USER MANUAL

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Laboratory Manager:	Mr John O'Loughlin (joloughlin@rotunda.ie)
Website	www.rotunda.ie

EMERGENCY CONTACT FOR THE LAB STAFF ON CALL
(From 6pm- 8am; Mon to Fri, from 12.45 pm Saturday all day Sunday /Bank holiday Monday): **BLEEP 538**

ON CALL MOBILE **086-2626101** ON CALL BEDROOM **Ext 1482**

Please when completing requests give as much clinical detail as possible.

PLEASE NOTE: PATIENTS MAY NOT REQUEST LABORATORY TESTS.

This manual documents information with regard to:

- **Providing an overview of the department of laboratory medicine**
- contacting staff for technical and advisory advice
- identifying tests available during routine hours, on Saturday mornings and during out of hours service
- the collection, transport additional requests (add-ons)

The following documents complement the manual:

Test Repertoire

LF-GEN-0066 Biochemistry Active Test Table

LF-GEN-0067 Blood Transfusion Active Test Repertoire Table

LF-GEN-0069 Histology Active Test Repertoire

LF-GEN-0068 Haematology Active Test Repertoire

LF-GEN-0070 Microbiology Active Test Repertoire

LF-GEN-0071 Andrology Active Test Repertoire

LF-GEN-0076 POCT Active Test Table Repertoire

***Blood Tube Guides**

LI-GEN-0006 Quick Pick Tube Guide

LI-GEN-0002 Blood Collection Tube Guide

LI-GEN-0005 Paediatric Tube Guide

EX-MICRO-0319 Recommended Swab Type

*Mainly for contingency if electronic chart is down

Ordering of Tests on the MN-CMS

LI-GEN-0016 MN-CMS Quick Reference Guide for the Department of Laboratory Medicine & LI-GEN-0017 MN-CMS Quick Reference Guide for Blood Transfusion.

Current editions are available on the hospital websites and hospital Q-Pulse. They are held as standalone documents to allow quick review and issuing when changes are made which need to be advised to the users without delay.

THE QUALITY POLICY OF DEPARTMENT OF LABORATORY MEDICINE AT THE ROTUNDA HOSPITAL

The Department of Laboratory Medicine is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users.

In order to ensure that the needs and requirements of users are met;

The department will comply with the requirements of:

- ISO 15189:2012 Medical laboratories-Particular Requirements for Quality and Competence.
- ISO 22870: Point of care Testing (POCT) Requirements for quality and competence
- INAB Flexible Scope of Accreditation for ISO 17025 and ISO 15189 Testing Laboratories
- INAB terms, conditions and regulations
- EU Directive 2002/98/EC titled Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components and amending directive 2001/83/EC
- EU Directive 2004/33/EC titled Technical Requirements for Blood and Blood Components.
- Statutory instrument 360 of 2005 titled Quality and Safety of Human Blood and Blood Components that adapts the EU Directives as defined above into Irish law.
- Notifiable Diseases and their Respective Causative Pathogens Issued by the HSE HPSC – EX-MICRO-0122
- Infectious Diseases under Infectious Diseases (Amendment) Regulations 2020 S.I. No. 53/2020) (Feb 2020)
- DC 1 Mandatory and Guidance Documents
- Directive of the European Parliament and of the Council Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medical Products

Scope of Accreditation **Rotunda Hospital Registration number 208T**

Please refer to:

- The INAB website (www.inab.ie) for the most recent scope.

- Master List of Flexible Scope of Accreditation Changes Record Form MF-GEN-0161

- On display in Laboratory Reception in conjunction with the certificate of accreditation

The department will commit to:

No	Quality Objective
1.	Provide a testing service where all tests as far as are practicable are compliant to ISO 15189 Medical laboratories - Requirements for Quality and Competence
2.	Provide an environment to ensure consideration of health, safety and welfare of its entire staff. Visitors to the department will be treated with respect, and due consideration will be given to their safety while on site
3.	Operate a quality management system to integrate the organisation, procedures, processes, risk assessment and resources
4.	Set and review quality objectives and plans in order to implement and maintain this quality policy
5.	Set KPI annually and review KPI in a controlled manner
6.	Ensure that all personnel are familiar with the quality manual and all procedures relevant to their work to ensure user satisfaction
7.	Uphold professional values, provide good professional practice, quality of examinations and ensure protection of personal information in compliance with the quality management system.

The department is committed to:

8.	Comprehensive orientation and induction programme for all new members of staff
9.	Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users
10	The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service
11.	The collection, stabilisation, transport, sample preparation, identification and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations and that all stages are embedded in the QMS. Ensuring laboratory staff are aware of patient consent required for certain tests.
12	Ensuring critical result notification and providing turnaround times within specified limits. *While Departments have internal criteria stipulating which reports should ideally be phoned to clinical staff, it remains the responsibility of the clinician who ordered the test to follow up and act upon its result.*
13	Providing clinically useful information through the laboratory examination of samples from patients and reporting of reliable results in a timely fashion.
14	The assessment of user satisfaction, in addition to internal audit and external quality assessment in order to produce continual improvement
15	Ensuring examinations are fit for intended use, comply with relevant legislation and ensure the highest achievable quality of all tests performed. The laboratory believes that all clinical investigation tests should come through the laboratory so that the standard of testing can be monitored. The Laboratory however does not accept responsibility for testing that is performed outside of this laboratory structure as it cannot guarantee the quality of this testing.

16.	Compliance with relevant environmental legislation
17.	Provision of a phlebotomy service in a safe and clean environment, which is organised to minimise errors, separated from all processing areas.
18.	The safe testing, distribution and transfusion of Blood and Blood Components.
19.	Providing a POCT/NPT service in Biochemistry, Haematology and Microbiology compliant to ISO 22870:2016, ISO 15189:2012

Signed: *Dr Emma Doyle* _____ **Date: 22/03/2023**

CHANGES TO THIS EDITION

OLD EDITION NO.: 11	**NEW EDITION NO.: 12**

Section No.	**Amendment**
Table of Contents	Update contacts.
3	Changed title
3	Updated for BT
4	Update to reflect current services
4.4	Updated for 2 scientists on site
4.2.4	Reference range for CSF remove indices for Biochemistry and ref active test table
4.5.3	Included urgent differentials
6.4.1	Updated to include handwritten samples for BT where unable to scan barcode ID. Removed reference to NICU samples
7.4.1	Minor change
7.4.2	Included special requirements
8	Minor Change
11	Minor Change
All	Update quality policy to define areas under POCT/NPT

TABLE OF CONTENTS

1. INTRODUCTION

Bartholomew Mosse, surgeon and man-midwife founded the Rotunda Hospital in 1745. Originally known as The Dublin Lying-In Hospital, it was the first maternity training hospital of its kind.

The Rotunda has provided an unbroken record of service to women and babies since its foundation in 1745 and has occupied its present premises since 1757.

Towards the end of the nineteenth century, the importance of the new speciality of pathology became apparent in Dublin. The first pathology laboratory opened in the Rotunda Hospital in 1897. In 1902 Dr R. Dancer Purefoy funded the building and furnishing of a laboratory. The Laboratory has continued to expand to the present day adopting the latest diagnostic tools available to medical scientists. This manual is intended to give the user an overall view of the services provided by the pathology department and how to request those services.

In November 2017 the Rotunda hospital implemented the Maternal Newborn – Clinical Management System (MN-CMS) for mothers and babies. In 2019 the gynae services were moved to the Millenium system. This replaced the existing paper patient health record with an electronic powerchart.

2. QUALITY STATEMENT

The Department of Laboratory Medicine at the Rotunda Hospital committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users. The quality of the service is supported by the attitudes, values and commitment of the laboratory staff. The Department of Laboratory Medicine has achieved accreditation under ISO 15189 Medical laboratories-Particular Requirements for Quality and Competence and ISO 22870 Point of Care Testing-Requirement for Quality and Competency (the schedule of accreditation is displayed in laboratory reception and on the INAB website - registration number 208MT). The laboratory gained flexible scope of accreditation in 2016.

Laboratory management is committed to:

- Staff recruitment (subject to public sector embargo on staffing) development and training to ensure a full and effective service to its user.
- The laboratory provides in-service education to all medical staff when they commence employment in the hospital. This includes haemovigilance & point of care training and specialised training e.g. LIMS and QMS.
- The collection, transport and handling of all specimens in a way to ensure the correct performance of laboratory examinations.
- Reporting of results in a timely, confidential, accurate and clinically useful manner and ensuring that the medical staff are aware of their responsiblilty for review of these results as approved by hospital management.
- Assessment of user satisfaction as a quality indicator to ensure user satisfaction with laboratory services.

An electronic version of this manual is available on the hospital Intranet under the Laboratory link and on Laboratory & Hospital Q-Pulse.

