PARTICIPANT MANUAL

Welsh Assessment of Serological Proficiency Scheme (WASPS)

www.waspsqa.org.uk

WASPS, Red Cell Immunohaematology, Welsh Blood Service, Velindre University NHS Trust, Charnwood Court, Parc Nantgarw, CARDIFF.

Issue 19.0
Effective Date: 31/07/2025

CONTENTS

1. Overview

The Welsh Assessment of Serological Proficiency (WASP) scheme was established in 1989 by the Welsh Blood Service (WBS) and Welsh regional hospitals as a direct result of variable performance by some hospitals in the UKNEQAS (BTLP) scheme.

It is an external quality assurance (EQA) scheme that is currently working in compliance with the ISO17043 standard for proficiency testing schemes.

It is recognised that with an ever demanding increase in workload transfusion laboratories are becoming increasingly reliant on the use of automation to meet these demands. However, many laboratories perform compatibility testing or employ a '*back-up*' technique of the same (*or similar*) IAT technology utilising manual IAT methods.

The scheme is based on a simulated compatibility test in which four antisera are tested against three red cell samples. The exercise is performed by individual members of staff using manual laboratory methods. Sufficient material is provided to each participant laboratory for all members of staff to participate, including on-call and multidisciplinary staff who may not routinely work in a blood transfusion laboratory.

The scheme aims to assist transfusion laboratories in improving practice, whilst providing managers responsible for service provision with the facility to monitor and assess individual staff competency. A review recommended that '*all practicing individuals responsible for reporting pathology results should be registered with current EQA individual assessment schemes*' **(Pathology Quality Assurance Review, 2014)**.

2. Scheme Organisation

Location/Contact Details

The scheme is hosted by the Velindre University NHS Trust and is based at the Welsh Blood Service in the Red Cell Immunohaematology (RCI) laboratory.

Address:	WASPS, Welsh Blood Service, Ely Valley Road, Llantrisant. CF72 9WB
Telephone:	+44 (0) 1443 622148
E-mail:	wasps@wales.nhs.uk
Online:	www.waspsqa.org.uk
X (Twitter):	@waspseqa

Key Scheme Personnel

Chair:	Cheryl Davies, Grange University Hospital.
Scheme Manager:	Mr Gareth Nottage, Welsh Blood Service.

Steering Committee

The Committee comprises of scientific members who provide advice and expertise as appropriate. Members of the committee serve a minimum three- year term, any participant in the scheme may nominate them (*Appendix 1*).

2. Scheme Organisation

Quality Assurance in Pathology Committee (QAPC) & National Quality Assurance Advisory Panels (NQAAPs)

The Quality Assurance in Pathology Committee (*formerly the Joint Working Group in Quality Assurance*) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assurance (EQA) schemes and monitoring of the EQA performance of clinical laboratories in the UK. This is achieved via discipline specific panels (NQAAPs) which report to the QAPC. The scheme reports annually to the Haematology NQAAP which oversees the correct operation of all national EQA schemes in both haematology and transfusion. The QAPC (JWG) has defined Conditions of EQA Scheme Participation which may be found at the RCPath website (www.rcpath.org). New UK participants agree to abide by these conditions when completing the registration form and existing participants indicate their continued acceptance of the conditions at re-registration.

Confidentiality

Upon registration, each laboratory will be allocated a unique code. To retain confidentiality, **THIS CODE IS KNOWN ONLY TO THE SCHEME MANAGER.** In cases of persistent unsatisfactory performance, however, laboratories concerned will be informed of the situation and identified to the chair of the National Quality Assurance Advisory Panel (NQAAP) for Haematology in line with the current WASP Performance Scoring System (*Appendix 2*). Laboratory identity will be disclosed but the laboratory code will remain anonymous.

2. Scheme Organisation

Accreditation

The scheme has undergone assessment to the ISO17043 standard by UKAS and is currently accredited. The schedule of accreditation is available online: www.ukas.com

Data Security

The Welsh Assessment of Serological Proficiency scheme (WASPS) is an external quality assessment provider and part of Velindre University NHS Trust. We collect personal data about you and relevant personnel within your organisation when you register with us to enable us to provide the external quality assessment service. We also collect information when you voluntarily complete surveys and provide feedback. You have the right to obtain a copy of personal data we hold about you, and for this to be provided free of charge. If you would like to receive some or all of your personal data (*called a Subject Access Request*), please contact us.

Advice/Information

Advice on any aspect of the scheme or other related matters on performance may be sought from the Scheme Manager by telephone or in writing (Address and relevant details on page 4). Enquiries relating to a specific exercise, exercise material or scheme registration should be directed to:

- wasps@wales.nhs.uk

2. Scheme Organisation

Complaints

Any complaints regarding the service provided by the scheme may be directed in writing to the following e-mail address:

- *WASPSComplaints@wales.nhs.uk*

All complaints will be entered onto the Q-Pulse incident management software. Complaints relating to exercise materials or packaging should be accompanied by photographic evidence where possible, as this will assist with investigation.

