SAMPLE ACCEPTANCE & REJECTION POLICY

Reviewer	Approver	Summary of Changes
Signature as recorded on Q-pulse Approval	Signature as recorded on Q-pulse Approval	Changes in Blue Addition in red under section 6
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Quality Manager	Quality Support Officer	
April 2025	April 2025	

ASSOCIATED PROCEDURES & FORMS	Sample Acceptance Criteria Form [PF-GEN-MF-25] Sample Disclaimer Form [PF-GEN-MF-26] Histology Sample Collection, Acceptance & Rejection Policy [PF-HIS-LP-42] Acceptance / Rejection of Cytology Samples [PF-CYT-LP-1] Form for Acceptance / Rejection of Cytology Samples [PF-CYT-LF-1] Acceptance & Rejection Criteria for Non-Gynae Cytology Samples [PF-CYT-LP-12] IBMS Guidance on Patient Sample and Request Form Criteria [PF-GEN-EXT-14] Guidelines on Medicolegal samples [PF-GEN-EXT-32] Microbiology Sample Acceptance guide [PF-PIP-62] Sample Stability in Biochemistry [PF-BIO-LF-54] User Handbook Website https://tests.synlab.co.uk
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1. Purpose and Scope

This policy aims to provide an overarching process to specimen acceptance and rejection to help balance the 'requirement to process' against the 'risk to patient safety'. It is consistent with both manually requested and electronic ordered examinations, and it provides a robust framework to ensure that all specimens are correctly & unambiguously identified. There are also some discipline specific procedural documentation to support individual operational practice which includes a defined procedure for accepting Blood Transfusion specimens.
Please note that this policy deals ONLY with the acceptance of specimens and request forms and not with processing problems related to sample integrity. Matching request data with the Master Patient Index (PAS) is also a separate issue, which is dealt with in associated IT policies.

The purpose of this document is to ensure that Pathology First (PF) meets best practice to ensure Patient Safety and the effective reporting of PF results and reports, ensuring compliance with all relevant standards and guidelines. The policy applies to all PF staff and to external organisations that use Pathology First Services. Before accepting clinical specimens, laboratory staff must ensure that the minimum criteria for positive patient identification have been met and that the Request Form and Samples are compatible.

The purpose of this policy is also to minimise the need to re-bleed patients unnecessarily. It takes into consideration unrepeatable samples and those collected by patients themselves. Samples must also be appropriate for the test(s) requested and compatible with current instrumentation. This is to be in compliance with ISO 15189:2022 std, clauses 5.4.6 and 7.2.6.2

This policy also deals with sample quality in terms of:
- Assay stability and the clinically acceptable times between sample collection and analysis.
- Assay interference from Haemolysis, Lipaemia etc.
- The decision-making process as to which assays can be reported and which must be excluded.

Implementation of this policy will ensure that:
- Pathology specimens are unequivocally identified to a patient.
- Results are reported to the requester at the correct location.

Non-compliance with this policy will result in requests being delayed or rejected.

Whilst this document does not specifically deal with Turnaround Times, it is worth noting that when these are set, consideration is given as to the needs of the user and the clinical appropriateness of sample age.

There are a number of considerations to be taken into account – primarily to be in the best interests of the patient where samples have been potentially compromised due to:
- Incorrect patient ID
- Sample stability breaches.
- Storage and Handling issues
- Use of incorrect sample container / anticoagulant
- Incorrect sample volume

Where a sample has been compromised but is considered to be clinically critical or unrepeatable, then patient safety shall be risk assessed. Where appropriate, the final report should indicate the nature of the problem, along with considerations around the interpretation of the results.

Please Note –

- Samples for blood transfusion must be signed by the person collecting the specimen.
- Request form must indicate whether special requirements are needed or not for the patient.

In Blood Transfusion, in addition to a signature on the sample and notification of special requirements on the request form, they also require:

- Samples and request forms to be dated and timed for sample validity purposes.
- Request forms to be signed by the sample collector.
- Clinicians to sign the request form if requesting blood products with reason for request.

