Rapid Diagnostic Testing for Blood Borne Viruses in International Protection Applicants

Pilot Evaluation Report

August 2025

Acknowledgments

We would like to thank the staff of Safetynet Primary Care and the National Reception Centre (NRC) at Balseskin for their valuable work, support and input to this pilot.
We thank also the Infectious Diseases teams in the Mater Misericordiae University Hospital, Beaumont Hospital and St. James's Hospital for their guidance and input in advance of this pilot commencing, and for their continuous support during the pilot.
Finally, we would like to thank the International Protection Applicants who participated in the pilot and gave valuable feedback.

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Table of Contents

Abbreviations

Ab	Antibody
ART	Antiretroviral therapy
BBV	Blood Bourne Virus
BoTP	Beneficiary of Temporary Protection
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IPA	International Protection Applicant
NRC	National Reception Centre
NSIO	National Social Inclusion Office
NTC	National Transit Centre
RASPs	Refugees and Applicants Seeking Protection
RDT	Rapid Diagnostic Test or Testing
sAg	Surface antigen
SLBT	Standard Laboratory Based Test
SOP	Standard Operating Procedure

1. Executive Summary

Background:

The number of International Protection Applicants (IPAs) arriving to Ireland has increased in recent years, adding to the significant number of Beneficiaries of Temporary Protection (BoTPs). In 2019, 4,781 people sought international protection compared to 13,227 in 2023 and 18,564 people in 2024[(1)]. By the end of December 2024, a total of 113,190 BoTPs had been granted temporary protection. The Report of the Refugee and Applicants Seeking Protection (RASPs, referring to both IPAs and BoTPs) Blood-Borne Virus/Tuberculosis Screening Implementation Advisory Group[(2)] recommended that testing for blood-borne viruses (BBVs) should be offered to all RASPs over the age of 16 years. In response, the HSE implemented this pilot in order to inform how to most efficiently and effectively test RASPs for BBVs via the use of Rapid Diagnostic Testing (RDT).

Aim:

The aim of this pilot was to assess the feasibility of RDT use for the RASP BBV testing programme in Ireland.

Methodology:

The HSE National Social Inclusion Office (NSIO) procured 200 lateral flow RDTs for finger prick whole blood testing for HIV, HBV and HCV from manufacturer and supplier Abbott in Quarter 4 2023. Phase 1 of the testing commenced in Quarter 1 2024 in two clinical sites – the National Reception Centre (NRC), Balseskin, Dublin and the National Transit Centre (NTC), Citywest, Dublin under the clinical remit of HSE and Safetynet Primary Care, respectively. The testing modality was reconsidered and changed due to challenges encountered during finger prick testing, leading to Phase 2 of the pilot, commencing in Quarter 2, 2024. Service provider feedback was that three whole blood finger prick RDTs were technically challenging, time-consuming and perceived to increase infection transmission risk. NSIO procured 100 oral swab lateral flow RDTs for HIV and HCV for Phase 2 from the distributor Cruinn.

Training for both testing modalities was provided by the kit suppliers. All individuals were also tested with conventional phlebotomised blood samples for laboratory-based analysis. The pilot was completed in Quarter 4 2024. This report is an evaluation of the RDT use for BBV testing in terms of implementation processes, acceptability and clinical accuracy.

Key Findings:

Across the two pilot sites, a total of 121 individuals were tested during Phase 1 of the pilot and 106 individuals were tested during Phase 2. The results of our pilot show that RDT is an accurate way of screening for BBVs highlighted by low false negative and false positive results as compared to the gold standard testing technique of SLBT/phlebotomy. The results obtained in this pilot are in line with those found in the WHO prequalification reports for the individual HIV, HBV and HCV tests.

Service User and Service Provider Feedback:

A total of 61 service users provided feedback via a questionnaire format across Phases 1 and 2 of the pilot. The overall feedback was very positive with 94% rating their experience as excellent and 5% rating their experience as good in Phase 2. With regards to service provider feedback for Phase 2, whereby oral swabs were used to test for HIV and HCV while a single finger prick test remained to test for HBV, this was deemed a much more acceptable way of testing, described as quick, straightforward, less invasive and likely to be more impactful than phlebotomy.

Conclusion and recommendations:

Our results demonstrate that RDT can be a convenient, accurate, quick and minimally invasive means of BBV testing as highlighted by both test performance and feedback from service users and providers.

We recommend the use of a finger-prick whole blood RDT combined with oral RDTs as a feasible testing method for BBVs in RASPs. This can be implemented alone or to complement phlebotomy and Standard Laboratory Based Test. This evaluation report also highlights certain areas as key for a successful implementation of RDT.

2. Introduction

This pilot looked at the implementation of RDT for BBV testing of IPAs at two sites, the NRC Balseskin, Finglas North, Dublin 11 and the NTC, Citywest, Dublin 24 under the clinical remit of HSE and Safetynet Primary Care respectively, from January 2024 to November 2024. The pilot was managed by members of Public Health team in the National Social Inclusion Office (NSIO) under the guidance of the previous NSIO Public Health Lead.

Some of the foreseen advantages of RDT were:

- Efficient testing of large cohorts of people
- Results available to a patient during the testing consultation, minimizing risk of loss to follow up in an often mobile population cohort
- Simple testing technique that can be performed by healthcare assistants, with training, and adapted easily to community settings
- Accurate testing technique that is acceptable to the patient
- Rapid identification of infectious diseases allowing for prompt Public Health response with swift onward referral to specialist care for management.

Context

The HSE National Ukraine Health Response Planning and Coordination Group was established in March 2022 to oversee the HSE health response for people fleeing war in Ukraine who were given the right to temporary protection within the EU under Temporary Protection Directive 2001/55/EC, i.e. BoTPs.

Recognising the similar needs of people arriving in Ireland seeking international protection, a Health Response Service Delivery Model Working Group was established in September 2022 to scope and design a future 'whole-of-organisation' service delivery model to support the health and social care needs of all RASPs – referring to both BoTPs and IPAs.

RASPs are people who are fleeing countries that often have higher prevalence of communicable infectious diseases than Ireland and may have under-resourced healthcare systems. Timely detection of infectious diseases such as these does not only decrease morbidity and mortality on an individual level, but also has a significant Public Health impact in terms of mitigating the transmission risk and decreasing healthcare cost as conditions are diagnosed before complex and costly-to-treat complications arise. Prompt treatment and viral suppression plays a key role in the prevention of new cases by reducing transmission risk.

Table 1 shows the detection rate of human immunodeficiency virus (HIV), hepatitis B virus (HBV) (HBsAg) and hepatitis C virus (HCV) (antibody) in IPAs tested in the NRC Balseskin in 2023[3]:

BBV tested	Total detection rate	New diagnosis	Known diagnosis
HIV	4.3% (79/1847)	0.8% (14/1847)	3.5% (65/79)
HBV	2.2% (41/1847)	1.7% (32/1847)	0.5% (9/1847)
HCV	0.8% (14/1847)	0.3% (6/1847) viraemic HCV	0.4% (8/1847)

Table 1 NRC Balseskin Annual Health Screening Data 2023

The figures above are expected to vary depending on the geographic area of origin of RASPs. For example, the prevalence of HCV is likely to be higher amongst BoTPs fleeing the war in Ukraine where the prevalence of HCV is estimated to be 3%. [4]

The subsequent HSE Health Response for Refugees and Applicants Seeking Protection Primary Care Infectious Disease Testing Service Delivery Model Report [5] recommended that a National RASP BBV/TB Screening Implementation Sub-Group be formed.

The Implementation Advisory Sub-Group was thus formed via the NSIO in February 2023. Regular meetings were held with the group which included a wide range of stakeholders. In November 2023 the group produced a report [2] with the following key recommendations:

- Testing for BBVs, by lateral flow RDT, should be offered to all of the target population over the age of 16 years, and to children over 18 months of age who are not accompanied by a biological parent
- The group also advised as next steps the engagement with procurement on suppliers for RDT test kits (including training); and the roll out of a RDT pilot

A pilot project was set up in February 2024, implemented by the NRC in Balseskin and Safetynet Primary Care operating out of the NTC in Citywest. This RDT pilot focused on testing for HIV, HBV and HCV. Key objectives of the pilot were to assess the feasibility, acceptability, accessibility and likely impact of using RDT in the IPA cohort for the purpose of BBV testing, as well as the accuracy of test results. Importantly, the pilot was also intended to help define the final Standard Operating Procedures (SOPs) prior to any national roll-out.

