

Molecular Virology

Diagnosics & Research Laboratory

Service Users Manual

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Foreword

Molecular Virology provides a specialist molecular testing and clinical liaison molecular virology service for clinicians investigating hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (type 1) (HIV-1). In the last five years, an average 3,664 patient samples were sent for testing to Molecular Virology per annum. This reflects the benefits of real-time viral load analysis in the clinical management of chronically infected individuals and the value of the services offered. Requests for this service can only be made through a relevant hospital consultant. The tests available and specific requirements for specimen collection and delivery are outlined in this document.

Molecular Virology is committed to providing the highest quality diagnostic and consultative services for all its users.



Professor Liam J. Fanning, PhD, DSc, FHEA UK, Director, MVDRL.

April 2023

1 Introduction

1.1 Overview

This manual is designed to give an overview of the services and laboratory tests provided by the Molecular Virology Diagnostic and Research Laboratory (MVDRL). The laboratory herein described as “Molecular Virology” (MV) is the MVDRL, Department of Medicine, University College Cork. Included is a brief description of the laboratory, our location for delivery of specimens, key contact personnel, hours of service, instructions for ordering laboratory tests and instructions for collection and transportation of specimens to the laboratory. A number of molecular virology diagnostic tests are performed routinely. Molecular Virology refers some specialised molecular testing to external laboratories and this manual includes the requirements for those tests. Requests for this service can only be made by hospital consultants or their designee.

This manual details the following:

- Available tests.
- Ordering information and specimen containers required.
- Information necessary in the labelling of forms and containers.
- Requirements for the collection and delivery of specimens to the laboratory.

In keeping with the laboratory’s commitment to continuous improvement, Molecular Virology has transitioned to a complete electronic test request and reporting format. The aim of digitisation is to enhance the provision of services by Molecular Virology leading to an improved and more secure service user experience. The modernisation of information management will allow for faster and more efficient results reporting and results recall by the requesting clinician. As such, the preferred method of requesting a laboratory test from Molecular Virology for HSE staff is now through the iSOFT Clinical Manager (iCM) software. iCM is the electronic patient record in CUH used to electronically request laboratory tests and view authorised test results in real time. Molecular Virology have no control over management, access or use of iCM. Please contact your dedicated HSE IT support team for further details on using the iCM system. Section 2.6 herein summarises the steps required to order laboratory tests from Molecular Virology.

Molecular Virology will continue to accept paper-copy requests forms to facilitate service users that are unable to do so electronically. Please note, overuse of paper-copy requesting will adversely affect turnaround time for all test requests beyond the control of the laboratory. All test requests must be made with the correct form when using the paper copy request option. Completion of all sections of the request form is required.

Test specimens must be collected as described herein and delivered to the laboratory within the assigned time requirements so that the best possible service can be delivered. Test requests may be rejected if acceptance criteria are not adhered to. The quality of information provided to the laboratory directly impacts the quality of the service provided. Provision of the correct test sample with legible and appropriate clinical details on the sample tube facilitates an efficient processing and turn-around of the test request.

The information in this manual is subject to change and will be updated regularly to reflect the most up to date services available.

1.2 Disclaimer

This user manual has been prepared by Molecular Virology and every care has been taken to ensure the contents are accurate and current at time of completion. **Users of the service should only use this manual as a guide to the testing procedures described herein and not as a complete or authoritative statement of testing available.**

Turn-around times described herein are from the date of receipt at the laboratory to the reports issuing date in calendar days. The turn-around times are median days typically achieved by the laboratory. Listed turn-around times are subject to change but the laboratory is committed to delivering a quality and timely service.

Molecular Virology shall not be liable to users of the manual nor to any other person, firm, company or other body for any loss, direct, indirect, or consequential, in contract or in tort of for any negligent misstatement or omission contained herein, by reason of, arising from or in relation to any such user, other person, company or body relying or acting upon or purporting to rely or act upon any matter contained in this manual.

2 General information

2.1 Laboratory address

Full name and address: Molecular Virology
Diagnostic and Research Laboratory
Department of Medicine
Clinical Sciences Building
University College Cork
Cork University Hospital
Wilton
Cork
T12 EC8P

Molecular Virology is in the Department of Medicine, University College Cork (UCC), on the first floor of the Clinical Sciences Building (CSB), Cork University Hospital (CUH). The CSB can be accessed in CUH via the connecting corridor from Outpatients. Turn right through the double doors at CUH Laboratory Reception and follow the corridor around to the left until you reach the CSB foyer. The entrance to the Department of Medicine is up the stairs on the right. The laboratory is in room 1.10. The CSB can also be accessed from the back of the CUH campus using the Services Delivery/Staff Car Park entrance.

