Enfer Medical GP User Manual
CAVAN GENERAL HOSPITAL GPs

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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. Specimens are processed from adults aged 16 years or older.

GPs requiring access to services at Enfer Medical should reside within the designated Hospital HSE Hub areas for Cavan General Hospital and can only request the service as agreed with Cavan General Hospital.

GPs requiring access to services that are outside the scope of general practice are required to contact Cavan General 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

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/enfer-medical-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 Cavan General Hospital GPs.

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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Clinical Queries: gpclinicalqueries@healthmail.ie

Website: www.enfermedical.ie

2.0 ENFER MEDICAL SUPPORTING CAVAN GENERAL HOSPITAL GENERAL PRACTITIONERS

Enfer Medical is committed to providing a quality service to General Practitioners (GPs) and for their adult patients operating and residing, primarily, within the Cavan General Hospital catchment areas. Specimens are processed from adults aged 16 years or older. The defined timelines for the delivery and receipt of patient GP specimens collected by General Practitioner services for testing in Enfer Medical are Monday to Friday from 8 am to 6 pm.

The current test repertoire available to General Practitioners is determined by the Cavan General Hospital laboratory consultants, and has been rolled out to Enfer Medical due to laboratory information system issues requiring increased staff vigilance in relation to reports being issued by Cavan General Hospital. To ensure an optimal microbiology service is provided, Cavan General Hospital has had to assess and reprioritise workload relating to patients in Cavan General Hospital and thus must temporarily suspend all microbiology work from General Practitioners and Nursing Homes effective, 25th November 2024. Microbiology specimens transported by Primary Care Courier Service from General Practitioners and Nursing Homes will therefore be redirected to Enfer Medical.

The aim of this manual is to:

1. Provide guidance to General Practitioners on the procedures and standards required to ensure a safe and effective laboratory service.
2. Define the laboratory investigations routinely available to GPs.

The laboratory testing services available to General Practitioners are listed in the Appendix 1 to 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, until further notice, this service will be limited to **Microbiology specimens only**, providing a focused and specialized approach to testing as requested by Cavan General Hospital Laboratory and management.

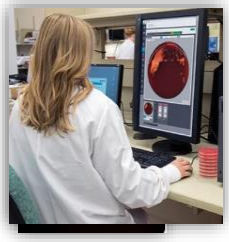
2.1 Enfer Medical – Fully Automated Microbiology Laboratory - **WASPLab®**

Enfer Medical is the first laboratory in Ireland to accredit a fully automated end-to-end microbiological culture solution i.e. the Walk Away Specimen Processing Laboratory – The Wasp and 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 will transform the way in which a medical laboratory provides culture and sensitivity results to patients in General Practice, allowing a 24–48-hour turnaround time for results for all urine and swab samples.

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 will support General Practice 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 pre-assess 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.

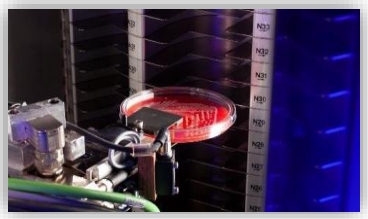


Plate capturing digitally – WASPLab® captures 48-megapixel plate images using industry-leading optics. Together with the media type, specimen sources, patient information and specimen workup, WASPLab® digitally presents all aspects of the culture. All culture data is accessible on WASPLab® workstations.

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.

3.0 STANDARD REQUIREMENTS FROM GENERAL PRACTITIONERS

Enfer Medical operates a normal service between 8am and 10pm. All GP practitioners 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) 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. In these circumstances, laboratory staff must follow procedures to contact the requesting GP to relay the result. All GP practitioners requiring laboratory medicine 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 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

The use of printed labels produced by the GP 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**
- **Date of Collection:** The date when the specimen was collected.
- **Time of Collection:** The time of collection is a mandatory requirement to determine specimen integrity and of importance also for self-collected specimens such as stool specimens.