3. Methodology

Pilot teams

Teams in Safetynet Primary Care at the NTC in Citywest and the NRC Balseskin in Finglas North Dublin were asked to undertake the pilot as they already had significant experience in BBV testing of IPAs via SLBT/phlebotomy. NRC Balseskin acquired blood samples by finger prick for RDT and by phlebotomy for SLBT, whereas Safetynet Primary Care provided sampling by phlebotomy and then used blood from the phlebotomy vial for the lateral flow RDTs. Regular meetings were held with both pilot sites to gain valuable, real-time feedback and to continuously assess the feasibility of the pilot.

Sample for RDT validation

The sample group were IPAs, at the NRC Balseskin or the NTC Citywest, who agreed for their BBV testing to be carried out via the pilot.

Sample for Operational Feasibility

As the NRC Balseskin was the only arm of the pilot assessing the practical feasibility of RDT by finger prick sampling, it was decided that the NRC Balseskin would be the site for a feedback survey of service users and providers involved in testing.

It is important to note that, as the Balseskin team did RDTs followed by phlebotomy, the pilot did not exactly model the design of any national programme as this dual testing would not be done in a national roll-out. This additional work was undertaken for internal test validation, and the complexities involved were considered when assessing operational feasibility.

The sample group of service users was selected during Phase 1 of the pilot from February 2024 to April 2024 and subsequently during Phase 2 of the pilot from June 2024 to November 2024. Phase 1 involved the use of three individual whole blood finger prick tests to check for HIV, HBV and HCV using tests Determine HIV, Determine HbsAg2 and HCV Ultra, respectively. Phase 2 consisted of OraQuick oral swab testing to test for HIV and HCV, whilst the finger prick blood test method of testing remained in place to test for HBV. The testing modality was reconsidered and changed due to service provider feedback that three whole blood finger prick RDTs were technically challenging, time-consuming and perceived to increase infection transmission risk.

All who consented to participate in the pilot at NRC Balseskin were asked if they would like to respond to a survey. Of note, the majority of those who agreed to participate in the pilot spoke English, but phone translator services were used for those who did not speak English. The survey was carried out in English.

Service provider feedback was gathered from the three clinical staff members of the NRC Balseskin testing team, who regularly carried out RDT as part of the pilot.

Accuracy validation of RDTs

The original design of the pilot study was to have two sites ordinarily involved in testing of RASPs and to use whole blood finger prick RDTs for HIV, HBV and HCV in parallel with the gold standard method of SLBT via phlebotomy as the confirmatory benchmark, for internal validation.

Testing procedures

The testing was performed in the NRC Balseskin Health Centre and in a clinical room in the NTC Citywest. Testing procedures were followed in line with the Guidelines for Safe and Effective Near-Patient Testing [(6)].

Phase 1:

RDTs suitable for whole venous blood, capillary blood, plasma and/or serum were used to test blood acquired by finger prick for the presence of HIV antibody (Ab), HBV surface antigen (sAg) and HCV Ab, respectively (Determine HIV Early Detect, Abbott Diagnostics, Japan; Determine HBsAg2, Abbott Diagnostics, Japan and Bioline HCV, Abbott Diagnostics, Korea). A system using lancets, capillary tubes, buffer and RDT lateral flow tests were used by NRC Balseskin. Only capillary tubes, buffer and RDT lateral flow tests were used by Safetynet Primary Care who pipetted the blood from the phlebotomy tubes they were using onto the lateral flow test. The test results were read as per the manufacturer's instructions. Additional equipment included timers and a tray with individual dividers for holding specimens.

Phase 2:

Again lancets, capillary tubes, buffer and RDT lateral flow tests were used by NRC, Balseskin to test for HBV. Safetynet Primary Care carried out the same process as Phase 1 whereby they used blood from phlebotomy samples for the HBV lateral flow tests. The HIV and HCV RDTs intended for use on blood were replaced by oral swab tests (OraQuick HIV Self Test, OraSure Technologies Inc. USA; and OraQuick HCV Rapid Antibody Test, OraSure Technologies Inc. USA). Both sites used OraQuick oral swabs for HIV and HCV testing during phase 2 of the pilot. The test results were read as per manufacturers' instructions, and the same additional equipment as in Phase 1 was required.

Training was carried out by Abbott in relation to the finger prick blood tests used in Phase 1, and by Cruinn in relation to the OraQuick oral swabs for HIV and Hepatitis C testing used in Phase 2.

WHO prequalification reports show sensitivity and specificity data for the individual RDTs as follows:

- OraQuick HIV oral fluid sensitivity (N=106) % (95% CI): 99.1% (94.8% - 100%) and specificity (N=376) % (95% CI): 100% (99.0% - 100%) (N = 893)[(7)]
- Bioline HBsAg whole blood showed sensitivity (95% CI) was 100% (98.1% – 100%) and the final specificity (95% CI) was 99.0% (N = 514)[(8)]
- OraQuick HCV oral fluid tests show sensitivity 98.1% (N = 753) and specificity 99.6% (N = 1423) [(9)]

RDT data collection and analysis

The results of all RDTs carried out along with the corresponding phlebotomy results were captured and analysed. Feedback was gained from IPA participants in the NRC Balseskin via a survey. In addition, a service provider focus group was carried out with the NRC Balseskin clinical staff in order to capture feedback regarding the practical implementation of the use of RDTs for testing for BBVs in this population.

Outcome measures

The key indicators measured were:

- Test accuracy
- Operational feasibility
- User satisfaction and acceptability
- Service provider acceptability
- Communication adequacy
- Likely accessibility and impact

4. Results

4.1 Test Accuracy

Across the two pilot sites, a total of 121 individuals were tested during Phase 1 of the pilot and 106 individuals were tested during Phase 2 of the pilot. The results obtained were as follows:

HIV testing Phase 1	
Reactive HIV Blood RDT	Positive HIV SLBT
0/121	0/121

Table 2a

HIV testing Phase 2	
Reactive HIV Oral RDT	Positive HIV SLBT
4/106	6/106

Table 2b

In Phase 2, four out of 106 had reactive RDT for HIV and six out of 106 had a positive SLBT. All individuals with positive tests were known to be HIV-infected and on antiretroviral therapy (ART). These individuals were excluded from subsequent analysis as RDTs are not licensed for testing individuals with established HIV infection on ART due to potential for false negative results (testing was undertaken in spite of this as part of internal test validation). Table 2c below shows the final data set for 100 people who were tested for HIV via oral swab with the six people on ART excluded.

Final data set HIV testing Phase 2	
Reactive HIV Oral RDT	Positive HIV SLBT
0/100	0/100

Table 2c

A total of 227 people were tested for HBV via finger prick blood RDT in Phases 1 and 2 of the pilot. RDTs for HBV were reactive in 5/227 individuals (2.2%) while 6/227 (2.6%) were confirmed positive with phlebotomised samples. The individual with a non-reactive RDT who had a reactive phlebotomised blood test was subsequently found to have a non-detectable HBV viral load which would fall under the sensitivity threshold pre-specified by the RDT manufacturer. This individual reported having a history of HBV in the past and had received treatment. For the remaining five people, it was a new diagnosis of HBV.

HBV testing Phase 1 & 2	
Reactive HBsAg Blood RDT	Positive HBsAg SLBT
5/227 (2.2%)	6/227 (2.6%)

Table 2d

Table 2f below shows that in Phase 2, one out of 106 people tested reactive via oral swab for HCV, which was not confirmed positive via phlebotomy. Possible factors recognised by the manufacturers which may contribute to a false positive result include incorrect verification waiting time for collection, improper sample collection e.g. of cheeks/tongue, and over collection of sample.

