Bloods Uk.



User Guide

This guide provides clear information to assist users in the provision of our services

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Bloods Uk.

About Us:

We are a private laboratory based in North East Lincolnshire, we offer a comprehensive range of tests to practitioners and clinics. Providing them with a personal and dedicated service for their pathology requirements.

Core Values:

- **Commit to Continuous Improvement and Excellence:** We relentlessly pursue personal and professional growth, always striving to enhance our skills and deliver superior performance.
- **Prioritise People and Exceptional Service:** We take care of our staff and ensure outstanding service to our customers, fostering a supportive and customer-centric environment.
- **Deliver Accurate and Timely Solutions:** We uphold the highest standards of accuracy and punctuality in our analyses and support, ensuring our customers receive reliable and timely insights.

Lab Hours

Monday-Saturday (excluding bank holidays)
09:00AM - 17:00PM*

*Closing times may vary dependant on the number of samples awaiting processing.

Quality Assurance:

Quality assurance is fundamental to upholding our core values. Our quality management system includes requirements for internal quality control processes as well as ongoing participation in external quality assessment schemes.

To ensure consistent quality and results, Bloods Uk utilises two external quality control schemes:

NEQAS

- Haematology
- Cystatin-c (Birmingham Quality NEQA)

RIQAS

- Chemical
- Lipids
- Immunoassay
- ISE
- HBA1C

Accreditation:

Bloods Uk holds CQC Registration under the diagnostics and screening regulated activity. Bloods Uk also hold ISO 17025 accreditation; our schedule of accreditation can be provided upon request or found on the UKAS register. This guide also details which offered tests are accreditied.

Consent Policy

Importance of Consent

Consent is a crucial component of medical testing and research. It ensures that patients are fully informed about the tests being performed on their samples and have voluntarily agreed to the procedure. This section outlines the responsibilities of clinics and practitioners in obtaining and documenting consent from their patients before sending samples to our pathology clinic for testing.

Responsibility of Users

Bloods Uk does not interact directly with the patients during sample collection. Therefore, it is the responsibility of the clinics and practitioners who send us these samples to obtain informed consent from their patients. This consent must be obtained in accordance with applicable laws, regulations, and ethical guidelines.

Guidelines for Obtaining Consent

Patients should be **informed** about the procedure and the process before the blood is drawn if a phlebotomist is used.

Consent can also be **implied**, this implied consent may come in the form of presenting the arm ready for blood withdrawal, for example.

Sample Volumes and Types

Bloods Uk can test both venous and capillary samples.

Our users should make their customers, whether they are collecting samples personally or allowing their users to take samples themselves, aware of the requirements for blood samples and the collection process.

Factors that should be taken into consideration are:

Time of Day: Some biomarkers, such as cortisol, have variations where the analyte is at its highest level in the morning and the levels gradually decrease during the course of the day. Therefore, ensuring the end user clearly states the time the sample was taken is important.

Selecting the Site: Selecting the appropriate side for venipuncture can contribute to a better-quality sample. The preferred site is the median cubital vein.

Order of Draw

To minimise the risk of cross-contamination between additives and to ensure the integrity of test results, blood samples shall be collected following the recommended order of draw.

1. Yellow top tube (e.g. serum or gel separator, where applicable)
2. Purple top tube (EDTA)
3. Grey top tube (fluoride/oxalate)

All users involved in sample collection should adhere to this order to reduce the potential for additive carryover that may adversely affect analytical results.

Sample Volumes and Types

Purple ('lavender') Vacutainer

These bottles are used for haematology where whole blood is required for analysis, i.e., FBC.

Purple vacutainers contain EDTA (ethylenediaminetetraacetic acid), which acts as an anticoagulant.

This kind of tube should be inverted around **8 times** to ensure the sample has properly mixed with the EDTA. **1 ml** is the required amount of sample for proper testing.

Yellow ('gold') Vacutainer

These bottles are used when performing a test which requires separated serum analysis, such as iron studies and lipid profiles.