Also note:

- Samples for DAT only, do not required to be signed.
- SUH ICE request forms notify if the patient has been transfused in the last 3 months.
- SUH ICE request forms notify of any irregular antibodies.
- SUH ICE request forms notify if the patient is pregnant and on labour ward.
- SUH ICE request forms notify if the patient is less than 4 months old as this changes the sample requirements.

2. Responsibility

It is the responsibility of Departmental Managers to ensure that all staff who take receipt of and process requests are aware of this protocol, the criteria for accepting and rejecting samples, the importance of compliance and how to seek advice when unsure whether requests can be accepted.

It is the responsibility of the requester to ensure that request forms are correctly filled in (to the agreed standards) and that the request is unequivocally traceable to an identified patient or site. It is the responsibility of Ward/Unit managers to ensure any labels applied to bottles are suitable and have been tested for their suitability and signed off by PF.

It is the responsibility of the blood taker / healthcare professional to ensure that at least three identifiers are written on the request form before the blood is taken and that the sample has the appropriate, corresponding identifiers on it. On the wards, in the absence of three identifiers, request forms must be referred to ward staff for additional data to be added. In Phlebotomy, the patient can be asked to add additional patient ID data.

The collection of samples is performed by a member of staff who is trained to collect the required sample type. The medical practitioner may take the sample themselves or arrange for another member of their staff to collect the samples. For the collection of blood samples, they may ask for the samples to be collected by the Pathology First Phlebotomy service. The specimen collector is responsible for:

- Positively Identifying the patient (Forename, Surname, Date of Birth, NHS, or Hospital number), labelling the specimen and ensuring that the information supplied on the request form and specimen are accurate and match, in each case. For Transfusion, the person taking the blood must sign the request form in the appropriate place.
- Ensuring that the specimens are packaged and transported to the laboratory according to the guidance given and consistent with relevant legislation in force. For Transfusion samples, the person taking the blood sample must sign the request form and sample in the appropriate places. Transport must also be within a timeframe to ensure the stability and integrity of the samples.

There are slightly different criteria applied to samples collected and labelled by patients themselves. In all cases refer to PF-GEN-MF-25 which is On Q-Pulse.

Laboratory staff are responsible for:

- Confirming that specimens and forms meet the agreed acceptance criteria, but depending on circumstances the laboratory staff may inform the requestor of any rejected request.
- Only analysing samples that have been correctly identified and are within the stability period for the assays requested.
- Checking Transfusion samples for historic blood group, this may involve interrogating the legacy computer system. Where no historic group is available a second sample must be requested – ideally bled by a different person.

3. Definitions

BSQR – Blood Safety and Quality Regulations
MHRA – Medicines and Healthcare Products Regulatory Authority
GP – General Practitioner
PAS - Patient admission System
PF - Pathology First

4. Records

All records / documentation generated as a result of a process shall be entered onto Qpulse. Disclaimer forms should be retained against the patient record on Winpath.

5. Identification and Labeling

Requirements for specimen and form identification are shown on the document [PF-GEN-MF-25]. This information is provided on the Pathology First User Handbook and, where requested, as a leaflet to service users.

5.1 Request Form Information

Pathology First requires the use of the electronic order communication systems wherever possible as the system interfaces with PAS systems and a request form will print with full demographic and order details. “Adequate and relevant clinical information” must be provided on the form, by the requestor to assist the laboratory in identifying high risk samples and to enable correct processing/validation of samples. Where electronic ordering is not available, the same criteria and level of information is required on a paper request form.

Pathology First phlebotomists must check the request form. If any details are incomplete the Phlebotomist should establish this before collection with either the patient or requestor. The collector should also complete the date & time of collection on forms as this is essential for some investigations and also provides a link between form and

sample. Multiple specimens taken at different times on a single patient MUST be labelled on the tube with the time (24-hour clock) when the specimen is taken e.g. oral glucose tolerance test. The request form should indicate that there are multiple specimens with the times recorded (24-hour clock) and the times should match the times written on the tubes in order to preserve the sampling sequence.

Where the gender is uncertain "U" should be used. Where it is known that patients are undergoing gender reassignment, advice should be sort from the clinical team who can best advise which references ranges are most appropriate.

The collector's name or phlebotomy code should also be added to the form and the number / type of samples recorded on the form if possible.

