Enfer Medical GP User Manual

Our Lady of Lourdes Hospital Drogheda 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 Our Lady of Lourdes Hospital Drogheda and can only request the service as agreed with Our Lady of Lourdes Hospital Drogheda.

GPs requiring access to services that are outside the scope of general practice are required to contact Our Lady of Lourdes Hospital, Drogheda, 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 (<u>https://www.enfermedical.ie/enfer-medical-accreditation/</u>). 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 Our Lady of Lourdes Hospital Drogheda 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.

Contact Us:

Enfer Medical, Unit T, M7 Business Park, Newhall, Naas, Co. Kildare, Ireland, W91FD74

Tel: + 353 45 819 000

Email:

Client Services: <u>clientqueries@enfermedical.ie</u> Clinical Queries: <u>gpclinicalqueries@healthmail.ie</u>

Website: www.enfermedical.ie





2.0 ENFER MEDICAL SUPPORTING OLOLHD 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 OLOLHD 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 OLOLHD laboratory consultants, based on best practice guidelines, including the requirements of national programmes. Medical scientists may assess the suitability of any laboratory tests ordered and reject requests based on laboratory procedures, technical/scientific competency, and patient history.

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.

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 he Request Form accompanying the specimen/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: <u>Please ensure that all laboratory test names are used exactly as</u> <u>they appear in Appendix 1.</u> 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.

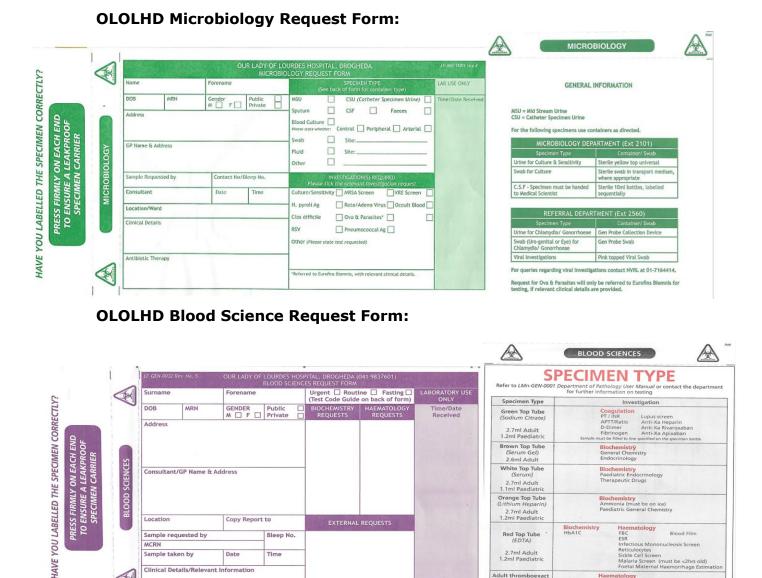
STRONGLY RECOMMENDED:

- **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.





Important Note:

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Clinical Details/Rele

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

Adult thromboexact Tube 2.7ml

Yellow Top Tube (Fluoride EDTA) 2.7ml Adult 1.2ml Paediat

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.

Haematology Platelets only



3.3 CRITERIA REQUIRED FOR SENDING URGENT SPECIMENS

- Clearly label the specimen and patient request form as **URGENT**.
- Apply an **urgent sticker** to both the **specimen outer bag** and the **test request form** to ensure quick identification.
- Ensure all other required information on the specimen label and request form is complete and legible.
- Notify the lab of the urgent status upon delivery, if possible, to expedite processing.
- Double-check that the correct test names (as listed in Appendix 1) are used on the request form for clarity.

BODG AVECKS AND REPORT HE BAG. PRO ONE PARE TO EXPROST HE ADMESSIVE. APRY NEESURE TO CLOSTINE WYTEKING OUTWARDS TO THE DODGS PRESSURE TO CLOSTINE WYTEKING OUTWARDS TO THE EDGS PRESSURE TO CLOSTINE WYTEKING OUTWARDS TO THE	0	Name	Emane	mickobio	LOGY REQUEST FORM SPECIMEN TYPE (See back of form for container type)	LAS USE ONLY
ARAIER ARAREN ARRIER ARREN ARE	DLOGY	DOB MRN Address GP Name & Address	Gender MF	Public Private	ASU CSU (Catheter Specimen Urine) Sputum CSP Paece Sputum CSP Paece Prevent Central Pergheral Arterial Smab Siter Fluid Siter Other Siter	
	MICROBIOLOGY	Sample Requested by Consultant	Contact No/Bie	rep No. Time	INVESTIGATION(5) REQUIRED Please tick the relevant Investigation request Culture/Sensitivity MRSA Screen VRE Screen	
DGP PATHOSEAL 95 PATHOSEAL 95 PATHOSEAL 95 is tested and approved for use as a 95kPa secondary container within Intelsius specimen transport packaging systems.		Location/Ward Clinical Details			H. pyroli Ag Rota/Adeno Virus Occult Blood Clos difficile Ova & Parasites* SV Pneumococcal Ag Other (Piece state test expussed)	
Supplied By: DGP Intelsion Ltd. www.intelsion.com DGP PATHOSEAL* is a Registered Trademark of DGP Intelsions Ltd.	Ø	Antibiotic Therapy			"Referred to Eurofivs Biomenis, with relevant clinical details.	

4.0 SPECIMEN TRANSPORT

OLOLHD GPs currently receive dedicated support from the HSE Primary Care logistics team to collect and transport specimens from GP practices to OLOLHD.

To ensure the timely processing and integrity of specimens, Enfer Medical collects specimens twice daily from OLOLHD for delivery to Enfer Medical in Naas at 2:30pm and 4.30/5pm. 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 OLOLHD GPs and their patients. Specimens are handled with care and transported promptly, we aim to uphold the highest standards of clinical excellence.

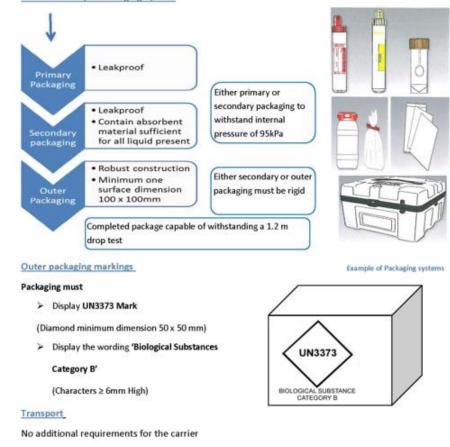
In accordance with the ADR 2019 Safety Legislation, there are specific packaging instructions and labelling requirements requiring triple packaging including:

- ✓ 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.
- \checkmark Outer rigid container protects the secondary container.
- ✓ Patient Request forms must be placed between the secondary container and the outer shipping container.



Summary of Requirements for UN 3373 Category B - Biological substances (liquids by road and sea)

Minimum 3 Layer Packaging System



5.0 PRE-ANALYTICAL GUIDANCE

Requests for urgent tests:

In circumstances where an urgent result is required for immediate patient management the laboratory is happy to prioritise testing. Please label the specimen as urgent and please email <u>clientqueries@enfermedical.ie</u> with details of the urgent request.

A mobile number or secure email must be provided by the requesting clinician or appropriate designate for the communication of urgent results. Emergency contact details (mobile phone) must be provided for contact inside and outside of normal practice hours.

Factors affecting test results – Specimen Stability:

Serum specimens which are highly haemolysed, or hyperlipaemic should not be sent to the laboratory. We have provided detailed specimen stability information for each test in Appendix 2.

In the absence of daily specimen pick-up from individual GP practices by the HSE Primary Care logistics team, specimens sent to Enfer Medical may have been taken some time prior to their arrival



at the laboratory. This could potentially lead to stability issues, which may affect the accuracy and reliability of the test results.