2.2 Hours of service

Routine hours:

Monday to Thursday	09:00-17.00	Laboratory reception closes at:	<u>16.30</u>
Friday	09:00-16.00	Laboratory reception closes at:	<u>15.30</u>
Saturday & Sunday	Closed		
Bank & Public Holidays	Closed (including Christmas Public Sector Holiday period)		

An out of hours' service is not available for testing, however, urgent samples will be accepted out of hours by CUH Laboratory Specimen receipt.

2.3 Molecular Virology contact details

Website: www.ucc.ie/en/meddept/people/liam-fanning/mvdr/

General enquiries:

Laboratory staff:	CUH internal line dial:	22552
	External line dial:	021-4922552

Any general queries related to service provision should be directed to laboratory staff using the contact details provided here. Authorised results are reported without delay, see **Section 3, Communication of Results**. Enquiries regarding the interpretation of results and associated medical advice should be made through the Laboratory Director. Additional contact details are provided in Table 1.

Table 1. List of Contacts

Position	Name	Phone	Email
Laboratory Director	Prof. Liam Fanning	021-4922554	l.fanning@ucc.ie
Virology Associate	Mr John Levis	021-4922552	j.levis@ucc.ie
Senior Molecular Diagnostics Specialist & Quality Manager	Dr Kevin Hegarty	021-4901267	k.hegarty@ucc.ie

2.4 Summary of services available

Section 9, Test Directory, provides a detailed description of all laboratory test services available in Molecular Virology. In summary, molecular virology test services provided and guidelines for sample collection and processing are:

HBV ^a	HCV	HIV-1 ^a
<ul style="list-style-type: none"> •Viral load, genotyping & resistance profiling (by referral) •Whole blood plasma (EDTA) •Minimum 6 mL whole blood for viral load (2 mL separated plasma) •Minimum of 12 mL whole blood for resistance^b 	<ul style="list-style-type: none"> •Viral load & genotyping •Serum •Minimum requirement of 4 mL whole blood (2 mL separated serum) 	<ul style="list-style-type: none"> •Viral load & resistance profiling (by referral) •Whole blood plasma (EDTA) •Minimum 6 mL whole blood for viral load (2 mL separated plasma) •Minimum of 12 mL whole blood for resistance^b

^aRequests for a virus resistance profile can only be fulfilled if the patients' viral load at time of request is at least 2.7 Log₁₀ units/mL. The Laboratory Director is available to discuss the suitability of performing resistance profiling on a case-by-case basis. ^bIf viral load of the patient is unknown at the time of resistance request, send a minimum of 18 mL whole blood plasma (EDTA) (6 mL separated sample) as the laboratory must measure the viral load prior to dispatching samples for resistance profiling.

Note: Laboratory workflow operates on a one test/one specimen process where multiple investigations are requested on the same patient. E.g., a test request for HBV viral load and HBV genotyping will require two separate blood specimen tubes.

2.5 Population served

Molecular Virology services are open to hospital consultants in the South/South West Hospital Group. Test samples from other regions are accepted for testing providing the test request has been made through the correct channels, i.e., a hospital consultant. Unfortunately, requests from general practitioners (GP) will not be accepted. GP service requests must be made through correct channels, i.e., through referral with a hospital consultant.

2.6 Requesting a laboratory test

By submitting a test request in any format, it is expected that the consent of the patient was obtained by the requesting clinician for the testing process to be engaged. The quality of information provided to the laboratory directly impacts the quality of the service provided.

Molecular Virology accepts both electronic and hard-copy (paper) test requests. Electronic requests are the preferred format for requesting a laboratory test. The CUH iSOFT Clinical Manager (iCM) system is the most efficient and robust way to request a laboratory test from Molecular Virology and we encourage all service users to take advantage of this system.

Urgent Requests: Contact the laboratory directly to discuss prioritisation requirements (see Table 1). Urgent test requests should be sent to Molecular Virology in a specimen transfer bag labelled “Urgent Sample” or “Urgent”.