If a patient present with 2 request forms for different clinicians, they MUST be treated as separate requests and where necessary additional samples taken. While the taking of additional blood is generally avoided in this case the medico-legal implications of shared care mean that this must be the case.

Forms from GP patients should contain:

- Surname and Forename
- NHS Number
- Date of Birth

If one of these details is unavailable, then the address should be included. The request form should also include:

- Ward, Clinic or GP Location
- Location for the report (if different)
- Name of requesting clinician
- Tests requested.
- Relevant clinical details

Forms from A&E where patients have been admitted alone and unconscious will be labelled with the A&E number or Major Incident number, Unknown Male / Female followed by 1, 2, etc if there are multiple casualties.

For Confidential patients such as those attending a GU clinic or having HIV tests a unique number, Date of Birth and gender will be the only information given. The clinical team will be the only staff to link the unique number to the patient.

All Neonates should have a Hospital Number, Surname, Date of Birth and Gender on Pathology requests. Where available the Forename should be used, but it is acknowledged that this may not always be decided immediately following the birth. In the case of multiple births, the form should indicate Twin 1, Triplet 1 etc.

5.2 Specimen Labelling

Specimen containers must be labelled at the time of collection, with cross-checking to positively identify the patient and ensure patient safety is not compromised. Pre-labelling of blood collection tubes is very poor practice, increases risks of misidentification and is not acceptable. Patient details on specimen and accompanying request form, must match. The specimens should have date & (ideally) time of collection completed. Samples must be labelled clearly, and patient PAS Addressograph labels should not be used. However other types of printed labels that have been tested and fit the tubes correctly, may be accepted. **Please note** transfusion samples MUST be signed by the collector and all the patient information handwritten.

Where sample labels are used (either at collection or in Specimen Reception) they should ideally be printed at the time of collection and carry the full patient demographic &/or laboratory barcode. This label should be the correct size for the sample bottle. Labels on Blood tubes should not obscure the "window" on the side of the tube to ensure visibility of the sample volume and where applicable to serum interface to check for haemolysis, lipaemia etc. Large labels cannot be accepted as they can get caught in the moving parts of analysers with grabbers. Labels can NEVER be used on Transfusion samples.

Any patient labels in use, must have been tested and signed off by Pathology First

Some samples such as Random & 24 Urine samples and Faeces are collected and labelled by patients themselves rather than by healthcare professionals. In these circumstances they may not be aware of certain information such as NHS numbers or the need to label samples with this information. In these cases, samples will be accepted provided they are labelled with their Name and Date of Birth with an appropriately completed request form. The Biochemistry consultants have agreed to accept 24 hours urine sample with just name on the container and have risk assessed this accordingly. Please see section 6.6 of this SOP

Please note:

- Samples will not be accepted if they are completely unlabelled, as these samples are not considered to be unrepeatable.
- Unlabelled samples must never be corrected by laboratory staff.

Samples collected / labelled by healthcare professionals MUST have all the criteria required.

For details that are required on different sample types of samples please see Appendix 1 of this SOP which relates to PF-GEN-MF-25

Times used on Samples and Form MUST be using the 24 hours clock – otherwise a viable sample may be rejected as unable to establish correct timeframe.

5.3 Specimen Checking and Acceptance

The procedure for correct identification of specimens requires that each specimen and the request form can be checked to ensure positive patient identification. In some cases, this is by keeping them together in a single bag for inspection. In other cases, certain phlebotomy areas (Basildon OPD and some community clinics) use Foam Racks to collect samples and in these cases the forms are kept with the racks during transportation for checking on arrival at Specimen Reception Please note that High Risk samples may be double bagged. In the event of leakage only the single patient's specimen(s) will be affected.

Please note – a project is currently under way to reduce the use of single-use large transport sample bags. To promote sustainability and environmental awareness, these sample transport bags will now be recycled instead of discarded after the specimens have been removed. This should reduce the disposal of single use plastics by approx. 30,000 sample bags per month. A pilot program for recycling commenced on 2nd September 2024, and the implementation of this program became operational on 22nd April 2025.

Sequential specimens on the same patient, e.g. glucose tolerance test, may be transported in one bag with the request form as per above. Samples which are unstable e.g. insulin, free fatty acids should be sent immediately to the laboratory. Each specimen should be identified with a time in addition to the other items.