It is crucial that GPs refer to Appendix 2, "Specimen Collection Guidance for Approved Services for Our Lady of Lourdes Hospital Drogheda," 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-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:

- Coagulation PT/INR
- Urine Chlamydia/Gonorrhoea (please note that the 24hr stability applies where a general urine pot is used, the use of Aptima urine collection pots extends stability to 48hrs).
- 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.
- ESR 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.
- Blood Film please note that where an FBC result reflexes to a Blood Film, specimens must be <= 24 hours to proceed to Blood Film analysis.

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 3 within.



6.0 GP TEST ANALYSIS

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.

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 OLOLHD.

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	А
Faecal Microbiological Analysis*	VTEC Positive	A
HBsAg*	Detected - new detection only	В
HCV Ab*	Detected - new detection only	В
HIV 1 or 2*	Detected - new detection only	В
Surveillance Screen -CPE (rectal/stool)*	Positive (first)	В
Swab	Any unexpected culture result (unusual pathogen, MDRO) where patient likely to be on inappropriate empiric therapy	с



Treponema Pallidum*	Positive spec detection in	В	
	Haemato	logy	
Analyte	Critical Low	Critical High	Category
Blood Film Morphology	Significa	А	
Haemoglobin	<7.0 g/dL	В	
INR	≥5.0		Α
Neutrophil Count	≤ 0.5 x 109 /L		Α
Platelet Count	≤ 30 x 109 /L		Α
	31 -50 x 109/L	≥ 600 x 10 ⁹ /L	В
White Blood Cell Count		≥ 30 x 109/L	В
PT*		>40 seconds	С
APTT*		>70 seconds	С
Fibrinogen*	<1.0 g/L		С
D-Dimer*		>500 ng/mL	С

	Biochemi	stry	
Analyte	Critical Low	Critical High	Category
Active B12*	<25 pmol/L		В
Vitamin B12	≤ 100 pg/L		В
Adjusted Calcium	≤ 1.8 mmol/L	≥ 3.5 mmol/L	Α
Adjusted Calcium		3.0 - 3.5 mmol/L	В
ALT		≥ 510 U/L	В
Amylase		≥ 625 U/L	Α
AST		≥ 510 U/L	В
Carbamazepine		≥25 mg/L	В
CO2*	<15.0 mmol/L	>35.0 mmol/L	В
Cortisol	≤50 nmol/L		Α
Creatine Kinase		≥ 5000	Α
Creatinine		≥ 354 µmol/L (on first occurrence)	А
CRP		≥ 300 mg/L	Α
Digoxin		≥2.5 µg/L	В
eGFR	≤ 15 mL/min (on first occurrence)		А
FT4		≥ 50 pmol/L	С
Glucose	≤ 2.5 mmol/L	≥ 25.0 mmol/L	Α
Hypogammaglobulinaemia	IgG <3 g/L		С
Lithium		>1.5 mmol/L	В
Magnesium	≤ 0.4 mmol/L		Α
		IgG >15 g/L	
Paraprotein	Any IgE/IgD	IgA > 10g/L	С
		IgM > 10 g/L	



Phenytoin		≥25 mg/L	В
Dhaamhamaa	≤ 0.3 mmol/L		Α
Phosphorus	≤ 0.45 mmol/L		В
Potassium	≤ 2.5 mmol/L	≥ 6.0 mmol/L	Α
Sodium	≤ 120 mmol/L	≥ 155 mmol/L	Α
Triglycerides		≥ 20 mmol/L	В
Troponin		≥99 percentile ng/L	Α
TSH*		>75 mIU/L	В
Urea		≥ 30 mmol/L	Α

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

* as per consultant recommendation.

7.0 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
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

8.0 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.

• OLOLHD GPs may contact members of our Clinical Team between the hours of 08:00 to 18:00 Monday to Friday by email at <u>gpclinicalqueries@healthmail.ie</u> <u>OR</u> 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.

9.0 CHRONIC DISEASE MANAGEMENT

We respectfully request that GPs be cognisant of the national referral criteria for the GP direct access to the Chronic Disease Management program. Please ensure that you only refer tests fulfilling the criteria below to the laboratory, to ensure that this service can be continued.

- One NTproBNP test will be facilitated for the first GP Structured Chronic Disease Management registration visit for each patient who has a diagnosis of type 2 diabetes, ischemic heart disease or atrial fibrillation. This is in line with the GP Agreement 2019. An allowance may also be made for individuals who have a pre-existing clinical diagnosis of one of the above chronic diseases and who are already registered on the Structured Chronic Disease Management Programme but who still require an NTproBNP test to establish a baseline for their condition;
- Outside of these criteria, an NTproBNP may be ordered in the following circumstances, where the GP feels it's clinically indicated:
 - 1. For investigation of a patient who has one of the above diagnoses and presents with deterioration in symptoms; consistent with heart failure; and
 - 2. As part of the investigative work up of a patient who presents with symptoms consistent with heart failure.



10.0 VITAMIN D TESTING AND GUIDELINES

Please note that Vitamin D testing should be restricted to specific patient groups as outlined in the HSE Laboratory Services Reform Programme Advice Note (2024) - Indications for the measurement of Vitamin D levels.

See Link Below:

National Guidelines for Vitamin D measurement

National Guidelines Advice for Laboratories and Users

1. Vitamin D testing should be reserved for specific patient groups; it should not be used as a general screen.

- 2. In general indications for testing for vitamin D should be one of the following:
 - a) metabolic bone disease
 - i. Osteoporosis or Osteopaenia
 - ii. Rickets or Osteomalacia
 - iii. Paget's Disease of Bone
 - iv. Pathological Fracture
 - v. Unexplained Hypocalcaemia, raised PTH, low or high Phosphate

b) Specific named clinical condition due to or leading to Vitamin D Deficiency

- i. Malabsorption, CKD, Liver Disease
- ii. Muscle weakness
- iii. Chronic inflammation
- iv. Certain Drug therapies: Glucocorticoids, Anticonvulsants, Antiretrovirals, Antifungals, Anti Oestrogens or Cholestyramine

3. Routine repeat resting is not required. For those with low baseline and malabsorption retesting in 6 months may be helpful.

4. The Department of Health have issued advice for the general population regarding vitamin D supplementation (see link above).

11.0 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 (<u>clientqueries@enfermedical.ie</u>)
- 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 <u>here</u> 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.

12.0 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.



13.0 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:

List of Approved Laboratory tests routinely available to OLOLHD GPs

Bioche	emistry	Haematology	Immunology	Microbiology
Thyroid Function (TFT)	Lipid Profile (fasting)	FBC & WBC Differential	Anti-CCP	Culture & Sensitivity
Liver Profile (LFT)	Renal Profile		Rheumatoid Factor	Fungal Culture
Iron studies/IBC Profile	Bone Profile	Vitamin B12/Folate (Fasting specimen)	Thyroid microsomal antibodies (TPO)	Mycobacterial investigation
LH & FSH	HbA1c	Ferritin	Tissue Transglutaminase antibody (tTg)	
Cortisol (time must be stated)	Creatinine Kinase	Coagulation screen (PT & INR	IgG/A/M Protein Electrophoresis	Stool investigation: FIT & <i>Helicobacter pylori-</i> Antigen
Oestrodial	T PSA (s upply Clinical details)	INR (Warfarin)	Connective Tissue Disease (CTD) Screen ANAB/ENA/DNA A	Ova & Parasites (based on clinical details)
Progesterone	Digoxin	ESR	Only 3 Allergy tests permitted in one test request: - Animal Disorders (allergy) - House dust mite (allergy) - Peanut Allergy - Mixed Grass pollen (allergy)	Urine Chlamydia / Gonorrhoea
Prolactin	Carbamazepine	Infectious Mononucleosis screen		Herpes Simplex Virus
Sex Hormone Binding Globulin (SHBG)	Phenobarbitone	G6PD		Varicella Zoster Virus (VZV) IgG (Immune status)
Testosterone	Phenytoin	Sickle cell/ Thalassaemia		STI screen (syphilis, HIV, HBsAg)
Lithium	B-HCG	maissuema		Measles/Mumps/Rubell a IgG screen
CA 125	Theophylline			Viral Hepatitis B & C screen (HBsAg + anti- HCV)
CA 15.3	Valproate			Hepatitis B Infection status (HBsAg, anti-HBc)
CA 19.9	C Reactive Protein (CRP)			Hepatitis A IgG (HAV IgG)
Calprotectin	АМН			Hepatitis B surface Antigen (HBsAg)
Alpha Feto-protein (AFP)	Lactate Dehydrogenase			Hepatitis B surface Antibody (Post vaccination)
Carcinoembryonic Ag (CEA)	NT Pro-BNP			Hepatitis C Antibody (anti-HC\ core IgG)



Bioch	nemistry	Haematology	Immunology	Microbiology
Androstenedione	Vitamin D			Hepatitis C PCR (HCV RNA; current infection)
Urate	Amylase			Syphilis serology
Glucose (random)	Magnesium			HIV Ag/Ab Combo assay
Glucose (fasting)	Microalbumin			Individual serology screens (HIV, Hep B, Hep C, Hep A)
Glucose (2hr PP) Tolerance	Protein/Creatinine Ratio			Individual Molecular screens (HSV PCR)



APPENDIX 2: Specimen Stability/Collection Guidance, TATs and reference ranges for Approved Services for OLOLHD

OLOLHD Ref.	Profile	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
			I	BONE PROFILE			
Calcium	Bone	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Adult ≥ 18 years 0 to <1 year 1 year to < 18 years	2.10 to 2.55 2.13 to 2.74 2.29 to 2.63
Phosphate	Bone	5mL venous serum or plasma	Next working day	Specimens should be tested within 3 days of collection and stored at 2-8°C	mmol/L	Adult \geq 18 years Female 0 to < 15 Days Female 15 Days to < 1 year Female 1 to < 5 years Female 5 to < 13 years Female 13 to < 16 years Female 16 to < 18 years Male 0 to < 15 Days Male 15 Days to < 1 year Male 1 to < 5 years Male 5 to < 13 years Male 13 to < 16 years Male 16 to < 18 years	0.74 to 1.52 1.80 to 3.4 1.54 to 2.72 1.38 to 2.19 1.33 to 1.92 1.02 to 1.79 0.95 to 1.62 1.80 to 3.4 1.54 to 2.72 1.38 to 2.19 1.33 to 1.92 1.14 to 1.99 0.95 to 1.62



<u></u>					1/1		
Total Cholesterol	Lipid	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Fasting Non-Fasting Female 0 to < 15 Days Female 15 Days to < 1 year Female 1 to < 18 years Male 0 to < 15 Days Male 15 Days to < 1 year Male 1 to < 18 years	 ≤ 5.0 ≤ 5.0 1.2 to 3.23 1.66 to 6.13 2.9 to 5.4 1.1 to 2.82 1.66 to 6.13 2.9 to 5.4
HDL	Lipid	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Fasting Adult \geq 18 years Non-Fasting \geq 18 years Female 0 to < 15 Days Female 15 Days to < 1 year Female 1 to < 4 years Female 4 to < 13 years Female 13 to < 18 years Male 0 to < 15 Days Male 15 Days to < 1 year Male 1 to < 4 years Male 4 to < 13 years Male 13 to < 18 years	1.0 to 2.0 1.0 to 2.0 0.4 to 1.08 0.3 to 1.85 0.84 to 1.63 0.92 to 1.88 0.83 to 1.86 0.4 to 1.08 0.3 to 1.85 0.84 to 1.63 0.92 to 1.88 0.82 to 1.77
LDL	Lipid	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Adult Fasting \geq 18 years Adult Non-Fasting \geq 18 years Female 0 to < 1 year Female 1 to < 10 years Female 10 to < 18 years Male 0 to < 1 year Male 1 to < 10 years Male 10 to < 18 years	$\leq 3.0 \\ \leq 3.0 \\ 0.34 \text{ to } 4.48 \\ 1.52 \text{ to } 3.32 \\ 1.18 \text{ to } 3.4 \\ 0.34 \text{ to } 4.48 \\ 1.22 \text{ to } 3.14 \\ 1.18 \text{ to } 3.4 \end{cases}$



Triglycerides	Lipid	5mL venous	Next working	Specimens should	mmol/L	Fasting	≤ 1.7
		serum or	day	be tested within 3		Non-Fasting	≤ 2.0
		plasma		days of collection		0 to < 15 Days	0.93 to 2.93
				and stored at 2-8°C.		15 Days to < 1 year	0.6 to 2.92
						1 to < 18 years	0.5 to 2.23
				LIVER PROFILE			
Total Protein	Liver	5mL venous	Next working	Specimens should	g/L	Adult ≥ 18 years	64 to 83
		serum or	day	be tested within 6	57 -	>60 years	62 to 81
		plasma		days of collection		0 to < 15 Days	53 to 83
		F		and stored at 2-8°C.		15 Days to < 1 year	44 to 71
						1 to < 6 years	61 to 75
						6 to < 9 years	64 to 77
						9 to < 18 years	65 to 81
Albumin	Liver	5mL venous	Next working	Specimens should	g/L	Adult ≥18 years	35 to 50
		serum or	day	be tested within 6		Adult 60-90 years	32 to 46
		plasma		days of collection		Adult >90 years	29 to 45
				and stored at 2-8°C.		Female 0 to < 15 Days	28 to 41
						Female 15 Days to < 1 year	25 to 46
						Female 1 to < 8 years	35 to 45
						Female 8 to < 15 years	37 to 47
						Female 15 to < 18 years	35 to 49
						Male 0 to < 15 Days	28 to 41
						Male 15 Days to < 1 year	25 to 46
						Male 1 to < 8 years	35 to 45
						Male 8 to < 15 years	37 to 47
						Male 15 to < 18 years	38 to 50
ALP	Liver	5mL venous	Next working	Specimens should	U/L	Male >=18 to 21 years	56 to 167
		serum or	day	be tested within 7		Male ≥ 22 years	50 to 116
		plasma		days of collection		Male 0 to < 15 Days	90 to 273
				and stored at 2-8°C.		Male 15 Days to < 1 year	134 to 518
						Male 1 to < 10 years	156 to 369
						Male 10 to < 13 years	141 to 460



						Male 13 to < 15 years Male 15 to < 17 years Male 17 to < 18 years Female >=18 - 29 years Female \geq 30 years Female 0 to < 15 Days Female 15 Days to < 1 year Female 1 to < 10 years Female 10 to < 13 years Female 13 to < 15 years Female 15 to < 17 years Female 17 to < 18 years	127 to 517 89 to 365 59 to 164 44 to 107 46 to 122 90 to 273 134 to 518 156 to 369 141 to 460 62 to 280 54 to 128 48 to 95
ALT	Liver	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	U/L	Male 0 to<1 year Male 1 to <13 years Male 13 to <18 years Male >=18 years Female 0 to<1 year Female 1 to <13 years Female 13 to <18 years Female >=18 years	5 to 33 9 to 25 9 to 24 <45 5 to 33 9 to 25 8 to 22 <34
GGT	Liver	5mL venous serum or plasma	Next working day	Specimens should be tested within 3 days of collection and stored at 2-8°C.	U/L	Male Adult \ge 18 years Female Adult \ge 18 years 0 to < 15 Days 15 Days to < 1 year 1 to < 11 years 11 to < 18 years	12 to 64 9 to 36 23 to 219 8 to 127 6 to 16 7 to 21
Total Bilirubin	Liver	5mL venous serum or plasma	Next working day	Specimens should be tested within 3 days of collection and stored at 2-8°C.	µmol/L	Adult \ge 18 years 0 to < 15 Days 15 Days to < 1 year 1 to < 9 years	3.4 to 20.5 3 to 284 1 to 12 1 to 7