DESIRABLE:

- **Gender of Patient:** Particularly important where investigations have gender-related reference ranges (e.g., hormone testing).
- **Specimen Type or Site:** For non-blood specimens (e.g., MSU, Ear Swab).

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 MANUAL PATIENT REQUEST FORMS

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 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.

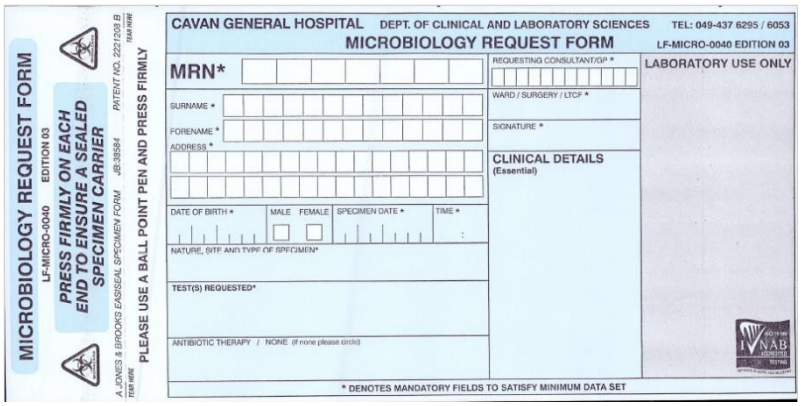
STRONGLY RECOMMENDED:

- **Gender:** Especially relevant where Male or Female are significant
- **Patient's Clinical Details and Relevant History:** Including drug, anticoagulant, or antibiotic therapy, to aid in the interpretation of results
- **Patient Preparation Conditions:** Such as fasting

Certain investigations may require additional information on the specimen or request form and we encourage GPs to provide all relevant clinical information where available.

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.

Cavan General Hospital Microbiology Request Form:


CAVAN GENERAL HOSPITAL DEPT. OF CLINICAL AND LABORATORY SCIENCES TEL: 049-437 6295 / 6053
MICROBIOLOGY REQUEST FORM LF-MICRO-0040 EDITION 03
MICROBIOLOGY REQUEST FORM
PRESS FIRMLY ON EACH END TO ENSURE A SEALED SPECIMEN CARRIER
PLEASE USE A BALL POINT PEN AND PRESS FIRMLY
MRN*
SURNAME *
FORENAME *
ADDRESS *
DATE OF BIRTH * MALE FEMALE SPECIMEN DATE * TIME *
NATURE, SITE AND TYPE OF SPECIMEN*
TEST(S) REQUESTED*
ANTIBIOTIC THERAPY / NONE (if none please circle)
REQUESTING CONSULTANT/GP *
WARD / SURGERY / LTCF *
SIGNATURE *
CLINICAL DETAILS (Essential)
LABORATORY USE ONLY
* DENOTES MANDATORY FIELDS TO SATISFY MINIMUM DATA SET

Important Note: The use of the GP Practice 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.

3.3 PROCEDURE FOR PACKAGING MICROBIOLOGY SAMPLES TO ENFER MEDICAL

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 delivered to the right laboratory. We've provided clear instructions to make the process as easy as possible, and we're here to support you every step of the way.

Microbiology Sample Packaging and Transport Instructions:

1. **Sample Preparation:** Place all Microbiology samples inside the **Enfer Medical labelled Biohazard DGP PATHOSEAL 95 bag**, ensuring it is sealed securely along with the patient request form.
2. **Labelling:** Enfer Medical has provided a designated yellow label to the **Biohazard DGP PATHOSEAL 95** to facilitate the sorting and triaging of Microbiology samples to Enfer Medical.
3. **Non-Microbiology Samples**: Please ensure that samples for other departments (e.g., Biochemistry, Haematology, etc.) follow the usual packaging processes, as they will be delivered and tested at **Cavan General Hospital**.
4. **Storage**: Store microbiology samples with Enfer labels in a separate container from all other specimens to clearly identify which samples belong in the Enfer delivery box and which belong in the Cavan General delivery box for HSE logistics.

