating in specific activity, which is determined by the known background prevalence, geographical location of the activity and the proportion of the population that have adequate immunity.
- The risk of transmission associated with specific activities, that can be influenced by the, type and number of close contacts, public health measures already in place, etc.
- The type of testing that is implemented (self-testing as compared to supervised-testing, pre-event as compared to regular testing).

To this end, in order that RADTs are used effectively in screening programmes for different activities and settings, research is needed to stratify, in real-time, the overall risk of SARS-CoV-2 transmission associated with common activities and to dating this risk assessment regularly as new evidence emerges and the demographics of SARS-CoV-2 infection within populations changes over time. Such risk stratification can then be matched to the most appropriate RADT testing approach to best mitigate this risk.

The RTEAG is coordinating collaborative efforts between Government departments, researchers in HIQA, University College Dublin, Evidence Synthesis Ireland, the Health Research Board and SPOR Evidence Alliance, Canada to develop a risk assessment model based on the factors listed above, to inform the best RADT testing strategy to limit the transmission of SARS-CoV-2 within specific activities. The model will be based on a series of evidence reviews around three different components.

1. The background risk of SARS-CoV-2 within the population participating in an activity.
2. The risk of SARS-CoV-2 transmission associated with the activity/setting.
3. The most appropriate testing approach to best mitigate the risk.

To address the first component, researchers in HIQA and University College Dublin have developed an algorithm which can provide a time-updated estimate of the risk of someone who is SARS-CoV-2 positive attending an activity/setting. This algorithm uses information such as the anticipated number of people attending an activity, the proportion of those from different age cohorts and the 14-day incidence of COVID-19 in this age group along with additional data on COVID-19 natural history, including latency period and duration of

infectiousness. Through regular updates, this algorithm will provide up-to-date estimates of the number of potentially infectious attendees for specific events and will be updated on a weekly basis.

A rapid review evidence synthesis is being conducted by researchers at SPOR Evidence Alliance, Canada which will examine and synthesise the evidence for each of the other two components outlined above. The rapid review will address the following research questions.

1. What is the effectiveness of different COVID-19 rapid testing strategies including self-administered versus supervised testing, and different testing frequencies (e.g., one off compared to serial testing at different intervals for different lengths of time) at detecting infectiousness or reducing transmission?
2. What is the risk of SARS-CoV-2 transmission associated with different activities (e.g., dining, exercising etc.) or settings (e.g., educational, hospitality etc.) and what factors contribute to risk e.g., type of contact, number of contacts, time within the risk environment?

Because the situation and response to COVID-19 is constantly evolving, the rapid review evidence synthesis will be in the form of a 'living evidence synthesis'. Once the initial rapid review is completed, it will be updated monthly for six months, to capture any new developments in the field.

In taking this approach, the RTEAG will be in a position to provide a framework for updated risk assessments linked to optimal RADT testing approaches for specific common events of strategic relevance to Government departments and the sectors they advise.

ENGAGEMENT WITH GOVERNMENT DEPARTMENTS

The RTEAG has engaged with representatives from the Department of Tourism, Culture, Arts, Gaeltacht, Sport and Media and the Department of Enterprise, Trade and Employment around their priorities for different activities and settings in which to use RADT. These Departments have provided the group with a list of specific activities for which they could see a possible use for RADTs. Examples include business conferences; dining; outdoor concerts etc. Once the risk assessment framework is developed the RTEAG will be able to provide the Departments with advice on appropriate RADT testing for these activities based on updated risk assessments to mitigate against the transmission of SARS-CoV-2 infection.

ADDITIONAL COLLABORATIONS

To keep informed about new developments in research about RADTs, the RTEAG has established a link with colleagues at the University of Birmingham, UK who are updating a

Cochrane Review⁹ assessing the diagnostic accuracy of point of care antigen and molecular based-tests for diagnosis of SARS-CoV-2 infection There are three Fellows from Evidence Synthesis Ireland working on these reviews who provide monthly updates to the RTEAG. In addition, the research group at the University of Birmingham is available to the RTEAG for consultancy.

⁹ Cochrane reviews are systematic reviews of primary research which use the most up-to-date and reliable evidence to inform healthcare guidance and best practice. They are internationally recognised as the highest standard in evidence-based health care.

Communication and Public Understanding

In relation to communications and public understanding, work has been undertaken to measure the level of public comprehension of the benefits and limitations of rapid tests, to synthesise international evidence on comprehension, post-test behaviour and communication, and to develop a suite of relevant communication materials.