HCV testing Phase 1	
Reactive HCV RDT Fingerprick	Positive HCV Phlebotomy
0/121	0/121

Table 2e

HCV testing Phase 2	
Reactive HCV RDT Oral Swab	Positive HCV Phlebotomy
1/106	0/106

Table 2f

4.2 Feedback from pilot sites – service users

During the course of the pilot being conducted, feedback was gained from the service users who were tested via RDTs and phlebotomy at the NRC Balseskin site.

Service User Feedback RDT Pilot Phase 1

Anonymous questionnaires were given to service users after they had undergone RDT for completion. 26 questionnaires were completed by service users. Feedback was sought with regards to the testing procedure, explanation of the tests, and overall experience. This questionnaire comprised a mixture of closed and open-ended questions.

The findings were as follows:

- With regards to their overall experience 24/26 (92.3%) service users rated it as excellent and the remaining 2/26 (7.7 %) rated their experience as good.

- When asked if service users were given enough information and support, 24/26 (92.3 %) responded 'yes', 2/26 (7.7%) left this response blank, while 0 users responded 'no'.

- When questioned if the test information was easy to understand 24/26 (92.3%) of service users ticked 'yes', while 2/26 (7.7 %) left this response blank and 0 users ticked 'no'

- Service users were asked if they found the testing painful, 21/26 (80.8%) replied that it was 'not painful', 5/26 (19.2 %) replied that it was 'not very painful' while 0 users replied that it was painful.

Of the 26 service users surveyed, 12 volunteered additional information to describe their experience. All of these 12 respondents gave positive feedback to describe their experience. Some of the feedback included *'The doctor took time to explain all that we need to know' 'Friendly and relaxed' 'It has been so good, all has been very well conducted' 'It was fast and the result came out fast, it's encouraging to take the test over and over again'.*

The service users were asked 'What should we stop doing?' with regards to the testing, 10/26 (38.5%) respondents replied *'nothing'* while the remaining 16/26 (61.5%) respondents left this answer blank.

Service User Feedback RDT Pilot Phase 2

35 questionnaires were completed by service users who were tested during Phase 2 of the pilot. Similarly to Phase 1 questionnaires, feedback was sought with regards to the testing procedure, with an additional focus on oral swab testing, as well as explanation of the tests, and the service users overall experience. This again comprised of closed and open-ended questions.

The findings were as follows:

- With regards to their overall experience 33/35 (94.3%) service users rated it as excellent, 2/35 (5.7%) rated their experience as good.

- When asked if service users were given enough information and support, 35/35 (100%) of service users responded 'yes'.

- Service users were asked about their experience of the oral swab for testing, 33/35 (94.3%) felt it was 'very easy' 2/35 service users left this blank.

- When questioned if the test information was easy to understand 35/35 (100%) of service users ticked 'yes'.

  Service users were asked if they found the testing painful, 21/35 (60%) replied that it was 'not painful', 10/35, 28.6% replied that it was 'not very painful', 1/35 (2.9%) replied 'painful' while 3/35 (8.6%) of service users did not respond to this question.

Of the 35 service users surveyed in Phase 2, 31 provided additional information to describe their experience. Of these respondents 30/31 service users gave positive feedback to describe their experience. One service user wrote *"I need translator to understand"*. The remaining feedback was positive, *"Excellent service, I felt very comfortable", "I had a good experience and the nurse explained everything clearly to me" "I've just been educated more on health matter" "It was pain free and quick results" "very gentle, simple and quick".*

The service users were asked "What should we stop doing?" with regards to the testing, 19/35 (54.3%) respondents replied *"nothing"* while the remaining 16/35 (45.7%) respondents left this answer blank.

4.3 Feedback from pilot sites – service providers

A semi-structured focus group was facilitated with service providers in NRC Balseskin and below are notes from this discussion.

1. **What is your job type within the health service where you work?**

One Senior Medical Officer and two Nurses working as Health Assessors based in the NRC Balseskin participated in the focus group.

2. **Please describe your role**

The two Health Assessors described their roles as assessing health needs of the IPAs and referring them on to relevant services. Both Health Assessors worked previously as midwives and have significant experience in testing for BBVs before the pilot using phlebotomy. The Senior Medical Officer oversaw the pilot on site, managed the referral pathways for reactive results and has worked as a General Practitioner (GP) previously.

3. **In your clinical practice have you encountered RASP clients who have undergone BBV RDT testing prior to this pilot programme?**

Participants had not used finger prick or oral swab RDTs before this pilot.

4. **Communication/ sensitisation**

Of the promotional materials that have been developed for the BBV RDT pilot evaluation programme, what have you found most helpful?

It was noted that the information leaflet and pilot participation consent form were satisfactory.

They noted that most people didn't read the leaflet but took it away with them for future reference. The participants agreed the information leaflet was useful as a prompt and that further translations for a national roll-out of the programme would be useful.

Asked whether an information video would be useful, there was consensus that there is not enough time to show a video and a video is not required.

One participant noted that the key aspect of explaining the pilot is developing trust and rapport with people, as it is not usual to offer a suite of testing approaches - finger prick/oral swab RDTs/ and phlebotomy.

Do you think there are gaps in information provided to IPAs regarding the BBV RDT pilot evaluation programme?

- **If yes, what do you think those gaps are?**
- **What do you think would be the best way to address those gaps in information?**

Please explain your answer Service providers agreed that the information available was sufficient. One participant re-iterated the importance of verbally explaining the process. One service provider highlighted that infographics/pictures highlighting how the finger prick RDT and oral swab RDTs would be carried out, would be useful to include in the information material provided to patients.

5. **Do you agree with the statement 'RDT screening is a quick and convenient way of testing for BBVs'**
    - **Strongly agree**
    - **Agree**
    - **Disagree**
    - **Strongly disagree**

Please explain your answer:

All service providers agreed with the statement that the RDT screening is a quick and convenient way of testing for BBVs.

One service provider did note that doing the three finger prick tests in Phase 1 was tricky, as most times more than one finger prick was required for the three RDTs; she also noted the screening is much easier with the introduction of the oral swabs for the Hep C and HIV RDTs.

Service providers noted that the finger prick RDT for the HBV being an open system versus phlebotomy does increase the infection risk for staff and stressed the importance of training in both the testing techniques and standard precautions as outlined in the national HSE guidelines for those carrying out BBV screening. The participants did agree that with a detailed and clear SOP and effective Infection Prevention and Control measures the risk can be minimised, and carrying out this type of screening is reasonable.

There was consensus that if there were three oral swabs tests, they would strongly agree with the statement above.

6. **Do you agree with the statement 'BBV RDT screening increases overall capacity for BBV testing among the RASP target population'**
    - **Strongly agree**
    - **Agree**
    - **Disagree**
    - **Strongly disagree**

All participants strongly agreed with the statement.

When asked by the facilitators whether the service providers could test more than one person at a time the service providers agreed that this was possible if the space and set up were correct, however with the caveat that one needs to have a robust system for labelling so results don't get mixed up. In addition it is important that the service user knows how long they need to wait for in order to get the results. They noted it does not take any longer to do the three tests than to do one test.

Overall

What are the strengths and weaknesses of the Programme?

Service providers noted the following strengths of the programme:

- BBV screening is an important area of clinical care for RASP.
- The results are very quick.
- This type of point-of-care screening is suitable for this transient patient cohort.
- Referral to follow up care is improved as can be done at the same consultation.
- Acceptable for the patient, finger prick is less sore than phlebotomy.
- Good option for people who do not like needles.

Service providers noted the following weaknesses of the programme:

- Finger prick testing can be tricky.
- Using the three finger prick tests was challenging, but for one test is no problem.
- Referenced open system for Hep B finger prick testing and risks associated with that.

Service providers noted the following potential challenges in delivering the programme:

- Language and accessibility of interpreters.
- Supply of the equipment.
- The reading of the results was not a challenge, but the need for training in giving reactive results is crucial. There is a need for someone to take responsibility for this who has a clinical background.

Accessibility

Is there sufficient information in the correct language (in terms of leaflets, information, and communication from the people carrying out the tests)?

One service provider recommended making the information leaflet visual, improving accessibility.

Do you see this service increasing access of BOTPs and IPAs to BBV screening?

All service providers strongly agreed.

Is lateral flow RDT testing acceptable (two oral and one finger-prick) to individuals among the target population?

