1. General Information

Nuffield Health

Nuffield Health are a registered charity (number: 205533) dedicated to providing high standards in healthcare on a not-for-profit basis. All surpluses generated from the supply of our services are reinvested for the benefit of patients in the communities that we serve.

Nuffield Health philosophy is to provide a high standard of care at a cost that represents the best value to the patients and clients.

Nuffield Health Pathology Services

Nuffield Health Pathology Laboratories operate in a hub and spoke network comprising 14 Hub Laboratories with varying numbers of spoke sites serving 37 hospitals across England, Wales and Scotland. We operate under a single quality management system that ensures our processes are wherever possible standard and of equally high quality across all our sites.

A The Central Laboratory at Warwick is our largest laboratory with an extensive repertoire of tests, other laboratories vary in size and scope, for an overview of the scope of an individual laboratory please refer to the relevant **See Appendix** at the back of this document.

2. Accreditation and Regulatory Compliance

UKAS

All Nuffield Health Pathology laboratories are UKAS accredited in compliance with ISO 15189:2022 Standards for Medical Laboratories, this accreditation standard is managed by the United Kingdom Accreditation Service (UKAS).

All Nuffield Health laboratories are included under Medical Laboratory No. **9338**

To obtain an up-to-date scope of accredited laboratory based tests in place for Nuffield Health please visit the UKAS website and search medical laboratories for accredited organisation **https://www.ukas.com/search-accredited-organisations/** and search for **Nuffield Health**.

Blood Safety and Quality Regulations 2005 (BSQR)

All Nuffield Health Pathology Laboratories operate in compliance with BSQR, ensuring blood and blood products are stored, prepared and transfused into patients safely and in compliance with EU Law. Compliance to BSQR is by submission of an annual compliance report to the Medicines and Health Regulatory Authority (MHRA).

3. Laboratory Location and Contact Information

This user Guide contains much generic information that is applicable to all sites, however for local contact details, laboratory opening hours and local repertoire please see the relevant **see Appendix 1**

4. Specimen Collection & Instructions on Patient Preparation & Consent

Specimens taken for pathology tests should be taken in accordance with local procedures and processes, the collection should be completed by staff who have been trained and assessed as competent to undertake phlebotomy.

In some instances the patient may require specific preparation or advice prior to specimens being taken examples of such preparations are detailed **see Appendix 2** If sample collection guidance is not provided in this **Appendix** refer to the Royal Marsden Manual for documented procedures on sample collection. This can be found on line and as a link on the Nuffield intranet, where Nuffield Health has a login to access the contents.

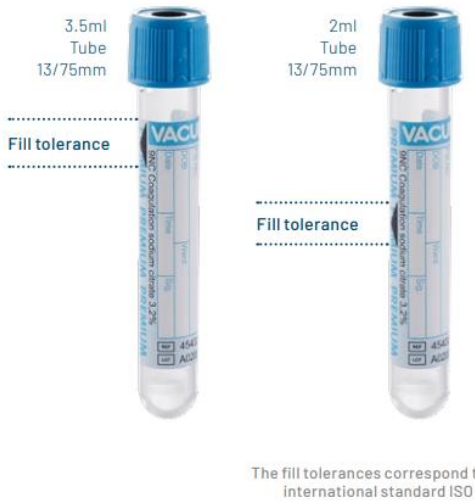
Expiry Date

The vacuum in the tubes can only fulfil its function if used prior to the expiry date printed on the label. The tube should no longer be used after this date.

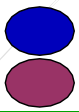
Mixing Ratios and Specimen Volumes

It is essential, that tubes are filled exactly, taking fill tolerances into account.

Serious errors can occur when citrate tubes for coagulation diagnostics are either over-filled or under-filled. Under or over filled tubes will be rejected.



There is a prescribed order of draw that is recommended by Greiner Bio-one ltd to ensure adverse effects on multiple samples being taken is minimized.