The Department of Laboratory Medicine is multi-disciplinary with the following departments/disciplines:

- Administration
- Biochemistry/Endocrinology
- Blood Transfusion
- Haematology
- Haemovigilance
- Histopathology / Cytopathology
- Microbiology/Serology/ Andrology
- Mortuary
- Phlebotomy
- Point of Care Testing
- Information and Communications Technology

This manual is intended to give an overall view of the services available in the department of laboratory medicine.

Individual tests available and test guidelines / TAT can be viewed on the Active Test Repertoire table.

Tests referred maybe viewed on the Referred Test Repertoire Table

Ref.: LF-GEN-0066-71&76 departmental Active Test Tables and

LF-GEN-0072 Referred Test Table

Blood Tube Guides are available on Q-Pulse and the hospital intranet. These are held for contingency as MN-CMS directs the user as to what sample tubes are required.

3. MAIN CHANGES TO LABORATORY SERVICE

The following major changes occurred in relation to the laboratory service in 2022 to2023:

- The laboratory performed a review of the out of hours service A two person roster was agreed and will be implemented in 2023.
- The SARs Cov 2 pandemic saw the laboratory introduce three testing platforms in response to demands. and an increased POCT testing service POCT facilities were increased with the addition of seven blood gas analysers in clinical areas.
- The Biochemistry department replaced the Cobas 6000 with two Roche pure analysers and introduced numerous new tests. A 2nd Pure analyser will be installed in 2023 and will provide 24/7 back up cover for the Biochemistry service.
- The Haematology Department installed the two XN-2000 FBC analysers. It is currently being verified for introduction into use in 2023.
- Histology and Haematology replaced some old supplementary equipment.

2021

- The Blood Transfusion laboratory introduced cffDNA testing for Rhesus negative women, non-immunised and preferably greater than 12 weeks gestation
- New stand alone Andrology Laboratory together with patient sampling room now available in New Gynae Building.
- Luminex Platform for SARS-CoV-2 PCR testing (4th Platform) and also HSV 1 and 2 PCR testing
- SARS-CoV-2 IgG Testing on Abbott Architect.

4. LABORATORY LOCATION AND SERVICES

The hospital is located on Parnell Square at the top of O'Connell Street in the centre of Dublin. The laboratory is located on the ground floor of the hospital. Laboratory reception is reached by entering the hospital through the main entrance, turn right and follow the signs.

Department/ Activity	**Opening Hours**
Department of Laboratory Medicine Reception *Contact labs by phone outside laboratory door*	Monday to Friday 8:30-18.00 Semen Analysis by appointment only via laboratory reception.
Routine Limited Inpatient Laboratory Diagnostic Service	Monday to Friday 8.00-18.00 Saturday 9.00-12.30 (see section 3.1) 8am -9am and 5pm -6pm
Phlebotomy Out-Patient Service For the full repertoire of tests carried out during these hours, refer to Section 12 of this document.	Monday - Friday: 08:30 – 15.30 (Ext.: 1458)
Out of Hours Service An On-Call laboratory service is provided for clinically urgent samples only.	Monday - Friday: 18:00 – 08:00 Saturday - Monday: 12:430– 08:00 Bank Holidays: 09:00 – 08:00 (following working day) **Note**: Microbiology provide a limited service Sunday Morning and Bank Holidays (9am to 12.45pm). This service is consultant led and any test required outside of urgent on-call samples must be addressed through the Consultant Microbiologist.
All specimens must be supplied with clinical details. Contact the medical scientist on call through the switch, or bleep No. 538 or by mobile on call mobile 086-2626101 or the on call bedroom Ext. 1482.	
(Scientist personal no. available from switch). Clinician/Consultant advisory support is available (number available from switch).	

4.1 Scientific and Clinical Advice

Scientific and medical advice on issues within the laboratory's range of interest and competence is available. Contact the laboratory office if there is no reply at extensions listed.

EMERGENCY CONTACT FOR THE LAB STAFF ON CALL: **BLEEP 538**
ON CALL MOBILE **086-2626101** ON CALL BEDROOM **Ext 1482**

Position	Name	Contact no. / Bleep
Director of Laboratory Services	Dr Emma Doyle	6868
Laboratory Manager	Mr. John O'Loughlin	1762
Consultant Microbiologist	Dr. Richard Drew	1466
Consultant Microbiologist	Dr Meaghan Cotter	
Consultant Andrologist	Dr Edgar Mocanu	1466
Consultant Chemical Pathologist	Dr Mohamed Elsammak Dr Ana Rakovac	1345
Consultant Histopathologist	Dr. Emma Doyle	6868
Consultant Histopathologist	Dr. Eibhlis O Donovan	6834
Consultant Histopathologist	Dr. Noel McEntagart	1358
Consultant Histopathologist	Dr. Keith Pilson	6816
Consultant Haematologist	Dr. Fionnuala Ni Ainle	Contact Reception.
Consultant Haematologist	Dr. Barry MacDonagh	Contact Reception.
Laboratory Office Enquiries	Caroline Bosse	1739
Laboratory Porter	Gerry Price	1739
Biochemistry/Endocrinology	Grainne Kelleher	1345/2522
Blood Transfusion/Haematology	Deirdre Murphy	1463/1464
Microbiology /Serology/Andrology	Dave Le Blanc	1466/1210
Histopathology	Kieran Healy	1467
Mortuary	Bill O'Neill/ Francoise Coussay	1442
Point of Care	Lorna Pentony	2569
ICT	Mike Maher	2569
Infectious Diseases Liaison Midwife	Mairead Lawless	Bleep 883
Infection Control ADOM	Anu Binu	Bleep 518
Infection Control Midwife	Alva Fitzgibbon	Bleep 522
Haemovigilance Officer	Rose Marie O'Donovan	6803 Bleep 725
Deputy Haemovigilance Officer	Emily Forde	1464/1463
Surveillance Scientist	Nicola Boran/David Le Blanc	1466/1210
Quality Manager Deputy Quality Manager	Susan Luke Emily Forde	6872 1464/1463
Health & Safety Officer Deputy Health & Safety Officer	Aiveen O'Malley Vacant	1345

Position	Name	Contact no. / Bleep
Training Co-ordinator Deputy Training Co-ordinator/ Journal Club	John O'Loughlin deputy	1762
Laboratory ICT Co-ordinator Deputy IT Co-ordinator	Mike Maher LIMS departmental reps where appointed .	2569 See departmental contact numbers
Point of care coordinator Deputy Point of Care each Department involved in Point of Care	Lorna Pentony Responsibilities rest with the Chief Medical Scientist in each department responsible for item of equipment. For those not assigned a department responsibility lies with the Lab manager	2569

4.2 Routine Tests Available per Department

Please note that all tests are accredited under the scope of ISO 15189 and in addition POCT tests are compliant to ISO 22870 by the Irish National Accreditation Board are identified in this section with a ✓.

4.2.1 Turnaround Times

Note: Turnaround times can be found in the active test tables for each department's scope of tests.

Please note the turnaround times stated are based on the assumption of optimum conditions. Turnaround times may be outside the stated ranges depending on a number of factors including:

- Time of day received: routine vs on call hours
- Resources available (staff, sick leave etc.)
- Current routine sample workloads and urgent sample workloads at the time of specimen receipt
- Instrument malfunction and/or essential maintenance.
- Prioritisation of samples of an urgent nature e.g. an urgent transfusion for a haemorrhage will be given precedence over an urgent PET screen.
- MN-CMS downtime - results may be available on APEX.

NOTE: It is important to include clinical details and pregnancy status on all request forms so requests of an urgent nature can be dealt with promptly, and the appropriate reference ranges can be applied to the results.

If the TAT is expected to be delayed, the users will be informed if there is a clinical need identified.

4.2.2 Reference Ranges

Please note reference ranges quoted may not be applicable in the event of a change of assay methodology or equipment. **Wards will be notified of relevant changes via memo** and it is advised that one always cross checks reference ranges with those quoted on the laboratory report and/or on APEX.

It is imperative to state the pregnancy status and number of days post-delivery on test requests so the correct reference ranges may be applied to final report.

4.2.3 Referral Test Reference Ranges

Refer to LF-GEN-0072 Referred Test Table for a complete list of referred tests.
In addition, for tests that are processed externally, please consult the hard copy of results or the referral laboratory for reference ranges.

4.2.4 CSF Reference Ranges

These values represent the approximate upper and lower limits of normality particularly in neonates and children.

Normal CSF Values for: Leucocytes	Neonates <28 days Infants 1-12 Months Children/ Adults 1 Year +	0-30 cells x 10^6/L 0-15 cells x 10^6/L 0-5 cells x 10^6/L
Erythrocytes	Any age	No RBCs should be present in normal CSF
Protein	Refer to LF-BIO-0066 Biochemistry active test table on the Rotunda Hospital website:	Link: Laboratory Medicine - rotunda
Glucose	Refer to LF-BIO-0066 Biochemistry active test table on the Rotunda Hospital website:	Link: Laboratory Medicine - rotunda

4.2.5 Post Mortem Examination

For Hospital policy please refer to Policy on Post Mortem Practices in the Rotunda Hospital CD-CEA-PM001 on Hospital Q Pulse.
It should be noted that post mortem examination are not covered under the scope of accreditation.

