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CONTENTS

FOR	REWORD
1.0	INTRODUCTION4
2.0	ENFER MEDICAL SUPPORTING SVUH GENERAL PRACTITIONERS &5
NUI	RSING HOMES5
2.1	Enfer Medical – Fully Automated Microbiology Laboratory - WASPLab® 5
3.0	STANDARD REQUIREMENTS FROM GENERAL PRACTITIONERS AND7
NUI	RSING HOMES7
3.1	CRITERIA REQUIRED FOR LABELLING PATIENT SPECIMENS
3.2	CRITERIA REQUIRED FOR COMPLETING PATIENT REQUEST FORMS
3.3	PROCEDURE FOR PACKAGING MICROBIOLOGY SAMPLES
4.0	SPECIMEN TRANSPORT & COLLECTIONS FROM SVUH11
5.0	PRE-ANALYTICAL GUIDANCE11
6.0	GP TEST ANALYSIS12
7.0	RESULTS12
9.0	CLINICAL ADVISORY SERVICES14
10.	0 USER FEEDBACK15
11.	0 DATA PROTECTION16
12.	0 REFERRAL POLICY16
APP	PENDIX 2: SPECIMEN STABILITY/COLLECTION GUIDANCE/TURNAROUND TIMES FOR APPROVED SERVICES FOR GPS and Nursing Homes
APP	PENDIX 3: Specimen receipt anomalies (Specimen receipt anomaly protocol and codes) \dots
The	following are examples of scenarios, where samples cannot be tested: 24

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 2 of 27



FOREWORD

Enfer Medical is committed to being the most accessible and efficient clinical diagnostic laboratory service in Ireland. Our goal is always to provide a high level of service to our colleagues in the health services, on behalf of their patients. We are clinically led and patient focused. We strive to continually improve our operational expertise, responding to the needs of our users and providing innovative testing solutions.

The Enfer Medical team works to the highest possible standards in all aspects of the company's business. We subscribe to ISO 15189:2022 international standard of accreditation and are accredited by the Irish National Accreditation Board (INAB) for medical testing. We are strongly committed to service development and the continuous professional development of our team to maintain excellence in all our undertakings.

The purpose of this manual is to act as a reference guide for the provision of a quality service to General Practitioners (GPs) and for their adult patients operating and residing, primarily, within their respective catchment areas.

GPs and Nursing Homes requiring access to services at Enfer Medical should reside within the designated Hospital HSE Hub areas for St Vincent's University Hospital and can only request the service as agreed with St Vincent's University Hospital.

GPs and Nursing Homes requiring access to services that are outside the scope of general practice are required to contact St Vincent's University Hospital, as this is not included in the testing service at Enfer Medical.

Included in the manual are details about the scope of service, range of tests available, expected turnaround times, our location, hours of operation, contact details for key personnel, availability of clinical advice, and other relevant information to allow users to easily access our services.

Rosemary Curran

Medical Director

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 3 of 27



1.0 INTRODUCTION

Enfer Medical provides a clinical diagnostic laboratory service in the specialities of clinical chemistry, haematology, microbiology, immunology, virology, and genomics. Our service is available to all public and private hospital laboratories, general practitioners, and clinicians from private services throughout Ireland. The laboratory is consultant-led, patient-centered, and quality-focused. A clinical advisory service is available for healthcare professionals and includes advice on the interpretation of individual patient results and appropriate patient management pathways.

The Enfer Medical team works to the highest possible standards in all aspects of the company's business. We subscribe to both ISO 15189:2022 international standard of accreditation and the highest standards of continuous professional development to maintain excellence in all our undertakings. In December 2021, we were awarded our INAB (Irish National Accreditation Board) certificate, registration number 395MT, and we are accredited to the ISO 15189:2022 standard as a medical testing laboratory. We are strongly committed to service development and to the provision of innovative testing solutions for our users.

Our list of accredited tests is detailed in our INAB Schedule of accreditation, and this, alongside our accreditation certificate, are both available on our website (https://www.enfermedical.ie/enfermedical-accreditation/). The schedule provides details on the test or assay used, specimen types, equipment or technique, and the relevant procedure number in use.

For the purpose of this User Manual, we have included in Appendix 1 to this document, a list of tests available to St Vincent's University Hospital GPs and Nursing Homes.

Clients will be immediately notified of any changes to testing that may impact ongoing testing. We also provide updates to changes on the schedule of accreditation through our website. Enfer Medical is committed to the sustained innovation of our services through continuous quality improvement, which may include formal academic research and the evaluation of novel approaches aimed at improving the health of patients and the wellbeing of the wider population.

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Website: www.enfermedical.ie



Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 4 of 27



2.0 ENFER MEDICAL SUPPORTING SVUH GENERAL PRACTITIONERS & NURSING HOMES

Enfer Medical is committed to providing a quality service to General Practitioners (GPs) and Nursing homes for their patients operating and residing, primarily, within the St Vincent's University Hospital catchment areas. The defined timelines for the delivery and receipt of patient specimens collected by General Practitioners and Nursing Homes services for testing in Enfer Medical are Monday to Friday from 8 am to 10 pm.