Figure 1. Designated Enfer Medical Label.

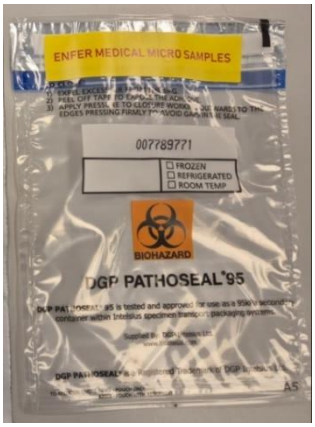


Figure 2. Label Position on UN3373 Mailer Bag.

4.0 SPECIMEN TRANSPORT

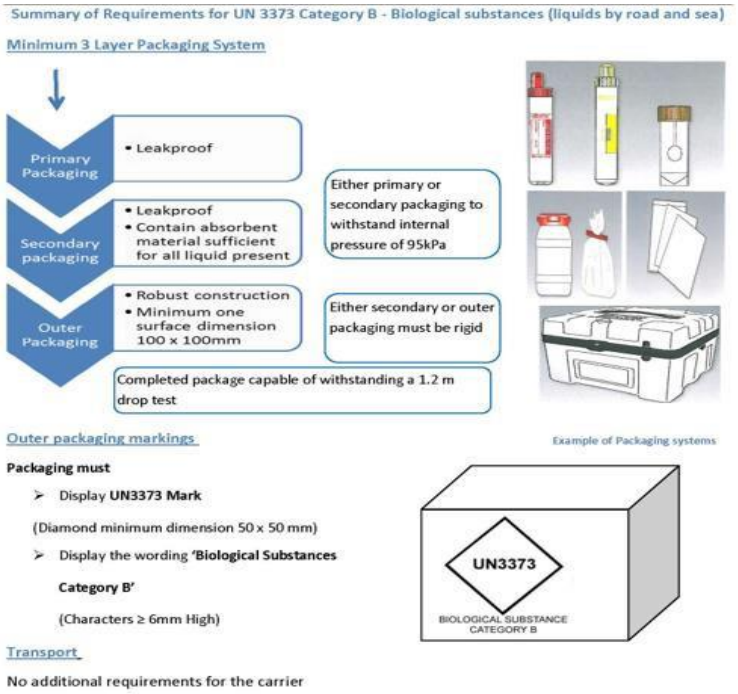
Cavan General Hospital GPs currently receive dedicated support from the HSE Primary Care logistics team to collect and transport specimens from GP practices to Cavan General Hospital and there will be no changes to this.

Enfer Medical works with HSE Primary Care logistics and once the samples are properly labelled and sorted into microbiology and 'all other' test categories, HSE Primary Logistics will collect and triage them accordingly. Microbiology samples will be redirected to Enfer Medical, while all other test samples will be sent to Cavan Hospital. The microbiology samples are typically delivered to Enfer Medical in late afternoon/early evening with results available within turnaround times outlined in Appendix 1. This process ensures timely and accurate testing and results sharing between the two laboratories.

This systematic approach allows for seamless logistics, minimizing delays and maintaining the integrity of the specimens. The Enfer Medical logistics team and partners are committed to providing a reliable service that meets the needs of Cavan General Hospital GPs and their patients. Specimens are handled with care and transported promptly. We aim to uphold the highest standards of clinical excellence.

In accordance with the ADR 2019 Safety Legislation, there are specific packaging instructions and labelling requirements requiring triple packaging including:

- ✓ Primary leak-proof container – tube or vial containing the specimen.
- ✓ Secondary watertight packaging, with absorbent material, intended to protect the primary container i.e. biohazard envelope.
- ✓ Outer rigid container protects the secondary container.
- ✓ Patient Request forms must be placed between the secondary container and the outer shipping container.