Post Mortem Examination There are two types of post mortem examination:

(a) Consented Hospital Post Mortem Examination – most common type of post mortem, which can only be undertaken with the consent of the parents/next of kin. Written consent from parents/next of kin must be obtained before undertaking a post mortem. Staff undertaking the responsibility for obtaining consent must be fully familiar with the Rotunda Hospital Policy on Consent (CD-PM-CON-002) and the Hospital Policy CD-CEA-PM001. Staff is advised that in the case of a foetus or baby from a couple who are not legally married it is the mother who must give the consent.

Post mortems can be requested form the Rotunda Hospital and the NE perinatal pathology group.

(b) Coroner's Post Mortem – the Coroner has a legal responsibility to investigate a death in certain circumstances.

Parental/next of kin consent is not required. All cases >500grams and >24 weeks gestation are now reportable to the Coroner. If the Coroner declines to take the case, written permission to perform a post mortem must be obtained from the parent/next of kin using the Hospital (non Coroner's) post mortem examination consent form. This form, together with an information booklet for parents and families regarding post mortem examinations, is available on each ward. Parents/next of kin should not be asked for consent if the death is or has been referred to the Coroner. If the Coroner orders a post mortem examination to be carried out, parents/next of kin are not legally permitted to withhold consent.

Contact the Consultant Histopathologist via the Switch to discuss the case and to ensure that it is acceptable for a hospital post mortem examination.

The Dublin City Coroner's Office must be notified at the earliest opportunity on Telephone:01-8746684

- Out of hours only: Dr Myra Cullinane 086 2941446
- Email: coroners@dublincity.ie

The Coroner must be furnished with the deceased details as follows:

1. Name
2. Address
3. Age/Date of Birth
4. Circumstances surrounding death

4.2.5.1 Post Mortem Examination Reports

Completion and Availability of the Report: the majority of post mortem reports will be completed within 8 weeks of the post mortem examination. In some cases, due to the complexity of investigations required, the report will take longer. In the event that the report will not be completed within this time frame, the Pathologist will issue a provisional report to the requesting clinician/obstetrician.

Reports concerning Coroner's post mortems are sent directly to the Coroner and a report may not be available for the clinician/obstetrician until after the death certificate has been issued by the Coroner (approximately 3 months).

4.2.6 Placental Examination

Placental examination is ordered electronically through MNCMS on the patients chart.

In order to include any placentas that would be of clinical importance (particularly for paediatricians) the following criteria for placental examination will also be included:

Birth weight < 2.2kg

Apgar score < 5 at 5 minutes

Cord PH < 7.0

Dysmorphic baby / Congenital anomaly

The above criteria would automatically include infants admitted to NICU, perinatal asphyxia and sepsis.

Placentas received from the Delivery Suite or externally form NE perinatal pathology group are triaged upon receipt in the mortuary. Those that meet all the referral criteria above will be examined fully as per normal protocol. If the request form does not meet all the clinical criteria, the placenta will be examined grossly and a report issued indicating that further histological examination will only be performed at the request of the clinician. This request should be made to the laboratory by contacting extension 1442 within 2 weeks of issue of this report.

4.3 Tests Available on Saturday Morning

4.3.1 Biochemistry/Endocrinology Tests

1. Full Biochemistry service with the exception of the following: Urinary PCR, bile acids and Fructosamine.
2. Endocrinology (see below).
3. βHCG run on Saturday, Sunday and Bank Holiday AM.

4.3.2 Blood Transfusion

Full service is available for inpatients where requested.

4.3.3 Haematology Tests

1. FBC
2. Urgent blood films
3. Urgent Kleihauers,
4. Reticulocytes
5. Differential WCC
6. Coagulation Screen (PT, APTT, FIB) including. INR
7. Sickle Screen
8. Rapid ICT card test for malarial antigens
9. D-Dimers (Outsourced)

4.3.4 Microbiology Tests

Full service available with the exception of Andrology and Serology. Limited PCR available for SARS-CoV-2, Influenza, C. diff, HSV and CT/NG..

Urgent Serology samples will be sent to the NVRL.

Currently microbiology is providing daily SARs Cov2 testing. Contact the laboratory or the microbiologist for up to date schedule.

Note: There is a limited service available on Sunday mornings and Bank Holiday Mondays which is consultant led. Please discuss with the Consultant Microbiologist if you require a sample to be analysed.

4.3.5 Histopathology and Cytopathology

The histopathology and cytopathology service is not available on Saturday mornings or out of hours. Contact scientist on call for out of hours emergencies, who will then contact the consultant histopathologist on call. Frozen sections for surgical cases are not available at the time of issue of this manual.

4.3.6 Post-Mortem Examinations

For all post-mortem examinations, contact the consultant histopathologist on call, through the switch.

4.4 On call service

The on call service is provided by two scientists on site from 27th January 2023. Specimens for processing or samples requiring separation should be left in laboratory reception on the blue tray at the hatch. Any other specimens being left into the laboratory out of hours but which do not require processing until the next day should be placed in the specimen fridge (where applicable) in laboratory reception.

Monday to Friday

- **6pm to 11pm -** It is not necessary to bleep for every sample left in the call tray up to **11pm** as the tray will be checked periodically during that time. *However if a sample is critical or if blood products are required, the lab should be contacted on bleep 538.*
- **11pm-3am BLEEP 538** to contact the laboratory for all urgent samples.
- **3am-8am**, please phone the **on call mobile 086-2626101** for urgent samples/blood product requests.
- Urgent samples *only* are processed on call; these samples must be marked **URGENT**.
- Non urgent samples can be placed in the specimen fridge.

Weekends

- **Saturday:** on call begins at 12.45.

Sunday/Bank holiday:

- **12:45pm(sat) 9am (Sun/Bank hol) to 11pm -** It is not necessary to bleep for every sample left in the call tray up to **11pm** as the tray will be checked periodically during that time. *However if a sample is critical or if blood products are required, the lab should be contacted on bleep 538.*

- **11pm-3am BLEEP 538** to contact the laboratory for all urgent samples.

- **3am-9am**, please phone the **on call mobile 086-2626101** for urgent samples/blood product requests.

- Urgent samples *only* are processed on call, these samples must be marked **URGENT**.

- Non urgent samples can be placed in the specimen fridge.

NOTE: REMEMBER TO CONTACT LAB IF A CODE RED IS CALLED.

Refer to appendices of this SOP for full on-call communication protocol.

Ref: LI-GEN-0025 On Call Communication Protocol

4.5 Tests Performed On-Call

4.5.1 Biochemistry

All routine biochemistry (with the exception of the following: urinary PCR, bile acids and Fructosamine).

Urgent HCG's will be processed on Sat/Sun and Bank Holiday AM only

4.5.2 Blood Transfusion

1. ABO and Rhesus Groups and Antibody screens
2. ABO Group (cell) and Direct Coomb's Tests
3. Issue of Anti-D Immunoglobulin if patient will be greater than 72 hrs post sensitising event by next routine day.
4. Issue of blood and blood products to Paediatric patients
5. Crossmatch and issue of blood and blood products to adults
6. Antibody investigations for inpatients where indicated

4.5.3 Haematology

1. FBC and differentials.
2. Reticulocyte counts.
3. Coagulation Screen including Fibrinogen
4. Sickle Screens.
5. Malaria – rapid ICT card for malarial antigens. If ICT card positive on call a second scientist may be called in to perform malaria speciation and if appropriate % parasitaemia , pending consultant approval.
6. Kleihauer on consultant request where indicated, or for RhD negative patients if the patient will be greater than 72 hrs post sensitising event by next routine day.

4.5.4 Microbiology

1. CSF examination and culture
2. Fluids from normally sterile sites for examination and culture
3. Urine examination and culture
4. Culture of wound swabs when requested by the consultant Microbiologist
5. Pregnancy tests
6. **Blood cultures: loading onto analyser & examination and culture of positives. Blood cultures are brought to the attention of the scientist on-call to ensure bottles are analysed within 4 hours. Positive blood cultures will be reported within 2-4 hours of signalling positive, but delays may incur due to unforeseen emergencies.**
7. Positive Blood Cultures will be run on the BioFire FilmArray and reported directly to the consultant microbiologist.
8. Influenza testing on the GeneXpert routinely up until 10pm and by request of the consultant Microbiologist thereafter. During peak season Influenza testing will be performed 24/7.
9. Dispatch of emergency virology specimen to National Virus Reference Laboratory, with consultant approval dispatch of emergency Vancomycin levels to TSH.
10. GBS PCR on GeneXpert for LVS/Rectal Swabs

11. Any sample requested by the Consultant Microbiologist.

4.6 POCT (Point of Care Testing)

The following are available in various locations throughout the hospital as point of care testing:

- Glucose
- Haemoglobin
- Blood Gas Analysis
- Rotational Thromboelastometry (ROTEM)*
- Pregnancy Testing**

*ROTEM not under the accreditation scope

*Note this test is not covered under the scope of accreditation when performed at point of care.