The current test repertoire available to General Practitioners and Nursing homes is determined by the St Vincent's University Hospital laboratory consultants, based on best practice guidelines, including the requirements of national programmes. To ensure an optimal microbiology service is provided, St Vincent's University Hospital has had to assess and reprioritise workload relating to patients in St Vincent's University Hospital and thus must divert all microbiology work from General Practitioners and Nursing Homes effective, 28TH July 2025

The aim of this manual is to:

- 1. Provide guidance to General Practitioners and Nursing Homes on the procedures and standards required to ensure a safe and effective laboratory service.
- 2. Define the laboratory investigations routinely available to GPs and Nursing Homes.
- 3. Outline the standard requirements from GPs and Nursing Homes in the receipt of the laboratory services.

The laboratory testing services available to General Practitioners and Nursing homes are listed in the Appendix 1 of this User Manual, where information on individual tests is available. Laboratory tests not listed in Appendix 1 will be reviewed and assessed based on clinical information provided.

Please note that, this service will be limited to <u>Microbiology specimens only</u>, providing a focused and specialized approach to testing as requested by St Vincent's University Hospital Laboratory and management.

The laboratory at Enfer Medical processes and tests specimens until from 08:00 AM to 10:00 PM daily. This ensures a prompt turnaround for all test results.

2.1 Enfer Medical – Fully Automated Microbiology Laboratory - WASPLab®

Our Microbiology and Virology Department is led by our Consultant Microbiologists, Dr Rosemary Curran, Dr Billie Caceda and Dr Ciaran O'Gorman.

As well as a varied menu in molecular and serological testing for infectious pathogens, Enfer Medical is the first laboratory in Ireland to accredit a fully automated end-to-end microbiological culture solution WASPLab®.

With the Vitek Prime for MALDI-TOF identification and Vitek 2 for AST and identification, Enfer Medical can offer the full end to end solution.

The capacity provided by such sophisticated automation transforms the way in which a medical laboratory provides culture and sensitivity results to patients in General Practice and Nursing homes, allowing a 24–72-hour turnaround time for results for all urine and swab samples.

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 5 of 27



Pathogen identification and antimicrobial sensitivity testing form an integral part of this automated solution reducing reliance on manual and laborious steps which drain scarce staff resources. Our expertise in urine and superficial site infection supports General Practice and Nursing homes in dealing with the most commonly community acquired infections.

WASPLab® provides a high-efficiency, modular, scalable, and customizable specimen processing and culture work-up system. Samples move from up front specimen processing to Smart Incubation, Digital Microbiology, and Artificial Intelligence for plate reading.

Streamlined automation to Digital Microbiology. WASPLab® revolutionises specimen handling from initial processing and Smart Incubation to AI- enhanced imaging, leading to AI -enhanced Digital Microbiology. Advanced algorithms preassess and sort culture plates, enabling microbiology scientists to efficiently read, interpret and batch result bacterial culture with the click of a button.





User interface centralises laboratory workflow – the intuitive WASPLab® interface

seamlessly links specimen processing, incubation, imaging, analysis and result output, eliminating inefficient manual workflow practices. With plate scheduling, incubator statues, pending cultures, patient demographics, and reporting all incorporated in the software, users have an integrated command centre, managing the entire workflow.

Faster Results with Smart Incubators – WASPLab® High-Capacity Smart Incubators optimise microbiology workflows. Dual robots' system swiftly retrieve plates from temperature-controlled shelves, while an enclosed system prevents condensation and enables consistent, uninterrupted incubation for rapid bacterial growth and improved turnaround time.



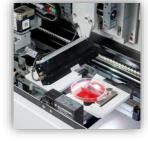


Plate capturing digitally – WASPLab® captures 48-megapixel plate images using industry-leading optics. Together with the media type, specimen sources, patient information and specimen workup, WASPLab® digitally presents all aspects of the culture. All culture data is accessible on WASPLab® workstations.

Time Zero – WASPLab® image acquisition technology utilises a telecentric linear camera to take an initial image of each plate entering incubation, enabling detection of bacterial growth through comparative image analysis over time. This foundational time zero snapshot powers accurate culture interpretation using PhenoMATRIX Artificial Intelligence software.

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 6 of 27



3.0 STANDARD REQUIREMENTS FROM GENERAL PRACTITIONERS AND NURSING HOMES

Enfer Medical operates a normal service between 8am and 10pm. All GP practitioners and Nursing homes are responsible for developing a system whereby test results returned from Enfer Medical are examined and appropriate action is taken in a timely manner.

Enfer Medical requires a register of General Practitioners (GPs), Nursing homes and all health care professionals and services who send specimens to the laboratory, including details of the appropriate contact number for transmission of critical results.

It is recognised that occasionally, unexpected critically abnormal results are found on analysis, such that laboratory staff become aware of a potential emergency before the treating General Practitioners or Nursing home. In these circumstances, laboratory staff must follow procedures to contact the requesting GP or Nursing Home to relay the result. All GP practitioners and Nursing homes requiring laboratory medical services must provide contact details for reporting "critical" patient results, including the provision of emergency contact details (mobile phone) for reporting of "critical" results outside normal practice hours. (Reference: HSE Communication of Critical Results for Patients in the Community National Laboratory Handbook). This is a mandatory requirement for access to Enfer Medicals laboratory services.