Order	Test(s)	Colour	Type	Special Instructions
FIRST	Blood Culture		Aerobic Anaerobic	Aerobic followed by anaerobic
	INR, APTT, D-Dimer		Sodium Citrate 3.2%	Ensure correct fill volume (to line) Mix gently by inversion 4-5 times
	Chemistry Tests		SST (Gel)	Invert 5-10 times
	Trace Metals		Trace Element Serum	Invert 5-10 times
	POCT Chemistry Tests (URGENT – U&E, Ca^{++} only)		Lithium Heparin	Mix gently by inversion 5-10 times

LAST	Full Blood Count, ESR, Blood Film, Reticulocytes		EDTA	Mix gently by inversion 5-10 times
	Group & Save, Crossmatch, Direct, Coombs Test		7ml EDTA	Mix gently by inversion 5-10 times
	Glucose (if delay In testing), Alcohol		Fluoride Oxalate	Mix gently by inversion 5-10 times

Recommended order of collection for Greiner®

1. Blood culture vials
2. Tubes with citrate or clotting activator (with/without gel, Serum CAT / Serum Gel CAT)
3. Tubes with clotting activator or citrate
4. Tubes with heparin with/without gel
5. Tubes with EDTA with/without gel
6. Tubes with glycolysis inhibitors
7. Tubes with other additives

Sample Mixing

Mixing of blood tubes immediately after collection is essential, inadequately mixed tubes can adversely affect the result and cause malfunctions in laboratory analysers.

Insufficient mixing of EDTA (purple) or lithium heparin (green) tubes may cause incomplete activation of the anticoagulant, leading to clots in the specimen. This will cause inaccurate results and possible clog analysers.

Insufficient mixing of SST (yellow/gold) tubes can delay clot formation, leading to fibrin formation in the sample and affect the barrier between the red cells and serum.
Fibrin clot formation can clog analysers leading to delays in processing.

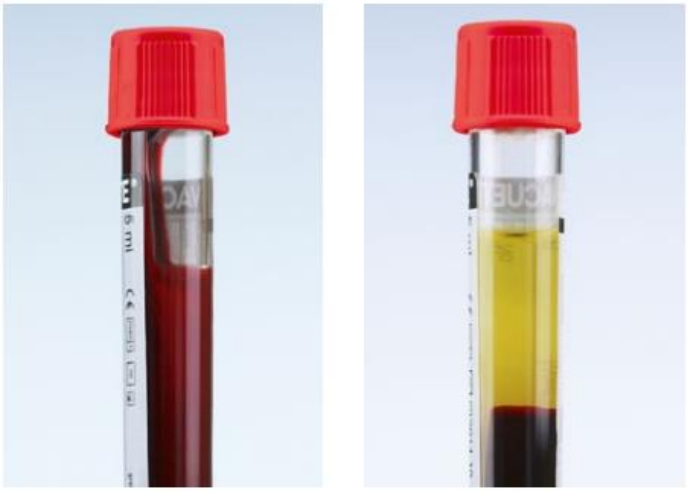
Centrifugation

Serum separator tubes (SST) require centrifugation prior to testing to separate the serum from the blood cells. If this is not performed correctly it can lead to haemolysis of the sample or fibrin clot formation.

Fibrin clots form when the sample has been centrifuged and separated before the clotting process is complete. This causes a small white/yellow deposit to appear in the serum layer of the specimen. This is the section sampled by the analyser when testing the specimen, which may sample the clot. This clogs the analyser and adversely affects accuracy of results for that specimen and subsequent specimens tested.

Fibrin clots also lead to incomplete separation of the specimen by the gel layer, this can cause red cells to leak into serum giving the appearance of haemolysis. This can also occur if the sample has not been in the centrifuge for long enough. See pictures below for examples.

- ✓ To ensure correct SST specimen preparation and avoid risk of fibrin in the serum the sample should not be centrifuged until 30 minutes post draw and must be clotted.
- ✓ SST tubes should be allowed to clot in an upright position



Samples that have coagulated in horizontal and upright positions.