All service providers agreed. It was also agreed that for those who do not speak English, the interpreter is very important in explaining the process.

Feasibility

The questions regarding the evaluation in relation to feasibility are as follows:

Did the lateral flow RDT screening work?

All service providers agreed, yes the RDT screening worked.

Was it easy to read the result?

All service providers agreed yes and it was easy to train people to read the result.

Where people happy to use the pilot service?

All service providers agreed yes, in general. There were people who refused, and some of those people refused the option of phlebotomy testing.

Who used the pilot service?

For this pilot site, all those who were screened were IPAs and the majority spoke English with a small number of people who did not speak English. The service providers noted there was a cross section of the population – males and females of different ages.

Did the processes work?

All service providers agreed yes the processes worked.

Impact

Did groups engage?

All service providers agreed yes the cohort engaged in the pilot.

Were BBVs diagnosed?

Yes, BBVs were diagnosed.

Were BBVs diagnosed in the new users (those who previously had not been screened)?

Yes,some people were newly diagnosed with HBV.

Acceptability

Was the pilot service acceptable to service users?

All service providers agreed yes the pilot was acceptable to service users.

Was the pilot service acceptable to service providers?

One service provider noted that it took a while to get logistics in place in terms of carrying out the tests and that anything that is new takes time, however once the processes were ironed out it was better.

Did they find it very painful?

One service provider noted that the finger prick was not as painful as phlebotomy and it was very quick.

Anything else?

Service providers noted:

"*Great test to have, marvellous to have a test that you can use so easily."*

"*Training is key for those carrying it out."*

5. Discussion

Comparison with Existing Methods

RDTs for BBV testing provide a convenient, accurate, quick and minimally invasive means of testing as highlighted by the results obtained, service user and provider feedback. While it is recognised that SLBT via phlebotomy is the gold standard for BBV testing, this requires significant systems in place such as trained phlebotomists, courier systems, arrangements with local laboratories along with the associated running costs. RDTs may represent a more accessible testing method for large scale community-based testing. The use of RDTs in RASPs may help to fulfil the obligations laid out in the EU Migration Pact 2024 [(10)] which Ireland has recently opted into, and that may result in policy at a national level with regards to migrant health screening.

In addition, a non-invasive means of testing as done in this pilot is generally more acceptable to the patient as highlighted by the service users feedback, which showed that in Phase 2 of the pilot, 94% of users rated their overall experience as excellent, 60% of patients surveyed replied that it was 'not painful', 29% replied that it was 'not very painful', and just 3% found the procedure 'painful' in Phase 2 of the pilot. A testing test which is more acceptable to an individual is likely to result in a larger uptake of testing.

It is important to note that this pilot was conducted among IPAs who are a cohort of people that may have to move locations at short notice and may not have reliable contact information or mobile phones, and language barriers may contribute to communication challenges. For this reason, the ability to deliver a 'reactive' or 'non-reactive' result at the same consultation is invaluable, allowing the potential of same day referral to specialist care and minimizing the risk of loss to follow up.

With regards to the specific testing techniques, retrieval of blood via the finger prick method and saliva via the oral swab does involve an open system as opposed to a closed phlebotomy system. This theoretically poses a greater infection risk versus phlebotomy. The testing technique for both finger prick method and oral swab will require formal training, along with training in communicating reactive and non-reactive results. The feedback from service providers in this pilot is that the testing technique is less technically difficult than phlebotomy.

Interpretation of results:

The results of our pilot show that RDT is an accurate way of testing for BBVs highlighted by low false negative and false positive results as compared to the gold standard testing technique of SLBT/phlebotomy. The results obtained in this pilot are in line with those found in the WHO prequalification reports for the individual HIV[(7)] HBV[(8)] and HCV[(9)] tests.

Of note, six patient samples were excluded from the HIV results data as they were known HIV patients established on anti-retroviral treatment. Two of these had false non-reactive results on oral swab RDT, and four had true reactive results. Prior to starting the pilot it was decided that we would test persons known to be living with HIV using the oral RDT in order to validate RDT accuracy, while aware that this test is not recommended by their manufacturers in that situation.

It is important that all testing service users are counselled that a non-reactive HIV result does not preclude the possibility of infection, especially in the context of recent infection risk exposure [7] when they should be advised to repeat testing 3 months after such exposure. It should also be highlighted that those availing of pre-exposure prophylaxis (PrEP) may have false negative HIV RDT results, and should be advised to avail of testing by SLBT/phlebotomy.

With regards to oral HCV RDT, 1 out of 106 people tested reactive via oral swab for HCV, which was not confirmed positive via phlebotomy. Incorrect testing technique can increase the possibility for false negative/ false reactive results. Issues such as over-swabbing, and/or oral hygiene including cleaning of dental products within 30 minutes of testing can affect test results. It is, therefore, essential that formal training is provided to all performing RDT with regards to the correct pre-test questioning and preparation, counselling and sampling/testing techniques.

Observations:

The most significant limitation of the present pilot is its sample size yielding only a handful of reactive RDTs. This makes drawing conclusions on test accuracy exclusively from this small pilot inappropriate. However, these results do suggest that the false reactivity rate is not expected to be overwhelming for the healthcare system to manage. As previously referred to, the accuracy of the tests themselves has been previously evaluated and confirmed in the WHO Prequalification Reports on significantly larger samples [7] [8] [9].

On analysis of service user feedback forms, we noted that many questions were left blank or unanswered, which we are inclined to believe may be related to language barrier or literacy limitations. This meant that part of potentially important feedback is left uncaptured. Such limitations could be addressed by having translated feedback forms or an interactive approach such as a focus group/ verbal feedback on site. Of note the majority of people tested in Balseskin spoke English which allowed the survey to be conducted in English. This may differ considerably in other settings.

The pilot was conducted in a clinical setting across two sites with trained staff experienced in testing and counselling patients. As a result, our findings may not be directly generalisable to other settings not ordinarily used for clinical purposes such as RASP accommodation facilities.

Of importance, the pilot was conducted with prior consultation of the local referring tertiary hospitals with agreements and systems put in place to facilitate swift referral and management of individual with reactive RDT results. It is highly advisable that prior to national roll-out of the BBV testing and treating programme a regional-specific review of referral pathways should be undertaken in consultation with specialist Infectious Disease, Hepatology and Genito-Urinary Medicine services as applicable to each geographical region as operational details may vary.

6. Conclusion

RDT for BBV in IPA and BoTP cohorts provides an opportunity to test at a larger scale for HIV, HBV and HCV in a swift, convenient and acceptable fashion. This further allows for timely, efficient and effective Public Health advice and management serving not only to decrease morbidity and mortality of the individual in question but also to protect members of the wider society and decreasing healthcare costs. The rapid results obtained at a point-of-care testing consultation can help to minimize loss of individuals to follow up, particularly in this highly mobile cohort.

This report highlights that RDT has the potential to normalise and de-stigmatise BBV testing practices across all population groups, allowing a more community based approach. Furthermore, it is hoped to increase accessibility and uptake of BBV testing amongst IPA and BoTP cohorts as they are infrequently linked to GP care and frequently residing in locations where SLBT/ phlebotomy testing would be challenging due to limited existing infrastructure or accessible testing sites.

The next steps for national IPAs and BOTP RDT BBV testing programme will involve adaptation of SOPs generated from this pilot, as well as regional and local training at each proposed testing site drawing on the insights gained from this pilot (see Appendices). Further collection of data with larger participant numbers will help to gain better understanding on utility and possible limitations of the RDT BBV testing in this context and will offer grounds for further review and development of testing processes as necessary.

7. Recommendations

Based on the findings of this pilot, we recommend using a programme of oral RDT to test for HIV and HCV, and whole blood finger prick RDT for HBV as a feasible alternative to test for BBVs in IPA and BoTP cohorts, for those aged 16 years and older.