2.6.1 Electronic requests

iCM is the electronic patient record in CUH used to electronically request laboratory tests and view authorised test results in real time. Molecular Virology have no control over management, access or use of iCM. Please contact your dedicated HSE IT support team for further details on using the iCM system.

Note: a printed addressograph label with patient identifiers and a bar-code readable MRN must be included with each test request. This is an additional label to the one used for labelling the specimen tube. Affix the addressograph label to the specimen transfer bag only, not the blood tube.

2.6.2 Hard-copy test requests.

Molecular Virology will continue to accept hard-copy (paper) test requests to facilitate service users that cannot access electronic test requesting systems. As part of the laboratories commitment to a continuous improvement model, we encourage all service users to switch to paperless test requesting systems where practical.

Test requests should only be made using official, virus specific, Molecular Virology test request and report forms (TRRFs). Correct and up to date TRRFs are available on the Molecular Virology website (www.ucc.ie/en/meddept/people/liam-fanning/mvdrl/) under “Molecular Virology Diagnostic Testing”.

Completing the TRRF:

- The patient identification section of the TRRF must be completed with care. The information on the TRRF must match the information on the specimen blood tube. Bar-coded addressograph labels are the preferred format for completion of the patients’ demographic details.
- The TRRF must include appropriate information including medication as certain substances can interfere with *in-vitro* diagnostic procedures, see **Section 2.9**.
- Contact details of the requesting clinician must be provided to validate the test request and so that the results generated can be returned without delay.

Note: Provision of legible and appropriate clinical details on the request form facilitates an efficient processing and turn-around of the test request.

2.6.3 Acceptance criteria for test requests

Essential information required includes:




1. Patients Medical Record Number (MRN/APX).
2. Patients full name (surname and forename).
3. Patients date of birth (DOB).
4. Requesting clinician(s).
5. Relevant clinical details including anti-viral therapies.
 - a. Please indicate if the patient is currently taking heparin as this medication can interfere with *in-vitro* diagnostic testing procedures, see **Section 2.9**.

Additional appropriate information if available:

1. Any extra relevant clinical information.
 - a. Include antibody/antigen status where relevant.
2. Change to patient's name or address.

2.7 General guidelines for specimen collection

In general, samples for viral load assessment should be collected following standard phlebotomy procedures and **sent to the laboratory within 6 hours of venipuncture**. Refer to the **Test Directory, Section 9** of this user manual, for a list of test services available and other relevant information regarding specimen collection.

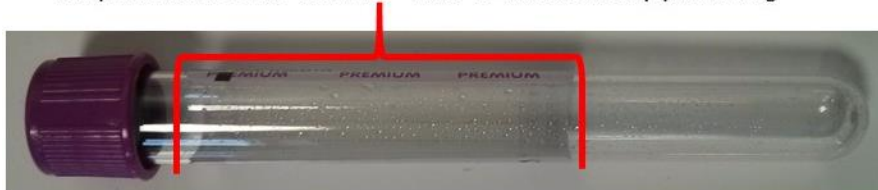
Specimen collection tubes required for Molecular Virology testing^a	
HBV and HIV testing: VACUETTE® TUBE 6.0 ml K3E K3EDTA 13x100mm lavender cap. <ul style="list-style-type: none">○ collection volume – fill tube.	
HCV testing: VACUETTE® TUBE 4.0 ml CAT Serum Clot Activator 13x75 red cap-black ring <ul style="list-style-type: none">○ collection volume – fill tube.	
Paediatric specimens: Use equivalent micro-tubes for plasma (EDTA) or serum clot activator. <ul style="list-style-type: none">○ collection volume; minimum 1.0 mL whole blood, preferably 2.0 mL.	

^aSuitable alternative tubes are accepted once they meet the criteria of the specimen required.

2.7.1 Acceptance criteria for sample containers

- **iCM test requests:**
 - Affix an iCM printed test request label to the blood collection tube.
 - Affix a bar-coded addressograph label to specimen transfer bag.
- **Hard-copy (paper) test requests:**
 - Affix a bar-coded addressograph label to the blood collection tube.
- Inaccurate separation of plasma from white blood cells and other blood components can cause aberrant HIV test results. Peeling or removing stickers post centrifugation can disturb the separated layers. Therefore, laboratory scientists performing the separation must have a clear view of the separated layers within the tube.