If a problem arises during routine hours, contact the POC coordinator on Ext 2569.

Reagent supplies are available Monday to Friday 9am to 5pm.

For instrument errors OUT OF HOURS, contact the medical scientist on call through the switch. The scientist when time allows will review and where possible correct error - if not possible it will be deferred for routine staff the following day.

5. PREPARATION OF THE PATIENT

- Antenatal Glucose Tolerance Test – patient must fast from 12 midnight on the evening prior to the test. This means that they cannot take any food or drink **including water** on the morning of the test.
- First Void Urine – collection of urine is explained to the patient to ensure first void sample is collected.
- Consent for blood tests is the responsibility of medical staff i.e. HIV testing, genetic testing. Consent must include that data may be shared with third

parties (e.g. referral labs, government agencies like CervicalCheck and the NCRI)

5.1 Collecting Urine Samples for Analysis – Basic Principles

Ref.: Appendix No. 5 of this manual.

6. COLLECTION AND TRANSPORT OF SPECIMENS

Blood specimens must be collected in appropriate plastic leak proof containers with a push cap. The containers must be clearly labelled with the patient details and date. They must be placed inside the plastic envelope attached to the request form if utilised or placed in the plastic bag supplied if ordered on MN-CMS. Glass containers are not acceptable.

All other specimens must be collected in appropriate screw cap containers.

Specimens are collected form the wards at 10am, 2pm and 4pm.

6.1 Positive Identification of the Patient (PPID)

6.1.1 In-Patients

To comply with best practice all in-patients undergoing sample collection must wear an ID band, and where possible, for MNCMS patients, this ID band should be scanned when collecting samples.

6.1.1.1 The Conscious Patient with ID Bracelet

1. Ask the patient to state full name and date of birth, if appropriate.
2. Check the details given by the patient against the ID Bracelet and/or the patient's request form. **Ensure that patient's Name, Date of Birth and Hospital Number on the patient's ID bracelet correspond with the information provided on the request form.**
3. Resolve any discrepancy, no matter how trivial, before proceeding. If necessary seek assistance from nursing staff.
4. If unable to resolve discrepancies successfully, take a note and inform the clinical nurse manager/midwife and return the request form if used, to the clinical nurse manager/midwife for resolution.

6.1.1.2 The Conscious Patient without a ID Bracelet (exceptional circumstances)

1. Ask nursing staff to apply ID Bracelet with positive patient ID.
2. Ask the patient to state full name and date of birth, if appropriate.
3. Compare data and resolve any discrepancies before proceeding.

6.1.1.3 The Patient is Unconscious, Mentally Incompetent or does Not Speak a Language Familiar to the Phlebotomist

1. Ask nursing staff to positively identify the patient (never rely on the ID Bracelet alone).
2. Compare the data with details in the patient's request form and on the patient's ID Bracelet.
3. Resolve any discrepancies before proceeding.

6.1.2 Outpatients

Out-patients may not always have ID bracelets:

1. Ask the patient to state full name and date of birth.
2. Check request form and/ or patients clinical notes to verify patient ID information.
3. Resolve any discrepancy, no matter how trivial, before proceeding. If unable to resolve discrepancies successfully, take a note and inform the clinical nurse manager/midwife, return the request form if used, to the clinical nurse manager for resolution.

6.1.3 Positive Patient Identification of Neonates

All newborn babies must have two identification bands applied at delivery. These must contain the following details:

- Baby Name
- Baby Hospital number
- Date of birth
- Sex of Baby
- Ask the baby's mother or guardian to state the baby's name and date of birth.
- Verify verbally with the mother or guardian the baby's details.

- Check the details given by the mother or guardian on the baby's ID band. Any discrepancies detected must be resolved before sampling.
- If a parent or guardian is not present details on the baby's identification band must be checked with details on the baby chart.

6.1.4 Paediatric Out-patients

These babies do not wear an ID band. A parent or guardian should be present when taking blood sample to ensure positive patient identification

- Ask the baby's mother or guardian to state the baby's name and date of birth.
- Verify verbally with the mother or guardian the baby's details.
- Check the details given by the mother or guardian on the baby's clinical notes and request. Any discrepancies detected must be resolved before sampling.

6.2 Collection of Blood Sample

Ref.: CM-PHL-0001 Blood Sampling in Phlebotomy

6.2.1 Action to be taken if there are Patient Problems

1. If an artery is entered accidentally, remove needle and apply pressure to the site, seek nursing/medical assistance.
2. If the patient becomes nauseous, provide reassurance, make patient comfortable instruct patient to breathe deeply and slowly.
3. If the patient faints, seek midwife, nursing or medical staff.
4. If a patient objects to tests do not argue with the patient but emphasise the tests were requested by the patients doctor. Report the patient's objections to the midwives/nursing/medical staff.
5. **Do not proceed without the patient's permission**.
6. If patient expresses objection to venepuncture, phlebotomy does not proceed, inform the midwife or clinical nurse manager in charge.
   Ref.: Par 6.1 Phlebotomists Association of Ireland Code of Practice 1996
7. Report all incidents to department head.
8. If patient enquires about test results, advise patients to discuss with nursing/midwifery/ medical staff.

6.3 Disposal of Materials used in Sample Collection

When finished, both apron and gloves must be disposed of in the clinical waste bin provided. This is located inside the patient's room. Dispose of all sharps used in the bins provided.

6.4 Containers

6.4.1 Minimum Patient Data required on a Specimen Container (except for Blood Transfusion and Histology)

- Hospital Number (preferable identifier)/ Date of Birth
- Surname
- Forename

Desirable data items include:

- Date/Time of Sampling
- Signature of sample taker (if handwritten)

Scanning of patient ID band is encouraged to produce a barcoded label containing patient demographics and test request.

For Blood transfusion samples, where PPID is removed (i.e. 'unable to scan barcode id' is selected or available for use), specimens for analysis must be HANDWRITTEN.

.

If there are any difficulties in scanning Patient ID bands, a handwritten sample is acceptable in blood transfusion once it is labelled with the patient's forename, surname, hospital number, date of birth and signature of sample taker.

Unlabelled samples and non-conforming sample/request forms will not be processed – exceptions are CSF, blood culture post commencing antibiotics and histology samples, after completion of amendment form (refer to LF-GEN-0013 Specimen Request Amendment Form).

6.4.2 Patient Data Required On Specimens for Histology

Histology specimens must be accompanied by a Histology Request form that outlines the clinical indication for the specimen. Histology specimen container must have a minimum of 3 identifiers:

- Hospital Number
- Patient Name
- Date of Birth

All specimens should be received in formalin fixative in the laboratory with the exception of:

A. Genetic Studies: Specimens for cytogenetics are to be sent to the laboratory immediately without fixative. **Do not put any part of the specimen into fixative**.

B. Specimens requiring microbiological culture: If a specimen requires microbial studies also, it should be sent down to the laboratory fresh.

C. Urgent frozen Sections.

D. Fluid Samples: Fluid samples for cytology should be **sent fresh**.

6.4.3 Patient Data Required on Specimens for Blood Transfusion

- Surname and forename (no forename is required for babies unless recorded in NM CMS or iPIMS, or if baby is readmitted and iPIMS record has been updated)
- DOB
- Hospital number /address if not a Rotunda hospital patient see below.
- Date of collection and where possible time.
- Signature of person taking the sample (if PPID not used)

Scan the patient's ID band when collecting the sample for MNCMS patients. In cases where this is not possible or if the patient is not on the MNCMS system, blood transfusion specimens must be handwritten and signed; samples without hospital numbers will not be processed. The only exception to this is home birth from Domiciliary midwifes or GP samples for anti-D issue where no hospital number is available. In this case, the patient address is the third unique identifier. It is the responsibility of the independent midwife/GP to positively identify the patient.

Where inadequacies in details exist, the specimen will be rejected.

There is a request form available for GP samples - RF-BT-0003. This is available from the hospital website under GP information

6.5 Specimens Received from Outside Users

Specimens are accepted by individuals (where tests have been ordered by a clinician), GP's, couriers or delivered by post to the laboratory reception.

Pathological specimens must be packaged in accordance to the Packaging Instructions P650.

1. The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport. Packaging shall be constructed and closed to prevent any loss of content that might be caused under normal conditions of transport.
2. The packaging shall consist of three components:
    a. A primary receptacle
    b. A secondary packaging, and
    c. An outer packaging
3. Pathology material must be placed in a securely closed, watertight primary container such as a test tube, vial, etc.
4. The primary container(s) must be enclosed in durable, watertight, secondary container. Several primary containers may be enclosed in a single secondary container. If multiple fragile primary receptacles are placed in a single secondary container, they shall be either individually wrapped or separated so as to prevent contact between them.
5. The primary container(s) shall be packed in secondary packaging in such a way that under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging.
6. A label indicating universal precautions is attached to the rigid secondary container. The label is not visible on the outer cover of the postage package but is visible to whoever unpacks it before the rigid protective secondary container is opened. Clinical information/patient details must be concealed from view.