Future Implementation –This evaluation report highlights certain areas as key for a successful implementation of RDT at a regional and national level:

a) Testing can be implemented alone or to complement BBV testing by phlebotomy and SLBT.

b) Quality formal training of service providers is essential in ensuring the most effective testing technique, interpretation of results and counselling of patients. Training should be supported with resources such as a SOP document (please see appendix). Healthcare staff should be trained in counselling patients on the significance of a ‘reactive’ test result. Service providers in this pilot believe that rapid diagnostic testing can be carried out by clinical staff at the level of a healthcare assistant.

c) Local arrangements will need to be defined with regards to onwards referral of 'reactive' RDT results. SOP documents should be adapted from those developed from this pilot to suit local arrangements, please see appendix.

d) Translated resources and trained interpreters are essential in providing this service, in the form of information leaflets and in gaining feedback. As highlighted from our service provider feedback focus group, visual imagery should also feature to aid comprehension, e.g., an image of an oral swab in the mouth as part of the information leaflet to help explain the testing technique.

e) As the operational nature of RDT BBV testing is likely to vary from Health Region to Health Region, and vary from this pilot, it would be valuable to continue to gain further feedback from service users and service providers either via questionnaire or focus groups.

f) Consideration should be given to the procurement of tests and likely volume of tests required by each Health Region. This will vary from Health Region to Health Region and will depend on such factors as the number of IPAs and BoTPs accommodated in the locality, the availability of healthcare workers to carry out testing, the adequacy of current use of SLBT/phlebotomy for testing and the availability of sites suitable to carry out the testing.

g) Rapid Diagnostic Testing should form part of an end to end care protocol which includes referral, vaccination and contact tracing. Please see flow info gram in the appendix for further information.

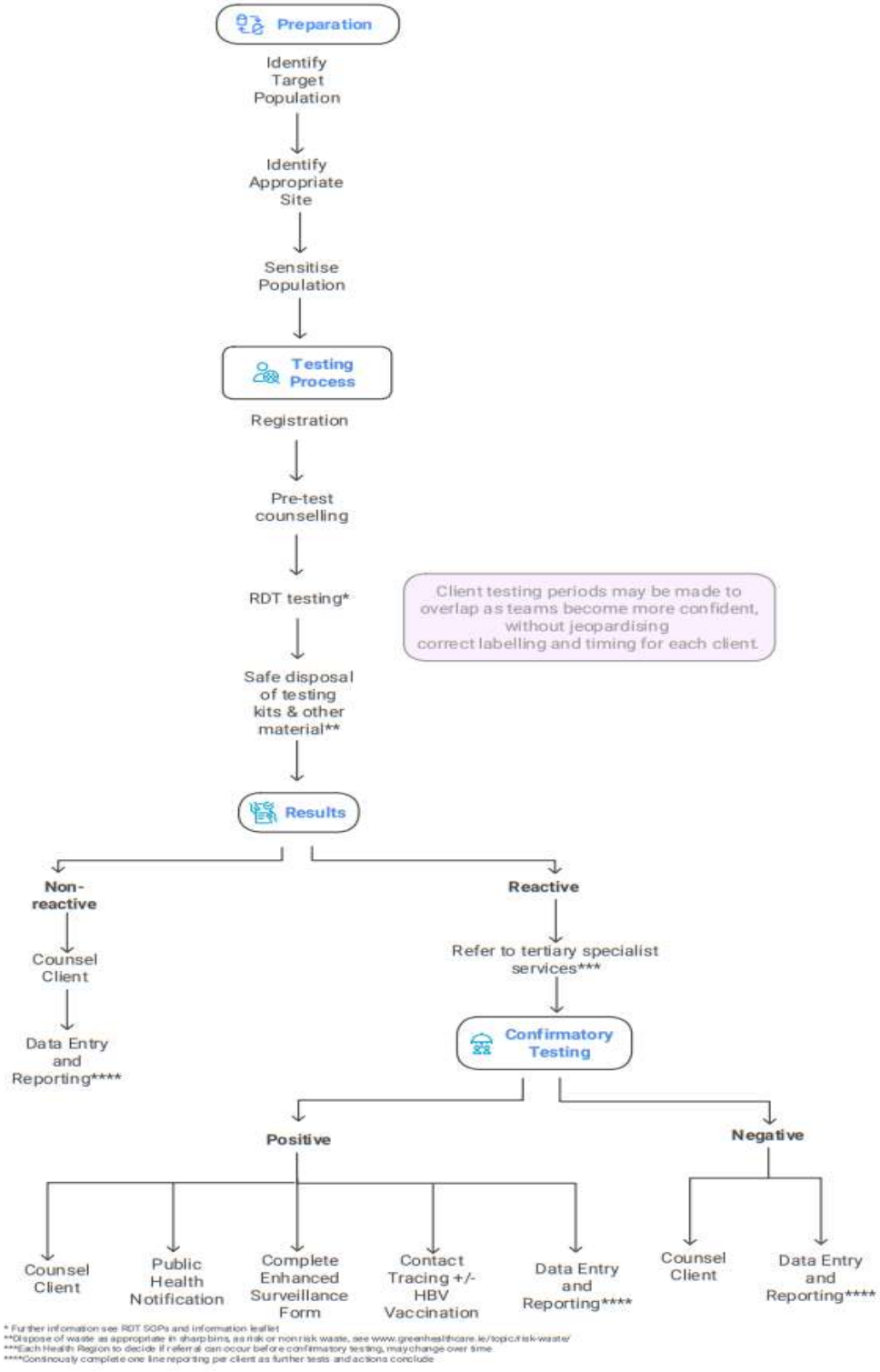
8. References

1. International Protection Office. (n.d.). Statistics. Retrieved from IPO Statistics
2. Health Service Executive. (2023). Report of the Refugee and Applicants Seeking Protection Blood-Borne Virus/Tuberculosis Screening Implementation Advisory Group. Retrieved from HSE Report
3. National Reception Centre, Balseskin. (2023). Annual Report.
4. Health Service Executive. (2022). Infectious Disease (blood borne virus) Assessment of people from Ukraine in Ireland.
5. Health Service Executive. (n.d.). Health Response for Refugees and Applicants Seeking Protection Primary Care Infectious Disease Testing Service Delivery Model Report.
6. National Near-Patient Testing Consultative Group. (2022). Guidelines for Safe and Effective Near Patient Testing (NPT). Retrieved from RCPI Guidelines
7. World Health Organization. (2023). Prequalification of In Vitro Diagnostics PUBLIC REPORT Product: OraQuick HIV Self-Test. Retrieved from WHO Report
8. World Health Organization. (2020). Prequalification of In Vitro Diagnostics PUBLIC REPORT Product: Bioline HBsAg WB1. Retrieved from WHO Report
9. World Health Organization. (2017). Prequalification of In Vitro Diagnostics PUBLIC REPORT Product: OraQuick HCV Rapid Antibody Test Kit. WHO Report
10. Government of Ireland. (n.d.). EU General Agreement on Migration and Asylum.

9. Appendices

Appendix A

End-to-End testing by RDT Flow-Chart (further details available in RDT SOPs & info leaflets)



Appendix B

Rapid Diagnostic Testing for HIV

Standard Operating Procedure

Read in conjunction with 1) Guidelines for safe and effective near-patient testing (NPT) 2022 Update[i], 2) End-to-End BBV testing flow chart & 3) HIV RDT information leaflet

Introduction to client and consent

- Provide the client with an information leaflet in their spoken language explaining the test procedure and purpose of it
- Use interpreter if required
- Explain that the Rapid Diagnostic test will screen for HIV antibody
- Explain to the patient that he/she will receive a 'non-reactive' or 'reactive' result for the test
- If the test is 'reactive' they will be referred to GP/tertiary specialist services for confirmatory blood tests
- Explain to the client if they are happy to proceed this will be interpreted as informed consent

Testing Specifics and Technique

Intended Use

The OraQuick ADvance HIV rapid antibody test is a single use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1(HIV-1) and Type 2(HIV-2) in oral fluid. The test is intended for use as a point-of-care test.

Restrictions

- The OraQuick ADVANCE HIV-1/2 Test is not intended to be used to test individuals who are receiving ART.

Summary and Explanation of the test

HIV is the causative agent of acquired human immunodeficiency. Testing for the presence of antibodies to HIV in body fluids like oral fluids is an accurate aid in the diagnosis of HIV-1/2.