Keep this area of the Vacuette® clear to aid laboratory processing



Please trim labels so that there is an unobstructed view on the side of the blood collection tube.

- Handwritten tube labels, with clear and legible script, are accepted with hard-copy test requests only.

Essential information required on the sample container includes:

1. Surname.
2. First name.
3. Patients MRN/APX.
4. Patients DOB.
5. Date and time of specimen collection.
6. Identity of person taking sample e.g., phlebotomists initials.
7. Sample type (details on prefixed manufacturers label are suitable for this purpose).

2.8 Transportation of (suspected) infectious material

Molecular Virology is a Biosafety Level 2 Laboratory. Specimens sent to the laboratory for testing must be considered as Biological Substance, Category B (UN 3373). Specimens that meet the criteria of UN 3373 are substances which are known or are reasonably expected to contain pathogens which can cause disease in humans or animals. The transport of specimens to the laboratory must be done in such a way as to minimise the risk of infection to those who may come into contact with the specimens.

2.8.1 General guidelines

As a rule, all laboratory specimens should be treated as potentially infectious and standard precautions applied. Infection control guidelines for dealing with biological spills should be followed in the event of leakage or spillage of a specimen during handling or transport.

- The correct specimen container must always be used when sending specimens to the laboratory.
- The primary specimen container must be suitable, closed correctly and **not externally contaminated**.
- The primary container must be correctly labelled so that the associated risk can be readily assessed if required, see **Sections 2.6 and 2.7**.
- Any evidence of contamination on the external surface of any specimen container, accompanying paperwork or packaging will result in specimen rejection and immediate disposal.
 - The requestor will be notified in the event of a specimen rejection because of a contamination event.

2.8.2 On-campus transportation

The following are guidelines for transportation of specimens to the laboratory from within the CUH campus:

- Specimens must be placed in a biohazard bag that is correctly sealed.
- ICM request specimens must include a bar-code readable addressograph label affixed to the external surface of the biohazard bag.
- Any accompanying paperwork must only be placed in the document slot out of direct contact with the primary specimen container.
- Specimens must never be sent in paper carrier bags.
- Under no circumstances should primary specimens be transported to the laboratory without suitable secondary packaging (i.e., plastic biohazard bag).
- Specimens must be handed directly to laboratory staff where practicable and not left outside the laboratory door unattended.
- **Do not** transport multiple specimens in one individual specimen bag. Only one specimen is permitted per plastic biohazard bag.
 - **Only additional specimens from the same patient for repeat testing or associated referral testing are to be included in the same plastic biohazard bag.**

2.8.3 Off-campus transportation

UN 3373 describes the Internationally recognized packaging requirements for Biological Substance, Category B. The requirements of UN 3373 must be adhered to when samples are being shipped/couriered to the laboratory from locations external to the CUH campus. Those who prepare and ship specimens fitting the criteria for UN 3373 are required to know the requirements for proper transport, see **Appendix 1**.

2.9 Rejection criteria for test requests

Molecular Virology is committed to completing all submitted examination requests. However, the safety of laboratory staff will not be compromised. Only specimen types suitable for molecular testing as described herein can be tested. Examination requests will be rejected where there is any ambiguity as to the identification of the specimen being tested.

The main reasons for test delay or cancellation are:

Test specimens:

- Leaking containers.
- Delay in delivery of specimen to the laboratory (>6hrs post venipuncture results in rejection).
- Incorrect labelling of specimen container.
- Incorrect or missing date of venipuncture.
- Discordancy between details recorded on specimen container compared to laboratory information system (LIS) (or TRRF where applicable).
- Insufficient specimen for testing.
 - **Note:** Refer to **Section 9, Test Directory**, for specific details on specimen volume requirements for each investigation. Larger sample volumes are required for test requests additional to the standard viral load assessment.
- Incorrect specimen.
 - **Note:** **Section 9, Test Directory**, details the specimen type requirements. Please refer to the Test Directory to avoid collection of specimens in the incorrect preservative/anticoagulant.
- Specimens which are highly haemolysed, hyperlipaemic, or which contain gross contamination.
- Heparinised specimens must be avoided.
 - The presence of heparin in the test specimen can cause inhibition in polymerase chain reaction (PCR) assays which are routinely used in molecular testing.