7. The secondary container shall be secured in outer packaging with suitable cushioning material. Any leakage of contents shall not compromise the integrity of the cushioning material or of the outer packaging.
8. Labels indicating a danger of infection must only be used for specimens which are suspected of containing a hazard pathogen so that all such specimens can be easily identified and transported directly to the appropriate laboratory department.
9. The name and address of the sender is put on the back of the licensed container in case of damage or leakage.
10. For transport the mark UN 3373 shall be displayed on the external surface of the outer packaging in a diamond (sides measuring at least 50mm x 50mm) on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2 mm; the letters and number shall be at least 6 mm high.

7. REQUESTING TESTS

The requesting clinician can order a test/s by ordering electronically on MN-CMS and attaching the generated barcode label to the sample. MN-CMS is applicable for all maternity, newborn, and gynae patients. Request forms may be used for other patients or as a contingency if the electronic chart is inaccessible.

It is the responsibility of the requesting clinician and person collecting patient specimens to ensure that request is correctly completed.

The requesting clinician must complete the appropriate request in full, including clinical details. The personal information received is treated as confidential in line with the hospital policy on personal information. If a request form is being used then it must remain attached to the specimen transport bag.

If samples are ordered electronically then the barcode label must be placed correctly on the sample container and multiple samples maybe placed in the bags provided preferably separated into each discipline.

The Rotunda Hospital has request forms covering all laboratory disciplines.

Please ensure that the barcode is fixed correctly to the container (See figure 1 below). Ensure that the correct label is fixed to the correct bottle, e.g. UE test on

Lithium heparin bottle. If the label is not correctly aligned, analyser barcode scanners will be unable to read the specimen.

Figure 1: Labelling of a Specimen Bottle

7.1 General Requests (not Blood Transfusion/Thrombophilia)

7.1.1 Requesting a Test

It is important to remember that this communication is the definitive and, at times, the only communication between the clinician requesting the test and the scientist performing the test. Please ensure that all relevant information is included on the request form.

All requests must contain the following items:

- Hospital Number (for hospital patients only)
- Surname
- Forename
- Date of Birth
- Address
- Specimen Type (for histology and microbiology)
- Ward/Location
- Date & Time of Collection (completed by person taking sample)
- Requesting Clinician (Team or GP name for out-patients)

- Signature of sample taker
- **Clinical Details & Gestation where relevant are VERY desirable and may be significant in the review of results in cases.**

Desirable but Not Essential Useful Information:

- Medication (important in Microbiology investigations)
- Previous History
- Gender in particular for patients attending infertility clinics where partners are attending.

NOTE: Large addressograph labels are acceptable on all request forms.

NOTE: SATU specimens are identified only by the following:

- A unique number
- Initials
- Date of Birth

NOTE: If a specimen is received with a referral letter, the letter is used as a substitute for the request form. Any discrepancies are resolved by telephoning the GP prior to analysis.

NOTE: Requests for Group B Strep PCR for the IMSRL must be completed on the IMSRL request form. Request for genetics analysis must be accompanied by appropriate referral laboratory request form. For foetal/Paediatric use a Crumlin request form for adults a TDL request form.

Link-TDL genetics and user page link https://tdlpathology.com/services-divisions/tdl-genetics/

NOTE: TESTING WILL NOT PROCEED IF REQUESTS ARE NOT COMPLETED IN FULL. This applies for add on tests being ordered. An additional request form or printed requisition (MN-CMS) must be sent to the laboratory in a timely manner.

7.1.2 Specimens

With the exception of Blood Transfusion and Histology, specimens must be labelled with a minimum of two unique identifiers i.e. full patient name and hospital number.

Note: Histology specimens are required to have three identifiers (hospital number, full name and D.O.B.) as stated in Section 5.4.2.

In the case of twins, it is preferable to also mark specimens twin I and twin II. For external patients, the date of birth replaces the hospital number.

NOTE: Small addressograph labels are acceptable on all specimens other than blood transfusion, once they hold the minimum information required. Barcodes generated form ordering samples on MN-CMS are acceptable on all samples.

When a semen sample is received for fertility analysis, the time of sample collection must be included on form.

Inadequacies in details **must** be resolved before specimen is processed.

Note: It is NOT acceptable to cross out patient's details on an addressograph label and write partners details in its place. Either place a new addressograph label on the sample or write on the sample bottle in the space provided.

7.2 Microbiology Requests

1. Swabs: site must be specified on request, and full clinical details given.
2. Semen samples for infertility: time of collection must be included. The laboratory operates an appointment system for infertility semen analysis. Patients are required to phone the laboratory office to book an appointment to leave the specimen. **The specimen must be received within one hour of being produced.** The laboratory has facilities for patients who may need to produce a specimen on site. This facility must be booked by appointment. Patients will be required to fill in a short form upon arrival at laboratory.
3. PCR and viral load samples: must be delivered to the laboratory immediately and brought to the attention of a medical scientist.
4. **Blood Cultures must be received in the laboratory within four hours of the sample being taken.**
5. **CSF Samples must be hand delivered to the laboratory staff.**
6. **Samples for SARS-CoV-2 PCR are not performed out of hours and should be left in the fridge until the next day. Samples are run seven days a week and results will be reported within 24 hours of receipt.**

7. **Samples for *C. difficile* are performed 7 days a week, however samples NOT taking the shape of the container (Formed/semi-Formed), will be rejected.**

7.3 Thrombophilia Requests

There is a specific request form for thrombophilia and Lupus anti-coagulant testing and the request form must be completed in full. This is available from the laboratory and on the intranet on the Laboratory/Haematology webpage. With the agreement of the consultant haematologists requests for Lupus anti-coagulant maybe processed with a request form from certain locations e.g recurrent miscarriage clinic

7.4 Blood Transfusion Requests

7.4.1 Request

All requests must contain the following items:

- Hospital Number (for hospital patients only)
- Surname
- Forename
- Date of Birth
- Date, Time of Collection and signature (completed by person taking sample if handwritten))
- Details of requester or Team/ consultant details (signature if handwritten)
- Clinical Details & Gestation where relevant

All requests should contain the following information:

- Address
- Ward/Location
- Team/Consultant
- Medication
- Previous History

Please ensure there are contact details provided for ALL URGENT REQUESTS.

NOTE: Large addressograph labels are acceptable on all request forms.

7.4.2 Request for Blood/Blood Products

Requests for blood must be made by printing off the blood product requisition from MN-CMS and sending it to the laboratory or a handwritten request form sent to the laboratory.

NOTE: The laboratory is not notified of the blood product request unless the printed request is brought to the laboratory or a verbal request has been made over the phone.

An urgent request for blood products may be placed by phoning the blood transfusion laboratory on extension 1463/1464. This must be followed up by a printed/handwritten requisition.

Requests for Blood and blood products should, in addition to the information in 6.4.1 also contain the following information:

- Previous transfusions, obstetric history, red cell antibodies or any adverse reactions
- Special requirements , if required e.g irradiated, CMV neg etc
- Type and number of blood products required and when. When requesting factor concentrates the brand name, for instance Alprolix,, Elocta, NovoSeven, must be requested and not the factor name Factor 8. When requesting albumin, the concentration required, either 5% or 20% must be stated.

Providing there are no antibodies, cross-matched blood is available in approximately 40 minutes.

Platelets are not held on site and can usually be available within one hour.

Factor concentrates may not always be held on site depending on the type. A limited number of the most common concentrates are stored. Contact blood transfusion laboratory as early as possible.

Plasma, fibrinogen and Novo Seven are held in the hospital and plasma can be available within 30 minutes of request. Novo Seven must be administered following consultation with a haematologist.

Please refer to hospital Q-Pulse for further information.

NOTE: testing will not proceed if requests are not completed in full.

7.5 Histology Requests

All specimens for histology and cytology must be accompanied by a completed request form that contains information about the type of specimen and relevant clinical information (why the specimen was taken). Where an order is placed theough the order communications function of MN-CMS, the requisition form must be printed and accompany the specimen to the lab. If it is not possible then the backup system is to complete a request form by hand.

7.6 Post Mortem Examination

For all types post-mortem examinations, contact the Consultant Histopathologist.
The hospital policy **must** be adhered to and may be accessed on Q-Pulse .
Ref.: CD-CEA-PM0001 Policy on Post Mortem Practices in the Rotunda Hospital
The Pathology Request Form PA 1064C and Hospital Consent Form for Post Mortems PA1064A for all types of pm **must** be completed and sent to the mortuary. These forms for all types of post mortems are available from the wards and from the assistant director of midwifery on duty out of hours.