Complainants will receive a letter of acknowledgement from the Scheme Manager within two working days. All complaints will be resolved within 30 working days of the original complaint being made, the letter identifying any follow up/corrective actions. Any unresolved complaints can be directed to the Chair of the National Quality Assurance Advisory Panel (Haematology) or the QAPC.

Appeals

Appeals relating to performance evaluation should be made in the first instance to the Scheme Manager and these will be dealt with in the same way as complaints. In the event that the appeal remains unresolved, it should be escalated to the Chair of the Steering Committee or to the Chair of the National Quality Assurance Advisory Panel (Haematology). Investigations and decision on appeals shall not results in any discriminatory actions.

2. Scheme Organisation

Participation

EQA forms an integral part of the assessment of the overall quality system in a laboratory where blood group serology is performed. The scheme aims to assist laboratories in improving transfusion practice, providing those responsible for service provision with the facility to monitor and assess individual staff competency. Exercise materials are only suitable for use by manual IAT techniques, participants are welcome to modify materials for use on automated testing platforms however the scheme is currently unable to provide performance scoring from any such testing.

Provision of identical samples to all participating laboratories allows inter-laboratory comparison and corrective action taken as a result of unsatisfactory performance can lead to an improvement in proficiency. Unlike other disciplines blood group serology results are not assigned as the result of statistical analysis. The results are analysed on the basis of whether they agree with the consensus, or 'true' result based on in-house testing. The scheme is not designed to identify significant differences between methodologies.

The potential major sources of error involved in serological testing are the incorrect preparation of the appropriate red cell suspension for the technology in use, use of inappropriate reagents and/or diluents, addition of inaccurate volumes of red cell suspensions and/or serum, the incubation of tests for the wrong length of time and under/over centrifugation.

3. Participation Costs

To participate in the scheme, laboratories register annually. Participants must register in **one** of two categories:

Small laboratory	**≤10 individuals**
Large laboratory	**>10 individuals**

Due to the individual analysis service provided by the WASP scheme, participating laboratories are charged a variable rate for exercises based on number of individual participants.

Small laboratory	**:**	**£390 per annum**
Large laboratory	**:**	**£560 per annum**

EQA services are subject to VAT at the current standard rate. In accordance with current regulations VAT is not applicable to NHS establishments within Wales. Should the scheme be unable to fulfil it's obligations with regards to the number of exercises distributed then appropriate refund arrangements will be made. Should a participant decide to withdraw during the registration period (April—March) this must be made in writing so that the relevant information may be passed to the finance team to ensure the appropriate invoice is raised.

4. Registration

At registration each laboratory is allocated a unique code that is used on performance reports in order to preserve confidentiality. Laboratories are required to provide the following information on the registration form:

- Individual to whom the exercise materials will be addressed
- Consultant Haematologist clinically responsible for blood transfusion
- The person to whom the invoice will be sent

Details of exercise materials and performance scores will be sent to both the Consultant Haematologist and Transfusion Laboratory Manager/Lead. A registration form is sent to prospective participants and a re-registration form is sent to all existing participants annually.

Accurate e-mail addresses are <u>essential</u> for the distribution of exercise summaries, reports and other correspondence.

To allow analysis of individual participants, each individual who performs WASPS exercises must be allocated with an individual code by the relevant laboratory manager/transfusion lead. It is **<u>not</u>** necessary for the Scheme Manager to know the identity of individual participants**.**

It is essential that the laboratory code number is quoted on all result sheets.

5. Exercise Details

5.1 Exercise Format

Three exercises are prepared annually (*April – March*) being distributed in the months of June, October and January. Each exercise is based on a simulated compatibility test in which four antisera are tested against three red cell samples. The exercises have concentrated on weak quantifiable examples of Anti- D, however, other specificity's have been utilised (e.g. anti-Fy^{a}, -E, -K). Only the Scheme Manager is aware of the final make-up of each exercise.

5.2 Exercise Materials

Red cell samples are derived from single blood donor donations and are suspended in Modified Alsever's solution containing antibiotics as an aid to prevent contamination. Serum samples are donations from one or more individuals.

Laboratories must ensure that the red cell samples are modified in line with the manufacturer's recommendations for the technology in use prior to testing

All exercise materials are tested at source and found negative for the mandatory microbiological tests required at the time of donation. Such testing does not ensure that these materials will not transmit infection. The contents and containers must be handled and discarded in accordance with organisational policies and compliance with relevant health and safety requirements. In the event of postal delays or breakages, additional or replacement material is available on request from the Scheme Manager (*wasps@wales.nhs.uk*). Amendments to reagent volume may be requested at any time.