Pathology staff must not amend details on either the sample or request form. Samples or request forms received without the 3 minimum essential patient identification criteria stated must be rejected.

For samples or forms with **minor** anomalies

- In-patients: where possible, interrogate PAS and or contact the ward for clarification and enter appropriate comments onto laboratory computer.
- For GP patients: where possible contact the GP practice for clarification and enter appropriate comments onto the laboratory computer.
- At the discretion of senior staff or supervisory staff in Support Services, samples with minor labelling errors, i.e. Brown / Browne or Leslie / Lesley may be accepted with the appropriate comment entered into the laboratory computer and printed on the report. However, the other key identifiers must be correct. In these cases the use of BERR or HERR or other department specific comments are used.
- Many people use pseudonyms, or may have changed their surname, so details should be checked on PAS at data entry.

ONLY EXACT MATCH SAMPLES ARE ACCEPTABLE FOR BLOOD TRANSFUSION

In some cases, where a sample may be regarded as unrepeatable, the appropriate pathology consultant might be asked for their advice.

Under no circumstances must any sample labelling be changed by Pathology First Specimen Reception or Laboratory staff. This breaches IBMS guidelines and can risk professional registration. Any comments should be added to Winpath &/or the request form NOT the sample.

6. Acceptance & Rejection of Forms / Specimens with Labelling Errors

Specimens may be rejected if they do not comply with the acceptance criteria detailed in PF-GEN-MF-25. Samples may also be rejected if they are broken or leaking/contaminated on receipt. The final decision to accept or reject a specimen rests with Pathology First.

Laboratories will not process unlabelled or mislabelled specimens which are reproducible or repeatable if they have **MAJOR** discrepancies. **MINOR** discrepancies may be accepted and are handled according to the policy below. Local laboratory procedures will be followed for issuing a report and notifying requesting clinician/ward that a repeat specimen collection is necessary. If a specimen is processed where there has been a discrepancy the final report should indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.

There are specific regulations and requirements associated with Blood Transfusion specimen as found in the BSQR guidelines and assessed by MHRA.

In a number of circumstances, it would not be possible to repeat the collection of the specimen. The laboratory would classify these as ‘Unrepeatable/unreproducible specimens’ or unique specimens - see section 6.4. If the sample would be rejected due to a **MAJOR** discrepancy and is classified as unrepeatable then a specimen

disclaimer form can be completed by the specimen collector. Other samples e.g. pre-treatment samples may be accepted at discretion of clinical team.

Biochemistry samples to be accepted with Consultant Biochemist authorisation - "For Biochemistry" - During routine hours the Consultant on-site can be contacted, if they are not available one of the consultants at another site may be contacted. Out of hours the Consultant Biochemist on call must be contacted. If it is agreed that the sample can be processed, then a Sample Disclaimer Form (PF-GEN-MF-26) must be completed. *Please see section 6.5.1 of this SOP.* This should be completed with all the required details and scanned into Dart and kept for at least 30 years. The test code - DISC/DICF – should be entered into WPE.
In certain circumstances lab staff can authorise analysis, this includes –

- CSF samples with a PAS label
- CSF samples received unlabelled but within a bag with the request form".

If samples are not suitable for analysis due to failure to meet sample acceptance criteria or are deemed unsuitable for analysis due to technical factors samples will not be returned to the user.

6.1 Labeling Discrepancies

All labelling discrepancies should be recorded on the laboratory computer system to clearly identify.

- Minor discrepancies -which may be processed with a comment added (except Transfusion)
- Major discrepancies which may be rejected unless unrepeatable

The absence of a request form or an unlabelled sample will be treated as a major discrepancy.

The following Minor Discrepancies between the specimen and the form may be accepted. If other information has been sent with the request form – e.g. cytology recall slip, printout from another clinical computerised system then this can be considered part of the request form. If a minor discrepancy could arise from there actually being 2 patients e.g. Mother and Daughter, or Twins then clarification should be sought from the requester.

Where the form contains the complete data set, and the sample has the correct Surname AND Forename AND Date of birth BUT no unique identifier then this will be accepted as a minor discrepancy with a comment on the report.