5.0 PRE-ANALYTICAL GUIDANCE

It is crucial that GPs refer to Appendix 1, "Specimen Collection Guidance for Approved Services for Cavan General Hospital," to ensure that specimens remain stable and suitable for testing, particularly for those with stabilities under 24-48 hours.

Proper adherence to these guidelines helps to maintain the quality and integrity of the specimens during transportation and processing.

Please note that the following tests have a 24-48 hour stability and for GPs who do not have a daily collection of specimens from HSE Primary Care Logistics, then we kindly advise that the following tests are only carried out on days that specimens are collected for delivery to the laboratory:

- C&S Urine - specimens should be tested within 24 hours of collection, however, specimens over 24hrs and under 48hrs can be tested but will be reported with a test comment.

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 immediately 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.

The laboratory reports SRAs (Specimen Receipt Anomalies) within 4 hours of identification of an issue to facilitate prompt recall of patients if required. Please review the SRA policy and Appendix 2 within.

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.

Reporting of Critical Results

Following discussions with GP representatives regarding the reporting of critical results, particularly for out-of-hours scenarios, it is recommended that in situations where a GP has urgent concerns for a patient, they should typically direct the patient to A&E or a hospital phlebotomy service for immediate attention, consequently, out-of-hours results from specimens sent to Enfer Medical are unlikely to require urgent reporting.

However, for out-of-hours Category A Critical Results (from 6pm each working day), GPs must provide an emergency mobile number as a mandatory part of receiving services from the laboratory. If a GP cannot be contacted by the mobile number provided or if they have not provided a mobile number, then the out of hours agency such as "NEDOC" will be contacted so that follow-up action can take place. In situations where NEDOC cannot accept/receive a critical result, then same will be reported directly to the laboratory in Cavan General Hospital.

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.**

Microbiology		
Analyte	**Result**	**Category**
C. difficile*	**Toxin Positive**	**A**
Faecal Microbiological Analysis*	**VTEC Positive**	**A**
HBsAg*	**Detected - new detection only**	**B**
HCV Ab*	**Detected - new detection only**	**B**
HIV 1 or 2*	**Detected - new detection only**	**B**
Surveillance Screen -CPE (rectal/stool)*	**Positive (first)**	**B**
Swab (Pus/Fluid aspirate)	**Any unexpected culture result (unusual pathogen, MDRO) where patient likely to be on inappropriate empiric therapy**	**C**
Treponema Pallidum*	**Positive specific serology- new detection in pregnancy only**	**B**

Source: Communication of Critical Results for Patients in the Community National Laboratory Handbook 2019 (EMED131).

* as per consultant recommendation.

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.

8.0 COMMUNICATION

Client Services Support

- Enfer Medical is committed to providing a seamless and responsive experience for our clients, including General Practitioners.
- 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 **clientqueries@enfermedical.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.

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 (Biochemistry & Haematology)	Jonny Finnegan
Laboratory Manager (Microbiology & Specimen Receipt)	Ann Reid
Laboratory Manager (Genomics)	Elaine Kenny

Position	Name
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 Clinical and Medical Scientists with the appropriate training can provide technical advice on the interpretation of laboratory results.

- Cavan General Hospital GPs may contact members of our Clinical Team between the hours of 08:00 to 18:00 Monday to Friday by email at gpclinicalqueries@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/Consultants

Position	Name
Consultant Chemical Pathologist	Prof. Carel Le Roux
Deputy Consultant Chemical Pathologist	Dr Royce Vincent
Consultant Haematologist	Dr Saad Ahmed
Deputy Consultant Haematologist	Dr Kanthi Perera
Consultant Microbiologist	Dr Rosemary Curran
Deputy Consultant Microbiologist	Dr Billie Caceda
Clinical Advice	Relevant Consultant or Clinical/Medical Scientist on duty
Client Services Team	Client Service Team Member

- 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 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 14 days of the NC being raised. This transparent and proactive communication ensures clients are informed and reassured about the steps taken to address the issue.

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.