5. Exercise Details

5.3 Distribution and Dispatch of Materials

All exercise material is addressed to the individual listed for contact on the registration form. Exercise materials are dispatched to participants by 'first-class' mail, unexpected changes will be notified to participants via e-mail. The nature of the contents (*'Exempt Human Specimens'*), the temperature of storage on receipt and the address of the sender are indicated on the outer packaging. All samples are transported at ambient temperature and should be tested as soon as possible on receipt. Laboratories who fail to receive an exercise within five working days of the dispatch date should contact the scheme (*wasps@wales.nhs.uk*).

5.4 Undertaking the Exercise

Exercises should be performed individually with no collaboration between different staff members or between different organisations, any evidence of collusion or falsification of results will be reported to NQAAP. Only the manual technique normally used for routine non-urgent testing should be performed, the exercise is not appropriate for urgent procedures.

A grading scheme is provided on all WASP result sheets, individual participants must adhere to this grading scheme when submitting results. Results submitted as either 'compatible' or 'incompatible' will not be accepted and the laboratory concerned will be invited to re-submit. Spare material should be kept by laboratories in appropriate storage until the exercise summary is received in case repeat testing is necessary.

5. Exercise Details

5.5 Completion of Results forms

Each participant laboratory is supplied with exercise material, individual results sheets and cumulative result sheet(s) for each exercise. Results should be entered onto the cumulative sheet containing the code number of the laboratory, technique, number of actual/possible participants, date of receipt, sample quality and individual participant's codes.

Only individuals present in participating laboratories during the two-week period of an exercise should be included in the participation rates reported to the scheme. Those individuals who are on leave for the entire duration of an exercise need not be included as possible participants. **N.B.** Supplying individual codes allows analysis of individual participants. It is NOT necessary for the Scheme Manager to know the identity of individual participants.

Cumulative results sheets must be returned to the Scheme Manager by the expiry date of the exercise. Results returned after this date may not be included in the analysis, and will result in the laboratory incurring a 'Performance Score' for that exercise. Results should be returned by:

E-mail : **wasps@wales.nhs.uk**

All data returned will be analysed to produce the exercise report. At present this is done by manual data entry onto a computer spreadsheet. All results are verified by a second confirmatory check.

5. Exercise Details

5.6 Late Results

The scheme tests the reagents by all relevant manual techniques shortly after the expiry date to provide evidence that they have remained viable. The results of each exercise must be returned by the expiry date, results received after the expiry date will only be analysed if the samples have been tested by the expiry date. The 'date tested' column on the cumulative results sheet (WASPS/010) must be completed for late results to be accepted.

5.7 Performance Scoring

The 'expected' results for each serum are determined by 'in-house' testing in the RCI laboratory. Materials are only distributed following extensive testing by all relevant manual techniques. Testing is also conducted 'in-house' on exercise material that has been subjected to the postal system.

Performance scores are based upon the comparison of individual results to the overall modal results within technique. Criteria for both laboratories and individual participants are given in Appendix 2. The appropriate corrective action following notification of Unsatisfactory Performance Score is also defined in Appendix 2. Should a laboratory incur a performance score through a fault in the operation of the scheme, this will be corrected and the laboratory notified by the Scheme Manager.

5. Exercise Details

5.8 Performance Scoring

Erroneous results arising from participants' actions remain as received for the assessment of individual performance e.g. incorrect communication of results to the scheme or contamination of exercise materials by a laboratory and/or individual participant. A 'serum' sample, or section, of an exercise may sometimes be excluded from performance scoring. This will be instigated as the result of significant deterioration in the serological reactivity of one or more 'serum', or quality of a red cell sample, during the course of an exercise e.g. where an antibody is no longer detectable by all manual IAT techniques either during the course of an exercise or on the expiry date.

5.9 Uncertainty of the assigned (target) value

Uncertainty of measurement provides a quantitative estimate of the quality of a test result, and therefore is a core element of a quality system for laboratories. The same principle applies to EQA where the uncertainty of the assigned or target value is a measure of the quality of the EQA material. The standard uncertainty of the assigned value in EQA depends upon the method used to derive the assigned value, the number of laboratories (consensus values) and other factors including homogeneity, transport and instability. Where the assigned value and standard deviation are determined from a consensus of participants' results the uncertainty of the assigned value is assumed to include the effects of inhomogeneity, transport and instability.

6. Reports

Each laboratory will receive a confidential report that provides a clear presentation of the quality of performance for both the laboratory and individual participants within a laboratory. A summary of laboratory performance is also distributed to each consultant haematologist for each laboratory. The report is produced and issued to all participants electronically within 20 working days of the exercise expiry date.