It contains two agents: silica particles and a serum-separating gel. The silica particles cause the blood cells to clump together, they are used to 'activate clotting'. The serum separator causes an inert polymer gel which creates a physical barrier between the blood and the plasma. After centrifugation, the separated serum can be removed.

This kind of tube should be inverted around **5 times** to ensure proper mixing, **1 ml** is required for tests using these tubes.

Sample Volumes and Types

Grey Vacutainer

These bottles are used for FBC analysis and biochemistry. Specifically, they are used for glucose testing, which can be fasting or non-fasting (the details of this will be on the lab form and bottle before collection and checked before processing).

This type of vacutainer contains two additives, sodium fluoride and EDTA. They act as an antiglycolytic agent and anticoagulant respectively.

This kind of bottle should be inverted 8 times to ensure proper mixing. Only a small amount of sample is needed for a glucose test however, the bottle should ideally contain at least 1 ml of blood.

Further Information

Expiration Dates - these should be checked on the tube as expired tubes may have a decreased vacuum and potential changes in any additives, risking the integrity of the sample.

Sample Transportation and Reception

Transportation

The transportation agreement that is made between Bloods Uk and it's users may vary and will be finalised through communication with Bloods Uk and the user, though the principles remain the same. We recommend that samples are posted using Royal Mail, specifically Special Delivery, although we do accept deliveries from other major delivery companies.

Samples should be packaged and labelled 'Biological Substance - Category B' with the UN3373 diamond.

The samples container (primary packaging) should be placed into a plastic container/transporter/KPA (secondary packaging) with absorbent material in such a way that, under normal conditions, the packaging will not be broken or punctured.



Storage

The Laboratory retention time of samples follows guidance from the Royal College of Pathologists.

As a guide EDTA samples are kept for 2 days and serum samples are kept for 7 days after the final report has been replaced.

Under certain circumstances it is possible to add tests on to samples that are already in the laboratory but this depends on the sample stability and any time restrictions and requirements.

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Sample Processing

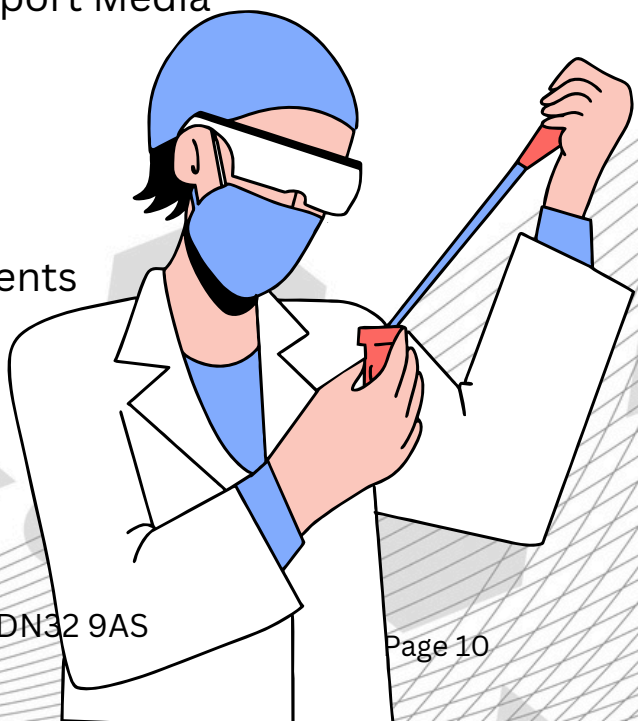
Accpetance Criteria

- Sufficient Volume for Vials
- Uncontaminated and Intact
- Consistent Information*
- Appropriate Container/Specimen Type
- Valid Collection Date
- Valid Container/Transport Media
- No Leakage
- No Obvious Haemolysis

Rejection Criteria

- Insufficient Volume for Vials
- Improper Labelling*
- Contamination or Compromised Integrity
- Mismatched Information*
- Inappropriate Container/ Specimen Type Specimen
- Out-of-Date Expired Container/Transport Media
- Leaking Specimens
- Missing Order Form

*More information on labelling requirements can be found on page 11.