APPENDIX 1: Specimen Stability/Collection Guidance and Turnaround Times for Approved Services for CAVAN GENERAL HOSPITAL

Microbiology Analytes

Test	Specimen Type	Turnaround Time	Stability and Storage
C&S (Urine)	Female and male MSU or CSU, urine minimum volume 10ml in urine monovette ideally containing boric acid.	1-3 working days depending on +/-	Specimens should be tested within 24 hours of collection and stored at 2-30°C prior to testing. Specimens collected in a non monovette device without boric acid - should be delivered to the laboratory and transferred to a monovette tube within 48 hours of collection. Specimens over 24hrs and under 48hrs can be tested but will be reported with a test comment.
C&S (Swab)	eSwab with regular flock swab used for collection of material from eye, ear, mouth, throat, nose, high- vaginal, superficial wound and deep wound sites. MRSA Dual eSWAB White Cap used for collection of swabs from nasal and groin sites for MRSA screening. Gel amies swabs used for collection of material from eye, ear, mouth, throat, nose, high-vaginal, superficial wound and deep wound swab sites Can also be used for MRSA, VRE, CPE screens.	2-3 days depending on +/- result.	Specimens should be delivered to the laboratory within 48 hours.
Faeces Culture	Random Faeces *Separate sample should be provided for this test.*	3-5 working days	Specimens should be tested within 2 days of collection and stored at 2-8°C.
Stool Investigation Clostridium difficile (*C.Diff*)	Random Faeces *Separate sample should be provided for this test.*	3-5 working days	Specimens should be tested within 2 days of collection and stored at 2-8°C.
Faeces Ova,Cysts & Parasites (PCR preferable)	Random Faeces *Separate sample should be provided for this test.*	3-5 working days	Specimens should be tested within 2 days of collection and stored at 2-8°C.
Stool Investigation FOB/FIT	QFIT *Separate sample should be provided for this test.*	3-5 working days	Specimens should be tested within 28 days of collection and stored at 2-8°C.

Test	Specimen Type	Turnaround Time	Stability and Storage
Stool Investigation Helicobacter Pylori Antigen	Random Faeces *Separate sample should be provided for this test.*	3-5 working days	Specimens should be tested within 3 days of collection and stored at 2-8°C.

APPENDIX 2: Specimen receipt anomalies (Specimen receipt anomaly protocol and codes)

SRA - Reporting Specimen issues to Source

Prep lab

1. When an issue is identified with a specimen, the person labelling the specimen should make a note on the patient request form of the error identified. This note should contain as much detail as available (i.e., when patient identifiers are incorrect saying incorrect is not sufficient, staff must note the exact details which were written on the specimen, for expired collection devices please note the date of expiry etc.). Specimens can then be labelled with a lab ID as per usual procedure and separated based on if they will proceed for testing or not.
2. If there is any concern that the specimen is from a different patient, the specimen should be placed on hold and not processed until the issue is clarified.
3. **Specimens to be tested** (Incorrect DOB/ Details missing on forms etc) can then be processed as normal, however for some specimens these details must be confirmed prior to reporting. Refer to EMWI043 for processing specimen queries.
4. **Specimens which will not be processed** can be kept separately to discard (e.g., Unlabelled specimens, leaked specimens, incorrect sampling device, miss matched specimens and PRFs).
5. When any additional information is supplied by the submitter such as "insufficient specimen" or "poor quality", additional names or date of birth, apply the code COML to the patient request form.

Log all SRA's detected on EMF109 (Specimen Receipt Anomaly Record) or LIMS system as appropriate. **Note for SH24 specimens**: In the case of multiple SRA's associated to a specimen all flags are applied. When all SRA's will allow the specimen to be '**Tested'** do not alter any SRA comments within the specimen report notes line' within LIMS. If a specimen is **'Not Tested'**, and contradicts the '**Tested'** SRA's, the **Not Tested** SRA supersedes all other SRA's and should be the reportable flag. In this case remove all **Tested** SRA's comments associated to the specimens within 'specimen report notes line' of LIMS. In the event of multiple **Not Tested** SRA's associated to a specimen, do not alter any SRA comments within the specimen report notes line' (Ref EMIM005 for further details).

