



Pathology Laboratory

**PRIMARY SAMPLE
COLLECTION MANUAL**

Ref No: LABM 002

Revision No: 1.0

Issue date: 13th January 2009

CONTENTS	PAGE
1.0 INTRODUCTION	3
2.0 GUIDE TO USING THIS MANUAL	4
3.0 GENERAL INFORMATION	4
3.1 Pathology Department Opening Times	4
3.2 Pathology Department Telephone Numbers	4
4.0 LABORATORY REQUEST FORMS AND SPECIMEN BOTTLES	5
4.1 General Information	5
4.2 Completing the Request Form	5
4.3 Labeling the Specimen Container	6
4.4 Quality of Blood Specimens	7
4.5 Non-conforming Specimen Bottles, Forms or Specimen Quality Issues	8
4.6 Further Additional requests	9
5.0 PACKING AND DELIVERY OF SPECIMENS	9
5.1 Health and Safety	9
5.2 Delivery	9
5.3 Urgent Specimens	9
5.4 Specimen Storage	9
5.5 Disposal of Waste	9
5.6 Storage of Examined Specimens	10
6.0 LABORATORY TESTS AND PROFILES	10
6.1 Laboratory Disciplines	10
6.2 Test Descriptions	10
6.3 Haematology Tests	11
6.4 Blood Transfusion Tests	11
6.5 Biochemistry Tests	12
6.6 Microbiology Tests	12
6.7 Immunology Tests	13
6.8 Histology Tests	13
7.0 REPORTING OF TEST RESULTS	14
7.1 On-line Results	14
7.2 Telephoning of Results	14
7.3 Faxing of Results	14
7.4 Printing of Reports	14
8.0 REFERENCE RANGES	14
8.1 Interpretation of Results	14
8.2 Clinical Advice	14

1.0 INTRODUCTION

- 1.1 This manual is designed to give an overall view of the services available in the Pathology Department. It is intended as a quick reference guide for all users of the service to ensure compliance with sample requirements and avoid any delays in testing due to inadequate or inappropriate samples.

Pathology Laboratory, Whitfield Clinic.

Quality Policy Statement

The Pathology Laboratory is committed to providing the highest standard of service to its users at all times. This will be achieved by its commitment to good professional practice to ensure the highest quality of work in all testing activities and examinations performed. It will at all times be committed to compliance with the requirements of ISO 15189 and AML BB by following the policies and procedures outlined in the Quality Manual and associated documents.

The management will ensure that all staff familiarise themselves with the quality documentation and implement the policies and procedures at all times. Management will also ensure that the resources and facilities in place are appropriate to the workload and related activities. They will also perform regular surveys of the users of the service to monitor satisfaction levels and will address any deficiencies identified.

Signed:

Dr. B. Hennessy
Consultant Haematologist

Date: _____

Noel Shanaghy
Laboratory Manager

Date: _____

- 1.2 The Pathology Laboratory has put in place a quality management system to meet the requirements of ISO 15189:2007. This system also covers haemovigilance activities. The commitment to quality is outlined in the Quality Policy Statement, see Figure 1.

Figure 1

2.0 GUIDE TO USING THIS MANUAL

- 2.1 A controlled hardcopy (printed on yellow paper) of this manual has been issued to each location which is a user of the service. It is also available on the Whitfield Clinic intranet.
- 2.2 The information required for specific tests are listed in the manual under specific disciplines viz. Haematology, Blood Transfusion, Biochemistry, Microbiology and Histology.

3.0 GENERAL INFORMATION

3.1 Pathology Laboratory Opening Times

- 3.1 The laboratory is open Monday to Friday except for public holidays, see Table 1.

Day	Hours
Monday	8.30am – 8.00pm
Tuesday	8.30am – 8.00pm
Wednesday	8.30am – 8.00pm
Thursday	8.30am – 8.00pm
Friday	8.30am – 6.00pm

Table 1

3.2 Contact Details

- 3.3 Telephone and fax numbers are given in Table 2.