All GP practitioners and Nursing homes must have a system in place whereby appropriately trained staff receive patient results and communicate the same within the timeframe indicated.

3.1 CRITERIA REQUIRED FOR LABELLING PATIENT SPECIMENS

Where possible, the use of printed labels produced by the GP or Nursing Home practice management system, tailored to the specimen container size, is the preferred labelling method as it enhances the accuracy and legibility of information. We have outlined below, both mandatory and desirable criteria for the labelling of patient specimens.

MANDATORY:

All specimens, including the specimen container, must be labelled with the following minimum dataset:

- **Patient's Full Name:** Surname and forename must be clearly identified. Please note that addressograph/patient labels must clearly differentiate between the patient's surname and forename.
- Patient's Date of Birth.

DESIRABLE:

- **Gender At Birth:** Particularly important where investigations have gender-related reference ranges.
- Specimen Type or Site: For non-blood specimens e.g., MSU, Ear Swab.
- **Date and Time of Collection**: The date and the time of collection is a requirement to determine specimen integrity, this is of importance also for self-collected specimens such as stool specimens. If it is not possible to include this on the patient specimens, it is essential to have it included in the Patient Request Form.

Document No: EMQM009 Revision: 001
Issued by: M. Buggy Date of Issue: 08/07/2025
Approved by: R. Curran Page: 7 of 27



Important: Kindly note that incomplete labelling requirements or where minimum criteria is not met, this may lead to specimen rejection. This could result in the need for a repeat specimen, potentially causing inconvenience to patients and delaying results. Enfer Medical has developed a schedule of Specimen Receipt Anomalies (SRAs), describing the scenarios in which testing analysis may be affected and/specimens may be rejected. This Schedule of SRAs also outlines scenarios in which testing proceeds but where test comments are included with results.

We appreciate your attention to ensuring all forms are fully completed to avoid any disruptions.

3.2 CRITERIA REQUIRED FOR COMPLETING PATIENT REQUEST FORMS

A separate St. Vincent's Patient Request Form is to be used/completed when sending microbiology samples to Enfer Medical. We respectfully request that the Request Form accompanying the specimen be legibly written. The legibility of the manual request form is crucial to ensure accurate patient details. Use of block capitals or a clearly typed form is recommended to reduce errors in patient identification, test selection, or location.

MANDATORY: The St. Vincent's Patient Request Form must include the following minimum dataset:

- Patient's Full Name: Forename and surname
- Patient's Date of Birth.
- Patient's Address: This is a mandatory field required for Healthlink result transfer
- Date of Collection: The date when the specimen was collected
- Time of Collection: Required in specific cases, such as stool specimen testing
- **Requesting Doctor's Name and MCRN:** Used as the destination for the report (GP practice stamp and sticker are very welcome).
- Specimen Type/Site: Mandatory for all non-blood specimens e.g., Ear Swab, MSU.
- Laboratory Test Required: Please ensure that all laboratory test names are used exactly as they appear in Appendix 1. This consistency is crucial for our specimen reception team to accurately match incoming specimens with the correct tests, reducing delays and minimizing errors during intake. In situations where there is uncertainty regarding the requested test name then testing will be put on hold pending clarification with the requesting GP.

STRONGLY RECOMMENDED:

- Gender at Birth: Particularly important where investigations have gender-related reference ranges.
- Patient's Clinical Details and Relevant History: Including drug, pregnancy, immunocompromised or antibiotic therapy, to aid in the interpretation of results. Additionally certain investigations may require additional information on the specimen request form and we encourage GP's, Nursing Homes to provide all relevant clinical information where available. E.g. "History of UTI infections", "repeat sample C&S required" etc.
- Patient Preparation Conditions: eg: Early morning sample

Important: Kindly note that incomplete patient request forms may lead to specimen rejection. This could result in the need for a repeat specimen, potentially causing inconvenience to patients and delaying results. We appreciate your attention to ensuring all forms are fully completed to avoid any disruptions.

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran

Revision: 001 Date of Issue: 08/07/2025 Page: 8 of 27



St. Vincent's University Hospital Microbiology Request Form:

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	CHEMISTRY	HAEMATOLO			
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	UST include time of sample:_) PT/INR	RF, anti-CCP A		
LFT TSH			Autoimmune Li Liver autoantib		
CRP PSA		☐ APTT	Coeliac Diseas		
	=	Other	Anti-tTG Ab		
Lipids FSH Anti-TPO Ab	Bone Profile				
			MICROBIOLOGY		
	ary ACR	☐ MSU C/S	□ HVS □	MRSA Screen	
HDA1c (separate ED)	TA sample included [])	Sputum	Throat Swab	C/S	
Fasting Non-F	asting	Faeces C/S	Swab Site:	,	
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IMPORTANT NOTE:

The use of the GP Practice or Nursing Home stamp and printed sticker are best practice when completing manual patient request forms.

