ORF-049, Issue 5.0, Effective Date: 19/11/2021
Ref: SOP: 023/ORG

# Welsh Blood Service Transfusion Laboratories

# PATIENT TESTING USER GUIDE

Welsh Blood Service
Ely Valley Road
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CF72 9WB.
Telephone: (01443) 622000
e-mail: wbs.rci@wales.nhs.uk

# PATIENT TESTING USER GUIDE



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## 1. Contact Details

| South Wales | North Wales |
|---|---|
| **Transfusion Laboratories**<br>Welsh Blood Service<br>Ely Valley Road<br>Pontyclun<br>Wales<br>CF72 9WB<br>Reception Tel: 01443 622200 | Pembroke House<br>Ground Floor Premises<br>Ellice Way<br>Wrexham<br>Clwyd<br>LL13 7YT<br>Tel: 0300 085 9397 or 0300 085 9398 |

### Consultants

| | |
|---|---|
| **Dr Kalinga Perera**<br>Consultant in Transfusion Medicine<br>E-mail: Kalinga.perera@wales.nhs.uk<br>Tel: 01443 622014 | **Dr Edwin Massey**<br>Medical Director<br>E-mail: edwin.massey@wales.nhs.uk<br>Tel: 01443 622371 |

### Laboratory Managers

| |
|---|
| **Mrs Georgia Stephens**<br>Head of Transfusion Laboratories<br>Email: Georgia.Stephens@wales.nhs.uk<br>Tel: 01443 622013 |
| **Ms Ann Jones**<br>Operations Manager Automated Testing<br>E mail: ann.jones12@wales.nhs.uk<br>Tel: 01443 622046<br>Tel: 01443 622048 – Automated Testing Laboratory |
| **Mrs Ceri White**<br>Head of RCI<br>E Mail- ceri.white3@wales.nhs.uk<br>Tel: 01443 622155<br>Tel: 01443 622151 (RCI Lab) |

### Additional Services Hosted by the Laboratory

| Diagnostic Services | Primary Lead | Ext. | Website Link |
|---|---|---|---|
| WASPS | Gareth Nottage | 2148 | https://portal.welsh-blood.org.uk/wasps/ |
| Scientific Education & Qualification Lead | Cheryl Davis | 2110 | N/A |

## 2. Introduction

The purpose of this user guide is to describe the range of tests and services provided by the Welsh Blood Service (WBS) diagnostic laboratories. It will be of use to medical, nursing and scientific staff in transfusion laboratories, haematology departments and others involved in e.g. antenatal care. The user guide contains information about the range of services available and contact details for key WBS staff.

The Red Cell Immunohaematology (RCI) Department is the reference centre in Wales for the resolution of blood grouping and complex antibody problems. Antigen negative blood for selected patients is also available on request via Hospital Services department.

The RCI Department investigates samples from patients with both warm and cold autoimmune haemolytic anaemia (AIHA) providing compatible blood as and when required.

Patients with warm type AIHA invariably present with a strong positive direct anti- globulin test (DAT) and may often have free autoantibody in their serum, making the identification of underlying alloantibodies extremely difficult. Failure to detect the alloantibodies may result in a haemolytic transfusion reaction and shortened post transfusion survival of transfused cells. The adsorption techniques used in the RCI department are designed to reveal and identify the presence of any underlying alloantibody.

The RCI department also investigates samples from patients receiving drug therapy which may interfere with antibody investigations e.g. Daratumumab, Isatuximab. It is recommended that samples from these patients are phenotyped prior to commencing drug treatment wherever possible.

The Immunohaematology section is responsible for anti-D and anti-c quantitation in the management of Haemolytic Disease of the Fetus & Newborn (HDFN) and fetomaternal haemorrhage estimation (FMH) by Flow Cytometry.

The RCI department participates in an all-Wales Fetal RhD screening service for RhD-negative expectant mothers to reduce the use of anti-D immunoglobulin (a human derived blood product) in the management of Haemolytic Disease of the Fetus and Newborn. The testing is performed by the Stem Cell Transplantation Laboratory within the Welsh Blood Service.

The Automated Serology Department is responsible for the routine blood grouping and red cell antibody screening of antenatal samples.

All test results are reported on hard copy reports, dispatched via WBS & Hospital Transport to Hospital Transfusion laboratories. Urgent copies of reports may be sent electronically on request. Results are also available on the ABS system, accessible via the WBS intranet site. Access to the ABS system can be requested by Hospital Transfusion Laboratory & Antenatal Clinic staff, by completion of the User Request Form, accessible via the ABS link on the WBS intranet site.