Service	Number
Main Laboratory	051-337 492/7489
Blood Transfusion	051-337 489
Lab Manager	051-31 9823
Haemovigilance	051-337 472
Consultant Haematologist	087-7985286
Laboratory Fax	051-359946

Table 2

4.0 LABORATORY REQUEST FORMS AND SPECIMEN BOTTLES

4.1 General Information

4.1.1 This section deals with the information that is required to be documented on the laboratory request form and the specimen bottle or container, prior to the analyses of samples.

4.1.2 The laboratory has a number of different request forms, see Appendix 1. These are used for different pathology analyses as outlined below. It is important that the correct form is supplied for a particular test.

4.2 Completing the Request Form

4.2.1 The following essential information must be documented in a legible manner on the request form including the back copy:

1. Patient's **Hospital Number**
2. Patient's **Full Name** (Surname, Forename)
3. Patient's **Full Home Address**
4. Patient's **Date of Birth**
5. Patient's **Location** (Hospital Ward or room number). Where the requesting Physician is at an external location to that of the Whitfield Clinic, the postal address of the location should be included.
6. Patient's **gender**
7. The name of the **requesting Clinician**
8. **Specimen type** and **anatomical site** where appropriate
9. **Examination(s)** required
10. **Date and time of specimen collection** (Time of specimen collection is not a requirement for Histopathology or Cytology specimens).
11. Relevant **clinical information** appropriate to the test(s) requested must be supplied e.g. history of administration of drugs, antenatal history, blood transfusion history etc. The minimum clinical information supplied relevant to the patient must include gender and date of birth for interpretative purposes.

12. A clear indication as to whether the tests requested are **urgent** or **routine**
13. The **signature** of the person **completing** the form and contact number.
14. It is important to ensure when the form is completed that all details are clearly transcribed to the back copy of the form including an addressograph label.
15. Specific requirements for **Blood Transfusion**:
 - Addressograph labels are **not** acceptable on Blood Transfusion request forms. All details must be handwritten.
 - If specific blood products are required i.e. CMV negative, irradiated, this should be requested and lab informed by phone.
 - The specific surgery or reason for a transfusion request must be documented on the transfusion form.
 - All request forms must be signed by the requesting clinician.

4.3 Labeling the Specimen Container

- 4.3.1 The following essential information should be documented in a legible manner on the specimen container:
1. Patient's full name
 2. Date of birth
 3. Hospital number
 4. Date and time of specimen collection
 5. All of the above indicators are mandatory when requesting tests on twins, patients with the same surname in the same location or specimens requesting blood grouping or crossmatching.

In all other cases the following indicators are mandatory:-

1. Patient's full name
2. Date of birth **or** hospital number
3. Date and time of specimen collection
4. The **initials** of the person **collecting** the specimen

4.3.2 Specific Requirements for **Blood Transfusion**

- Blood transfusion specimens must have the **signature** of the person collecting and labeling the specimen.
- Addressograph labels are **not** acceptable on Blood Transfusion specimens.
- Incomplete, incorrect or illegible specimens cannot be accepted.
- Initial bloods from patients due for surgery should be taken at pre-admission.

Note: Crossmatched blood will only be reserved for 24hrs after date required.

4.4 Quality of Blood Specimens

- 4.4.1 Laboratory personnel must inspect prior to testing each blood specimen received for:-
- Evidence of Haemolysis
 - Gross Lipemia
 - Presence of clots in all specimens requesting full blood count and coagulation tests
 - Insufficient sample
- 4.4.2 In such instances, a second specimen may be requested or the issued report will have an appended comment noting the presence of haemolysis, lipemia or clots as appropriate.

4.5 Non-conforming Specimen Bottles, Forms or Specimen Quality Issues

- 4.5.1 Where the requirements with respect to labeling the request form and specimen container or specimen quality issues are not met the following will apply.
- 4.5.2 Specimens, Table 3.