						9 to < 12 years 12 to < 15 years 15 to < 18 years	1 to 9 2 to 12 2 to 14
Globulin	Liver	5mL venous serum or plasma	Next working day	Specimens should be tested within 6 days of collection and stored at 2-8°C.	g/L	18 to 150 years	20 to 35
			A A	RENAL PROFILE			
Sodium	Renal	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Adult ≥ 18 years <18 years	136 to 145 133 to 146
Chloride	Renal	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Adult ≥ 18 years <18 years	98 to 107 95 to 106
Urea	Renal	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Male <50 years Male >50 years Female <50 years Female >50 years Female 0 to < 15 Days Female 15 Days to < 1 year Female 1 to < 10 years Female 10 to < 18 years Male 0 to < 15 Days Male 15 Days to < 1 year Male 1 to < 10 years	3.2 to 7.4 3.0 to 9.2 2.5 to 6.7 3.5 to 7.2 1.0 to 8.2 1.2 to 6 3.2 to 7.9 2.6 to 6.8 1.0 to 8.2 1.2 to 6 3.2 to 7.9



						Male 10 to < 18 years	2.6 to 7.5
Creatinine	Renal	5mL venous	Next working	Specimens should	µmol/L	Female Adult ≥ 18 years	49 to 90
creatinine	Renui	serum or	day	be tested within 7	μποι/ Ε	Female 0 to <15 days	29 to 82
		plasma	ddy	days of collection		Female 15 days to <2 years	9 to 32
		plusifiu		and stored at 2-8°C.		Female 2 to <5 years	18 to 38
						Female 5 to <12 years	27 to 54
						Female 12 to < 15 years	40 to 72
						Female 15 to < 18 years	43 to 74
						Male Adult \geq 18 years	64 to 104
						Male 0 to <15 days	29 to 82
						Male 15 days to <2 years	9 to 32
						Male 2 to <5 years	18 to 38
						Male 5 to <12 years	27 to 54
						Male 12 to < 15 years	40 to 72
						Male 15 to < 18 years	55 to 96
eGRF	Renal	5mL venous	Next working	Specimens should	mL/min	≥18 years	Diagnosis of
		serum or	day	be tested within 7	/1.73m		CKD is entirely
		plasma		days of collection	2		based on eGFR
		P		and stored at 2-8°C.			once <60
							mL/min/1.73m2
			IRON S	TUDIES/IBC PRO	OFILE		
Iron	Iron Studies	5mL venous	Next working	Specimens should	µmol/L	Male Adult ≥ 18 years	11.6 to 31.2
		serum or	day	be tested within 7		Female Adult \geq 18 years	9.0 to 30.4
		plasma		days of collection		Female 0 to < 14 years	2.8 to 22.9
		1		and stored at 2-8°C.		Female 14 to < 18 years	3.5 to 29.0
						Male 0 to < 14 years	2.8 to 22.9
						Male 14 to $<$ 18 years	5.5 to 30.0
Ferritin	Iron Studies	5mL venous	Next working	Specimens should	ng/mL	Female Adult \geq 18 years	4.6 to 204.0
		serum	day	be tested within 7	5.	Female 4 to 14 Days	99.6 to 717.0



				days of collection		Female 6 Months to < 1 year	8.4 to 181.9
				and stored at 2-8°C.		Female 1 to < 5 years	5.3 to 99.9
						Female 5 to < 14 years	13.7 to 78.8
						Female 14 to < 18 years	5.5 to 67.4
						Male Adult ≥ 18 years	21.8 to 274.7
						Male 4 to 14 Days	99.6 to 717.0
						Male 15 Days to < 6 Months	14.0 to 647.2
						Male 6 Months to < 1 year	8.4 to 181.9
						Male 1 to < 5 years	5.3 to 99.9
						Male 5 to < 14 years	13.7 to 78.8
						Male 14 to < 16 years	12.7 to 82.8
						Male 16 to < 18 years	11.1 to 171.9
TIBC	Iron Studies	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection	µmol/L	All ages	50 - 72
				and stored at 2-8°C.			
Transferrin	Iron Studies	5mL venous	Next working	Specimens should	mg/dL	Male 18 to 60 years	174 to 364
		serum or	day	be tested within 7		Male 61 to 80 years	163 to 344
		plasma		days of collection		Female 18 to 60 years	180 to 382
				and stored at 2-8°C.		Female 61 to 80 years	173 to 360
						0 to < 9 Weeks	104 to 224
						9 Weeks to < 1 year	107 to 324
						1 to < 18 years	220 to 337
Transferrin	Iron Studies	5mL venous	Next working	Specimens should	%	Males ≥ 18 years	≤50 %
Saturation		serum or	day	be tested within 7		Females \geq 18 years	≤45 %
		plasma		days of collection		Female 0 to < 1 year	4.1 to 59
				and stored at 2-8°C.		Female 1 to $<$ 14 years	6.5 to 39
						Female 14 to $<$ 18 years	5.2 to 44
						Male 0 to < 1 year	4.1 to 59
						Male 1 to < 14 years	6.5 to 39
						Male 14 to $<$ 18 years	9.6 to 58



				LH/FSH			
FSH	LH/FSH	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mIU/mL	Male Adult \geq 18 years Adult Follicular Phase Adult Ovulatory Phase Adult Luteal Phase Adult Post-menopause Female 30 Days to < 1 year Female 1 to < 9 years Female 9 to < 11 years Female 11 to < 18 years Male 30 Days to < 1 year Male 1 to < 5 years Male 5 to < 10 years	1.27 to 19.26 3.85 to 8.78 4.54 to 22.51 1.79 to 5.12 16.74 to 113.59 0.38 to 10.4 0.42 to 5.45 0.44 to 4.22 0.26 to 7.77 0.09 to 2.41 0 to 0.91 0 to 1.62
LH	LH/FSH	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection	mIU/MI	Male 10 to < 13 years Male 13 to < 18 years Male Adult \geq 18 years Adult Follicular Phase Adult Mid-Cycle	0.35 to 3.91 0.78 to 5.1 1.24 to 8.62 2.12 to 10.89 19.16 to 103.03
				and stored at 2-8°C.		Adult Luteal PhaseAdult Luteal PhaseAdult Post-menopauseFemale 4 Days to < 3 Months	1.20 to 12.86 10.87 to 58.64 0 to 2.41 0 to 1.19 0 to 0.33 0 to 4.34 0.37 to 6.52 0 to 13.1 0 to 8.38 0.19 to 3.81 0 to 2.89 0 to 0.33 0 to 4.34 0 to 4.11