**Service Provision**

- Patient Testing Service including compatibility testing

- Antenatal Service including anti-D and anti-c quantitation and cell free fetal RhD screening
- Reagents Section incorporating the Welsh Assessment of Serological Proficiency Scheme (WASPS)
- Feto-maternal haemorrhage (FMH) estimation

### Laboratory Tests

- ABO Confirmation
- D typing investigations
- Antibody Investigation – routine
- Auto Antibody Investigations
- Antenatal antibody investigations including titres
- Quantitation of anti-D & anti-c
- Direct Antiglobulin Test Investigations
- Feto-maternal haemorrhage (FMH) estimation by flow cytometry
- Red Cell Phenotyping e.g. for sickle cell patient, potential bone marrow recipients/donors, Daratumumab patients

In addition to these tests, expert serological advice is available from our staff 24/7 in addition to clinical advice from WBS consultant haematologists.

## 3. Laboratory Hours

### Routine – Monday to Friday 09.00-17.00 (excluding Bank Holidays)

The RCI laboratory MUST be contacted if you require compatibility testing or urgent investigation, RCI staff will allocate a number to be recorded on the RCI Antibody Investigation Request Form. This will enable us to make any initial preparations so that the investigation can start as soon as the samples arrive at the WBS. Please record on the request form if you require a telephone or e-mailed report of any serological investigation requested.

For Betsi Cadwaladr Hospitals – urgent samples may be required to be referred to NHSBT (Liverpool). Please contact RCI Laboratory or On-call BMS as soon as possible when samples have been referred to NHSBT. This may be the next working day, depending on the BCU staff availability.

### Out of Hours Requests

The emergency resolution of serological investigations and provision of compatible blood is available 24 hours a day 365 days a year.

The out of hours service is staffed by a HCPC registered specialist BMS for Transfusion Science who is routinely employed within the RCI department.

**N.B.** When sending samples out of hours, for investigation the following day or over the weekend for testing on Monday, users are requested to contact the RCI department so that the testing may commence as soon as possible.

### Contact Arrangements out of hours

| |
|---|
| **On-call Specialist BMS for Urgent Compatibility Testing** |

| |
|---|
| Contact: 0788 755 0377 |
| If no response, please phone Issues on call number: 0776 829 3963 |
| In the rare event where you do not receive a response from either number please contact WBS switchboard (01443 622000) who will forward your request as a matter of urgency. |

### Duty Consultant for WBS

Consultant Advice may be obtained from the WBS Duty Consultant. Contact WBS main switchboard (01443 622000) and ask for the WBS Duty Consultant.

## 4. Sample Requirements and Reporting

All testing must be completed within 7 days of the date bled. Samples which are 7 days old on receipt will be rejected and not be tested. All materials used during the collection process should be disposed as per local Trust or Health Board guidance.

Additional testing that may be requested on an existing sample received by the laboratory must be discussed with the relevant departmental lead. See Section 1 for contact details.

Results will only be released to requesting clinician (or healthcare professional) and will not be released to patients/carers.

### Request Forms

Please complete the request forms as detailed below and complete ALL sections as appropriate.

| **Please complete the standard WBS diagnostic request forms as detailed below and complete ALL sections as appropriate.** | |
|---|---|
| RCI Patient Investigation Form (WBS Form) | This form is to be used for all RCI requests including antibody investigations, compatibility testing, ABO & D anomalies. |
| RCI FMH Referral Form (WBS Form) | This form is to be used for all referrals for Fetal Maternal Haemorrhage estimation by flow cytometry |
| All Wales Antenatal Request Card for Fetal RhD Screen | This form is to be completed for any Fetal RhD screening requests |
| All Wales Ante-Natal Request Form | This form is to be completed for all tests relating to Antenatal Patients |

### High Risk Samples

The appropriate Laboratory Manager (Ref contact details) must be notified of any known or suspected high risk samples prior to the dispatch of the sample.

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- All 'high risk' sample forms must have 'High Risk/Biohazard' stickers attached to them.
- The samples must be sealed in Biohazard bags with enough absorbent material to absorb any spillage in case of breakage.
- The forms must be separated from the samples in the Biohazard bags.

These samples must be separately packaged and the box used for transportation must also be labelled 'Danger of Infection'.

The WBS operates a zero tolerance policy for sample and request form labelling.

For all referred samples - only handwritten sample tubes will be accepted.