SPECIMEN ISSUES	ACTION	DOCUMENTATION
➤ No specimen received.	➤ Ward informed by phone and specimen requested.	➤ Details of call recorded on request form.
➤ Specimen unlabelled .	➤ Ward informed by phone. A second specimen must be collected.	➤ Details of call recorded on request form.
➤ Addressograph label on blood transfusion specimen	➤ Ward informed by phone. A second specimen must be collected.	➤ Details of call recorded on request form.
➤ Two of the three mandatory unique identifiers are not correct or absent from the specimen (Full name, DOB, hospital no.)	➤ Ward informed by phone. A second specimen must be collected. ➤ In exceptional circumstances where a repeat specimen is impossible the collector having been informed must accept responsibility for the specimen.	➤ Details of call recorded on request form. ➤ If tested the report will show details of the non-conforming event.
➤ Specimen site not identified <i>or</i> ➤ Specimen collected at incorrect time or date and time of collection not indicated	➤ Ward informed by phone and a second specimen requested. ➤ If a second specimen is not received the collector having been informed must accept responsibility for the specimen.	➤ Details of call recorded on request form. ➤ If tested the report will show the non-conforming event.

Table 3

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Revision No: 1.0

Page: Page 7 of 15

4.5.3 Forms, Table 4.

FORM ISSUES	ACTION	DOCUMENTATION
<ul style="list-style-type: none"> ➤ No request form provided with Specimen <i>or</i> ➤ Inadequate or incorrect patient details:- <ul style="list-style-type: none"> • hospital number • name • address • date of birth • ward or location • gender • clinic information 	<ul style="list-style-type: none"> ➤ Ward informed by phone and a second specimen is requested if the originator does not correct the error. ➤ If tested the report will show the non-conforming event. 	<ul style="list-style-type: none"> ➤ Details of call recorded on request form. ➤ Collector or nominee signs for the correction of the error on the request form.
<ul style="list-style-type: none"> ➤ Incorrect test requested ➤ No test requested ➤ No patient details on back copies of form ➤ Ordering Physician not identified ➤ Specimen collected at incorrect time or date and time of collection not indicated 	<ul style="list-style-type: none"> ➤ Ward informed by phone and asked to correct or provide missing details. ➤ If tested the report will show the non-conforming event. 	<ul style="list-style-type: none"> ➤ Details of call recorded on request form. ➤ Collector or nominee signs for the correction of the error on the request form.

Table 4

4.5.4 Specimen Quality, Table 5.

SPECIMEN APPEARANCE/ QUALITY ISSUES	ACTION	DOCUMENTATION
<ul style="list-style-type: none"> ➤ Evidence of Haemolysis ➤ Gross Lipemia ➤ Presence of clots in specimens requesting FBC and coagulation tests ➤ Age of specimen 	<ul style="list-style-type: none"> ➤ The laboratory will make a decision on whether or not the specimen is suitable for testing and a second specimen is requested as appropriate. ➤ The Pathology department may report results within a multi test profile on analytes unaffected by the specimen quality, while not reporting affected analytes in the profile. ➤ If tested the report will show the non-conforming event 	<ul style="list-style-type: none"> ➤ Details of specimen quality recorded on request form.

Table 5

4.6 Further Additional Requests

- 4.6.1 If on sending a specimen for testing and further additional requests are required, please contact the laboratory to investigate the feasibility of using the initial specimen for analysis as age of specimen may impact on the validity of test results. A request form must accompany such a request but the lack of the request form will not impede the processing of an urgent request.

5.0 SPECIMEN DELIVERY AND HANDLING

5.1 Health and Safety

- 5.1.1 It is the policy of the Pathology Laboratory to treat all specimens as potentially infectious or high risk. Therefore it is advised to take universal precautions in the collection, packaging and the delivery of specimens.

5.2 Delivery

- 5.2.1 In order to ensure efficient processing of specimens it is important that once collected they are delivered to the laboratory as soon as possible. Routine specimens are usually batched for testing so any delay in delivery could result in the specimen waiting for a later batch for testing.

5.3 Urgent Specimens

- 5.3.1 If a result is required urgently it is important to tick the Urgent box on the request form and also ring the laboratory to inform them of the specimen. The laboratory will then phone with the result as soon as it is available.

5.4 Specimen Storage

- 5.4.1 Specimens taken out of hours or shortly before the laboratory closing time need to be refrigerated in the laboratory overnight in the specimen fridge. Histology specimens do not require refrigeration.