						Male 15 to < 17 years Male 17 to < 18 years	0.79 to 4.76 0.94 to 7.1
						Male 17 to < 10 years	0.94 (0 7.1
		VI	TAMIN B12	& FOLATE FASTI	NG PRO	DFILE	
Vitamin B12	Vit12 & Folate Profile	5mL venous serum	Next working day	Specimens should be tested within 3 days of collection and stored at 2-8°C.	pg/ml	Adult \ge 18 years 5 days to <1 year 1 year to < 9 years 9 to < 14 years 14 to < 17 years 17 to < 18 years	187 to 883 259 to 1576 283 to 1613 252 to 1125 244 to 888 203 to 811
Folate	Vit12 & Folate Profile	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	ng/mL	Adult \geq 18 years5 Days to < 1 year	3.1 to 20.0 10.6 to 45.3 3.9 to 45.3 11.9 to 45.3 13.1 to 45.3 11.4 to 45.3 11.9 to 45.3 11.9 to 45.3 7.9 to 45.3
				TFT PROFILE			
TSH	TFT	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mIU/L	Adult \ge 18 years 4 Days to < 6 Months 6 Months to < 14 Years 14 to < 18 Years	0.35 to 4.94 0.73 to 4.77 0.70 to 4.17 0.47 to 3.41
FT4	TFT	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	pmol/L	Adult \ge 18 years 0 to <1 year 1 to <18 years	9.01 to 19.05 10.5 to 18.8 9.98 to 14.29



	CTD – Connective Tissue Disease Screen											
ANAB	CTD Screen	5mL venous serum	3 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	IU/mL	N/A	Pos/Neg					
DNAA	CTD Screen	5mL venous serum	3 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	IU/mL	N/A	<10 Negative					
ENA	CTD Screen	5mL venous serum	3 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	IU/mL	N/A	Pos/Neg					



Clinical Chemistry Analytes

OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
25-OH Vitamin D2	5mL venous serum	Next	Specimens should be	nmol/L	Adult ≥ 18 years	50 to 125
and D3 (please		working day	tested within 3 days of		5 to 14 Days	4.25 to 85
include clinical			collection and stored at		15 Days to < 3 Months	15.4 to 101
indications on the			2-8°C.		3 Months to < 1 year	17.3 to 118
patient test request					1 to < 9 years	33.1 to 137
form) per section					9 to < 14 years	31.7 to 116
10.0 above					14 to < 18 years	12 to 106
Alpha-fetoprotein	5mL venous serum	Next	Specimens should be	ng/mL	Adult ≥ 18 years	0.89 to 8.78
(AFP)		working day	tested within 7 days of		0 to < 1 Month	0 to 2000
			collection and stored at		1 to < 6 Months	9.8 to 1359
			2-8°C.		6 Months to < 1 year	0.4 to 103.1
					1 to < 18 years	0.8 to 34.8
Anti Mullerian	5mL venous serum	Next	Specimens should be	pmol/L	Female 18-25 years	6.82 to 95.22
Hormone (AMH)		working day	tested within 6 days of		Female 26-30 years	1.22 to 52.66
			collection and stored at		Female 31-35 years	0.53 to 52.48
			2-8°C.		Female 36-40 years	0.20 to 51.03
					Female 41-45 years	0.00 to 23.35
					Female ≥ 46 years	0.00 to 8.19
					Female 0 to 28 days	≤ 6.7
					Female 29 days to <1 year	≤ 31.2
					Female 1 to <5 years	1.3 to 43.7
					Female 5 to <8 years	1.4 to 39.5
					Female 8 to <12 years	2.9 to 52.8
					Female 12 to <15 years	3.0 to 46.6
					Female 15 to <18 years	2.1 to 84.1
					Male 0 to 2 days	68.0 to 523.7
					Male 3 to 7 days	138.3 to 1023.7
					Male 8 to 10 days	195.2 to 1200.9
					Male 11 to 20 days	140.1 to 1130.9



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
					Male 21-28 days	212.0 to 951.4
					Male 29 days to <1 year	203.8 to 971.7
					Male 1 to <5 years	268.6 to 1229.9
					Male 5 to <8 years	206.2 to 956.5
					Male 8 to <12 years	84.0 to 976.4
					Male 12 to <15 years	8.8 to 286.8
					Male 15 to <18 years	16.8 to 130.0
					Males ≥ 18 years	5.20 to 114.60
Amylase	5mL venous serum	Next	Specimens should be	U/L	Adults 18-70 years	25 to 125
	or plasma	working day	tested within 7 days of		Adults ≥70 years	20 to 160
			collection and stored at		1-18 years	25 to 101
			2-8°C.		13 weeks to <1 year	3 to 50
					15 days to <13 weeks	2 to 22
					0 to <15 days	3 to 10
Anti-TPO	5mL venous serum	Next working day	Specimens should be tested within 3 days of collection and stored at 2-8°C. Specimens should be tested within 8 hours if unspun.	IU/mL	0 to 150 years	< 5.61
Beta-HCG	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	IU/L	Adult ≥ 18 years Female 0-3 months Female > 3months to <18 years Male 0-3 months Male > 3months to <18 years	<5 ≤50 <1.0 ≤50 <1.4
Bone Profile (Calcium & Phosphate)	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Please see specific analyte profile component	Please see specific analyte profile component



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
CA-125	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	U/mL	Female \geq 18 years Female 0 to < 4 Months Female 4 Months to < 5 years Female 5 to < 11 years Female 11 to < 18 years Male 0 to < 4 Months Male 4 Months to < 5 years Male 5 to < 11 years Male 11 to < 18 years	 ≤35.0 2.4 to 22 7.7 to 33 4.7 to 30 5.9 to 39 2.4 to 22 7.7 to 33 4.7 to 30 5.4 to 28
CA15-3	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	U/mL	Adult \geq 18 years 0 to < 1 Week 1 Week to < 1 year 1 to < 18 years	≤31.3 3.4 to 24 4.9 to 33 3.9 to 21
CA19-9	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	U/mL	Adult \ge 18 years 0 to < 1 year 1 to < 18 years	≤ 37 0 to 64 0 to 41
Calprotectin	QFIT	1-3 working days	Specimens should be tested within 28 days of collection and stored at 2-8°C.	ug/g	Adult ≥ 18 years	<50 ug/g 50-250 ug/g 100 - 250 ug/g >250 ug/g
Carbamazepine	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mg/L	Adults ≥ 18 years	In combination with other anti convulsants: 4- 8mg/L If prescribed on its own 6-12mg/L



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
Carcinoembryonic Antigen (CEA)	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C. Specimens Should be tested within 24 hours if unspun.	ng/ml	Adult \ge 18 years 0 to < 1 Week 1 Week to < 2 years 2 to < 18 years	<pre>≤5.00 8.1 to 62 8.1 to 62 0 to 2.6</pre>
Creatinine Kinase (CK)	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	U/L	Male Adult ≥ 18 years Female Adult ≥ 18 years <18 years	30 to 200 29 to 168 25 to 300
Cortisol	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C. Specimens should be tested within 8 hours if unspun.	nmol/L	Adult \ge 18 Before 10am collection Adult \ge 18 After 5pm collection 2 to < 15 Days 15 Days to < 1 year 1 to < 9 years 9 to < 14 years 14 to < 17 years 17 to < 18 years	102.1 to 535.2 80.0 to 477.3 13.1 to 339.5 14.3 to 458.1 47.8 to 297 60.5 to 349.2 76.9 to 452.5 97 to 505.7
Digoxin	5mL venous serum SST	1-2 working days	Specimens should be tested within 14 days of collection and stored at 2-8°C.	ug/L	Adult ≥ 18 years	0.5-2.0
Folate	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	ng/mL	Adult \ge 18 years 5 Days to < 1 year 1 to < 3 years 3 to < 6 years 6 to < 8 years 8 to < 12 years 12 to < 14 years 14 to < 18 years	3.1 to 20.0 10.6 to 45.3 3.9 to 45.3 11.9 to 45.3 13.1 to 45.3 11.4 to 45.3 11.9 to 45.3 7.9 to 45.3