BASELINE PUBLIC UNDERSTANDING IN IRELAND

The RTEAG devised a series of survey questions to gauge a baseline level of public understanding in relation to RADT. These questions were added to the regular Amárach Public Opinion Tracker survey fielded on August 9th 2021.

The results indicate that public understanding of how, where and why one would use an RADT is low. Less than half the adult population (48%) knew that a “rapid antigen test” was less good than a “standard PCR test” at detecting whether a person has COVID-19. While 57% recognised that a benefit of RADT was as a means to screen people before attendance at activities or events, more than one-third (36%) thought that RADTs were a quick way for people experiencing some symptoms to get tested and more than one quarter (27%) thought they were a convenient way for someone to make sure they don’t have COVID-19. Relatedly, 39% thought that where a person with some symptoms took an RADT and got a negative result, they had no need to self-isolate, with a further 4% saying it was fine to socialise and 12% saying they did not know how to interpret a negative test.

Ideally, individuals who take an RADT will see information at the time of taking the test, such that they will be better informed than the public in general. However, the Amárach data show that this is not the case among those (8%) who had taken an RADT prior to the survey. This group were more likely to think that an RADT is as sensitive as a PCR test, more likely to think that RADT are quick ways for someone with symptoms to get tested, and more likely to think that a negative test implies no need for a person with mild symptoms to self-isolate.

Overall, the results suggest widespread misconceptions in Ireland about the sensitivity of RADT, how they are of benefit, and the implications of test results. This baseline level of public understanding presents a clear set of communications challenges.

INTERNATIONAL EVIDENCE

The RTEAG has engaged a behavioural science researcher (one day per week) to undertake an international evidence synthesis in relation to comprehension of tests and how best to design the communication that surrounds them. At this stage a brief interim summary is as follows.

Although the above findings for Ireland were generated from some rapidly assembled survey questions, they are broadly in line with international evidence about misconceptions in the understanding and interpretation of COVID-19 test results. In general, individuals’ estimates

of the likelihood of having the virus after receiving (positive or negative) RADT results are inaccurate. Among other influences, people's estimates typically give insufficient weight to the overall level of infection within the population. Moreover, large minorities are inclined to think that test results (both RADT and PCR) are essentially reliable, believing that they tell you for sure whether you have the disease. These findings for COVID-19 tests are consistent with evidence from the wider literature on the results of medical screening tests, which find that both lay people and medical experts tend to overestimate the post-test probability of having the relevant condition and to give insufficient weight to low base rates.

International evidence also finds that many people believe it makes sense to take an RADT if they are experiencing symptoms or after a contact with an infected person. One recent UK study found that 44% of symptomatic people who took a COVID-19 test used an RADT rather than a PCR test however it should be noted that UK guidelines are not explicit in that people with symptoms should not use RADT. In addition to taking an RADT when symptomatic, another commonly held view is that RADT are of use before contact with vulnerable people, friends and family.

One concern is that people who use an RADT and get a negative result will alter their behaviour based on a misconception that they definitely do not have the virus. Here the international literature is more mixed. A majority of people think that self-isolation is required after a positive PCR or RADT. The evidence that people take more risk after receiving negative test results is relatively weak, with many studies finding no effects and some studies finding small differences.

Encouragingly, there is evidence that people's understanding of test results can be meaningfully affected by the form of communication. In particular, explicit references to uncertainty in the communication of results make it less likely that people view the results as telling them for sure whether they have or do not have COVID-19. Some studies have found large effects. Others have found that the effect extends beyond the perception of probability to people's intended behaviour post-test. In addition to the communication of uncertainty surrounding the result, the use of natural frequencies to explain probability improves understanding, not only among laypeople but also among experts.

COMMUNICATION MATERIALS

The purpose of the communications materials developed by the RTEAG are to support and inform sectors who may wish to use RADT in specific settings to develop their own suite of materials for use as appropriate.

As with all public health communications relating to the pandemic, it is essential to ensure that there is a clear message/call to action embedded in communication outputs from the RTEAG. In this instance, given the above evidence, it is to ensure that any person displaying symptoms of COVID-19 continues to follow public health advice which currently advises to arrange a PCR test rather than relying on an RADT.

Similarly, when RADTs are rolled out by a specific sector, it is important to emphasise that it should only be used in addition to the existing public health measures in place at that time.

The RTEAG has developed a key messages document incorporating these and other messages relating to the use of RADTs. This document can be used as the basis of communications materials developed by sectors as they plan to roll out RADTs in their area. A Frequently Asked Questions document supports the main messages piece and answers general questions that the public may have in relation to RADTs – sectors can use this document to inform their own sector specific FAQs.