Materials required to carry out the test

- Divided pouch which contains Oraquick ADVANCE HIV-1/2 test, and desiccant Oraquick ADVANCE HIV-1/2 developer solution vial containing 1mL phosphate buffered saline solution containing polymers and antimicrobial agent.
- Reusable test stands
- Timer capable of timing 20 to 40 minutes
- Biohazard waste bags or containers
- Disposable gloves

Precautions

- Handle specimens and materials in contact with specimens as if capable of transmitting infectious agents.
- Wear disposable gloves while handling and testing specimens. Change gloves and wash hands thoroughly or use alcohol sanitiser after performing each test. Dispose of used gloves in a biohazard bag or container.
- Use of gloves for oral specimen is recommended as any biologic specimen should be treated as potentially infectious. Test administrators with broken skin should wear gloves when performing oral fluid testing.
- Wash hands thoroughly after performing each oral fluid test and after contact with oral fluid.
- Don't reuse specimen collection loops, test Device or developer solution. Dispose of these components properly. Reuse of these components can transmit infectious agents.
- Don't use the test beyond the expiration date on the pouch.

Please see “HSE AMRIC Standard Precautions Explainer”: HSE AMRIC . This also has a link for a range of posters, including for Infection Control, Prevention Protection Equipment and Hand Hygiene.

Storage

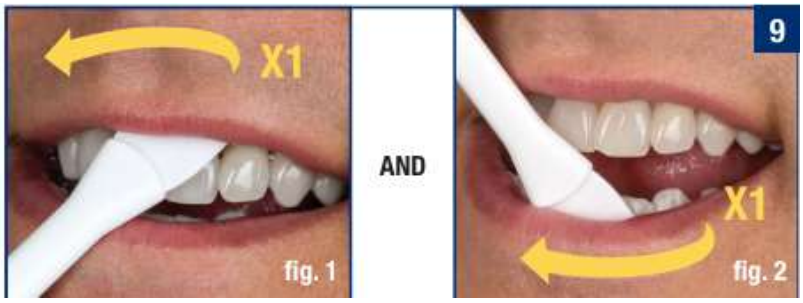
- Store unused Oraquick ADVANCE HIV-1/2 tests unopened at 2-27 degrees.
- Don't open the pouch until you are ready to perform a test.
- If stored refrigerated, ensure that the pouch is brought to operating temperature 15-37 degrees before opening.

General test preparation

- Allow all components to come to operating temperature 15-37 degrees.
- Place the Reusable Test Stand on your workspace. Use only the stand provided with the OraQuick ADVANCE HIV-1/2 kit.
- Place the Oraquick ADVANCE HIV-1/2 Test Developer solution vail into the test stand. Hold the vial firmly in the stand and remove the cap by rocking it back and forth while pulling it off.
- Don't open the pouch until you are ready to perform a test. Check the pouch for damage or holes. **Do not use if damaged.**
- Check for a desiccant packet in the pouch. If it is not present or damaged, discard the pouch and open the new one.
- Don't cover the 2 holes on the back of the device with labels. Blocking the holes may cause an invalid result.

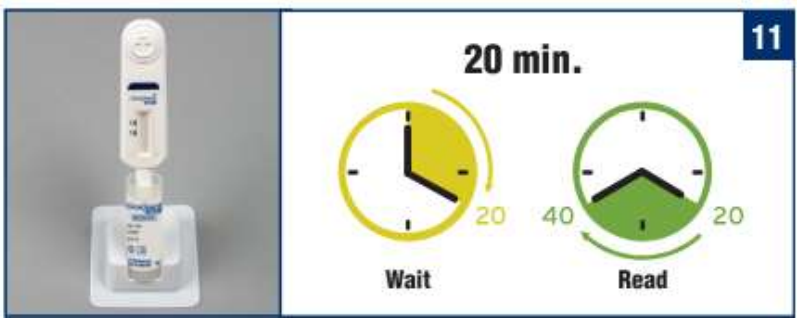
Sample Collection

- Ensure prior to testing that the client has not had anything to eat, drink or chewed gum for at least 15 minutes.
- Have the client wait for at least 30 minutes prior to testing if they have used any oral care products.
- Remove the Oraquick ADVANCE HIV-1/2 Test from the pouch.
- Don't touch the flat pad.
- Swab completely around the lower and upper outer gums **ONE TIME.**
- Don't swab the roof of the mouth, tongue or cheeks.



Run test

- Insert the Test Device into the Developer solution.
- Set the timer for 20 to 40 minutes.



Test result and interpretation

- ☐ **NON – REACTIVE:** A test is non-reactive if a line appears in the C zone and NO line appears in the T zone. A non-reactive test result means that HIV antibodies were not detected in the specimen. Patient is presumed not to be infected with HIV.

- ☐ **REACTIVE**: A test is Reactive if a line appears in the C zone and the line appears in the T zone. Lines may vary in intensity. The test is reactive regardless of how faint these lines are. A reactive test result means that HIV antibodies have been detected in the specimen. Confirmation of a reactive result by another test method is required.

- ☐ **INVALID**: A test is invalid if there was a problem running the test, either related to the specimen or the Device. An invalid result cannot be interpreted. See examples below: No line in C Zone; partial line one side of C and/or T Zone(s); red background obscures result. Repeat the test with a new pouch and a new specimen.

General Test Clean Up

- Dispose of the unused test materials and gloves in a biohazard container/bag (see End-to-End BBV testing flow chart).
- When using gloves, change your gloves between each test to prevent contamination.
- Use a freshly prepared 10% solution of bleach to clean up any spills.

Referral

- If a test is 'non-reactive' advise the client that no further action is needed, unless they were exposed during the "window period" from about three months prior to test.
- If the test is 'reactive', reassure the client that there is effective treatment of this disease, provided for free in Ireland. However, these rapid tests are not 100% accurate, and all reactive tests need to be confirmed by taking a blood sample for standard laboratory testing. Advise client to avoid all contacts (sexual or sharps) while awaiting results of confirmatory testing.
- Follow local arrangements on whether confirmatory testing by phlebotomy/SLBT needs to be done before referral to specialist services (this may change over time). If so, arrange for confirmatory testing.
- Refer to specialist services in keeping with local arrangements.

Mishap

- For any adverse event, clinical or non-clinical incident, please refer to the HSE Incident Management Framework

Data Entry and Reporting

- In the absence of a Programme Information Management System, an Excel sheet with one line per client needs to be filled in for each client, and continuously completed as further tests and actions are concluded. This will ensure good basic follow-up of clients, monitoring of numbers tested, reactivity rates, etc. See below, and also Appendix E.

1. Could be drop down hospital or clinic
2. Just Y required, filled in when completed

References

Guidelines for safe and effective near-patient testing (NPT) 2022 update, National Near-Patient Testing (NPT) Consultative Group, Dublin, Ireland Version 6.2 April 21, 2021.

OraQuick ADvance HIV rapid antibody test https://uk.oraquick.com/how-to-use

Appendix C

Rapid Diagnostic Testing for Hepatitis B

Standard Operating Procedure

Read in conjunction with 1) Guidelines for safe and effective near-patient testing (NPT) 2022 Update[ii], 2) End-to-End BBV testing flow chart & 3) Hep B RDT information leaflet

Introduction to Client

- Provide the client with an information leaflet in their spoken language explaining the test procedure and purpose of it
- Explain that the Rapid Diagnostic Test will screen for Hepatitis B virus
- Explain to the patient that he/she will receive a 'non-reactive' or 'reactive' result for the test.
- If the test is 'reactive' they will be referred to GP/hospital for confirmatory blood tests
- Explain to the Client if they are happy to proceed this will be interpreted as informed consent

Testing Specifics and Technique

Intended Use

Determine™ HBsAg 2 is a single use visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. The test is intended as an aid to detect HBsAg from infected individuals.

Summary and Explanation of the test

Hepatitis B virus (HBV) is a DNA virus transmitted percutaneously, sexually and perinatally. HBsAg is the first serological marker to appear in acute HBV infection.