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
FSH	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mIU/mL	Male Adult \geq 18 years Adult Follicular Phase Adult Ovulatory Phase Adult Luteal Phase Adult Post-menopause Female 30 Days to < 1 year Female 1 to < 9 years Female 9 to < 11 years Female 11 to < 18 years Male 30 Days to < 1 year Male 1 to < 5 years Male 5 to < 10 years Male 10 to < 13 years Male 13 to < 18 years	1.27 to 19.26 3.85 to 8.78 4.54 to 22.51 1.79 to 5.12 16.74 to 113.59 0.38 to 10.4 0.42 to 5.45 0.44 to 4.22 0.26 to 7.77 0.09 to 2.41 0 to 0.91 0 to 1.62 0.35 to 3.91 0.78 to 5.1
Glucose	5mL venous sodium fluoride/potassium oxalate plasma	Next working day	Specimens Should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Fasting Adult ≥ 18 years Fasting <4 weeks Fasting 4 weeks to <18 years	4.0 to 7.0 2.5 to 5.5 3.0 to 6.0
Glucose Tolerance	X2 5mL venous sodium fluoride/potassium oxalate plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Two-hour plasma glucose concentration two hours after 75g anhydrous glucose in an oral glucose tolerance test (OGTT) Gestational Diabetes	Normal <7.8 Impaired glucose tolerance 7.8-11.1 Diabetes >11.1



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
HbA1c	5mL Whole blood EDTA	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/m ol	Adults ≥ 18 years <18 years	<2 20 to 42
High Sens. CRP	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mg/L	Adult \ge 18 years 0 to <15 days 15 days to < 15 years 15 to <18 years	<pre>≤5 0.3 to 6.1 0.1 to 1 0.1 to 1.7</pre>
IBC Profile/ Iron Studies Profile (Iron, Ferritin, TIBC, Transferrin, Transferrin Saturation)	Please see specific analyte profile component	Next working day	Please see specific analyte profile component	Please see specific analyte profile compon ent	Please see specific analyte profile component	Please see specific analyte profile component
LDH	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	U/L	Adult \geq 18 years Female 0 to < 15 Days Female 15 Days to < 1 year Female 1 to < 10 years Female 10 to < 15 years Female 15 to < 18 years Male 0 to < 15 Days Male 15 Days to < 1 year	125 to 220 309 to 1222 163 to 452 192 to 321 157 to 272 130 to 250 309 to 1222 163 to 452
LFT Profile (Total Protein, Albumin, ALP, ALT, GGT, Total Bilirubin, Globulin)	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	Please see specific analyte profile	Please see specific analyte profile component	Please see specific analyte profile component



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
				compon ent		
LH	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mIU/MI	Male Adult \geq 18 years Adult Follicular Phase Adult Mid-Cycle Adult Luteal Phase Adult Post-menopause Female 4 Days to < 3 Months Female 3 Months to < 1 year Female 1 to < 10 years Female 10 to < 13 years Female 13 to < 15 years Female 15 to < 17 years Female 17 to < 18 years Male 4 Days to < 3 Months Male 3 Months to < 1 year Male 1 to < 10 years Male 10 to < 13 years Male 13 to < 15 years Male 13 to < 15 years Male 13 to < 15 years Male 13 to < 17 years Male 15 to < 17 years Male 17 to < 18 years	1.24 to 8.62 2.12 to 10.89 19.16 to 103.03 1.20 to 12.86 10.87 to 58.64 0 to 2.41 0 to 1.19 0 to 0.33 0 to 4.34 0.37 to 6.52 0 to 13.1 0 to 8.38 0.19 to 3.81 0 to 2.89 0 to 0.33 0 to 4.34 0 to 4.34 0 to 4.11 0.79 to 4.76 0.94 to 7.1
Lipid Profile (Total Cholesterol, HDL, LDL, Triglycerides)	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Please see specific analyte profile component	Please see specific analyte profile component
Lithium	5mL venous serum or plasma (Sodium heparin K2 EDTA)	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	Trough Toxicity	1.00 to 1.20 0.6 to 1.50



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range	
Magnesium	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mmol/L	18-20 years Adult > 20 years 0 to < 15 Days 15 Days to < 1 year 1 to < 18 years	0.7 to 0.91 0.66 to 1.07 0.82 to 1.62 0.81 to 1.27 0.86 to 1.17	
Microalbumin	Urine (MSU)	Next working day	Specimens should be tested within 6 days of collection and stored at 2-8°C.	mg/L	0 to 150 years	<30	
Oestradiol	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	pmol/L	Male ≥18 years Adult Follicular Phase Adult Ovulatory Phase Adult Luteal Phase Adult Post-menopause Female 15 days to <1 year Female 1 to < 9 years Female 9 to < 11 years Female 11 to < 12 years Female 12 to < 14 years Female 14 to < 18 years Male 15 days to < 1 year Male 1 to < 11 years Male 1 to < 13 years Male 13 to < 15 years Male 15 to < 18 years	88 to 161.52 88 to 921.42 139.50 to 2382.48 88 to 1145.35 88 to 102.79 0 to 25 0 to 10 0 to 48 0 to 94 11 to 172 0 to 255 0 to 255 0 to 25 0 to 13 0 to 26 0 to 28 0 to 38	
Phenytoin	5mL venous serum SST	1-2 working days	Specimens should be tested within 4 days of collection and stored at 2-8°C.	mg/l	Adult ≥ 18 years	40-80mg/l	



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
Potassium	Not accepted due to short stability	Not accepted due to short stability	Not accepted due to short stability	Not accepte d due to short stability	Not accepted due to short stability	Not accepted due to short stability
Pro-BNP	5mL venous serum	Next working day	Specimens should be tested within 3 days of collection and stored at room temperature. Specimens should be tested within 24 hours if unspun.	ens should be within 3 days of on and stored at ens should be within 24 hours if pg/ml Adult ≥ 75 years Adult<75 years Adult<75 years Adult<75 years <th< td=""><td>≤ 125.0 ≤ 450.0 ≤ 300</td></th<>		≤ 125.0 ≤ 450.0 ≤ 300
Progesterone	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	nmol/L	Male Adult \ge 18 years Follicular Phase Luteal Phase Post-menopause 1st Trimester Pregnancy 2nd Trimester Pregnancy 3rd Trimester Pregnancy Female 4 Days to < 1 year Female 1 to < 10 years Female 1 to < 10 years Female 15 to < 18 years Male 30 Days to < 1 year Male 1 to < 10 years Male 1 to < 10 years Male 1 to < 15 years Male 10 to < 15 years Male 10 to < 15 years	<1.60 <1.60 3.82 to 50.56 <1.60 8.90 to 468.41 71.55 to 303.05 88.72 to 771.15 0 to 4.2 0 to 1.1 0.4 to 2.7 0.64 to 32.62 0 to 2.1 0 to 1.1 0.4 to 2.7 0.5 to 1.8



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range	
Prolactin	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mIU/L	Males \ge 18 years Females \ge 18 years 0 to <1 year 1 to <18 years	72.66 to 407.40 108.78 to 557.13 115 to 1342 72 to 592	
TPSA 5mL venous serum Next working d		Next working day	Specimens should be tested within 7 day of collection and stored at 2-8°C.	ng/mL	Adult <50 years 50-59 years $ext{60-69}$ years $ext{270}$ years Female 0 to < 1 Week Female 1 Week to < 1 year Female 1 to < 18 years Male 0 to < 1 Week Male 1 Week to < 6 Months Male 6 Months to < 12 years Male 12 to < 18 years	< 2.00 <3.00 <4.00 <5.00 0 to 0.039 0 to 0.01 0 to 0.015 0 to 0.047 0 to 0.038 0 to 0.353 0 to 0.566	
Renal Profile (Sodium, Chloride, Urea, Creatinine, eGFR)	5mL venous serum or plasma	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	Please see specific analyte profile compon ent	Please see specific analyte profile component	Please see specific analyte profile component	
Rheumatoid Factor	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	IU/mL	Adult ≥ 18 years	<14.0 IU/mL	