Electronic test request details:

- Discordancy between details recorded on the LIS compared to the specimen container.
- No identifiable requesting clinician.

Test request forms:

- Incomplete forms/missing labels.
- Incorrect or missing MRN/APX.
- Contaminated (unidentified staining) of TRRF.
- Incorrect or illegible “**Clinical Details**” section on TRRF.
- Illegible patient demographics.
- Illegible name of requesting clinician.

Note: Identifiers on the request form must match exactly the identifiers on the blood collection tube.

Note: **Section 9, Test Directory**, provides specific details on the types and volumes of specimens required for specific test requests.

Note: Please contact the laboratory if in any doubt about specific requirements.

2.10 Specimen retention policy

In accordance with the guidelines of the Health Service Executive’s “Record Retention Periods: Health Service Policy 2013”, Molecular Virology will retain all serum/plasma specimens for a minimum of 2 years following date of receipt unless otherwise arranged.

2.11 Policy on protection of personal information

In the course of their work, Molecular Virology staff are required to collect and process personal data as defined by the General Data Protection Regulations (GDPR) (EU) 2016/679. It is the policy of Molecular Virology to comply with the GDPR (EU) 2016/679 in relation to all “personal data” collected and processed while processing specimens received for testing. Further details on Molecular Virology’s data protection policy are available on the University’s website (<https://www.ucc.ie/en/ocla/comp/data/>).

2.12 Complaints and feedback

Feedback from users is encouraged so that improvement opportunities can be identified. Please contact the laboratory to report any concerns or suggestions that you may have regarding the quality of service provided. See Section 2.3 for laboratory contact details.

3 Communication of results

- Electronic test request results are reported and available for viewing on the CUH LIS or iCM systems as soon as they are authorised. Molecular Virology have no control over management, access or use of the CUH LIS or iCM systems. Please contact your dedicated HSE IT support team for further details.
- Where a test request was made using a hard-copy (paper) request, MV will generate an electronic request for testing and reporting unless otherwise instructed.
- Telephone enquiries regarding patient results are available during hours of regular service, see **Section 2.2. Hours of service**.
- Enquiries regarding the interpretation of results and associated medical advice should be made through the Laboratory Director.

Routine communication of results by telephone, email or text message is not standard practice in Molecular Virology. However, the requirement for issuing/discussing results outside of standard practice is understood and will be considered on a case-by-case basis. Communication of results outside of routine reporting mechanisms will only be considered/authorised following consultation with the Laboratory Director (or an appointed designee) and will be limited to emergency situations only.

Under no circumstances will clinical staff other than the requesting clinician or a designee of their choosing be issued reports (verbal or otherwise). Patient consent is required if a copy of the report is not going to the source of the original request. Consent to issue a copy of the report to anyone other than the requesting clinician (or designee of their choosing) needs to be provided in writing by the patient. Molecular Virology Consent Forms are available for download on the Molecular Virology website.

4 Same-day results

Processing time required for molecular testing can range from 6 to 8 hours. Therefore, users should be aware that same day turn-around is not always achievable. The testing platform used by the laboratory is a batch system where diagnostic runs are performed only when the required number of samples is available for testing. Molecular Virology is committed to providing a clinically relevant service and understands that downstream clinical decisions can be dependent on molecular diagnostic results. Therefore, it is recommended that service users contact the laboratory ahead of requesting tests to discuss the possibilities of expediting testing on an individual, case-by-case basis. Therapeutic or infection control decisions should not be deferred pending laboratory results without consultation with the Laboratory Director.

5 Supplementary testing

Molecular Virology can facilitate repeat testing of samples following review of clinical details and following consultation with the Laboratory Director. Repeat testing is dependent on the quality and volume of sample that was originally submitted. Refer to **Section 9, Test Directory** for specific details on sample requirements.

6 Referral laboratories

National Virus Reference Laboratory (NVRL)

University College Dublin,
Belfield, Dublin 4, D04 E1W1.

Virus Reference Department

PHE Colindale, 61 Colindale Ave,
London NW9 5HT, UK.