6. Anomalies noted that are not covered within these SRA's should be brought to the attention of a line manager and as required, the clinical team, for a decision on the most appropriate follow up action.

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.
Discrepant DOB* **(Will be tested, hold until patient details are confirmed)**	SRA_DDB	Please confirm patient Date of Birth. DOB on specimen: DOB on request form:

Reason for SRA	SRA Code	Comment
Discrepant Name* **(Will be tested, hold until patient details are confirmed)**	SRA_DPN	Please confirm patient name Name on specimen: Name on request form:
Gender unknown **(Will be tested, hold until patient details are confirmed)**	SRA_GEN	Please confirm patient gender.
No specimen received* **(Will NOT be tested)**	SRA_NSR	A form was received for the above patient. However, there was no accompanying specimen. Testing will **NOT** proceed.

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.
Discrepant DOB* **(Will be tested, hold until patient details are confirmed)**	SRA_DDB	Please confirm patient Date of Birth. DOB on specimen: DOB on request form:

Reason for SRA	SRA Code	Comment
Discrepant Name* **(Will be tested, hold until patient details are confirmed)**	SRA_DPN	Please confirm patient name Name on specimen: Name on request form:
Gender unknown **(Will be tested, hold until patient details are confirmed)**	SRA_GEN	Please confirm patient gender.
No specimen received* **(Will NOT be tested)**	SRA_NSR	A form was received for the above patient. However, there was no accompanying specimen. Testing will **NOT** proceed.
Compromised specimen. **(Will be tested, confirm with client and consultant)**	SRA_ Com_Tested	This specimen has been compromised. Please interpret the results with caution.
No Form Received* **(Will NOT be tested)**	SRA_SNF	Please note, no request form was received with the specimen for this patient. Please send a repeat specimen and request form for testing if clinically relevant. Testing will **NOT** proceed.

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.

Reason for SRA	SRA Code	Comment
Matching request form/specimen received* **(Will NOT be tested)**	SRA_SIF	The specimen received for the above patient was received with a matching request form however a second form for a different patient was also received. As we are unable to confirm the provenance of this 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.
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.
Duplicated Specimen* **(Will NOT be tested)**	SRA_DUP	Duplicate specimens and PRF forms were received for this patient, the PRFs were dated with differing request times. We are unable to process these specimens as the origin of the specimen cannot be confirmed. Please send a repeat specimen if clinically indicated.
Process Error **(Will NOT be tested)**	SRA_PE	We apologise that this specimen could **NOT** be tested due to a laboratory processing error. 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.

Reason for SRA	SRA Code	Comment
Specimen Leaked* **(Will be tested)**	SRA_MESS	The outside of the tube containing this specimen was contaminated, posing a *** POTENTIAL RISK OF INFECTION*** Testing will proceed. Please ensure that this does not occur in the future.
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.
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.

Reason for SRA	SRA Code	Comment
Discrepant Date Format **Will be tested, hold until date details are confirmed**	SRA_DDF	Please note the collection date on the specimen received is in a discrepant format.
Collection Time **(Will be tested. Hold, confirm time if clinically relevant)**	SRA_Time	Please note there is no collection time for the specimen received.
Collection Date & Time **(Will be tested. Hold, confirm date & time if clinically relevant)**	SRA_DANDT	Please note there is no collection date and time for the specimen received.
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.
Haemolysed specimen **(Will NOT be tested)**	SRA_HAEM	Please note this specimen was grossly haemolysed and is not suitable for analysis. Testing will NOT proceed.

Reason for SRA	SRA Code	Comment
Paediatric specimen **(Will NOT be tested)**	SRA_PAED	Please note the specimen received was for a paediatric patient. Testing will NOT proceed.
Pregnancy Status **(Will be tested)**	SRA_PNN	A form was received for the above patient. However please confirm patient pregnancy status.