Conclusions

- Ongoing engagement with Government Departments is important to support their planning for current and future needs for RADT as a component of preparedness planning.
- Currently, PCR testing is the gold standard for diagnosis of SARS-CoV-2 infection and anyone with symptoms of COVID-19 should book an appointment for PCR test which can be booked at <https://covid19test.healthservice.ie/hse-self-referral/>.
- RADTs are an additional tool and not a substitution for existing public health measures (layered approach).
- Although RADTs do not identify all cases of COVID-19, RADTs are cheap and can be deployed at scale. RADTs can reliably detect those most likely to be infectious and the speed of the result enables rapid intervention to prevent onward transmission.
- Operational readiness is an important component of the changing dynamics of the pandemic response to ensure that response can be easily adapted and scalable to evolving needs hence the importance of the development of tools to support the use of RADTs where appropriate. These tools provide a template for the use of RADT in future epidemics or pandemics.
- In a landscape of continual change as demonstrated by the unpredictability of this pandemic, it is possible rapid antigen testing may play an important part of future testing programmes. The tools developed by the RTEAG will assist with ease of implementation if required.
- A scientifically robust and evidence-based, risk stratification approach to the use of RADTs in different settings should continue. Given the dynamic nature of the COVID-19 pandemic, regular updates of scientific evidence are necessary to inform and update risk stratification.
- There is clear evidence, both in Ireland and elsewhere, of widespread misconceptions among the public regarding how to use RADTs appropriately, what RADT results mean for the likelihood of having the virus, and the implications of test results for subsequent behaviour. Public engagement to outline the benefits, limitations and appropriate use of RADTs is therefore essential, making use of available behavioural evidence to design and deploy effective communications.

Appendix 1: Membership

Professor Mary Horgan, President, Royal College of Physicians of Ireland, Consultant in Infectious Diseases, Professor of Infectious Diseases University College Cork and consultant at Cork University Hospital (Chair of the RT Expert Advisory Group).

Dr Jeff Connell, Assistant Director, Principal Clinical Scientist, National Virus Reference Laboratory, University College Dublin, Belfield, Dublin 4.

Dr Ronan Glynn, Deputy Chief Medical Officer, Department of Health.

Professor Pete Lunn, founder, and head of the Behavioural Research Unit at the Economic and Social Research Institute, Adjunct Professor, Department of Economics, Trinity College Dublin.

Professor Patrick Mallon, Professor of Microbial Diseases at the University College Dublin School of Medicine, and a Consultant in Infectious Diseases at St Vincent's University Hospital.

Professor Kingston Mills, Professor of Experimental Immunology at Trinity College Dublin, and Director of Trinity Biomedical Sciences Institute.

Ms Niamh O'Beirne, HSE National Lead for Testing and Tracing.

Professor Patrick O'Mahony, Chair of the Health Information Quality Authority and Chair of the Board of the Irish Medicines Verification Organisation.

Dr Anna-Rose Prior, Consultant Clinical Microbiologist at Tallaght University Hospital.

Professor Breda Smyth, Director of Public Health at HSE West, Consultant in Public Health Medicine.

Appendix 2: Terms of Reference

The Terms of Reference are as follows:

- Support government departments seeking to deploy rapid tests in their respective sectors.
- Support government departments in the design and assessment of pilots for their respective stakeholders.
- Provide guidance to government departments on the use of rapid tests.
- Support government departments in developing and updating training material for areas/sectors where rapid testing is recommended/advised.
- Support government departments in developing standard operating procedures for the use of rapid tests in settings where rapid testing is recommended/advised.
- Maintain a list of currently validated tests for guidance.
- Monitor rapid tests in development and those emerging on to the market.
- Communicate the strengths and limitations of rapid tests to the general public.
- Support development of a platform to upload results.