5.5 Disposal of Waste Material Used in Specimen Collection

- 5.5.1 All materials used in specimen collection should be treated as potentially hazardous and discarded using sharps containers and appropriate colour coded bags. Please refer to hospital guidelines Waste Management Policy, WHITENV001 on JCI portal.

5.6 Storage of Examined Specimens

5.6.1 Specimens are stored for defined periods of times for look back purposes. The times of storage are defined in Table 6.

Specimen Description	Storage Requirement	Storage Location	Minimum Retention Period
Whole Blood	4°C	Laboratory fridge	2 weeks

Table 6

6.0 LABORATORY TESTS AND PROFILES

6.1 Laboratory Disciplines

6.1.1 The laboratory provides a full range of laboratory tests in all disciplines:

- Haematology
- Blood Transfusion
- Biochemistry
- Microbiology
- Immunology
- Histology

6.1.2 On-site testing is carried out for routine tests in all disciplines and all other tests including Histology work is referred out.

6.2 Tests Descriptions

6.2.1 Each laboratory test is described under the following headings:

- Test name** - Test name or profile
- Specimen type** - Type or anatomical site
- Container type** - Bottle or tube
- Additive required** - Anticoagulant or chemical in tube or bottle
- Volume required** - Minimum volume of specimen required for testing
- Special requirements** - Special needs for specific tests
- Turnaround time** - Time from receipt in lab to results available

6.3 Haematology Tests

6.3.1 The range of tests available and their requirements are defined in Table 7.

Test Profile	Spec Type	Specimen Requirements			Special Requirements	Turnaround Time
		<u>Additive Required</u>	<u>Volume Required</u>	<u>Container Type</u>		
FBC	Blood	EDTA	3ml	Lavender Vacutainer	None	Routine – 2hrs Urgent – 20min
ESR	Blood	EDTA	3ml	Lavender Vacutainer	None	Routine – 3hrs Urgent – 1.5hrs
Blood Film	Blood	EDTA	3ml	Lavender Vacutainer	None	3 days
INR	Blood	Citrate	4.5ml	Blue Vacutainer	None	Routine – 2hrs Urgent – 30min
APTT	Blood	Citrate	4.5ml	Blue Vacutainer	None	Routine – 2hrs Urgent – 30min
B12	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
Folate	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
Ferritin	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days

Table 7

6.4 Blood Transfusion Tests

6.4.1 The range of tests available and their requirements are defined in Table 8.

Test Profile	Spec Type	Specimen Requirements			Special Requirements	Turnaround Time
		<u>Additive Required</u>	<u>Volume Required</u>	<u>Container Type</u>		
Group & Screen	Blood	EDTA	3ml	Lavender Vacutainer	Hand-written patient details	Routine – 4hrs Urgent – 1hr
Crossmatch	Blood	EDTA	3ml	Lavender Vacutainer	Hand-written patient details	Routine – 4hrs Urgent – 1hr
Antibody Investigation	Blood	EDTA	3ml	Lavender Vacutainer	Hand-written patient details	Up to 10 days
HLA Antibodies	Blood	EDTA	3ml	Lavender Vacutainer	Hand-written patient details	Up to 10 days

Table 8

6.5 Biochemistry Tests

6.5.1 The range of tests available and their requirements are defined in Table 9.

Test Profile	Spec Type	Specimen Requirements			Special Requirements	Turnaround Time
		<u>Additive Required</u>	<u>Volume Required</u>	<u>Container Type</u>		
Full Profile	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 3hrs Urgent – 45min
Liver Profile	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 2hrs Urgent – 30min
Cardiac Profile	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 2hrs Urgent – 30min
Bone Profile	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 2hrs Urgent – 30min
Lipid Profile	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 2hrs Urgent – 30min
Renal Profile	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 2hrs Urgent – 30min
Glucose	Blood	Fluoride Oxalate	8ml	Grey Vacutainer	None	Routine – 2hrs Urgent – 30min
Amylase	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 2hrs Urgent – 30min
CRP	Blood	Lithium Heparin	8ml	Green Vacutainer	None	Routine – 2hrs Urgent – 30min