All writing on the request form must be clearly legible (BLOCK CAPITALS preferred) so that the information provided is legible, thus ensuring proper identification of the patient and all tests requests. Writing should be in ballpoint pen (not marker) to ensure the information is copied through to each sheet of the request form.

Document No: EMQM009 Revision: 001
Issued by: M. Buggy Date of Issue: 08/07/2025
Approved by: R. Curran Page: 9 of 27



3.3 PROCEDURE FOR PACKAGING MICROBIOLOGY SAMPLES

To help ensure a smooth and efficient process for handling microbiology test specimens, we kindly ask that you follow the steps outlined below for proper sample segregation, labelling, and transportation. These simple yet important procedures will help prevent any mix-ups and ensure that specimens are sent to the correct laboratory.

All GP Practices and Nursing homes are being provided with A3 Biohazard DGP Pathoseal 95 Outer Bags in addition ID Labels to be used for specimens being sent to Enfer Medical. We've provided clear instructions to make the process as easy as possible, and we're here to support you every step on the way.

Microbiology & Non-Microbiology Sample Packaging and Transport Instructions:

- 1. **Sample Preparation:** Each GP and Nursing Homes microbiology samples should be prepared and packaged for transport in accordance with existing arrangements i.e. patient samples should be placed inside routine UN3373 Biohazard Bags ensuring each biohazard bag is sealed and that the SVUH Patient Request Form is placed in the dedicated pocket.
- 2. **Grouping of GP and Nursing Home Microbiology Samples:** Please place all of your GP or Nursing Home microbiology samples destined for Enfer Medical in the A3 Biohazard Pathoseal 95 Bag provided by Enfer Medical see photo below. Please place the GP Practice ID Designated Label provided on the front of this A3 Outer Bag.
- 3. **Non-Microbiology Samples**: Please ensure that samples for other departments (e.g., Biochemistry, Haematology, Immunology etc.) follow the usual packaging processes, as they will be kept separate from Enfer Medical destined samples when delivered to St. Vincent's University Hospital.
- 4. **Transport of Samples to SVUH:** Existing arrangements will continue for the collection of samples for delivery to SVUH which will include the A3 Bag of GP and Nursing homes Microbiology samples and other Non-Microbiology Samples.



Figure 1. Example of Enfer Medical UN3373 Pathology Specimens Bag & GP Practice/Nursing Home ID Label.

To reorder bags and labels please email: Orders@enfermedical.ie

It is essential that GP and Nursing homes microbiology samples are separated and packaged as above as this allows the Sample Receipt Team at SVUH to clearly identify which samples belong to SVUH delivery and which samples are for collection by Enfer Medical.

Document No: EMQM009 Revision: 001
Issued by: M. Buggy Date of Issue: 08/07/2025
Approved by: R. Curran Page: 10 of 27



4.0 SPECIMEN TRANSPORT & COLLECTIONS FROM SVUH

St Vincent's University Hospital GPs and Nursing homes currently receives dedicated support from the HSE Primary Care logistics team and external couriers to collect and transport specimens from GP practices and Nursing homes to St Vincent's University Hospital and there will be no changes to this.

All Enfer Medical labelled microbiology samples received at SVUH will be redirected to Enfer Medical, while all other test samples will be processed by the laboratory at St Vincent's University Hospital.

To ensure the timely processing and integrity of specimens, Enfer Medical collects specimens from SVUH twice a day at 15:00 & 1800 (Monday- Thursday) and at 15:00 & 19:00 on Fridays from SVUH for delivery to Enfer Medical in Naas. This systematic approach allows for seamless logistics, minimizing delays and maintaining the integrity of the specimens. Please note that specimen delivered by GP's and Nursing Homes to SVUH after the last Enfer collection time will not be collected by Enfer Medical until the first collection on the next working day.

The Enfer Medical logistics team are committed to providing a reliable service that meets the needs of St Vincent's University Hospital GPs and Nursing homes and their patients. Specimens are handled with care and transported promptly. We aim to uphold the highest standards of clinical excellence.

5.0 PRE-ANALYTICAL GUIDANCE

It is crucial that GPs and Nursing homes refer to Appendix 2, "Specimen Collection Guidance", to ensure that specimens remain stable and suitable for testing, particularly for those with stabilities and for_specimens which must **NOT** be sent to the laboratory on a Friday.

Proper adherence to these guidelines helps to maintain the quality and integrity of the specimens during transportation and processing. Please note that in line with best practice guidelines, we recommend that microbiology samples are sent to the laboratory on the day of sample collection.

Criteria for rejection of specimens:

In rare cases specimens may not be suitable for testing on arrival to the laboratory. In that case the specimen will be rejected at the receipt stage and the service user will be notified and an explanation as to why the specimen could not be processed will be provided. Reasons why specimens are rejected include but are not limited to:

- Specimens received beyond the stability limits and/or not at the correct temperature indicated for each test.
- Incorrect specimen type received.
- Leaking specimens, specimen not received or specimen insufficient for analysis as stated below within specimen requirements.
- Non-compliant specimens or request forms, i.e., those missing specimen date information, missing specimen test request and/or missing specimen site/type information.
- Specimens received without the necessary patient identifiers.
- Problems during transport of specimens where the specimen is compromised.
- Illegibility.