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
TFT Profile (TSH and FT4)	5mL venous serum	Next working day	Specimens should be tested within 6 days of collection and stored at 2-8°C.	Please see specific analyte profile compon ent	Please see specific analyte profile component	Please see specific analyte profile component
Uric Acid	or plasma working day t		Specimens should be tested within 3 days of collection and stored at 2-8°C.	µmol/L	Male Adult \geq 18 years Female Adult \geq 18 years Female 0 to < 15 Days Female 15 Days to < 1 year Female 1 to < 12 years Female 12 to < 18 years Male 0 to < 15 Days Male 15 Days to < 1 year Male 1 to < 12 years Male 1 to < 19 years	220 to 450 150 to 370 164 to 757 94 to 377 106 to 289 153 to 349 164 to 757 94 to 377 106 to 289 156 to 454
Protein-Creatinine Ratio: Urinary Creatinine	Urine – 30ml aliquot from 24 hr collection – state total volume	1-2 working days	Specimens should be tested within 6 days of collection and stored at 2-8°C.	umol/L	Male Adult ≥ 18 years Female Adult ≥ 18 years	Males 3540- 20000umol/L (1st morning urine) Females 2550- 20000umol/L (1st morning urine)
Protein-Creatinine Ratio: Urinary Protein	Urine – 30ml aliquot from 24 hr collection – state total volume	1-2 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	g/L, g/24hr	Adult ≥ 18 years	Less than 0.15 g/24hr



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
Valproic Acid	5mL venous serum SST	1-2 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mg/L	Adult ≥ 18 years	50-100mg/L
Sex Hormone Binding Globulin	5mL venous serum	Next working day	Specimens should be tested within 8 days of collection and stored at 2-8°C.	nmol/L	Female \geq 18 years Female 4 Days to < 1 Month Female 1 Month to < 1 year Female 1 to < 8 years Female 8 to < 11 years Female 11 to < 13 years Female 13 to < 15 years Female 15 to < 17 years Female 17 to < 18 years Male 4 Days to < 1 Month Male 1 Month to < 1 year Male 1 to < 8 years Male 8 to < 11 years Male 11 to < 13 years Male 13 to < 15 years Male 15 to < 18 years Male 15 to < 18 years	19.8 to 155.2 14.4 to 120 36.2 to 229 41.8 to 189 26.4 to 162 14.9 to 108 11.2 to 98.2 9.8 to 84.1 10.8 to 155 14.4 to 120 36.2 to 229 41.8 to 189 26.4 to 162 14.9 to 108 11.2 to 98.2 9.7 to 49.6 13.5 to 71.4
Testosterone	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2-8°C.	nmol/L	Male 18 to 49 years Male \geq 50 years Female 18 to 49 years Female \geq 50 years Female \geq 50 years Female 4 Days to < 9 years Female 9 to < 13 years Female 13 to < 15 years Female 15 to < 18 years Male 4 Days to < 6 Months Male 6 Months to < 9 year Male 9 to < 11 years Male 11 to < 14 years	8.33 to 30.19 7.66 to 24.82 0.48 to 1.85 0.43 to 1.24 0.04 to 2.15 0 to 0.98 0.36 to 1.54 0.49 to 1.7 0.3 to 10.4 0 to 1.24 0 to 0.81 0 to 15.4



OLOLHD Ref.	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
					Male 14 to < 16 years Male 16 to < 18 years	1.25 to 21.9 5.13 to 27.6
Protein/Creatinine Ratio	As above	1 – 2 working days	Specimens should be tested within 6 days of collection and stored at 2-8°C.	mg/mm ol	Adult ≥ 18 years	0-13mg/mmol
Androstenedione	5mL venous serum	1-3 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	nmol/L	Adult ≥ 18 years	Male 1.5 - 6.5 Female 0.0 - 10.1
Phenobarbitone	Urine – 30ml aliquot from 24 hr collection	1-2 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mg/L	Adult ≥ 18 years	10-30mg/L
Theophylline	5mL venous serum	1-2 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.	mg/L	Age 0 - 30d Other	28 - 70 55 - 111



Haematology Analytes

Test	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
Coagulation Screen (PT/INR)	Sodium Citrate Plasma	Next working day	Specimens should be tested within 24 hours of collection and stored at room temperature.	Seconds	0 – 99 yrs	PT Up to 5yrs 10.6 - 11.4 5 to 100yrs 10.1 - 12.1 10 to16yrs 10.2 - 12.0 17 to 99yrs 10.8 - 13.9
INR	Sodium Citrate Plasma	Next working day	Specimens should be tested within 24 hours of collection and stored at room temperature.	Ratio	0 – 99 yrs	INR Non anticoagulated 1.10-1.3
ESR	Whole blood EDTA	Next working day	Specimens should be tested within 24 hours of collection and stored at 2-8°C. Specimens over 24hrs and under 48hrs can be tested but will be reported with at test comment.	mm/hr	<16 years Male 17- 70 years Female 17- 70 years Male > 70 Female > 70	1- 13mm/hr ≤ 15mm/hr ≤ 20mm/hr ≤ 30mm/hr ≤ 35mm/hr



Test	Specimen Type			ability and St	orage	Units	Demographics	Reference Range	
Test FBC & Differential	Specimen Type	Turna Next working day		Anin 3 Anin 3 Anin 3 Anin 3 Anin 3 Anin 3 Anin 3 Anin 3 Anin 4 Anin 4 An	eter pod Count globin (g/ tocrit (L/L Cell Volume ell haemo ell haemo tration (g/ Il distribut count (10 plood cell o phil count ocyte court vte count (10 phil count (11)	(10^12/L) dL)) e (fL) globin (pg) globin 'dL) ion width (fi)^9/L) count (10^9/L) (10^9/L) (10^9/L) (10^9/L) (10^9/L) (10^9/L) (10^9/L) nt (10^9/L) (10^9/L) nt (10^9/L) nt (10^9/L) nt (%) ent (%) ent (%) (%) ent (%)	Adults >18 yrs %) L)	Adult Male Female 4.5-5.5 13.0-17.0 15.0 0.40-0.50 0.46 Male and Fe 83-101 27-32 31.5-34.5 11.6-14 39-46 150-410 4.0-10.0 2.0-7.0 1.0-3.0 0.2-1.0 0.02-0.5 0.02-0.1 50-100 0 40-80 20-40 2.0-10.0 1.0-6.0 <1.0-2.0 0.5-2.5	Adult 3.8-4.8 12.0- 0.36- male (>18)
Blood Film	Whole blood EDTA	1-3 working	Specimens should be tested with				All ages	0 N/A	



Test	Specimen Type		around Stabilit	ty and Storage	Units	Demographics	Reference	Range
		Time						
		days from FBC result	24 hours of collection and stored at 2- 8°C.					
Ferritin	5mL venous serum	Next working day	Specimens should be tested within 7 days of collection and stored at 2- 8°C.	ng/mL		Female Adult ≥ 1 Female 4 to 14 DFemale 15 Days tFemale 6 MonthsFemale 1 to < 5 yFemale 1 to < 5 yFemale 1 to < 14 Female 1 to < 14 Male Adult ≥ 18 yMale 4 to 14 DaysMale 4 to 14 DaysMale 4 to 14 DaysMale 15 Days to $<$ Male 6 Months toMale 1 to < 5 yeaMale 5 to < 14 yeaMale 14 to < 16 yMale 14 to < 16 yMale 16 to < 18 y	ays o < 6 Months to < 1 year years years 8 years ears < 6 Months < 1 year rs ears years	4.6 to 204.0 99.6 to 717.0 14.0 to 647.2 8.4 to 181.9 5.3 to 99.9 13.7 to 78.8 5.5 to 67.4 21.8 to 274.7 99.6 to 717.0 14.0 to 647.2 8.4 to 181.9 5.3 to 99.9 13.7 to 78.8 12.7 to 82.8 11.1 to 171.9
Vitamin12/Folate Fasting Profile	5mL venous serum	Next working day	Specimens should be tested within 3 days of collection and stored at 2- 8°C.	Folate, Ferritin: Vitamin B12: p		See test specific o	lemographics	See test specific ranges
Sickle Cell Screen	Whole blood EDTA	1-3 working days	Specimens should be tested within 7 days of collection and	Qualitative		N/A		N/A