## Request Form Requirements

| Details | Requirement | Outcome if missing from request form |
|---|---|---|
| Patient name (Surname & Forename) | Mandatory | Discard & request repeat sample*** |
| Date of birth | Mandatory | Discard & request repeat sample*** |
| Hospital number/NHS number | Mandatory | Discard & request repeat sample*** |
| First line of address | Mandatory | Will contact if not given |
| Signature of person requesting the tests | Mandatory | Will contact if not given |
| Clinical details/ tests and/or number of units required including any special requirements i.e. CMV neg, irradiated | Mandatory | Will contact if not given |
| Date and time units required and indication of urgency of the tests | Mandatory | Will contact if not given |
| Diagnosis | Desirable | Sample will be tested |

*** For hospital patient referrals, where the details are missing from the RCI request form, RCI staff will contact the referring laboratory to request the 'original' request form is e-mailed to be checked for full details.

## Sample Labelling Requirements

| Details | Requirement | Outcome if missing from sample |
|---|---|---|
| Patient name (Surname & Forename) | Mandatory | Discard & request repeat sample |
| Date of Birth | Mandatory | Discard & request repeat sample |
| Hospital number/NHS number | Mandatory | Discard & request repeat sample |
| First line of address | Not required | N/A |
| Signature of person taking the sample | Mandatory | Discard & request repeat sample |
| Date sample taken | Mandatory | Discard & request repeat sample |

In cases of clinical urgency or where it is not possible to obtain repeat samples e.g. FMH samples, the RCI laboratory may agree to process a sample referred without all requested identifiers in accordance with locally documented procedures (copy available on request).

Please contact the RCI laboratory if any referred samples need urgent testing on: 01443 622151/622155.

## 5. Consent & Identification

Please note that it is the responsibility of the requestor to obtain informed consent and verify the identification of the patient for the requested tests. Surplus material may also be stored for further diagnostic testing to benefit the individual and anonymously for quality control, education and training and approved research and development.

## 6. Confidentiality

The laboratories have access to the data and information needed to provide a service that meets the needs and requirements of internal and external customers. The laboratory information system (whether computerise or paper-based) provides for the collection, processing, recording, storage, and retrieval of data, and has documented procedures in place to ensure the confidentiality of patient information and the security of the data during each step of the process.

WBS laboratories comply with the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) and the Caldicott principles.

## 7. Important Factors that may affect Serological Tests

The following factors may affect any of the serological tests that are performed by the Laboratory:

| Factors that may affect testing | How to minimise effects |
|---|---|
| Sample storage and transportation temperature | Store at 2-8$^{O}$C pre- and post- transportation.<br>Transport at ambient temperature is acceptable |
| Sample storage time | Samples should arrive at WBS within<br>24 hours of collection. |
| Anticoagulant | Ensure correct blood tubes are used - see the 'Standard Tests and Samples Required' Table |

Please contact the relevant Laboratory for help and advice on any of the above.

## Standard Tests and Minimum Samples Required

| Testing Required | | EDTA |
|---|---|---|
| Grouping anomalies | Patient/Donor | 6ml |

| | | |
|---|---|---|
| Routine antenatal samples | Maternal/Paternal | 6ml |
| Further investigation antenatal samples inc. Quantitation referrals | Maternal | 2 x 6ml |
| FMH investigation | Maternal | 1 x 6ml |
| Cell Free Fetal RhD Screening | Maternal peripheral blood | 1 x 10ml |
| Antibody investigations/Daratumumab/routine compatibility testing | Patient | 2 x 6ml |
| Autoantibody investigations | Patient | 3 x 6ml |
| Thermal Amplitude titres | Patient | See below |
| Donath-Lansteiner Investigation | Patient | See below |
| Full phenotyping inc. daratumumab referrals | Patient | 1 x 6ml |

**N.B**. for Transfusion investigation referrals, the pre-transfusion sample must be referred, in addition 1 x 6ml EDTA & 1 6ml clotted post transfusion must be referred.

**For thermal amplitude titration studies:**

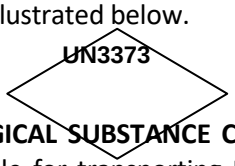
- 6mls clotted sample, allowed to clot at 4°C
- 2 x 6mls clotted samples, separated at 37°C before storing at 4°C
- 6mls EDTA sample

**For Donath-Lansteiner Investigations**

- 2 x 6 ml clotted sample (separated at 37°C)
- 6mls EDTA sample

## 8. Blood Sample Transportation

Blood samples should normally be transported at ambient temperature and delivered to the Laboratory in as timely a manner as possible and ideally within 24 hours of collection. All specimens must be packaged in accordance with the current **Post Office regulations** and European Agreement concerning Carriage of Dangerous Goods by Road Regulations & packing instructions 650 (ADR 2007) to prevent breakage or spillage in transit. They must be, clearly labelled according to the ADR 2007 regulations and display the hazard diamond as illustrated below.