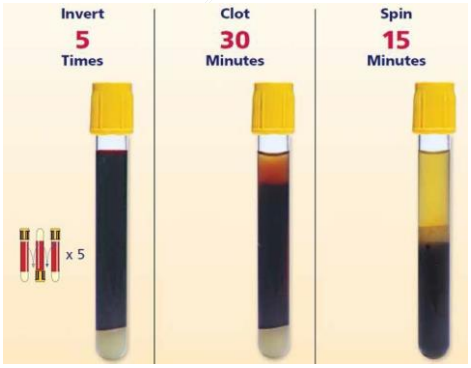
Centrifugation recommendations of VACUETTE® tubes:

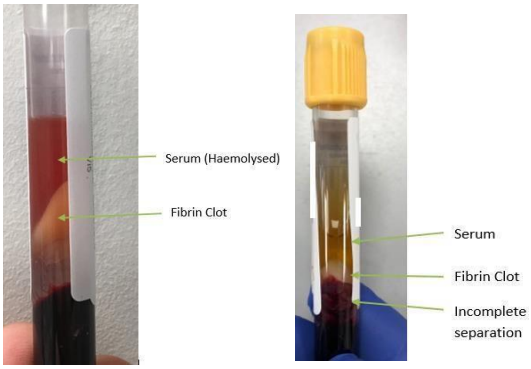
Tube type	Inversions (mixing)	Recommended g-force / relative centrifugal force (RCF)	Time [min]
Serum Fast with Separator	5-10 times	1800g	10
		3000g	5
Serum Tube with/without Separator		1800-2200g	10-15
EDTA Tube with/without Separator			
Heparin Plasma Tube with/without Separator			
Standard Glucose Tube			
Homocystein Detection Tube		2000-2200g	10
VACUETTE® FC Mix Tube	10 times	1800g	10
Coagulation Tubes			
- Platelet tests (PRP)	4-5 times	150g	5
- Routine tests (PPP)		1500-2000g	10
- Preparation for deep freeze plasma (PFP)		2500-3000g	20

The English terms g-force or RCF stand for relative centrifugal force and should not be confused with rotations per minute.

For angled head centrifuges samples should be spun for 10 Minutes at 1000 – 1300 RCF in accordance with the guidance from tube suppliers Greiner Bio-one. This time may be reduced if spinning at a higher RCF.

The images below demonstrate how samples should appear following centrifuging.





Centrifugation Recommendations for S-Monovette tubes

Based on BS 4851 (EU code)	ISO 6710:2017	S-Monovette®	Relative centrifugal force (g)				
			2000 x g	2500 x g	3000 x g*	3500 x g*	4000 x g*
		Serum	10 min	10 min	6 min	4 min	4 min
		Serum gel	15 min	10 min	4 min	4 min	4 min
		Lithium Heparin	10 min	10 min	7 min	7 min	7 min
		Lithium Heparin Gel	15 min	15 min	10 min	7 min	7 min
		Lithium Heparin Gel*	8 min	7 min	5 min	4 min	4 min
		EDTA	n.v.	n.v.	7 min	6 min	5 min
		EDTA Gel	15 min	10 min	10 min	7 min	7 min
		Citrate	9 min	8 min	7 min	6 min	5 min
		Fluoride	9 min	8 min	7 min	6 min	5 min
		GlucoEXACT	9 min	8 min	7 min	6 min	5 min
		Citrate PBM 1.8 ml Centrifuge radius > 17 cm	9 min	8 min	7 min	6 min	5 min
		Citrate PBM 1.8 ml Centrifuge radius > 9 to ≤ 17 cm	n.v.	n.v.	10 min	n.v.	n.v.

n.v. = non-validated
* applies for all S-Monovettes with the exception of 8 mm diameter (S-Monovettes paediatrics)

Centrifugation at 20° C

SARSTEDT

Invert each S-Monovette® once immediately after disconnecting it from the safety needle, and after completing blood collection, carefully invert all specimens with anticoagulants several times.

Re-centrifugation

- ✓ Repeated centrifugation of sample tubes is not recommended.
- ✓ Lysed blood components may diffuse back from the centrifuged blood cells into the serum/plasma.
- ✓ As a consequence cell-sensitive parameters such as potassium, phosphate, glucose or LDH are changed.