7 Abbreviations

APX	See MRN
CSB	Clinical Sciences Building
CUH	Cork University Hospital
DOB	Date of Birth
EDTA	Ethylene diamine tetra-acetic acid
GP	General Practitioner
GDPR	General Data Protection Regulation
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HSE	Health Service Executive
iCM	iSOFT Clinical Manager
iSOFT	International supplier of software applications for the healthcare sector
IU	International Units
LIS	Laboratory information system
MRN	Medical Record Number
MV	Molecular Virology
MVDRL	Molecular Virology Diagnostic & Research Laboratory
PCR	Polymerase Chain Reaction
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
TRRF	Test Request and Report Form
UCC	University College Cork

8 Appendices

Appendix 1:

Transport Packaging requirements for UN 3373 Substances:

Any packaging for biological substances must include three components:

- A primary receptacle: the tube, vial or other container typically made of glass or rigid plastic (including the stopper, cap or other closure elements) that is in direct contact with the specimen.
- A secondary packaging (including cushioning and other materials) that fully encapsulates the primary receptacle.
- An outer packaging for shipping or transit.

In addition, one external surface of the outer packaging clearly must show the text “BIOLOGICAL SUBSTANCE, CATEGORY B.” Adjacent to this, inside a diamond mark whose lines are at least 2 mm thick, must appear the text “UN 3373” in characters at least 6 mm high.

Components must meet specific requirements, including being capable of passing specific test procedures based on receptacle or packaging type. In addition, compliance with the regulations is based, in part, on overall performance; so there can be no substitutions of a component from one manufacturer with a similar – but untested – component from another manufacturer.




Refer to <https://www.un3373.com/category-biological-substances/category-b/> for further details.

9 Test directory

Note: Separate blood specimen tubes must be provided for each molecular virology investigation. Failure to provide required blood tubes will lead to rejection of the test request.

Note: All specimens, regardless of requested test, must be delivered to the laboratory within 6 hours of venipuncture to ensure specimen stability.

Note: For paediatric specimens, use equivalent micro-tubes for specimen collection. Please send at least 1.0 mL and preferably 2x 1.0mL samples.

Virus	Diagnostic Method	Specimen Required	Volume	VACUETTE® Cap (preferred ¹)	Testing Frequency ²	Target Turnaround Time ²
Hepatitis B Virus	PCR – quantitation of viral load.		6.0 mL		Weekly	7 days (median time)
	Genotyping – virus resistance profile. Recommended only in patients with $\geq 2.7 \text{ Log}_{10} \text{ IU/mL}^4$.	VACUETTE® TUBE 6.0 ml K3E K3EDTA 13x100mm lavender cap	2x6.0 mL		By arrangement	By arrangement
Hepatitis C Virus	RT-PCR – quantitation of viral load.		4.0 mL		Weekly	6 days (median time)
	Genotyping – virus resistance profile.	VACUETTE® TUBE 4.0 ml CAT Serum Clot Activator 13x75 red cap-black ring	4.0 mL		Bi-weekly	15 days (median time)
	Genotyping – patient/virus pharmacogenetic profiles.	Specialist tests, e.g., IL28B or Q80K. Please contact laboratory ³	NA ³	NA ³	Referral by arrangement	Referral by arrangement
Human Immunodeficiency Virus Type 1	RT-PCR – quantitation of viral load.		6.0 mL		Weekly	5 days (median time)
	Genotyping – virus resistance profile. Recommended only in patients with $\geq 2.7 \text{ Log}_{10} \text{ cp/mL}^4$.	VACUETTE® TUBE 6.0 ml K3E K3EDTA 13x100mm lavender cap	2x 6.0 mL		Referral by arrangement	Referral by arrangement
	Proviral DNA Test	Specialist tests - contact laboratory ³	NA ³	NA ³		

¹These caps illustrate the preferred specimen collection tubes (Vacurette), however, suitable alternative tubes are accepted once they meet the criteria of the specimen required. ²Testing frequency and turnaround times are presented as median times and actual turnaround times are governed by several factors outside of the control of Molecular Virology. However, the laboratory aims to process, test and issue reports as quickly as the programme for testing permits. Please contact the laboratory for more information on testing schedules. ³Specialist pharmacogenetic tests are available through consultation with the Laboratory Director. ⁴Samples with a viral load of $< 2.70 \text{ Log}_{10} \text{ units/mL}$ can be considered for resistance profiling following consultation with the Laboratory Director. NA = not applicable. PCR = polymerase chain reaction. RT-PCR = reverse transcription PCR. EDTA = ethylene diamine tetra-acetic acid.