Labelling Requirements

To ensure sample integrity, the following minimum labelling requirements must be met at collection and verified upon receipt in the laboratory.

Verification Process

- Sample vial details are cross-checked against the lab form.
- Both are verified against the LIMS system during registration.

Handling Discrepancies

- Name Errors:
  - If three or more incorrect letters in the first or last name, user confirmation is required.
  - Minor errors (1–2 letters) may be accepted without confirmation.
- DOB Errors:
  - A one-digit discrepancy across the vial and form may be accepted.
  - Multiple DOB discrepancies across vial, form, and LIMS require user confirmation.
- Sex/Gender Mismatch: User must be contacted for verification.
- Other Discrepancies: The attending BMS may contact the user at their discretion.

Outcome & Sample Acceptance

- No immediate rejection for minor errors—user will be contacted for verification.
- If the user confirms ownership, the sample is processed with necessary amendments.
- If ownership cannot be confirmed, the sample may be rejected.

Pre-Analytical Variables

Collection and Handling Errors

Underfilling of EDTA blood collection tubes can lead to erroneously low blood cell counts and hematocrits, morphologic changes to RBC and staining alteration.

Overfilling of the EDTA blood collection tube will not allow the tube to be properly mixed and may lead to platelet clumping and clotting.

FBC samples are acceptable up to 3 days post venipuncture, however certain parameters such as MCV and WBC differential may be affected by delayed analysis.

White blood cell (WBC) and platelet counts can be affected by cryoglobulins. Cryoglobulins aggregate and may be falsely identified as platelets and/or WBCs by the haematology analyser.

Haematology/Coagulation

Haemolysis can result in a spurious increase of serum/plasma analytes including potassium, total protein, AST, ALT, CK, phosphate, Lactate Dehydrogenase (LDH), urea, iron, folate and magnesium. Whereas albumin, ALP, GGT chloride. glucose and sodium can be falsely lowered.

Pre Collection Requirements

Request Forms

Bloods Uk will not receive request forms directly from patients, the samples that we are sent and tested come only from our users. However the request forms created by are users are vital for samples processing and acceptance. Therefore, we ask that all users ensure that the following information is present on the request forms:

- Customer Name
- DOB
- Gender
- Test Required
- Sample Date and Time Taken

When receiving the samples, the request forms are checked against the bloods vials and the information logged in the system, to check all details match. Once satisfied the samples can move onto the next stage. (See acceptance/rejection criteria and labelling requirements).

Processing

The samples are then spun in the centrifuge to ensure proper mixing and accounts for any separation of plasma and serum during transit.

After this the assay are run in the relevant analysers, either the cobas c311/e411 and/or the Horiba H550, depending on the test chosen.

Reporting

How Results are Reported

Once the assays have been successfully completed, the analysers automatically transmit the test results to the laboratory's internal system for processing. The results are then compiled into a formal report through our secure laboratory information management system (LIMS).

Each report is generated with the practitioner's branding, ensuring consistency with their service presentation. The report includes all relevant analytes, reference ranges, and units of measurement, and is presented in a clear, user-friendly format for both practitioner and client review.

Following generation, the report is uploaded to a secure practitioner portal. Users are notified that the results are available and can log in to their account to view, download, or share the report as needed. This system allows for streamlined access to results and supports fast, efficient reporting across all users.



Considerations

Stability

Samples should always, where possible, be dispatched as soon as possible to protect the integrity of the samples. We recommend that users inform their clients to send samples Monday-Thursday to avoid any issues with postal systems.

If the issues are encountered, users may contact the laboratory for further information and should make their users aware of the guidelines pertaining to biomarker stability.

Referrals

At present, Bloods Uk does not refer any tests to external laboratories. All testing is performed in-house at our own laboratory, ensuring full control over quality, accuracy, and turnaround times.