7.6.1 Placenta Request Form

The placenta order details should be completed on the electronic order and the request form printed from the electronic chart in all cases in which a placenta is submitted for examination.

8. QUALITY OF SERVICE

Requirements with respect to completing the request and to labelling specimen must be followed; a non-conformance will result from the following reasons:

Specimen Issues	**Action**	**Documentation**
• No specimen received • Specimen not identified • Specimen unlabelled • BT samples labelled incorrectly e.g. PPID override, no signature if handwritten • Mandatory identifiers must be on specimen	A second specimen must be collected or specimen taker must take responsibility in cases of an emergency (note for BT, only emergency uncrossmatched blood products will be issued) or where the specimen cannot be repeated. If tested the report will reflect the non-conformance. Exceptions are CSF, blood cultures and histology specimens where samples cannot be repeated. Allow sample taker to correct error.	If specimen is processed LF-GEN-0013 Specimen Request Amendment Form is completed. A non-conformance may be raised.
Request/ordering Issues	**Action**	**Documentation**
• Inadequate or incorrect patient details. • Incorrect/No test requested • Ordering physician not identified • Specimen collected at incorrect time /date or time of collection not indicated. • Sample not marked at ``collected`` on the powerchart	A second specimen is requested if the requester or clinical staff looking after the patient does not correct error. Laboratory has to contact clinical area and request the sample be collected	If specimen is processed LF-GEN-0013 Specimen Request Amendment Form is completed. A non-conformance may be raised.
Specimen / Quality Issues	**Action**	**Documentation**
• Evidence of Haemolysis • Gross lipemia • Presence of clots • Age of specimen	**The laboratory will decide on whether the specimen is suitable for the requested test.** A repeat sample will be requested as appropriate. If tested the report	Not Applicable

	will show the non-conformance.	

Where specimens from MNCMS are not labelled appropriately, e.g. barcodes not straight on bottle, incorrect test on incorrect sample type, a delay will occur in processing sample or the specimen may be rejected.

Where barcode ID band is not scanned for Blood Transfusion samples, this sample is not suitable for crossmatching and a repeat will be required.

Criteria for Specimen Rejection (Other than Labelling Discrepancies)

Department	Insufficient Specimen	Clotted	Haemolysed	Incorrect Specimen Type	Age of Specimen	Incorrect Anticoagulant	Leaking Specimen	Inappropriate Test Request
Haematology	●	●		●	●FBC>2hrs Blood films >8hrs*	●	●	●
Coagulation	●	●	●	●	●>4hrs	●	●	●
Blood Transfusion	●	●	●	●	> 24 hrs at RT	●	●	●
Biochemistry	●	●	●	●	●>24hrs	●	●	●
Endocrinology	●	●	●	●		●	●	●
Microbiology	●		●	●	● Urines>24hrs Semen for Infertility >2hrs Post Vasectomy Samples >3 days, incorrectly packaged, no form received or leaking Viral Load >24hrs Stools – Formed Samples	●	●	●
Virology serology	●		●	●	●	●	●	●
Histology	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Cytology	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

*Specimens must be kept refrigerated.
These are the most common reasons for specimen rejection. It is not possible to document every probable situation. However if the medical scientist considers that the specimen quality will adversely affect the test result the specimen will be rejected.
Histology laboratory does not reject any specimens. Microbiology and Biochemistry will not reject CSF samples.
Stool samples that do not take the shape of the container will be rejected for *C. difficile* and/or *Norovirus*

9. SPECIMEN RETENTION POLICY

The following information is in accordance with the guidelines of the 'The Retention and Storage of Pathological Records and Archives' – 5th Edition Royal College of Pathologists 2015 and the National Pathology Accreditation Advisory Council 'Retention of Laboratory Record and Diagnostic Material' 2nd Edition.

The recommendations that follow outline the minimum retention time for various clinical materials.

There are separate storage facilities for:

- Clinical material
- Blood and blood products

Storage facilities are in accordance with current legislation, regulations and guidelines.

9.1 Specimens and Preparations

Specimens and Preparations	Retention Time
Histopathology Samples	
Surgicals - wet tissue	Minimum 4 weeks after issue of final report
Paraffin blocks-and slides	Held for minimum 30 years (Initially in Histopathology in storage and then in offsite storage facility)
Frozen sections	As Paraffin blocks see above
Placentae	Minimum 1 month
Post Mortem Samples	
Blocked tissue	Minimum 30 years
Slides	Minimum 30 years
Cytopathology	
Slides	Held for minimum 10 years in offsite storage facility
Cytopathology specimens and preparations	Minimum 4 weeks after issue of final report.
Biochemistry/Endocrinology Samples	
Routine Plasma, Serum (adult) and baby	7 days
Original Paediatric specimen, urine	End of day reported
CSF / HbA1c / Urine samples	7 days
Referred Blood specimen	Specimen not retained as entire primary sample is sent out. In the case where sample requires additional testing at the RHD the sample is held for 1 day as above.
Microbiology Samples	
Swabs including GBS, pus, Fluids, tips, stool and specimens sent for examination except *	2 days at RT
*Urine specimens (Culture or HcG)	24 hours at Room Temp
*Blood cultures - negative	Not <5 days on BacT Alert
*Blood Cultures - Positive	Once Final Report authorised
*Blood samples for serology-blood	2 weeks Refrigerated
*Serology separated samples-sera	2 years Frozen (-20)
*CSF specimens	1 week refrigerated
*STI – Negative Samples	End of day testing at RT
*STI – Positive Samples	12 Weeks Frozen at -20
*Stool Samples – Positive for Norovirus/C. diff	Frozen at -20 for 2 years
*Semen	End of testing day at RT
*SARS-CoV-2 PCR and other Respiratory Samples (eNAT or UTM)	1 Week at RT for Negative and 1 Month Frozen at -20 for Positive
*HSV 1 or 2 Positive	12 weeks frozen at -20
*Placentae (referred from P.M. room)	End of testing day at RT
Culture Plates	1-2 days at RT
Significant isolates selected	5 years "Protect beads" (-20)
Stained slides	2 weeks** at RT
All MRSA	indefinitely "Protect beads" (-20)
Any significant isolate	5 indefinitely "Protect beads" (-20)
Isolates from QC	indefinitely "Protect beads" (-20)

** Some slides are kept for educational purposes pertinent to Microbiology.

***Some slides are kept for educational and training purposes.

Haematology & Blood Transfusion Samples	
FBC/Coagulation	At least 6 days post testing
Blood films/Kleihauer slides	Minimum 6 weeks***
Lupus/Thrombophilia Testing	At least 4 weeks post issue of report
Haemoglobinopathy samples	Discard post checking of report
Adult plasma for group/save and/or x-match/flow	At least 2 weeks ****
Babies blood/cord blood for group/DCT	At least 1 week

****** Antenatal and Maternal plasma 72 hrs pre or post-delivery for at least 4 months**

Some plasma samples are kept for educational and training purposes.

9.2 Residual Samples for Research Purposes

The laboratory must seek explicit consent through the Consultant in charge of the patient from patients/guardians in order to use residual or surplus samples. In the absence of explicit consent, prior approval must be granted by the Hospital Ethics Committee in order that samples may be used for purposes other than the examinations requested e.g. method development. If used, all samples must be anonymised.

With certain unique samples, e.g. dried blood specimens or biopsies, only a portion of the sample must be used. Sufficient sample must be retained in the event of further investigations being required.

Residual or surplus samples may only be used for research related to a specific or group of disorders provided prior approval is granted by the Ethics Committee or appropriate body. Ethical approval must be sought independently for every proposed study. Policy on use of residual samples for research purposes is under constant review by Hospital Ethics Committee. Specimens received for routine processing may be used for quality control purposes.

9.3 Post Mortem Material

Disposal of post mortem material is currently undertaken at the family's wishes. Following the post mortem, on the rare occasion that there might be any retained organ/s these are stored in the mortuary in formalin fixative until all results are finalised and post mortem report complete (generally about 8 weeks). In some cases, due to the complexity of investigations required the report may take longer.

Depending on the wishes of the parents, retained organs / tissue are stored in the PM room until returned to them for burial or cremation. Otherwise they are disposed of according to hospital practice.

Ref.: CD-CEA-PM001 Policy on Post Mortem Practices in the Rotunda Hospital

10. REPORTS

Results will be telephoned:

- When previously arranged, e.g. on "Urgent" samples with prior verbal notification
- When asked to do so on the request
- When results may be of relevance to immediate clinical management.

The method by which this is done is clearly defined to ensure the results only reach an authorised receiver and that results are clear and unambiguous. The security of the personal records is ensured and the risk of error reduced.

Reports are available to all users on APEX & MN CMS once they have been authorised by the laboratory.

Results provided verbally are followed by a electronically generated report to the powerchart. or a hard copy if not on MN CMS

Reports contain all relevant reference ranges.