Test	Specimen Type		urnaround me	Stabilit	y and Storage	Units	Demo	ographics	Reference	Range
			stored 8°C.	at 2-						
G6PD	5ml EDTA Plasma	1-4 working days	tested days o	be within 7 f ion and	U/g Hb		A	Adult ≥ 18 years		5.6 - 11.2 U/g Hb
Infectious Mononucleosis (Monospot)	5ml EDTA Plasma	Next working day	tested days o	be within 6 f ion and	Detected/ Not D	Detected/ Inv	alid N	NA		NA



Immunology Analytes

Test	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
Tissue Transglutaminase antibody (tTg)	5mL venous serum	1-2 working days	Specimens should be tested within 14 days of collection and stored at 2-8°C.	U/mL		0U/mL-10U/mL Coeliac disease unlikely (please note that if the patient has no dietary gluten results may appear false negative. Consistent with coeliac disease
Protein Electroophoresis IgA/IgG/IgM	5mL venous serum	1-3 working days	Specimens should be tested within 2 days of collection and stored at 20-25°C.	g/L	Albumin Age 3d Age 13 Age 17 Over Globulin IgA Age 1 Age 3 Age 9 Age 13 Age 9 Age 13 Age 9 Age 13 Age 9 Age 13 Age 19 Over >19 IgG Age 11m Age 3 Age 6 Age 9 Over >9	28 - 44 $38 - 54$ $32 - 45$ $34 - 50$ $19 - 35$ $0.00 - 0.83$ $0.20 - 1.00$ $0.30 - 3.00$ $0.50 - 3.60$ $0.50 - 3.60$ $0.50 - 3.50$ $0.70 - 4.00$ $2.3 - 14.1$ $4.5 - 9.2$ $5.0 - 14.6$ $5.7 - 14.7$ $7.0 - 16.0$



Test	Specimen Type	Turnaround Time	Stability and Storage	Units	Demographics	Reference Range
					IgM	
					Age 3	0.0 - 1.50
					Age 9	0.20 - 2.10
					Age 13	0.30 - 2.4
					Age 19	0.20 - 2.6
					Over >19	0.40 - 2.30
					<u>Paraprotein</u>	- Detected/Not detected
					<u>Protein</u>	63 - 83
					Protein Immunofix	Detected/not detected
Animal Disorders (allergy) only 3 allergy tests per sample (cross all allergens)	5mL venous serum	1-2 working days	Venous blood specimens should be tested within 7 days of collection and stored at 2-8°C.	kIU/I	N/A	Allergy Grading
House dust mite allergy) only 3 allergy tests per sample cross all allergens)	5mL venous serum	1-2 working days	Venous blood specimens should be tested within 7 days of collection and stored at 2-8°C.	kIU/I	N/A	Allergy Grading
Peanut Allergy only 3 allergy tests per sample cross all allergens)	5mL venous serum	1-2 working days	Venous blood specimens should be tested within 7 days of collection and stored at 2-8°C.	kIU/I	N/A	Allergy Grading
Aixed Grass pollen allergy) only 3 allergy tests per sample cross all allergens)	5mL venous serum	1-2 working days	Venous blood specimens should be tested within 7 days of collection and stored at 2-8°C.	kIU/I	N/A	Allergy Grading
Anti-CCP	5mL venous serum	1-2 working days	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.	U/mL	N/A	<7 U/mL : Negative 7/10 U/mL : Equivocal >10 U/mL : Positive



Test	Specimen	Turnaround	Stability and Storage	Units	Demographics	Reference Range
	Туре	Time				
Connective Tissue	Please see	Next working	Please see specific analyte	Please see	Please see specific analyte	Please see specific analyte
Disease (CTD) Screen	specific analyte	day	profile component	specific	profile component	profile component
	profile			analyte		
	component			profile		
				component		



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 at 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.



Test	Specimen Type	Turnaround Time	Stability and Storage
Faeces O,C&P (PCR preferable)	Random Faeces <i>Separate sample should be provided for this test.</i>	3 working days	Specimens should be tested within 2 days of collection and stored at 2-8°C.
<i>Stool Investigation</i> Faecal immunochemical Test	QFIT <i>Separate sample should be provided for this test.</i>	1-3 working days	Specimens should be tested within 28 days of collection and stored at 2-8°C.
Fungal Culture	Specimens should be collected into folded paper squares secured and placed in a plastic bag or in commercially available packets designed specifically for the collection and transport of skin, nail and hair specimens.	3 working days	Specimens should be kept at ambient room temperature and transported and processed as soon as possible although, provided the specimens are kept dry, the fungus will remain viable for 14 days.
Stool Investigation Helicobacter Pylori Antigen	Random Faeces Separate sample should be provided for this test.	3 working days	Specimens should be tested within 3 days of collection and stored at 2-8°C.
Syphilis Screen	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 72 hours of collection hours if stored at room temperature. Venous blood specimens should be tested within 7 days of collection if stored at 2- 8°C.



Test	Specimen Type	Turnaround Time	Stability and Storage
Urine Chlamydia & Gonnorrhea	Female and male urine specimens, with a final volume between the black fill lines of an Aptima urine specimen transport tube.	Next working day	Specimens should be tested within 30 days of collection and stored at 2-30°C prior to testing. Specimens collected in a non-Aptima collection device should be delivered to the laboratory and transferred to an Aptima tube within 24 hours of collection. First Catch Urine (FCU) technique should be applied in order to maximise chances of a positive specimen (due to overnight accumulation of organisms in the urethra).
STI screen (syphilis, HIV, HBsAg)	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.
Viral Hepatitis B & C screen (HBsAg + anti- HCV)	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.
Hepatitis B Infection status: (HBsAg, anti-HBc)	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.
Hepatitis A IgG (HAV IgG)	5mL venous serum	1-2 working days	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.
Hepatitis B surface Antigen (HBsAg)	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.
Hepatitis B surface Antibody (Post vaccination) - AHBs	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.
Hepatitis C Antibody (anti-HCV core IgG)	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.



Test	Specimen Type	Turnaround Time	Stability and Storage
Hepatitis C PCR (HCV RNA; current infection)	2 x EDTA	1-2 working days	Venous blood specimens must be tested in the laboratory within two days of sample collection.
HIVAg/Ab Combo assay	5mL venous serum or plasma	Next working day	Venous blood specimens should be tested within 14 days of collection and stored at 2-8°C.
Herpes Simplex Virus PCR	Aptima multisite swab/Urine	5 working days	Venous blood specimens should be tested within 2 days of collection and stored at 2-8°C.
Varicella Zoster Virus (VZV) IgG (Immune status)	5mL venous serum	1-3 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.
Measles/Mumps/Rubella IgG screen	5mL venous serum	1-3 working days	Specimens should be tested within 7 days of collection and stored at 2-8°C.



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

SRA - Reporting Specimen issues to Source

<u>Prep lab</u>

- 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 <u>must be</u> <u>confirmed</u> 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.

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