In the event of a major incident—such as equipment failure, power outage, or other unforeseen circumstances—testing may be temporarily halted. In such cases, users will be promptly informed, and results may be delayed until normal operations resume.

Should Bloods Uk decide to implement referral testing in the future, we will ensure that any external laboratories used are fully accredited and have undergone the necessary inspections. Prior to any testing taking place, a formal External Service Agreement (ESA) will be established to ensure quality and traceability.

Considerations

Turnaround Times

At Bloods Uk we aim to test all samples received within 24 hours. Turnaround times are calculated from the time of sample receipt in the laboratory and the report validation of the sample.

These times are quoted as working days. Reports are validated and reported once all daily received samples are completed.

Measurement of Uncertainty

Bloods UK performs all assays in accordance with the manufacturers' instructions (Roche for biochemistry and immunoassay, and Horiba for full blood count analysis).

Overall assay performance is continually monitored through Internal Quality Control (IQC) and External Quality Assessment (EQA)—see page 4 for further details. These quality assurance measures support the accuracy and reliability of all test results.

Measurement of Uncertainty (MU) is evaluated annually for each analyte using SDI data from EQA schemes. This assessment ensures that MU values remain within acceptable performance limits. Full details of the methodology and MU values can be found in BUK_LI_014_Measurement of Uncertainty Policy_v05. This information is available to users on request.

Analytes Tested

Due to the nature of our testing and the capability of the analysers within Bloods Uk, we exclusively test serum samples. Below is the list of analytes tested at Bloods Uk and what analysers are used to test the analytes.

COBAS e411

- Ferritin
- Free Testosterone
- Cortisol
- Prolactin
- Oestradiol
- Progesterone
- LH
- FSH
- DHEA-S
- SHBG
- Free T4
- TSH
- Free T3
- Total PSA
- ATG
- ATP
- Vitamin B12
- Vitamin D
- Folate

Horiba Yumizen H550

- Haemoglobin
- RBC
- Haematocrit
- MCV
- Red Cell Distribution Width
- Mean Cell Hb (MCH)
- MCHC
- Platelets
- MPV
- WBC
- Neutrophils
- Lymphocytes
- Monocytes
- Eosinophils
- Basophils

COBAS c311

- Albumin
- ALP
- ALT
- AST
- Cholesterol
- Chol: HDL ratio
- HDL
- LDL
- Non-HDL Cholesterol
- Triglycerides
- CK
- Creatinine
- eGFR
- CRP
- Cystatin-C
- GGT
- Globulin
- Glucose
- Iron
- Magnesium
- Sodium
- Testosterone
- Total Bilirubin
- Total Protein
- Urea
- Uric Acid
- HbA1c – IFCC
- ApoA(not accredited)
- ApoB (not accredited)

Reference Ranges

The reference ranges used on our reports are compiled from a range of different NHS trusts. The ranges were reviewed in August 2025 and undergp review every two years, or earlier if there is an industry change. Critical ranges are pulled from the RCPath guidelines on communicating critical results, version 2.

It should also be noted that reference ranges will be the same for capillary and venous samples, and capillary ranges are not standardised. However, measurements of uncertainty with capillary samples can be provided upon request, as can the reference ranges themselves. Furthermore, reference ranges do differ in regard to gender and age so please ensure these are accurate on orders and lab forms to ensure accurate ranges.

Full Blood Count (FBC) Time-sensitive Parameters

Due to the nature of the laboratory service, which includes the receipt of samples via postal delivery, there may be instances where Full Blood Count (FBC) samples are received by the laboratory more than 24 hours after venepuncture.

Users are responsible for packaging and dispatching samples in accordance with the requirements detailed within this User Guide. Samples are routinely sent using tracked postal services; however, the laboratory recognises that delays beyond 24 hours post-collection may occur in certain circumstances, i.e. samples collected on Saturday clinics are not received until Monday.