The report gives a graphical representation of: -

- Laboratory Performance
- Cumulative Performance for previous three exercises
- Individual Participant Performance

It also includes a summary of the material distributed, the aim of the exercise, a comparison of techniques used and summary of each laboratories participation rate. The reports may be utilised for informational and educational purposes. Supplementary reports or information may also be distributed. Each report will possess an issue date, should a report require amendment(s) a new issue date will be given along with a brief summary of the alteration.

Extracts from scheme reports may only be used outside of the immediate laboratory (e.g. presentations, official documents) with the permission of the Scheme Manager.

7. Quality

The needs of participants are kept under constant review and regularly reviewed.

This is achieved by:

- encouraging participants to give their views, concerns and comments to members of the Steering Committee and/or scheme management;
- representatives of the scheme attending relevant scientific conferences;
- the issue of participant questionnaires.

Scheme management have identified the following quality objectives:

- Issue of one-page summary report to all laboratories within five working days of exercise expiry;
- Issue of full report to all laboratories within 20 working days of exercise expiry;
- All complaints to be acknowledged within two working days of receipt;
- Enquiries received by electronic mail responded to within three working days;
- Issue of a annual report to the National Quality Assurance Advisory Panel (NQAAP) for Haematology;
- Steering Committee meetings to be held a minimum of three times per annum;
- Scheme management to conduct an Annual Management Review (AMR)

Assessment of user satisfaction and any complaints received are conducted at the annual management review. Surveillance of the process will also be completed to ensure continuous improvement by monitoring report errors, amended reports, complaints, unsatisfactory reagents and internal/external audit findings.

APPENDIX 1

WASP STEERING COMMITTEE

Cheryl Davies	Chair
Gareth Nottage	Scheme Manager
Ceri White	Welsh Blood Service
Michael Cheung	Nuffield Health Wessex
Anke Meess	Glangwili Hospital
Greg Andrikopoulos	Llandough Hospital
Trisha McClure	Nuffield Health Brentwood
Tom Bullock	NQAAP (Haematology) *ex-officio*

Members of the committee serve a minimum three-year term.

Any participant in the scheme may nominate them.

APPENDIX 2

WASPS Performance Scoring System

Rules for Performance Scoring		Penalty under scoring system
1.	Deviation >-2 from the mode	100
2.	Deviation >-1 from the mode	40
3.	Deviation >+1 from the mode	10
4.	Deviation >+2 from the mode	40
5.	False positive reaction	50
6.	Failure to detect an incompatibility	100
7.	Failure to return results	50

Rules for Laboratory Performance Scoring	
Laboratories accrue the sum of :	
1.	The average score of individual participants who default under rules 1 to 5.
2.	The score of individuals who default under rule 6

The scores allow translation into 3 categories of performance:

0 – 49 indicates satisfactory performance.

50 – 99 indicates borderline performance, the reason for which needs to be reviewed.

>100 indicates unsatisfactory performance, needing corrective action to eliminate the cause and prevent recurrence.

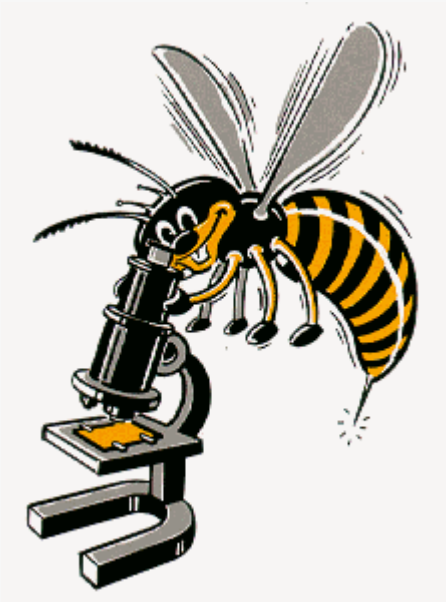
N.B. The scores and corresponding colour of performance will be reflected on the Individual Participant Graph.

APPENDIX 2

Rules for Notification of Unsatisfactory Performance Score

I. On the first occasion a laboratory is identified with an Unsatisfactory Performance Score they will be notified by a standard letter from the WASPS Scheme Manager.

II. A laboratory gaining an unsatisfactory performance score in two exercises, within a twelve month registration cycle, will be deemed to be a persistent unsatisfactory performer (PUP). Laboratories concerned will be informed of the situation and identified to the chair of the appropriate National Quality Assurance Advisory Panel (NQAAP), who will facilitate and where necessary authorise the appropriate corrective action.



www.waspsqa.org.uk

Welsh Assessment of Serological Proficiency Scheme / Cynllun Asesiad Hyfedredd Serolegol Cymru

Ely Valley Road Talbot Green Llantrisant CF72 9WB
Heol Cwm Elai Tonysguboriau Llantrisant CF72 9WB