Materials required to carry out the test

- Chase Buffer 1 bottle (2.5 mL) containing phosphate buffered saline, preservative and antimicrobial agent.
- Lancet – single use
- Capillary tube – single use

- Alcohol swab, gauze pad
- Timing Device
- Disposable gloves

Precautions

- Handle specimens and materials in contact with specimens as if capable of transmitting infectious agents.
- Wear disposable gloves while handling and testing specimens. Change gloves and wash hands thoroughly or use alcohol hand sanitiser after performing each test. Dispose of used gloves in a biohazard bag or container.
- Wash hands thoroughly before and after performing each test.
- Don't use the test kit beyond the expiration date.

Please see “HSE AMRIC Standard Precautions Explainer”: HSE AMRIC . This also has a link for a range of posters, including for Infection Control, Prevention Protection Equipment and Hand Hygiene.

Storage

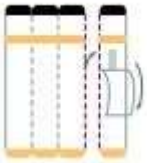
- Store Determine™ HBsAg 2 test cards and chase buffer at 2-30 ˚C until expiration date.
- Immediately reseal all unused tests in the foil pouch containing the desiccant by pressing the seal closed.
- Do not use wet devices or damaged packages.

General test preparation

- Don't open the pack until you are ready to perform a test.
- Caution – Glass capillaries may be damaged during transport or when in use. Handle with care.

Sample Collection

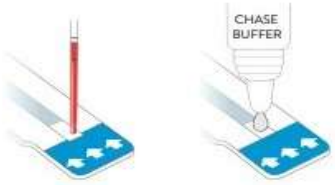
- Remove the desired number of test strips from the test card by bending and tearing the perforation.
- Remove the protective foil cover from each test.
- After removing the protective foil cover from each test strip start the assay within 2 hours.
- Place one strip on a flat clean surface where the test is to be performed.



- Before collecting a finger prick specimen, place a capillary tube on a clean dry surface.
- Choose the fingertip of the middle, ring or index finger. Warm the hand if needed.
- Clean fingertip with alcohol and allow to air dry.
- Position the hand palm-side up. Place the lancet off-centre on the fingertip. Firmly press the lancet against the finger and puncture. Dispose of the lancet in a biohazard sharps container.
- Wipe away the first drop of blood with a sterile gauze pad.
- Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the finger several times.
- Touch the tip of the capillary tube to the drop of blood, avoid air bubbles. Fill the tube with whole blood up to between the two marked lines (50 ul).

Running the Test

- Add 50 ul of whole blood to the sample pad. When all the blood has been transferred from the capillary tube to the middle of the sample pad immediately apply one drop of chase buffer to the sample pad.

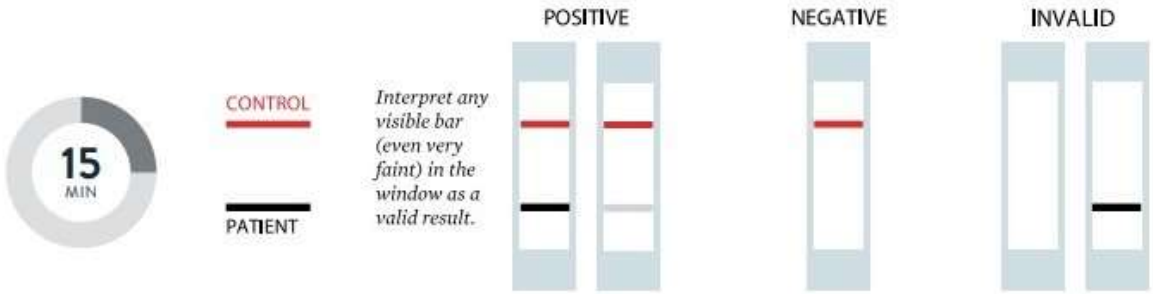


- Set the timer for 15 to 30 minutes.

Test result and interpretation

- Read the result between 15 and 30 minutes after the addition of the sample.
- **Do not read the test result after 30 minutes.**
- The control line should appear for all results, if it does not appear the result is invalid and should be repeated.

- **Reactive:** Two bars – one red and one black bar appear in the window. The red bar corresponds to the control bar and the black bar corresponds to the patient bar.
- **Non-reactive:** One red bar appears and no black bar appears in the window.
- **Invalid:** if there is no red control bar in the window, even if a black patient bar appears in the window, the result is invalid. Repeat the test using a new test strip.



Mishaps

General Test Clean Up

- Dispose of the unused test materials and gloves appropriately (see End-to-End BBV testing flow chart).
- When using gloves, change your gloves between each test to prevent contamination.
- Use a freshly prepared 10% solution of bleach to clean up any spills.

Referrals

- If a test is 'non-reactive' advise the client that no further action is needed.
- If the test is 'reactive', reassure the client that there is effective specialist care of this disease, provided for free in Ireland. However, these rapid tests are not 100% accurate, and all reactive tests need to be confirmed by taking a blood sample for standard laboratory testing. There may also very occasionally be false negative test results. Advise client to avoid contacts (sexual, shared toiletries or sharps) while awaiting confirmatory testing.
    - Follow local arrangements on whether confirmatory testing by phlebotomy/SLBT needs to be done before referral to specialist services (this may change over time). If so, arrange for confirmatory testing.
    - Refer to specialist services in keeping with local arrangements.
- For any adverse event, clinical or non-clinical incident, please refer to the HSE Incident Management Framework

Data Entry and Reporting

- In the absence of a Programme Information Management System, an Excel sheet with one line per client needs to be filled in for each client, and continuously completed as further tests and actions are concluded. This will ensure good basic follow-up of clients, monitoring of numbers tested, reactivity rates, etc. See below, and also Appendix E.

1. Could be drop down hospital or clinic
2. Just Y required, filled in when completed

References

[1] Guidelines for safe and effective near-patient testing (NPT) 2022 update, National Near-Patient Testing (NPT) Consultative Group, Dublin, Ireland Version 6.2 April 21, 2021.

Abbott Determine™ HBsAg 2 test information https://www.globalpointofcare.abbott/ww/en/product-details/determine-hbsag-2.html

Appendix D

Rapid Diagnostic Testing for Hepatitis C

Standard Operating Procedure

Read in conjunction with 1) Guidelines for safe and effective near-patient testing (NPT) 2022 Update[iii], 2) End-to-End BBV testing flow chart & 3) Hep C RDT information leaflet

Introduction to Client

- Provide the client with an information leaflet in their spoken language explaining the test procedure and purpose of it.
- Explain that the Rapid Diagnostic Test will test for Hepatitis C virus antibody
- Explain to the patient that he/she will receive a 'non-reactive' or 'reactive' result for the test
- If the test is 'reactive' they will be referred to GP/hospital for confirmatory blood tests
- Explain to the Client if they are happy to proceed this will be interpreted as informed consent

Testing Specifics and Technique

Intended use

The OraQuick HCV rapid antibody test is a single use anti HCV in vitro diagnostic medical device (IVD). It is an immunoassay for qualitative detection of Immunoglobin G (IgG) antibodies to hepatitis C virus (HCV) in oral fluid.

Summary and Explanation of the test

Hepatitis C is a viral infection, which causes inflammation of the liver. It can be transmitted percutaneously, sexually and perinatally.

Biological principles of the test

The OraQuick HCV rapid antibody test is a manually performed, visually read, 20 minutes immunoassay for the qualitative detection of antibodies to HCV in human oral fluid collected using a flat pad which is then inserted into developer solution. The developer solution facilitates the capillary flow of the specimen into the device and onto the assay strip.

Materials required to carry out the test

- Divided pouch which holds an Oraquick HCV rapid test, desiccant and an Oraquick HCV rapid test developer vial containing 1mL phosphate buffered saline solution containing polymers and antimicrobial agent.
- Reusable test stands
- Timer capable of timing 20 to 40 minutes
- Biohazard waste bags or containers
- Disposable gloves

Precautions

- Handle specimens and materials in contact with specimens as if capable of transmitting infectious agents.
- Wear disposable gloves while handling and testing specimens. Change gloves and wash hands thoroughly or use alcohol sanitizer after performing each test. Dispose of used gloves in a biohazard bag or container.
- Use of gloves for oral specimen is recommended as any biologic specimen should be treated as potentially infectious. Test administrators with broken skin should wear gloves when performing oral fluid testing.
- Wash hands thoroughly after performing each oral fluid test and after contact with oral fluid.
- Don't reuse specimen collection loops, Test Devise or developer solution. Dispose of these components properly. Reuse of these components can transmit infectious agents.
- Don't use the test beyond the expiration date on the pouch.