Document No: EMQM009

Issued by: M. Buggy

Approved by: R. Curran

Revision: 001

Date of Issue: 08/07/2025

Page: 11 of 27



6.0 GP TEST ANALYSIS

The laboratory at Enfer Medical processes and tests specimens from 08:00 AM to 10:00 PM daily. This ensures a prompt turnaround for all test results.

The full list of tests carried out at Enfer Medical is listed in Appendix 1. Please note that the Turnaround Time (TAT) for results is measured from the time of receipt of a specimen into the laboratory at Enfer Medical and is therefore influenced by the time in which a specimen is delivered to SVUH and in turn collected by Enfer Medical.

The TAT for microbiology specimens at Enfer Medical can be viewed in Appendix 2.

7.0 RESULTS

Results are transmitted electronically via Healthlink, providing a fast, secure, and reliable method for delivering test results directly to General Practitioners. At Enfer Medical, this system ensures seamless communication between the laboratory and clinicians, enabling the quick transfer of microbiology and other test results. For GPs who are not Healthlink active, then results reports will be sent via Healthmail. For GPs who have neither Healthlink or Healthmail functions within their practice, then result reports will be sent by post.

Please note that to ensure accurate test result mapping, users of the Helix Practice Software may need to contact Clanwilliam for guidance on their internal mapping requirements.

Reporting of Critical Results: For out-of-hours Category A Critical Results (from 6pm each working day), GPs and Nursing Homes must provide an emergency mobile number as a mandatory requirement to receive services from the laboratory. If a GP or Nursing Home cannot be contacted by the mobile number provided or if they have not provided a mobile number, then a nominated out of hours agency will be contacted so that follow-up action can take place. With this in mind, please refer to the below *Enfer Medical Critical Results Guide and Procedure* for further details.

Category	Reporting
Category A	Results require communication within 2 hours. This classification indicates potential immediate danger to the patient, or a potential life-threatening illness when urgent intervention is required.
Category B	Results require Communication within 24 hours, and preferably on the same working day.
Category C	Results could have an immediate impact on a patient's management (either treatment or investigation) however action is likely to be taken on the next working day. Communication on the next working day is satisfactory.

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 12 of 27



Extract from Microbiology Critical Result List as applicable to the Tests included in this Service					
Analyte	Analyte Result				
C. difficile*	Toxin Positive	Α			
Faecal Microbiological Analysis*	VTEC Positive	Α			
Surveillance Screen -CPE (rectal/stool)*	Positive (first)	В			
Swab (Pus/Fluid aspirate)	Any unexpected culture result (unusual pathogen, MDRO) where patient likely to be on inappropriate empiric therapy	С			

Source: Communication of Critical Results for Patients in the Community National Laboratory Handbook 2019 (EMED131). * as per consultant recommendation.

8.0 COMMUNICATION

Client Services Support

- Enfer Medical is committed to providing a seamless and responsive experience for our clients, including General Practitioners and Nursing Homes.
- The Client Service Team at Enfer Medical plays a central role in this process, triaging queries in real-time to the appropriate personnel. This enables us to address inquiries as efficiently as possible, aligning with our dedication to exceptional client service. We understand the importance of timely and accurate information, and our commitment to real-time query management reflects our ongoing efforts to exceed client expectations.
- A telephone service for healthcare professionals is available from 08:00 to 20:00 each working day. All enquiries to the laboratory shall be dealt with promptly by the client services team with referral to a member of the laboratory, commercial or clinical team where appropriate.

Tel no. details: +353 (0) 45 819 000

- Additional communication is facilitated through the ENFER MEDICAL website and by direct contact with the laboratory.
- In the event an urgent report is required, the GP must alert the laboratory by telephone/by email at gpclinicalqueries@healthmail.ie and early state the nature of the urgency and must ensure it is clearly indicated on the Request Form.
- Phoning the laboratory for results: Please contact the Client Services Team at 353 (0) 45 819 000.

Document No: EMQM009 Revision: 001
Issued by: M. Buggy Date of Issue: 08/07/2025
Approved by: R. Curran Page: 13 of 27



Key Laboratory Personnel

Position	Name
Medical Director	Dr Rosemary Curran
Operations Director	Dr Paul Simmons
Consultant Chemical Pathologist	Prof. Carel Le Roux
Consultant Microbiologist	Dr Rosemary Curran
Consultant Haematologist	Dr Saad Ahmed
Quality Manager	Margaret Buggy
Laboratory Manager	Jonny Finnegan
Laboratory Manager (Genomics)	Elaine Kenny
IT Manager	Tom Tobin
Commercial Director	Dolores Barry
Group Health and Safety Manager	Susan Wall
Clinical Advice	Consultants on duty
Client Services Team	Client Service Team Member
Service Feedback	Commercial and QA Managers
GDPR Requests	Data Protection Officer

9.0 CLINICAL ADVISORY SERVICES

Enfer Medical provides a consultant-led clinical advisory service to our users. Our Medical Consultants are responsible for the provision of clinical advice. Our appropriately trained Medical and Clinical Scientists can provide technical advice on the interpretation of laboratory results.