Faxed reports are no longer available the Rotunda laboratory

10.1 Issuing of Reports during Normal Opening Hours

Results are entered/sent into the laboratory information system (APEX) and authorized upon completion. By default these results are available on the electronic chart. Results of requests, which have been accepted (agreed) as urgent, are

phoned to the relevant ward/GP, as are abnormal results which fulfil the department's result phoning criteria.

Tests which were requested on the MN-CMS once authorised, the result is sent automatically to the chart on authorisation on APEX.

Where results are not available on MN CMS, The report is printed and placed in the correspondence pigeonhole. Hospital reports are delivered to wards and clinics (Mon-Fri) if a manual request was received on a request form.

Reports returned from external referral laboratories are included in the routine report deliveries if a paper health care record is being used.

In the case of the MN-CMS then the returned report is scanned and attached to the patients record.

Hospital reports to external users are posted to the requesting clinician.

10.2 Issuing of Reports On-Call

Results are entered and are authorised into the laboratory information system (Apex),Electronic results are transmitted to MN-CMS as they are authorised on APEX.

Any abnormal results will be telephoned to the ward or to the requesting clinician. Results are available on the APEX system once testing is authorised. Where calls originate from external agencies the results are phoned and a written report dispatched on the first working day the referral laboratory when received.

10.3 Ward Access to Laboratory Results

Once laboratory results are authorised, they are available for access via PC's at ward and clinics. Results available on MN-CMS can be viewed by staff who are authorised to log on to the system. Users who have been given access to the PAS system may apply to the laboratory for an individual APEX password, which will allow access to ward enquiry (WENQ). Passwords must not be shared. Apex maintains a record of which results were viewed by whom and at what time.

Instructions on how to access laboratory results are included below see Appendix 1 and are available on the Hospital Intranet under Laboratory.

10.4 Clinical Advice and Interpretation on Reports

Laboratory Management ensure that advice on the selection of examinations and the interpretation of results is available to meet the needs and requirements of users. The quality of this advice relies on the clinical advice provided by the clinical staff.

This advice, where required includes:

- The choice of examinations and the use of the services including repeat frequency and the required type of specimen.
- The precision and accuracy of methods used in the Laboratory
- The clinical significance of results and their relation to reference ranges
- Where possible the suitability of the requested analyses to solve the clinical problem in question
- Additional examinations which may be helpful
- The necessity for repeat examinations where appropriate

For further clinical advice and interpretation on laboratory results please contact individual laboratory sections as detailed in Section 3.1 of this document.

11. TIME LIMITS FOR REQUESTING ADDITIONAL EXAMINATIONS

Department	Time Limit
Biochemistry	
Biochemistry	Dependant on test required 4 to 24 hrs from venepuncture
Endocrinology	Dependant on test required (max 7days)
Haematology	
FBC	Same day
Reticulocytes	Same day
Malaria	Same day
Coagulation Studies (Incl Lupus + Thrombophilia)	3 hours from venepuncture
ESR	Same day
D-Dimer	6 hours from venepuncture
Kleihauer	48 hours
Sickledex	Up to 7 days
Haemoglobinopathy	Up to 7 days
Microbiology, Histology & Blood Transfusion	
Microbiology	Two days unless sample frozen – See retention times
Histopathology/ Cytopathology	4 weeks-generally histopathologist not clinician decides on what additional histology tests will be performed.
Serology	2 Years. Requires Written Request
Blood Transfusion	Adult Patients will require two groups prior to issue of group specific blood and blood products.
Albumin, Fibrinogen and Factor concentrates	For these batch products e.g. factor concentrates, no group is required, only a completed request form.
Adult Red cell transfusions	For ante/post natal patients RCC transfusions may be requested so long as the transfusion will be completed within 72 hours of the sample being taken. For gynae patients within 7 days of the sample being taken provided they were not transfused within the last three months
RAADP	Will be issued for patients on the basis of a booking visit RhD negative blood group provided they are less than 32 weeks gestation on administration. For patients >32 weeks a sample is required prior to issue.
Group specific blood products	For plasma and platelets, adult patients must have been grouped within last month and preferable not discharged.

Department	Time Limit
Paediatric red cells and group specific blood products	For antenatal issue of Anti-D Immunoglobulin sample must be taken within 72 hours of sensitising and Anti-D Immunoglobulin administered within 72 hours of event. Additional Anti-D Immunoglobulin may be issued for up to 6 weeks post administration of the initial Anti-D on the same request. With the exception of Anti-D Immunoglobulin, a written request must be received for all products. For patients less than 12/40 weeks gestation Ig anti-D will be issued on samples within 7 days of venepuncture For Babies issue of RCC's requires a least one group and DAT on the baby, and a negative antibody screen, either on a maternal sample not more than 72 hours prior to delivery or post-nataly, otherwise a repeat baby sample is required for antibody screen and possibly crossmatch. A second babies group is required for group specific Blood products.
Anti-D immunoglobulin for TOP cases	Anti- D will be issued to patients availing of TOP service as required determined by blood group.
FREDA Test	The FREDA test is sent out to the IBTS and has a 2 week turnaround time. It's preferable not to take before eleven weeks.

For any other queries, contact the relevant laboratory.

11.1 Requesting Additional Examinations (Verbal Requests)

Users of Laboratory services may request additional examinations on specimens already sent to the Laboratory provided that the Laboratory has sufficient specimen remaining to perform the additional tests and that the specimen is still of optimal quality to allow the reporting of accurate and meaningful results.

Additional requests for examinations may be made verbally over the telephone. The Medical Scientist receiving the phone call will, if necessary, discuss the additional request with senior personnel before accepting the request. This is to ascertain the benefits of re-testing a sample that may or may not be suitable for re-testing at the time of request. **The requestor MUST forward an additional request form or printed requisition generated from the MN-CMS documenting the 'add –on' test**

or a MN CMS label. The requestor should note the accession number of the sample on the request to allow the laboratory identify the sample for additional testing.

For requests of tests carried out at the NVRL a request form must be sent to the serology laboratory with the additional test marked on the request form. The laboratory staff will then contact the NVRL.

11.2 Requesting Repeat Examinations

On occasion the Laboratory may request a repeat sample for examination for the following reasons:

- Failure of the initial testing process.
- Unsuitability of the specimen.
- The necessity as advised by the Laboratory for further examinations on the original sample.
- Concern of Laboratory staff at authorisation stage over the validity of the results relative to recent previous results on specimens from the same patient.

12. PROBLEMS / COMPLAINTS

Minor: Please phone or email the chief medical scientist in the department concerned (see list at the front of this manual) or contact the laboratory /quality Manager

Major: Write or mail to the Laboratory / Quality Manager or Director of Department of Laboratory Medicine Services.

13. REPERTOIRE OF TESTS

Individual tests available and test guidelines can be viewed on the Active Test Repertoire table.

Tests referred maybe viewed on the Referred Test Repertoire Table

Ref: LF-GEN-0066-71& 0076 Active Test Table and LF-GEN-0072 Referred Test Table

Blood Tube Guides are available on Q-Pulse, the hospital intranet and in clinical areas.

14. ORDERING TESTS ON MN-CMS

Refer to the following documents:

- LI-GEN-0016 MN-CMS Quick Reference Guide for the Department of Laboratory Medicine
- LI-GEN-0017 MN-CMS Quick Reference Guide for Blood Transfusion
- LI-GEN-0018 MNCMS Frequently Asked Questions

These documents provide the user with information on ordering the tests on MN-CMS, collection requirements and information on labelling, placing in the supplied bags for collection and transport to the laboratory.

15. APPENDICES

1. Appendix No. 1: Accessing Laboratory Results on Apex
2. Appendix No. 2: Protocol for Intrauterine Transfusions (IUT) in the Rotunda Hospital
3. Appendix No. 3: Management of Adverse Transfusion Reactions/Events
4. Appendix No 4: EX-MICRO-0319 Recommended Swab Types
5. Appendix No. 5: Collecting Urine Samples – Basic Principles
6. Appendix No. 6: Collecting Blood Culture Samples
7. Appendix No. 7: Flow Chart of Laboratory On-Call

Appendix No. 1: Accessing Laboratory Results on APEX

To Log on:

- Click on the Apex icon on your desktop.
- At the prompt "login" type in APEX.
- Your "Username" is usually your surname followed by first letter of your forename.
- Enter your password.
- Three options appear on the screen.
- 1. WRNQ – for Ward Enquiry.
- 2. UPASS - to change your Password.
- 5. X - to Log off system.

To Look up Laboratory Results:

- Option 1 will bring up the enquiry screen
- Enter the patients Hospital no. then the first two letters of the Surname.
- Type in 2 or S to select specimen list, return x2. This brings up the list of specimens requested on the patient.
- Use the down arrow key to scroll down to the result required and when it is highlighted hit return to bring that result up on screen.
- **NB: In Apex you use the page up & page down keys on the key to search back for previous results NOT the up and down arrows**
- Cumulative reports available by typing U as option at end of reports page Remember you may need to use the down arrow to scroll up and down the page to see all the results. You will need to type X to exit the cumulative option.
- When finished type X to exit the results page, type X to exit the ward enquiry and finally type X to exit APEX.