Where FBC samples are analysed more than 24 hours after venepuncture, some red cell indices may be affected due to time-dependent changes in red cell morphology. This principle is described in internationally recognised pre-analytical haematology guidance, including recommendations from the International Council for Standardization in Haematology (ICSH), and is supported by published haematology literature on specimen stability.

Full Blood Count (FBC) Time-sensitive Parameters

The red cell indices most susceptible to delayed analysis include:

- MCV (Mean Cell Volume) – Red cells may swell over time, resulting in an increased MCV.
- RDW (Red Cell Distribution Width) – Variability in red cell size may increase with prolonged storage.
- MCHC (Mean Cell Haemoglobin Concentration) – May decrease as a consequence of red cell swelling without proportional haemoglobin change.
- MCH (Mean Cell Haemoglobin) – As a calculated parameter, this may be indirectly affected by changes in red cell volume and count.

These changes may result in red cell indices that are not fully representative of the in-vivo state at the time of sample collection. Other FBC parameters, such as haemoglobin concentration, are generally more stable but should still be interpreted in the context of sample age.

Users should be aware of these limitations when submitting samples via postal services and should interpret affected red cell indices with appropriate clinical caution where analysis occurs beyond 24 hours post-venepuncture.

Full Blood Count (FBC) Time-sensitive Parameters

The laboratory aims to process Full Blood Count samples as soon as practicable upon receipt. Upon receipt, appropriate measures are taken to preserve sample integrity, such as prompt testing and controlled storage conditions, in line with internal procedures.

Despite these controls, there will be instances where samples are received more than 24 hours after venepuncture due to transit time. In such cases, time-dependent changes in red cell indices may still occur, as described above, and results should be interpreted in this context.

Samples analysed beyond 24 hours post-venepuncture are not currently explicitly identified as such on issued reports. Where users consider it appropriate for sample age to be referenced within reports, this can be discussed and agreed as part of the ESAs.

Users are strongly encouraged to ensure that end users are made aware of the potential impact of delayed analysis on specific red cell indices, particularly where samples are submitted via postal services. The laboratory is available to support users in relaying this information where required and to provide clarification on result interpretation in the context of sample age.

Full Blood Count (FBC) Time-sensitive Parameters

While red cell indices are recognised as the most susceptible parameters to delayed analysis, it is important to note that white blood cell (WBC) parameters may also be affected when samples are analysed beyond 24 hours post-venepuncture, particularly when samples are transported via postal services.

Prolonged storage of whole blood, even under controlled conditions, can result in cellular degradation and morphological changes, which may impact the accuracy and reliability of differential white cell counts.

The following effects may be observed:

- Neutrophils – May exhibit degenerative changes, including cytoplasmic vacuolation and nuclear changes, which can affect accurate classification and lead to apparent reductions in count.
- Monocytes – May show increased fragility and morphological alteration over time, potentially impacting enumeration.
- Eosinophils and Basophils – These populations are typically low in number and may be disproportionately affected by cellular degradation, leading to increased variability or reduced reliability in reported values.
- Total White Cell Count – May remain relatively stable in the short term; however, prolonged delays can lead to gradual deterioration in sample integrity, affecting overall accuracy.

Full Blood Count (FBC) Time-sensitive Parameters

In addition, cell lysis and apoptosis may occur with extended storage, contributing to shifts in measured populations and reduced confidence in differential results.

These changes are described in recognised haematology guidance, including recommendations from the International Council for Standardization in Haematology (ICSH), which highlight the importance of timely analysis for preservation of cellular morphology and analytical accuracy. Published literature on EDTA sample stability also supports that white cell morphology and differential counts may be compromised beyond recommended timeframes.

Where analysis occurs beyond 24 hours post-venepuncture:

- White cell differential results should be interpreted with caution, particularly where clinical decisions rely on subtle changes in leukocyte populations.
- Any unexpected or borderline results should be considered in the context of sample age and, where clinically indicated, repeat sampling may be recommended.
- The potential for degradation-related variability should be recognised, particularly in postal sample pathways.