St. Vincent's University Hospital GPs and Nursing Homes may contact members of our Clinical Team between the hours of 08:00 to 18:00 Monday to Friday by email at **apclinicalqueries@healthmail.ie** OR by contacting our Client Services Team who will direct the query without delay to the relevant member of the Clinical Team (see below) or their Deputy.

Enfer Medical Clinical Advisory Team/Consultant Microbiologists

Position	Name
Consultant Microbiologist & Medical Director	Dr. Rosemary Curran
Deputy Consultant Microbiologists	Dr. Billie Caceda Dr. Ciaran O'Gorman
Clinical Advice	Relevant Consultant or Clinical/Medical Scientist on duty
Client Services Team	Client Service Team Member

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 14 of 27



- Enfer Medical takes pride in offering a comprehensive and traceable clinical advisory service to Healthcare Professionals, ensuring optimal support when needed for patient result interpretation and management pathways.
- At Enfer Medical, the Client Service Team plays a central role in this process, triaging queries in real-time to the appropriate personnel. This enables us to address enquiries such as urgent clinical queries as efficiently as possible, aligning with our dedication to exceptional client and clinical service. We understand the importance of timely and accurate information, and our commitment to real-time query management reflects our ongoing efforts to exceed client expectations.

10.0 USER FEEDBACK

Enfer Medical highly values client feedback as an integral component of our quality management systems. We actively encourage users to share their experiences, suggestions, or concerns through our dedicated feedback channels. This valuable input not only contributes to the enhancement of our services but is also a testament to our dedication to providing the best possible laboratory experience. Clients can access real-time feedback on our website or submit their comments directly.

We prioritise the integration of client feedback into our quality management system meetings, where it forms a crucial part of our discussion points. By engaging with and implementing feedback, Enfer Medical ensures that our laboratory services align with the needs and expectations of our clients, fostering a collaborative and responsive approach to quality assurance.

Beyond improvement efforts, this feedback process is a critical component of our complaints handling process. By actively engaging with and addressing client feedback, we ensure a robust and responsive approach to resolving concerns and maintaining the highest standards of service quality.

Where a GP or Nursing Home needs to raise a complaint, they should contact one of the below:

- Designated Client Service Contact: Mags Treacy (clientqueries@enfermedical.ie)
- Quality Manager: Margaret Buggy (quality@enfermedical.ie)
- Operations Director: Paul Simmons (paulsimmons@enfermedical.ie)
- Client Services section on www.enfermedical.ie

Or alternatively by raising a ticket here using the following link here or by using the link on our website. The information will be treated as confidential and investigated thoroughly. This process will link into the Quality Management System procedure for incident investigation.

Complaints will be acknowledged on receipt. Resolution of complaints will be undertaken within the shortest timeframe achievable. If resolution cannot be achieved within one month, the complainant will be notified.

The findings and corrective actions are documented in an investigation report, and the findings are then shared with the client, from our Enfer Medical Quality Assurance Manager, within 10 working days of the NC being dosed. This transparent and proactive communication ensures clients are informed and reassured about the steps taken to address the issue.

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran

Revision: 001 Date of Issue: 08/07/2025

Page: 15 of 27



11.0 DATA PROTECTION

Policy on protection of personal information:

Enfer Medical is committed to protecting the privacy of personal information of its service users and patients. In the course of their work our staff are required to collect and use certain types of information about people, including 'personal data' as defined by the Data Protection Act 2018. The service user has a responsibility to ensure that this personal data is:

- Obtained fairly.
- Recorded correctly, kept accurate and up to date.
- Used and shared both appropriately and legally.
- Stored securely.
- Not disclosed to unauthorised third parties.
- Disposed of appropriately when no longer required.

All staff working at Enfer Medical are required under the Data Protection Act 2018 to ensure the security and confidentiality of all personal data they process on behalf of service users and patients.

12.0 REFERRAL POLICY

For the purposes of additional or confirmatory investigations, specimens may be referred to an accredited external laboratory, where possible. Enfer Medical approves referral Laboratories for use, and these are evaluated, selected, and monitored by the clinical and quality teams at Enfer Medical and will be listed on the Approved Referral Laboratory List. The referral laboratory is clearly identified on the final report.

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran

Revision: 001 Date of Issue: 08/07/2025 Page: 16 of 27



APPENDIX 1: SVUH Approved GP & Nursing Homes Microbiology Tests at Enfer Medical

URINE - MICROSCOPY, CULTURE & SENSITIVITY:

Microscopy, Culture and Sensitivity: Urine - MSU/CSU

Culture and Sensitivity: Nephrostomy Urine

Culture and Sensitivity: Urostomy Urine

SWABS - CULTURE & SENSITIVITY:

Culture and Sensitivity: Throat Swab

Culture and Sensitivity: Mouth Swab

Culture and Sensitivity: Nasal Swab

Culture and Sensitivity: Vaginal/High Vaginal/Low Vaginal/Vulval Swab

Culture and Sensitivity: Deep Wound Swab

Culture and Sensitivity: Superficial Wound Swab

Culture and Sensitivity: **Skin Swab**

Culture and Sensitivity: Ear Swab

Culture and Sensitivity: Eye Swab

Culture and Sensitivity: Cervical Swab

Culture and Sensitivity: Penile Swab

Culture and Sensitivity: Urethral Swab

SPUTUM ROUTINE CULTURE:

Culture and Sensitivity: **Sputum**

SWABS - ROUTINE SURVEILLANCE SCREENING:

MRSA Screening Swab

CPE Screen Swabs

VRE Screen Swabs

SWABS - COVID/FLU/RSV:

Swabs for COVID/Flu/RSV

FAECES – ROUTINE CULTURE & PCR:

Routine Faeces: Salmonella, Shigella, Campylobacter, STEC

Routine Faeces: Clostridium difficile

Revision: 001 Date of Issue: 08/07/2025 Page: 17 of 27



OTHER - CULTURE & SENSITIVITY:

Culture and Sensitivity: Body Fluid

Culture and Sensitivity: Aspirate

Culture and Sensitivity: Joint/Synovial Fluid

Culture and Sensitivity: **Tissue**

Culture and Sensitivity: **Device/IUD**

Culture and Sensitivity: Pus

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 001 Date of Issue: 08/07/2025 Page: 18 of 27



APPENDIX 2: SPECIMEN STABILITY/COLLECTION GUIDANCE/TURNAROUND TIMES FOR APPROVED SERVICES FOR GPS and Nursing Homes

Microbiology Analytes

ANALYTE SPECIMEN TYPE		TURNAROUND TIME	STABILITY AND STORAGE			
URINE - MICROSCOPY, CULTURE & SENSITIVITY						
Urine	Female and male MSU or CSU 5-10ml in urine ideally in monovette containing boric acid (Which must be completely full) OR sterile container	1-2 working days	Specimens should be stored at 2–8°C before testing. For specimens collected in tubes containing boric acid, testing can be performed up to 4 days (96 hours) after collection. For specimens without boric acid, testing is acceptable for up to 2 days (48 hours), while samples up to day 3 (72 hours) may be tested but with a comment noting the sample is beyond recommended stability and results should be interpreted with caution.			
Nephrostomy Urine Urostomy Urine	5-10ml in Sterile Container	1 - 2 working days	Specimens must arrive at the laboratory on the day of sampling (ideally before 3pm) and stored at 2-8°C. Please do not submit samples for this test on a Friday.			

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 002 Date of Issue: 08/07/2025 Page: 19 of 27



ANALYTE	SPECIMEN TYPE	TURNAROUND TIME	STABILITY AND STORAGE			
ROUTINE SWABS - CULTURE & SENSITIVITY						
Throat Swab Mouth Swab Nasal Swab High Vaginal Swab Vaginal/Low Vaginal/Vulval Swab Deep Wound Swab Superficial Wound Swab Skin Swab Ear Swab Eye Swab	eSwab with regular flock swab used for collection of material OR Gel amies swabs	2-3 working days	Specimens must be delivered to the laboratory within 3 days of sample collection.			
Cervical Swab (Endocervical Swab) Penile Swab Urethral Swab	Swab in transport medium	2- 4 working days	Specimens must arrive at the laboratory on the day of sampling (ideally before 3pm) and stored at 2-8°C. Please do not submit samples for this test on a Friday.			

Revision: 002 Date of Issue: 08/07/2025 Page: 20 of 27



ANALYTE	SPECIMEN TYPE	TURNAROUND TIME	STABILITY AND STORAGE				
SPUTUM - ROUTINE CULTURE							
Sputum	Sterile Container	2-4 working days	Specimens must arrive at the laboratory on the day of sampling (ideally before 3pm) and stored at 2-8°C. Please do not submit samples for this test on a Friday.				
	SWABS - ROUTINE SURVEIL	LANCE SCREENI	NG				
MRSA Screen	MRSA Dual eSWAB Blue Cap used for collection of swabs from nasal, throat and groin sites for MRSA screening. Gel amies swabs can also be used for MRSA screens.	1-2 working days					
СРЕ	Rectal Swab	1-3 working days	Specimens must be delivered to the laboratory within 3 days of sample collection.				
VRE Screen	Gel amies swabs	1-3 working days					

Revision: 002 Date of Issue: 08/07/2025 Page: 21 of 27



ANALYTE SPECIMEN TYPE		TURNAROUND TIME	STABILITY AND STORAGE
	SWABS - RESPII	RATORY	
 Respiratory PCR Panel: Influenza A RNA Influenza B RNA Respiratory Syncytial Virus (A/B) RNA SARS-CoV-2 RNA 	Aptima Multi-site Swab of Nose/Throat	2-3 working days	Specimens should arrive at the laboratory on the day of sampling (ideally before 3pm) and stored at 2-8°C. Please do not submit samples for this test on a Friday.
	FAECES – ROUTINE CU nsure that individual samples are provide emistry tests e.g. Calprotectin will requir	d for each faeces test	•
Routine Salmonella, Shigella, Campylobacter, STEC	Random Faeces in Sterile Container	1-3 working days	Specimens should arrive at the laboratory on the day of sampling and stored at 2-8°C.
Clostridium difficile toxin	Stool in Sterile Container	1-3 working days	Specimens should arrive at the laboratory on the day of sampling and stored at 2-8°C.