For samples other than Transfusion, the following discrepancies are acceptable provided a comment is added to the report:

- NHS number OR Hospital number AND phonetically correct Patient surname AND Date of Birth
- NHS number OR Hospital number AND Patient surname AND minor discrepant Date of Birth – discrepant Date of Birth is defined as error in either the day OR month OR year.
- Phonetically correct Patient surname AND Patient forename AND Date of Birth
- Minor discrepancy in NHS number OR Hospital number (single digit discrepancy or switch of 2 digits) AND Patient surname AND Patient Forename AND Date of birth

Samples for blood transfusion must be signed by the person collecting the specimen.
Request forms must indicate whether special requirements are needed or not for the patient.

6.1.1 Unique identifier

If the unique identifier is not present on the sample, then it must be present on the request form or an alternative additional identification such as address present and checked on PAS. If there is no other unique/3rd identifier on the sample **OR** form, then this will be considered **MAJOR.**

6.1.2 Surname & Forename

A discrepancy in spelling of Surname or Forename between the form and the specimen which is phonetically the same or is an abbreviation may be accepted as **Minor** PROVIDED a unique identifying number (NHS, Hospital Number, or A&E number) and/or DOB is given and is correct – i.e. DAVIS/DAVIES, LIZ/ELIZABETH. The exceptions to this rule are Transfusion samples where all information must be 100% correct. Any other discrepancy than those lists will be considered **MAJOR**.

6.1.3 Date of Birth

A minor discrepancy in DOB between the form and the specimen may be accepted only if the surname, forename and **EITHER** a unique identifying number (NHS, Hospital Number, or A&E number) is given **OR** the address is given on the request form. However, care should still be taken when using an address as an Identifier as for example a father and son may have the same name at the same address but very different DOB. The exceptions to this rule are Transfusion samples where all information must be 100% correct.

A minor discrepancy is considered to be an error in either the day **or** month **or** year. Errors in more than one of these will be considered as an incorrect DOB, which is a major discrepancy. A discrepancy in DOB without **EITHER** a unique identifying number (NHS, Hospital Number, or A&E number) **OR** the address on the request form will be considered **MAJOR**.

6.2 Master Patient Index

If there is a discrepancy between the specimen and the form, it might be possible to resolve the problem by checking the Master Patient Index (PAS) or NHS Tracing service. However, care must be taken in accepting apparent major discrepancies under these circumstances. Always consult a senior member of staff if unsure.

6.3 Alterations to Patient Identity

No forms or specimens will be accepted by any department where correction fluid has been used to alter patient identification details. Specimens for Transfusion or blood grouping requests will not be accepted if patient identification data has been crossed out or altered on the specimen or request form.

For all other departments, if more than one of the data items has been crossed out or altered on the specimen or request form, the request will only be accepted if: the reason for the alteration is documented on the request form and is signed (& name printed) by the person making the alteration. The subsequent report will show a clear disclaimer detailing the shortcomings of the sample and/or request. This will alert the requesting practitioner to take responsibility for the results, and for any action taken as a result of the report.

Please note – it is never acceptable for staff to go the Laboratory to retrospectively label or make changes to a sample.

6.4 Samples to be re-collected

6.4.1 Sample collected by Pathology First Phlebotomist

When there is a problem with a sample collected by the Pathology First Phlebotomists on a ward, in the community or in the Outpatient clinics, the following action should be taken:

- Every effort should be made to get the patient re-bled as soon as possible.
- The appropriate comment code PTBR (Patient to be recalled) should be entered onto the laboratory computer. The Referrals team re-call patients.
- An accurate record should be made on the laboratory computer record stating if and why the sample was rejected or accepted.

Please note that Pathology First do not recall patients on the ward. The Phlebotomist will attempt to bleed to patient again. If this is unsuccessful, the form will be returned to the ward. The Phlebotomist completed paperwork for the team to capture this information.

6.4.2 Samples collected by Trust Staff

For in-patients (bled by Trust staff) where the sample acceptance criteria has not been met, the Specimen Reception staff at the appropriate ESL will telephone the ward. They will to inform them that the sample has been rejected and will need to be recollected

When there is a concern / issue with samples collected by other external users such as GP's or Community Midwife, they will receive notification on a Pathology report that a sample has been rejected and certain tests could not be carried out. If the sample is regarded as urgent then they should be advised by telephone of the problem and the corrective action required.