In addition, the statement '**BIOLOGICAL SUBSTANCE CATEGORY B'** must be noted on the packaging. Packaging materials must be suitable for transporting UN3373 Biological substance Category B or UN 2814 as appropriate and addressed to:

Red Cell Immunohaematology Laboratory
Welsh Blood Service, Ely Valley Road, Pontyclun, CF72 9WB

For Betsi Cadwaladr Hospitals, samples may be forwarded to the N. E. Wales Base: Stock Holding Unit (SHU) for onward dispatch to RCI via routine WBS daily transport.

For other arrangements please contact the RCI Laboratory for help and advice.

## Procedures for Specimen Handling

Our procedures for handling blood samples and other specimens are available on request.

## Turnaround Times

This is defined as the interval between the entry of patient information on LIMS computer system (day 1) and the generation of a report.
The reports will be despatched to the originating hospitals by the WBS routine transport or via Hospital Transport Drivers.
The turnaround times are monitored on a regular basis to ensure set targets are achieved. They are defined below:

| Service | Diagnostic Section | Target Turnaround Times (90% within.....) |
|---|---|---|
| Grouping anomalies | Patient & Donor Referral | **5 working days** |
| Routine antenatal samples | Automated Testing | **3 working days** |
| Further investigation antenatal samples | Patient Referral | **5 working days** |
| Anti D/anti-c quantitation | Immunohaematology | **5 working days** |
| FMH investigation | Immunohaematology | **1 working day** |
| Fetal RhD Screening | Transplantation Services | **10 working days** |
| Antibody investigations & Phenotype referrals | Patient Referral | **5 working days** |
| Antibody investigations & Urgent compatibility testing | Patient Referral | **As agreed with referring hospital** |

# 9. Antenatal Antibody Clinical Decision Levels

Ref: Current BSH Guidelines for Blood Grouping & Antibody Testing in Pregnancy

| Antibody Detected | Titre/Quantitation Level | Reported Risk of Haemolytic Disease of the Fetus & Newborn (HDFN) | Further Samples |
|---|---|---|---|
| Anti-D | Quant: Below 4iu/ml | HDFN unlikely to occur when level remains less than 4iu/ml | Monthly samples up to 28 weeks |

| | | | |
|---|---|---|---|
| | Quant: 4-15 iu/ml | There is a risk of HDFN | & 2 weekly thereafter.<br><br>Paternal Sample |
| | Quant: Greater than 15iu/ml | There is a high risk of HDFN when level exceeds 15iu/ml | |
| Anti-c | Quant: less than 7.5iu/ml | HDFN unlikely to occur when level remains below 7.5iu/ml | |
| | Quant: 7.5-20iu/ml | There is a risk of HDFN | |
| | Quant: Greater than 20iu/ml | There is a high risk of HDFN when level exceeds 20iu/ml | |
| Anti-K | All titre levels | The risk of HDFN is considered significant | |
| All other clinically significant antibodies e.g. $Fy^a$, $Fy^b$, $Jk^a$, $Jk^b$ | Titre less than 32 | The risk of HDFN is not considered significant | Retest at 28 weeks gestation<br><br>Paternal Sample |
| | Titre 32 or greater | The risk of HDFN is considered significant | Monthly samples up to 28 weeks & 2 weekly thereafter.<br><br>Paternal Sample |
| Clinically insignificant antibodies e.g. $Le^a$, $Le^b$, $P_1$, HI | Titre not required | No risk of HDFN | Retest at 28 weeks |
| **NB** Reports will be amended to take into account additional information e.g. paternal type results, previous history of HDFN | | | |

## 10. Compliments and Concerns

If you have any concerns, compliments or suggestions for improvement, please contact either, Mrs Ceri White or Ms. Ann Jones:

- via telephone on 01443 622037 or 622046 respectively
- via e-mail using ceri.white3@wales.nhs.uk or ann.jones12@wales.nhs.uk
- or in writing to Georgia Stephens, Head of Transfusion Services, Ely Valley Road, Talbot Green, Pontyclun, CF72 9WB

Although we are committed to providing our customers with an excellent service there may be times when we fail to fully meet your requirements. As a learning organisation we firmly believe that every concern is to be valued as an opportunity to discuss with our customers how the service can be improved. Complaints will be processed in line with the Duty of Candour regulations, where appropriate.