Table 9

6.6 Microbiology Tests

6.6.1 The range of tests available and their requirements are defined in Table 10.

Test Profile	Spec Type	Specimen Requirements			Special Requirements	Turnaround Time
		<u>Additive Required</u>	<u>Volume Required</u>	<u>Container Type</u>		
MRSA screen	Swab	N/A	N/A	N/A	Keep refrigerated	2 days Neg – 1 day
Urine C/S	Urine	N/A	Min 1ml	Sterile jar	Keep refrigerated	3 days
Swab C/S	Swab	N/A	N/A	N/A	Keep refrigerated	3 days
Fluid/Pus C/S	Fluid or Pus	N/A	Min 1ml	Sterile jar	Keep refrigerated	3 days
C. difficile	Faeces	N/A	Min 1ml	Sterile jar	Keep refrigerated	3 days
AAFB/TBC	Sputum	N/A	Min 1ml	Sterile jar	Keep refrigerated	AAFB – 3 days TBC – 6 weeks

Author: N. Shanaghy

Reviewer: A. Dowling

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Revision No: 1.0

Page: Page 12 of 15

Table 10

6.7 Immunology Tests

6.7.1 The range of tests available and their requirements are defined in Table 11.

Test Profile	Spec Type	Specimen Requirements			Special Requirements	Turnaround Time
		<u>Additive Required</u>	<u>Volume Required</u>	<u>Container Type</u>		
RhF	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
ANA	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
Auto-antibody Screen	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
Immunoglobulins	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
Protein Electrophoresis	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
TPO	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
IgE	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
CEA	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
CA125	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
CA199	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
PSA	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days
TSH	Blood	SST/Gel	3.5ml	Gold Vacutainer	None	3 days

Table 11

6.8 Histology Tests

6.8.1 Histology specimens are referred to the Histology Laboratory in Waterford Regional Hospital.

7.0 REPORTING OF RESULTS

7.1 On-line Results

7.1.1 All results once released are available to all users on the ISIS laboratory system.

7.2 Telephoning of Results

7.2.1 As all results are available on-line by ISIS the laboratory does not normally phone results.

7.2.2 The laboratory will telephone the results of tests where critical levels have been reached or where clinically indicated, see Table 12.

Whitfield Clinic – Critical lab Values		
Chemistry		
TEST	RESULT ABOVE	RESULT BELOW
Glucose	11.0 mmol/L	2.4 mmol/L
Sodium	155 mmol/L	125 mmol/L
Potassium	6.2 mmol/L	2.7 mmol/L
Calcium	3.10 mmol/L	1.76 mmol/L
Phosphate	2.60 mmol/L	0.39 mmol/L
Urea	26.8 mmol/L	NA
Magnesium	1.5 mmol/L	0.4 mmol/L
Creatinine (non-dialysis)	300 µmol/L	NA
Triglycerides	15 mmol/L	NA
Haematology		
TEST	RESULT ABOVE	RESULT BELOW
Hemoglobin	NA	7 g/dL
Platelets	1,000 X 10 ⁹ /L	30 X 10 ⁹ /L
White Cell Count	30 X 10 ⁹ /L	2 X 10 ⁹ /L
HCT	.60 ratio	NA
Neutrophils	50 X 10 ⁹ /L	0.5 X 10 ⁹ /L
Lymphocytes	75 X 10 ⁹ /L (new cases only)	NA
Microbiology		
TEST	RESULT	
MRSA	Positive*	

* Infection Control Nurse informed

Table 12

7.3 Faxing of Results

- 7.3.1 To ensure confidentiality of results it is the policy of the laboratory not to fax reports except in exceptional circumstance when it is authorised by the requesting clinician and specific arrangements to ensure confidentiality are agreed.

7.4 Printed Reports

- 7.3.1 Hard copies of reports are printed at scheduled times and are available for collection or delivery to the wards.

8.0 REFERENCE RANGES

8.1 Result Interpretation

- 8.1.1 Reference ranges when appropriate are given with test result both on-line and printed on the hardcopy report.

8.2 Clinical Advice

- 8.2.1 Clinical advice on Haematology and Blood Transfusion is available from the Consultant Haematologist.