If the request is to be rejected and the sample not processed, **the laboratory report** should clearly indicate the action taken as a consequence of any inadequate labelling.

6.5 Unrepeatable specimens

A specimen may be considered unrepeatable or very difficult to repeat for any the following reasons:

- It is unique (e.g. tissue sample).
- It is obtained by an invasive technique that may pose a significant risk to the patient (e.g. CSF, Bone Marrow or Amniotic Fluid).
- The clinical status of the patient may have changed since the specimen was collected (e.g. post drug overdose, post transfusion, post-surgery or antibiotic therapy).
- Some Dynamic Function tests
- The patient has passed away.

Discipline	Types of Unrepeatable Specimens
Transfusion and blood grouping	No specimens will ever be considered unrepeatable, and all labelling discrepancies will result in the specimen being rejected
Cellular Pathology	All Histology and most Non Gynae Cytology specimens will be considered unrepeatable.
Haematology	CSF Bone marrow Synovial fluid Sample for Haematinics where the patient has been Transfused. Sample for coagulation where FFP or anticoagulation treatment has been given
Biochemistry	CSF and blood specimens that fulfil the following criteria when the clinical status of the patient has changed since the original specimen was taken. • Post drug overdose - the original drug may now have been metabolised. • Blood Alcohol levels which will have reduced over time. • Post a hypoglycaemic episode, which has not been repeated, on a patient where the assay of insulin (and/or C-Peptide) is important. • Postmortem specimen where re-sampling is not possible. • Blood specimens from small neonates where re-sampling poses a real risk or problem to the infant. • Samples collected Inter-operatively such as PTH levels. • Specimens from Dynamic Function tests • Blood gas specimens where repeat sampling is a problem. For advice – speak to one of the Biochemistry Consultants
Microbiology	• CSF specimens as the sampling procedure poses a risk to the patient. • Tissue • Pus from deep sites • Perioperative swabs / tissue samples Fluids such as joint and BAL (pleural fluids and ascites may be repeatable; discuss with Consultant Microbiologist)

The acceptance of an inadequately labelled sample, which is considered unrepeatable, will be at the discretion of the Pathology Consultant – or in their absence the Operations Manager / Quality Manager. In these cases, the sample should be returned to the requester using the Disclaimer form – PF-GEN-MF-26

A record must be made on the computer system that the sample was inadequately labelled and the reason why it was unrepeatable. The name of the person accepting the sample must also be included. The disclaimer form should be scanned onto the Winpath record using DART and retained for at least 30 years.

Please note – the Disclaimer form is only to be used in exceptional circumstances as listed above. It is not to be used as a general habit in case of unlabelled or poorly labelled samples. This is because of the risk to patient safety.

6.5.1 Disclaimer Form for Unrepeatable Samples

If a clinician requests that a sample is processed as it is classified as unrepeatable then they must discuss the case with the most senior member of staff available / pathology consultant. If the sample is designated

as unrepeatable then, at the discretion of the laboratory staff, the requestor/collector can complete and sign a "disclaimer form". The code DICF should be added to the Laboratory computer system to indicate the sample has been processed via a disclaimer and the disclaimer form should be scanned and maintained against the patient record.

Blood Transfusion samples are never considered unrepeatable. If a disclaimer is requested for a Blood Transfusion sample, then only Consultant Haematologist can authorise this course of action.

If the laboratory does not agree that the sample is unrepeatable or is not happy for a disclaimer to be completed, then refer the requesting clinician to a Pathology Consultant for authorisation.

Due to the incorrect use of forms for Micro please add a specific line to state: -

- Only to be used for unrepeatable Paediatric blood cultures,
- CSFs and other unrepeatable samples e.g. intraoperative tissue.