Acknowledgement of the concern will be made and will indicate the probable timescale of the investigation. On completion of the investigation, the complainant will be notified in writing of the result of the investigation and any corrective actions that have been instigated.

## 11. Terms and Conditions

The WBS standard terms and conditions of service shall apply where a Service Level Agreement has not

been signed. A full set are available on request, the key elements of which are detailed below:

### Invoicing

Velindre University NHS Trust (VUNHST) shall invoice the customer for work undertaken on completion of the individual task, where appropriate. Payment is due within 30 days of receipt of invoice. Any Debts not paid within 30 days shall be considered to be outstanding and may incur interest charges at a daily rate of 0.05%, of the outstanding balance, until the amount has been settled.

### Method of payment

The general method of payment shall be in accordance with current policy as stated on the reverse of the Invoice. No receipt will be given unless specifically requested. Any customer requesting a service supplied by WBS shall be deemed to agree to these terms and condition. VUNHST shall invoice the customer for work undertaken on completion of the individual task, where appropriate. Payment is due within 30 days of receipt of invoice.

## 12. Quality Assurance

The WBS Diagnostic laboratories are committed to effective quality management at every level. All work is undertaken within the framework of a documented quality system and according to good laboratory and good manufacturing practice (GLP and GMP respectively).

Techniques and procedures are validated, described in standard operating procedures (SOPs), and conducted by staff whose proficiency is regularly assessed. Where relevant, measurement of uncertainty is calculated for examinations. Further information is available on request.

An internal audit schedule is an integral part of the Quality Management System (QMS) and supports current external licensing and accreditation inspections by the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom Accreditation Services (UKAS) and other relevant accreditation bodies.

The WBS diagnostic service is committed to continuously improving the quality and range of services provided and welcomes any comments or suggestions from our users. A questionnaire is distributed every 2 years as a minimum to monitor customer opinions.

### Quality Assessment

Standards of testing are maintained by the rigorous use of internal quality assurance protocols and through participation in appropriate External Quality Assessment Services (e.g. UK NEQAS).

All staff involved in routine and on call serology participates in UK NEQAS, Blood Transfusion Laboratory Practice and in each of the 3 WASPS exercises distributed annually.

Participation in a UKEQAS scheme for Antibody Quantitation (Anti-D & anti-c) and NEQAS scheme for FMH estimation is undertaken by staff involved in the routine testing.

## 13. Accreditation & Regulation

The WBS diagnostic laboratories are UKAS accredited Medical Laboratory No. 9326 (ISO 15189:2022). The full schedule of accreditation may be viewed at:

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9326-Medical-Single.pdf

The laboratories have been approved by the Institute of Biomedical Sciences (IBMS) & the Health & Care Professions Council (HCPC) for training purposes.

As part of the WBS, the diagnostic laboratories are also regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) for compliance to the Blood Safety & Quality Standards (BSQR) (2005) as amended. (License Holder WDA(H) 17853)

## 14. Further information/contacts for services provided

More detailed information on any of these services can be obtained, on request. Please contact Mrs Ceri White, Head of RCI, Ms. Ann Jones, Automated Serology Operations Manager or one of the following operational leads:

| Diagnostic Services | Primary Lead | Ext. | Section |
|---|---|---|---|
| • Grouping anomalies<br>• Antibody investigations & routine compatibility testing<br>• Autoantibody investigations<br>• Thermal Amplitude titres<br>• Full phenotyping<br>• Further investigation – antenatal samples | Ceri White | 2151 | Patient & Donor Referral |
| • Anti D/anti-c quantitation<br>• FMH investigation | Lynne Porter | 2154 | Immunohaematology |
| • Cell free Fetal RhD screening | Jennifer Pepperall | 2041 | Stem Cell Transplantation Laboratory |
| • Reagent Production inc. WASPS | Gareth Nottage | 2148 | Reagent Production |
| • Blood Grouping and Bacteriology | Louise Clark | 2052 | Automated Testing |
| • Microbiology | Dewi Reed | 2052 | Automated Testing |

## 15. Training

The WBS has been approved as a training laboratory by the Health & Care Professions Council (HCPC) and the Institute of Biomedical Science (IBMS). This accreditation is renewed every five years.

The WBS is able to provide a bespoke laboratory training programme for hospitals wishing to send BMS Students/haematology lab staff/nurses to the WBS as part of their training.

Please contact Scientific Education Qualification Lead on 01443 622110 to arrange training requests or to find out more information.

## ATTACHMENTS

None