Appendix 3: Meetings

The Rapid Testing Expert Advisory Group met on the following dates:

- 14th July 2021
- 21st July 2021
- 28th July 2021
- 4th August 2021
- 11th August 2021
- 18th August 2021
- 25th August 2021
- 1st September 2021
- 8th September 2021
- 15th September 2021
- 22nd September 2021
- 29th September 2021

The minutes of each meeting are available at:

- <https://www.gov.ie/en/collection/8b585-minutes-and-agendas-from-meetings-of-the-rapid-testing-expert-advisory-group/>

Appendix 4: Rapid Testing Key Messages

KEY GENERAL TESTING MESSAGES

- Over the last 17 months, as Ireland has dealt with the COVID-19 pandemic, widespread PCR testing, the most effective means to detect SARS-CoV-2 (the virus that causes COVID-19), has been a critical part of our response and this will continue.
- The HSE continues to develop and evolve their PCR testing strategy which now includes GP referral; online self-referral; and pop-up testing for short periods of time in areas where HSE Public Health teams believe easier access to COVID-19 testing will help control the spread of infection.
- PCR tests use samples collected by trained personnel. These samples are analysed in the laboratory with results available within 24-48 hours.
- It is important that if you display symptoms of COVID-19, like cough, fever, headache, sore throat and blocked or runny nose - isolate and get a PCR test immediately. You can book a PCR test at your nearest test centre online at www.hse.ie, or if you are concerned about your symptoms, you can contact your GP and they can refer you for a COVID-19 test if necessary.

KEY RAPID TESTING MESSAGES

- Rapid Tests support the public response to protect us from COVID-19.
- Rapid Tests offer the potential for low-cost screening for COVID-19 among asymptomatic people.
- Rapid Testing may be used to complement the existing national HSE PCR based testing programme.
- Rapid Tests can either be conducted for you (supervised sample collection and testing) or can be done yourself (self-collection and self-testing) with a result available within 15-30 minutes. It is important that you only use a test that has been approved for these specific uses.
- Rapid Tests are less sensitive than PCR tests for detecting all cases of COVID-19 but can identify those individuals who are most infectious.
- Rapid Testing should not be used if you have symptoms suggestive of COVID-19.
- If you have any symptoms suggestive of COVID-19, PCR tests should be performed.
- If an individual has a positive Rapid Test, a confirmatory PCR test is required and obtained through the HSE system PCR testing system.
- If an individual has a negative Rapid Test, the individual should continue to follow public health guidelines and if becomes symptomatic should obtain a PCR test.

WHERE THE HSE IS CURRENTLY USING RAPID TESTS

- The HSE is currently working with the Department of Further and Higher Education, and the Department of Children, Equality, Disability, Integration and Youth on pilot antigen testing programmes to learn more about how Rapid Tests might be used more widely in third-level and childcare settings.
- The HSE has also used Rapid Tests for some hospital patients and in places where there is an outbreak of COVID-19.

Appendix 5: Rapid Testing FAQ

Home Antigen Tests (Rapid Tests)

WHAT ARE ANTIGEN TESTS?

SARS-CoV-2 (the virus that causes COVID 19) antigen tests use a swab to take a sample from your nose. You do this swab yourself at home. The swab does not need to go to a lab, and you get your results quickly – usually within 15 minutes

WHAT ARE THE LIMITATIONS OF ANTIGEN TESTS?

No test is 100% accurate. All tests have limitations. The antigen test does not detect the virus that causes COVID-19 as well as PCR tests but can rapidly identify most people who are infectious. Antigen tests may not always pick up if you have been infected with the virus.

WHAT IF I HAVE SYMPTOMS OF COVID-19?

If you have symptoms of COVID-19, you should not rely on antigen tests to diagnose COVID-19. In this case, you should book a PCR test online at www.hse.ie; or if you are worried about your symptoms, you can call your GP for advice and they may then refer you for a COVID-19 PCR test.

HOW DO I DO AN ANTIGEN TEST?

There may be slight differences in the steps you follow to do an antigen test, depending on the brand of test you are using. You should look at the instructions that come with your antigen test, which will give you detailed advice on how to do the test. Everything you need to do the test will be in the box with the test kit. Read the instructions very carefully.

WHAT SHOULD I DO IF MY ANTIGEN RESULT IS POSITIVE?

If your antigen test is positive, you need to self-isolate (stay in your room) and urgently book a PCR test to confirm a positive result. You can book a PCR test online at www.hse.ie. If you are concerned about any symptoms, you should contact your GP.

WHAT SHOULD I DO IF MY ANTIGEN TEST IS NEGATIVE?

You should continue to follow all of the current public health advice such as wearing your mask. If you are in a programme of antigen testing, you should do your next antigen tests as directed.

WHERE CAN I GET MORE INFORMATION?

www.gov.ie

www.hse.ie

Public Health England – Types of Test

Public Health England - Understanding lateral flow testing for people without symptoms

National Institute for Public Health and the Environment (Netherlands) - Practical information about testing

Coronasmitte.dk (Denmark) – Tests for COVID-19 Federal Institute of Drugs and Medical Devices

(Germany) - Antigen tests for SARS-CoV-2

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