Revision: 002 Date of Issue: 08/07/2025 Page: 22 of 27



ANALYTE	SPECIMEN TYPE	TURNAROUND TIME	STABILITY AND STORAGE	
	OTHER - CULTURE & S	SENSITIVITY		
Body Fluid Aspirate	Sterile Container	2-7 working days		
Joint/Synovial Fluid	60ml Sterile Container	2-5 working days	Specimens must arrive at the laboratory on the day of sampling (ideally before 3pm) and stored at 2-8°C.	
Tissue	Tissue in sterile container containing saline	Up to 14 working days	Please do not submit samples for this test on a Friday.	
Device/IUD	Device	11-12 working days		
Pus	Sterile Container	2-7 working days		

Revision: 002 Date of Issue: 08/07/2025 Page: 23 of 27



APPENDIX 3: Specimen receipt anomalies (Specimen receipt anomaly protocol and codes)

The following are examples of scenarios, where samples cannot be tested:

General comments:

Reason for SRA	SRA Code	Comment
Unlabelled Specimen (Will NOT be tested)	SRA_NL	We have received a request form for the above patient. However, the accompanying specimen was not labelled. Testing will NOT proceed. Please send a repeat specimen if clinically indicated.
Insufficient identifiers (Will NOT be tested)	SRA_OP1	Please note that the specimen received was not labelled with the minimum requirement of three patient identifiers. Testing will NOT proceed. To prevent patient identification errors please ensure all request forms are completed with a minimum of 3 patient identifiers which match the specimen.
Form not Complete (Will NOT be tested)	SRA_FNC	Please note, the request form received for this patient was not fully completed. Testing will NOT proceed. To prevent patient identification errors please ensure all request forms are completed with a minimum of 3 patient identifiers which match the specimen.

Document No: EMQM009 Issued by: M. Buggy Approved by: R. Curran Revision: 002 Date of Issue: 08/07/2025 Page: 24 of 27



Reason for SRA	SRA Code	Comment
Specimen Leaked (Will NOT be tested)	SRA_LK	The specimen received for the above patient has LEAKED IN TRANSIT. This specimen will NOT be tested. Please send a repeat specimen if clinically indicated.
Specimen Date (Will NOT be tested)	SRA_SDT	The collection date on the specimen received exceeds the time period for testing. This specimen will NOT be tested. Please send a repeat specimen if clinically indicated.
Specimen Stability (Will NOT be tested)	SRA_STAB	The specimen received for the above patient was beyond its stability. Please send a repeat specimen if clinically indicated.
Incorrect collection device used. (Will NOT be tested)	SRA_SC	The specimen received for this patient was collected in the incorrect collection device. This specimen will NOT be tested. Please send a repeat specimen if clinically indicated.
Matching request form/specimen received* (Will NOT be tested)	SRA_SCF	This specimen was received with a matching request form, however a second specimen for a different patient was also within the package. As we are unable to confirm the provenance of the specimen, testing will NOT proceed. Please send a repeat specimen if clinically indicated.
Insufficient specimen (Will NOT be tested)	SRA_INS	Insufficient specimen for testing. Testing will NOT proceed.

Revision: 002 Date of Issue: 08/07/2025 Page: 25 of 27



Reason for SRA	SRA Code	Comment
Expired Collection Device (Will NOT be tested)	SRA_EXP _/_/_	The specimen received for the above patient was collected in an expired device. This specimen will NOT be tested. Please send a repeat specimen if clinically indicated.
Specimen Mismatch (Specimen received with form for another patient) (Will NOT be tested)	SRA_MMAT	The specimen for the above-named patient was received with a request form for a different patient. Testing will NOT proceed. Please send a repeat specimen if clinically indicated.
Damaged Label (Will NOT be tested)	SRA_DAML	The specimen(s) received for this patient had a damaged label on the collection device and the patient information cannot be confirmed. Testing will NOT proceed. Please send a repeat specimen if clinically indicated.
Damaged collection device (Will NOT be tested)	SRA_DAMCD	The specimen for this patient was received in a damaged collection device. Testing will NOT proceed. Please send a repeat specimen if clinically indicated.
Empty collection device (Will NOT be tested)	SRA_ECD	A request form was received for the above patient however, the accompanying collection device was empty. Testing will NOT proceed. Please send a repeat specimen if clinically indicated.

Revision: 002 Date of Issue: 08/07/2025 Page: 26 of 27



Reason for SRA	SRA Code	Comment
Undetermined content (Will NOT be tested)	SRA_UDC	We received a specimen for this patient however, the laboratory could not determine the contents of the specimen. Testing will NOT proceed. Please send a repeat specimen if clinically indicated.
Incorrectly used device (Will NOT be tested)	SRA_IUD	Please note the specimen received was incorrectly collected and not suitable for analysis. Testing will not proceed. Please send a repeat specimen if clinically indicated.

Revision: 002 Date of Issue: 08/07/2025 Page: 27 of 27