6.6 Patient Collected Samples

Some samples such as Random & 24 Urine samples and Faeces are collected and labelled by patients themselves rather than by healthcare professionals. In these circumstances they may not be aware of certain information such as NHS numbers or the need to label samples with this information. In these cases, samples will be accepted provided they are labelled with their Name and Date of Birth and accompanied with an appropriately completed request form.
In Biochemistry, the consultants have agreed to accept sample labelled with just First name and Surname and have requested that if the Date of Birth is missing that the sample should still be accepted. This information has been passed on to the PSS staff and any queries about whether to accept or not should be referred to the appropriate biochemistry consultant as they have the clinical knowledge to risk assess any specific cases of concern.

Please note:

- Samples will not be accepted if they are completely unlabelled, as these samples are not considered to be unrepeatable.
- Unlabelled samples must never be corrected by laboratory staff.

Samples collected / labelled by healthcare professionals MUST have all the criteria indicated on page 1.

7. Sample Integrity Issues

In some cases, samples that are correctly labelled, can be rejected because the quality / integrity of the sample has been compromised and could therefore produce erroneous results if analysed. Some of the common causes affecting sample quality are:

- Time between sample collection and receipt. Some assays are labile and need to be analysed as soon as possible after collection or separated to preserve the appropriate analyte. All samples should arrive in the laboratory within 6 hours of collection – however some samples need to arrive in less time than this.
- Samples that have not been prepared correctly – i.e. Biochemistry samples that need centrifugation etc.

In addition Haemolysis, Lipaemia, Icterus / Xanthachromia can affect some assays and Serum Indices are generally set up to gauge the scale of these factors and whether it is safe to run assays or if they need to be excluded.

In many cases it will be possible to analyse some assays that are not affected by the quality issue, but to reject others. The ultimate decision on what can be tested or what cannot rests with the appropriate Pathology Consultant for that section of the laboratory.

Where assays are excluded, a comment is added to Winpath to notify the requesting clinician as to why the assay was rejected.

7.1 Sample Volumes

For all tests there must be sufficient volume to be able to carry out the tests requested. If there is not sufficient volume, then some or all of the tests requested might be rejected and will require re-collection.

For certain tests the correct blood to anticoagulant ratio is important to ensuring the correct results are obtained. This is particularly important in Coagulation sample which should always be collected up to the "fill" line on the tube. However other tests such as full blood counts and Blood Glucose can also be adversely affected by having the wrong blood volume collected.

7.2 Sample Stability

Please note that many samples have a time window in which they are suitable for analysis and any delays may affect the quality of the results. This is true for all disciplines and sample types. Excessive delays that may have occurred can result in the sample having to be rejected, for some or all, of the tests requested. In these cases, coded comments will be added to indicate what the problem / delay was.

Consideration needs to be given to the time from sample collection from the patient, as well as transportation, and these times should be indicated on the sample &/or request form. In the case of patient collected samples this may not be included on either form or sample and a comment will be added warning the requesting clinician that this information was not available.

Periodic monitoring of sample collection to analysis and sample collection time not stated has added into the Audit Schedule to better be able to assess the scale of this.

8. References

- Guidelines for specimen and request form labelling [PF-GEN-MF-25]
- Institute of Biomedical Sciences: (July 09) Professional Guidance: Patient Sample and Request Form [PF-GEN-EXT-14]
- Identification Criteria - https://www.ibms.org/go/media/publications/professional-guidance
- BCSH Guidelines
- BCSH Guideline on Administration of Blood Components (2009)
- BCSH Guidelines on Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories (2004)
- UKAS – Medical laboratories – (ISO 15189: 2022 version of the standard clause 7.2.6.2

APPENDIX - Examples of Labelling Discrepancies

These examples all refer to a patient with the following definitive details:

Hospital number: 123456

NHS number: 111 222 333

Surname: Mouse Nee: Mouselet

Forenames: Minnie Minor

DOB: 01/01/21

Address: 15 Donald Duck Drive
Disneyland
Taunton
TA2 9SW

Registered G.P.: Dr Quacker
The Pond Practice
Puddletown

Data on sample	Data on form	Commentary	Action
Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456** DOB: **01/01/21** Address **15 Donald Duck Drive** **Disneyland** **Taunton** **TA2 9SW**	Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456** DOB: **01/01/21** Address **15 Donald Duck Drive** **Disneyland** **Taunton** **TA2 9SW**	Minimum data set present on specimen and form	Accept in all depts.
Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456** DOB: **01/01/21**	Minimum data set present on specimen and form for all depts. except in Blood Transfusion	Accept Reject in Blood Transfusion
Surname: **MOUSE** Forename: **MINNIE** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINNIE** DOB: **01/01/21** Unique ID:**123456**	Minimum data set present without unique identifier on sample however unique identifier present on form	Accept and add comment to the request. Reject in Blood Transfusion
Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456**	Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456**	Minimum data set present on specimen and form for department except Transfusion	Accept Reject in Blood Transfusion
Surname: **MOUCE** Forename: **MINNIE** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINNIE** Unique id: **123456** DOB: **01/01/21**	**Minor discrepancy** in surname plus no unique identifier on sample	Accept and add comment to the request. Reject in Blood Transfusion

Data on sample	Data on form	Commentary	Action
Surname: **MOUSE** Forename: **MINOR** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINOR** DOB: **01/01/21** Address: **15 Donald Duck Drive** **Disneyland** **Taunton** **TA2 9SW**	**Minor Discrepancy** Minimum data set not present without unique identifier on specimen or form and with second Forename not first - check address on MPI to confirm	Reject or Accept and add comment to the request depending on departmental policy. Always Reject in Blood Transfusion
Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456** DOB: **01/01/20**	Surname: **MOUSE** Forename : **MINNIE** Unique ID :**123456** DOB: **01/01/21**	**Minor discrepancy** in DOB on sample but otherwise minimum data set present	Accept And add comment to the request. Reject in Blood Transfusion
Surname: **MOUSELET** Forename: **MINOR** DOB: **01/01/21** Unique id: **123456**	Surname: **MOUSELET** Forename: **MINOR** DOB: **01/01/21** **Unique id: 123456** Address: **15 Donald Duck Drive** **Disneyland, Taunton** **TA2 9SW**	**Minor discrepancy**. Minimum data set present on specimen and form – but referencing previous surname and 2nd Forename. – checked on MPI and request change if needs updating	Reject or Accept and add comment to the request depending on departmental policy. Always Reject in Blood Transfusion
Surname: **MOUCE** Forename: Absent Unique id: **123456** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINNIE** Unique id: **123456** DOB: **01/01/21**	**Major discrepancy** as there are 2 errors • Surname wrong on sample • No forename on sample	Reject or Accept and add comment to the request depending on departmental policy Always Reject in Blood Transfusion
Surname: **MOUSE** Forename: Absent Unique id: **123456** DOB: **01/01/22**	Surname: **MOUSE** Forename: **MINNIE** Unique id: **123456** DOB: **01/01/21**	**Major discrepancy** as there are 2 errors • DOB incorrect on sample • No forename on sample	Reject or Accept and add comment to the request depending on departmental policy Always Reject in Blood Transfusion
Surname: **MOUSE** Forename: **MINNY** Unique id: **123465** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINNIE** Unique id: **123456** DOB: **01/01/21**	**Major discrepancy** as there are 2 errors • Unique identifier wrong on sample • Misspelt Forename on sample	Reject or Accept and add comment to the request depending on departmental policy Always Reject in Blood Transfusion
Surname: **MOUSE** Forename: **MINNIE** Unique ID: **123456** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINNIE** Unique ID: **G089898** DOB: **01/01/21**	**Major discrepancy** in unique identifier.	Reject or Accept and add comment to the request depending on departmental policy Always Reject in Blood Transfusion
Surname: **MOUSE** Forename: **MINNIE** Address: **15 Donald Duck Drive** **Disneyland, Taunton** **TA2 9SW** DOB: **01/02/20**	Surname: **MOUSE** Forename: **MINNIE** Address: **15 Donald Duck Drive** **Disneyland, Taunton** **TA2 9SW** DOB: **01/01/21**	**Major discrepancy** in DOB and no unique ID number	Reject
Surname: **MOUSE** Forename: **MINNIE** Unique id: **123456** DOB: **01/01/21**	Surname: **MOUSE** Forename: **MINNIE** Unique id: **123465** DOB: **01/01/20**	**Major discrepancy** Minor discrepancies in both unique ID and DOB amount to	Reject