Please see “HSE AMRIC Standard Precautions Explainer”: HSE AMRIC . This also has a link for a range of posters, including for Infection Control, Prevention Protection Equipment and Hand Hygiene.

Storage

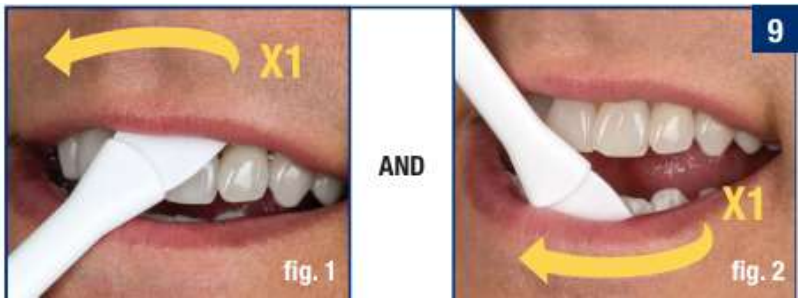
- Store unused Oraquick HCV rapid tests unopened at 2-27 degrees.
- Don't open the pouch until you are ready to perform a test.
- If stored refrigerated, ensure that the pouch is brought to operating temperature 15-37 degrees before opening.

General test preparation

- Allow all components to come to operating temperature 15-37 degrees.
- Place the Reusable Test Stand on your workspace. Use only the stand provided with the OraQuick HCV rapid kit.
- Place the Oraquick HCV rapid Test Developer solution vial into the test stand. Hold the vial firmly in the stand and remove the cap by rocking it back and forth while pulling it off.
- Don't open the pouch until you are ready to perform a test. Check the pouch for damage or holes. **Do not use if damaged**.
- Check for a desiccant packet in the pouch. If it is not present or damaged, discard the pouch and open the new one.
- Don't cover the 2 holes on the back of the device with labels. Blocking the holes may cause an invalid result.

Sample collection (oral fluid)

- Ensure prior to testing that the client has not had anything to eat, drink or chewed gum for at least 15 minutes.
- Have the client wait for at least 30 minutes prior to testing if they have used any oral care products.
- Remove the Oraquick HCV rapid Test from the pouch.
- Don't touch the flat pad.
- Swab completely around the lower and upper outer gums **ONE TIME.**
- Don't swab the roof of the mouth, tongue or cheeks.



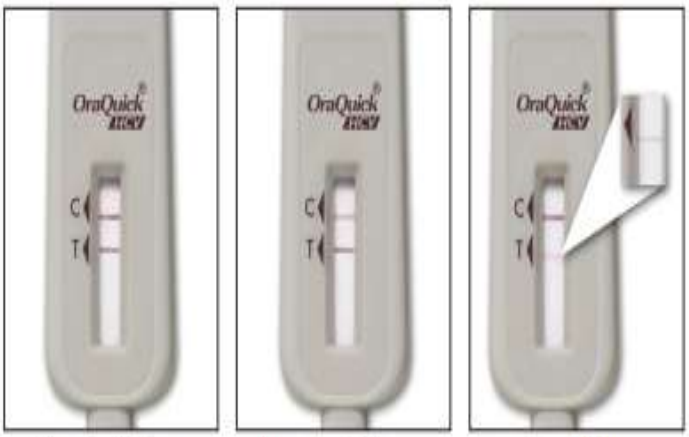
Run test

- Insert the Test Device into the Developer solution.
- Set the timer for 20 to 40 minutes.

Test result and interpretation

- **NON-REACTIVE**: A test is non-reactive if a line appears in the C zone but NO line appears in the T zone. A non-reactive test result means that HCV antibodies were not detected in the specimen. Patient is presumed not to be infected with HCV.

- ☐ **REACTIVE**: A test is reactive if a line appears in the C zone and the line also appears in the T zone. Lines may vary in intensity. The test is reactive regardless of how faint these lines are. A reactive test result means that HCV antibodies have been detected in the specimen. Confirmation of a reactive result by another test method is required.



- ☐ **INVALID**: A test is invalid if there was a problem running the test, either related to the specimen or the device. An invalid result cannot be interpreted. See examples below. Repeat the test with a new pouch and a new specimen.

General test clean-up

- Dispose of the unused test materials and gloves appropriately (see End-to-End BBV testing flow chart).
- When using gloves, change your gloves between each test to prevent contamination.
- Use a freshly prepared 10% solution of bleach to clean up any spills.

Referral

- If a test is 'non-reactive' advise the client that no further action is needed, unless they were exposed during the "window period" from about three months prior to test.
- If the test is 'reactive', reassure the client that if blood tests confirm active infection, there is effective treatment of this disease, provided for free in Ireland. However, these rapid tests are not 100% accurate, and all reactive tests need to be confirmed by taking a blood sample for standard laboratory testing. Advise client to avoid all contacts (sexual or needles) while awaiting results of confirmatory testing.
    - Follow local arrangements on whether confirmatory testing by phlebotomy/SLBT needs to be done before referral to specialist services (this may change over time). If so, arrange for confirmatory testing.
    - Refer to specialist services in keeping with local arrangements.

Mishaps

- For any adverse event, clinical or non-clinical incident, please refer to the HSE Incident Management Framework

Data Entry and Reporting

- In the absence of a Programme Information Management System, an Excel sheet with one line per client needs to be filled in for each client, and continuously completed as further tests and actions are concluded. This will ensure good basic follow-up of clients, monitoring of numbers tested, reactivity rates, etc. See below, and also Appendix E.

Name	DOB dd/mm/yyyy	Temp Protection or IPA No	Health Region	BBV screen date dd/mm/yyyy	HIV Reactivity (+/-)	Referred to Clinic[1]	HIV Confirmed Positive (Y/N)	HIV Positive ESF done and sent to PH (Y)[2]	HCV Ab Reactivity (+/-)	Referral to Clinic[1]	HCV antigen or RNA result viraemic (Y/N)	HCV viraemic case ESF done and sent to PH (Y)[2]	HBsAg Reactivity (+/-)	Referred to Clinic[1]	HBsAg confirmed Positive (Y/N)	HBsAg Positive (Y/N)	anti-HBc IgM Positive (Y/N)	HBsAg Positive case ESF done and sent to PH (Y)[2]	HBV Vaccinated (Y)[2]	Batch number	Sexual contacts identified, tested, and vaccinated as indicated (Y)[2]	Household contacts identified, tested, and vaccinated as indicated (Y)[2]

1. Could be drop down hospital or clinic
2. Just Y required, filled in when completed

References

[1] Guidelines for safe and effective near-patient testing (NPT) 2022 update, National Near-Patient Testing (NPT) Consultative Group, Dublin, Ireland Version 6.2 April 21, 2021.

(2024) Oraquick HCV. Available at: https://orasure.com/products-infectious/OraQuick-HCV.html#HowTo

Appendix E

Reporting template for monitoring screening process

	Name	DOB dd/mm/yyyy	Temp Protection or IPA No	Health Region	BBV screen date dd/mm/yyyy	HIV Reactivity (+/-)	Referred to Clinic[1]	HIV Confirmed Positive (Y/N)	HIV Positive ESF done and sent to PH (Y)[2]	HCV Ab Reactivity (+/-)	Referred to Clinic[1]	HCV antigen or RNA result viraemic (Y/N)	HCV viraemic case ESF done and sent to PH (Y)[2]	HBsAg Reactivity (+/-)	Referred to Clinic[1]	HBsAg confirmed Positive (Y/N)	HBeAg Positive (Y/N)	anti-HBc IgM Positive (Y/N)	HBsAg Positive case ESF done and sent to PH (Y)[2]	HBV Vaccinated (Y)[2]	Batch number	Sexual contacts identified, tested, and vaccinated as indicated (Y)[2]	Household contacts identified, tested, and vaccinated as indicated (Y)[2]
1																							
2																							
3																							
4																							
5																							
6																							
7																							
8																							
9																							
10																							

1. Could be drop down hospital or clinic
2. Just Y required, filled in when completed