To Change your Apex Password:

Apex will count down a reminder that your password is expiring. Change it before it expires, as if it expires you are locked out and your password has to be reset from the Laboratory.

- Option 2 will bring up the change password screen.
- Enter your current password.
- Enter your new password twice (minimum six characters) and return to accept. The system will now automatically log you out and ask you to log on again with your new password. This is now valid for a further 90 days.

Appendix No. 2: Protocol for Intrauterine Transfusions (IUT) and Neonatal Allo-immune Thrombocytopenia (NAITP) in the Rotunda Hospital

REQUESTS FOR IUT'S

The Blood Transfusion Laboratory should be informed of the intrauterine transfusion at least 5 days in advice of the procedure. This is to ensure the availability of antigen negative blood for the IUT. The notification form for intrauterine transfusion must be commenced at this time.

It is preferable to arrange an IUT for a Wednesday, Thursday or Friday and following a bank holiday weekend it is preferable to arrange the procedure for a Thursday or Friday. This is in order to provide the freshest blood available for IUT.

Sample Requirement for IUT'S s:

Take a maternal blood transfusion sample at least 48 hours but not more than 72 hours pre IUT. See sample and request form requirements for blood transfusion.[1]

NAITP

If ordering platelets for a neonate the Blood Transfusion Laboratory should be informed

If there is clinical suspicion of NAITP, so the appropriate platelet product may be ordered from the IBTS.

The following investigations are necessary to make a diagnosis of NAITP:

Screening of maternal plasma against common known platelet antigens and additional screen for GOV antibodies.

Screening of maternal sample against paternal platelets (requires source of fresh paternal platelets) to exclude the presence of a low incidence antibody as a cause of NAITP #

Genotyping of mother, father and baby for HPA 1-5 antigens.

Samples are currently referred to Platelet Immunology Reference Laboratory in UK for these assays.

NOTE: cases of NAITP occur where there is no identifiable antibody. Where there is a strong clinical suspicion of NAITP the mother should be advised about the possible risk of recurrence in future pregnancies and the importance of early fetal medicine assessment when she does become pregnant.

Request Form and Sample Requirements:

Please complete the IBTS NAITP request form which includes the clinical information required, available in laboratory. The following samples are required (correctly labelled with patient's full name, date of birth, hospital number if available and date of collection):

10-20mls clotted and 5-10mls EDTA blood from the mother.

10-20mls in EDTA from the father and Paediatric EDTA sample from the baby.

Inform the IBTS Duty Registrar or Consultant (01 4322800) of all urgent investigations for NAITP (where neonatal platelet count is <50 or platelet transfusion may be required).

Appendix No. 3: Management of Adverse Transfusion Reactions/Events

A Serious Adverse Reaction is an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in or prolongs hospitalisation or morbidity.

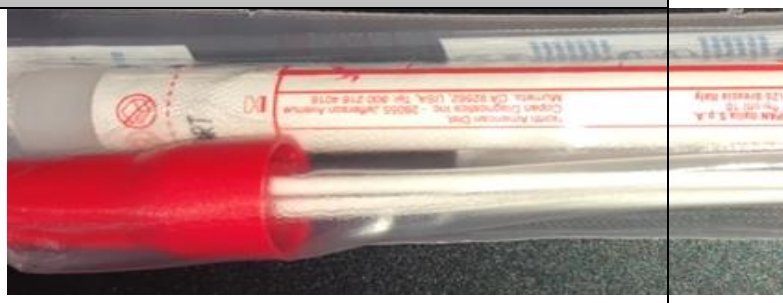
A Serious Adverse Event – can be defined as "any untoward occurrence associated with the collecting, testing, processing, storage and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs hospitalisation" e.g. Incompatible blood component transfused to a patient.

Management of a Serious Adverse Reaction

Like other treatments blood can benefit or harm the patient. Good treatment decisions balance the likely benefit against the potential risks for each individual patient. When a reaction occurs the appropriate management can reduce the harm to the patient reporting, and investigating the event can help reduce the risk of its reoccurrence.

- **When a transfusion reaction is suspected STOP unit and check identification of patient and the ABO group of the patient and donor unit IMMEDIATELY. Inform the blood transfusion department immediately as another patient may also be at risk of receiving the wrong blood.** Contact the Laboratory at 1464/1463 or on-call bleep 538 and the Haemovigilance Officer bleep 725/ ext. 6803.
- **Contact medical doctor to assess & manage patients symptoms**
- **Inform Consultant Haematologist, this can be done through the laboratory or switch board.**

LF-BT-0023 Transfusion Reaction Investigation Form **must be completed by the Medical person attending the patient.** These forms are available at the back of Prescription and Administration Record for Blood and Blood Components booklet. A flow chart for Management of Transfusion Reaction is also available in this booklet. Ref.: LF-BT-0023 Transfusion Reaction Investigation Form

Appendix No. 4 **Recommended Swab TypesTEST**	**MN-CMS code**	**SWAB NAME**	**COLOUR of SWAB TOP**	**IMAGE**
GBS PCR	**Group B Strep GeneXpert RH**	**Transystem Sterile transport: 2 Prongs**	**Red**	
Bacterial culture **(endometritis, chorioamnionitis, perineal wound infection)** **Screening Swabs**	**Culture and Sensitivity** **RH**	**Transystem Sterile transport: 1 prong**	**Dark blue**	
PCR for Bacterial Vaginosis, **Chlamydia,** **Gonorrhoea,** **Mycoplasma genitalium** **Trichomonas**	**Bacterial vaginosis PCR** **STI screen (CT/NG/ MG/TV)**	**eNAT**	**Light Blue**	

SARS-CoV-2 **Influenza**				
PCR for **HSV 1 & 2** **Viral Swab for NVRL**	**HSV Screen** **(excluding blood/CSF)** **Viral Culture, PCR**	**UTM**	**Red Top with UTM liquid**	

Appendix No. 5: Collecting Urine Samples for Analysis - Basic Principles

Fig 1: Obtain informed consent and explain procedure to optimise specimen quality.	Fig 2: Instruct patient to wash hands before and after specimen collection.	Fig 3: Appropriate specimen is collected – see description of sample types below. Ensure lid is securely tightened to avoid leaks.	Fig 4: Ensure sample is labelled (name, HN, d.o.b, specimen type). Return to lab promptly for testing.

First Void Urine

First void urine is the **first amount of urine passed at any time**- NOT a midstream sample, and NOT necessarily an early morning sample. The patient therefore needs to be instructed to **collect only the first 20mL (approx) of urine**.
A minimum of 10ml FVU (the first part of the stream) or midstream is collected by the patient into a clean polypropylene container without preservative.

Early Morning Urine

Early morning urine is the **first urine passed at the start of the day**. This urine is most concentrated and is frequently used for bacterial cultures and microscopic examinations such as TB (*a special container should be collected from lab for TB samples*).

Mid-stream Sample - "Clean Catch"

This involves taking **a 'middle' sample while the urine is being voided**, avoiding the initial and end stages of the void. The patient should be **instructed to wash the genital area prior to collection** and avoid touching the inside of the sterile container with their hands or genital area. This method of collection reduces the risk of sample contamination from bacteria colonised around the distal urethra, as these bacteria are washed away with the initial urine flow. This sample is frequently used for bacterial culture or cytology.

Second Fasting Sample

This is the second urine sample of the day while still fasting from the night before. This sample is often used to confirm glycosuria.

Supervised Sample

The **collection of this sample is directly observed by the nurse/midwife** to ensure the sample is from the named patient. This sample is used for drug testing.

Appendix No. 6: Collecting Blood Culture Samples

- If blood for other tests is to be taken at the same venepuncture, inoculate the blood culture bottles first to avoid contamination. It is preferable to take blood for culture separately.
- Disinfect the skin at the venepuncture site
- Disinfect the septum of the blood culture bottle with an alcohol wipe or steret and allow todry.
- Withdraw blood from a peripheral vein and divide the sample equally among blood culture bottles. Do not take samples through an intravenous catheter or other access device unless no other access is available.

Children and Neonates

- Use a single paediatric bottle appropriate for small volumes of blood.
- Preferably, a volume of 1-2mL in neonates for each blood culture set. The amount of blood from the neonate that is added to the blood bottle should be indicated (although not always) on the request form.
- Do not exceed the manufacturer's recommended maximum volume for each bottle:

Adults

- A set is defined as one or more bottles taken at any one time
- Preferably, a volume of 20-30mL for each blood culture set (NOTE: More than 2 bottles per set may be indicated)

General rules for blood cultures

- Take two sets during any 24h period for each septic episode. For neonates, take a single set of special paediatric bottles
- Transport blood cultures to the laboratory as soon as possible and leave at room temperature**. DO NOT REFRIGERATE**.

Appendix No. 7: Flow Chart of Laboratory On-Call