5. Referral to hub laboratories from a spoke laboratory

- ✓ Different tests have varying stability times.
- ✓ If a sample is too old for the test to be reliable the lab may reject the sample.
- ✓ Consideration to sample handling must be considered and samples may need to be separated and frozen prior to transportation to the hub laboratory.
- ✓ Samples should be delivered to the laboratory as soon as possible, and consideration should be given to sample stability to meet courier/ transport times or if delays are expected, e.g. over bank holiday

6. Haemolysis, Icterus and Lipaemia

Haemolysis, icterus and lipaemia (HIL) are conditions affecting specimens that may interfere with testing and accuracy of the result. They have varying causes but with good technique the risk of hemolysis can be minimized though icterus and lipaemia are generally outside the control of the phlebotomist.

Minimizing the effects of hemolysis is in the control of the phlebotomist and is achieved through good phlebotomy technique and specimen handling procedures as described in this guidance.
The Fuji analyser methodology is not significantly affected by interference from HIL but laboratory analysers can be. Laboratory analysers measure HIL levels and if they are significant enough to interfere with testing the result will not be released as they are liable to error.

- ✓ Haemolysis exhibits as a red colour in serum – due to red cells in serum or breakdown of red cells prior to centrifugation.
  - Ensure correct phlebotomy technique is followed – do not 'milk' draw sites or leave tourniquet on longer than one minute.
  - Follow correct centrifugation procedure as described above.
  - Avoid mechanical disruption to the cells, mix gently by inverting, not vigorously.
- ✓ Icterus appears as an orange colour in the serum – caused by raised bilirubin in the blood, outside control of the phlebotomist.
- ✓ Lipaemia causes serum to appear turbid and milky – cause raised lipid components. Avoid specimen collection directly after fatty meals if possible.

Figure 2 Haemolysis (left), Lipaemia (center), Icteric (right)

7. Patient Consent

- ✓ Patients presenting with a request form for blood tests will be viewed as providing implied consent and the venepuncture procedure will be explained to ensure that patients fully understand and are comfortable with the process.

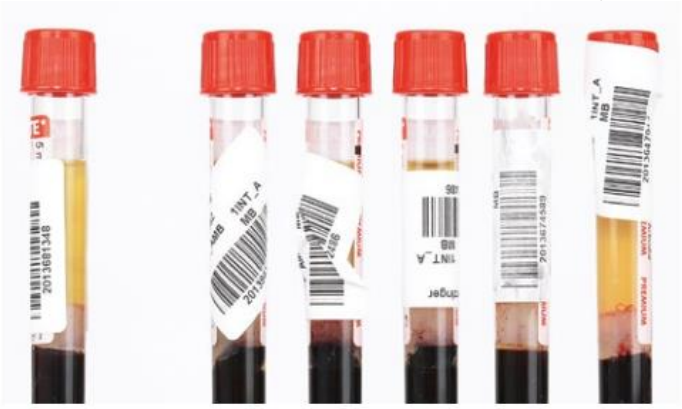
- ✓ Any patients requiring information regarding the tests requested, their function and clinical implications will be referred to the requesting clinician. The patient will be offered the opportunity to defer venepuncture until the requisite information has been obtained.
- ✓ Special or more invasive procedures may require a more detailed explanation and, in some cases, recorded consent.
- ✓ In emergency situations the laboratory may carry out necessary procedures providing they are in the best interest of the patient.

8. Specimen Labelling & Request Form Completion

Pathology Specimen Labelling

The laboratory uses automatic barcode scanning when loading samples onto the analysers. Correct orientation of the sample label ensures the analyser can read these barcodes, making sure the sample is correctly identified and the right tests are requested.

If barcodes cannot be read laboratory staff need to manually enter the information into the analyser which can cause delays to testing and opportunities for transcription errors to occur. See below for the correct way to orientate labels:



Incorrectly attached labels, compared to correctly attached label (left)

- ✓ Ensure label situated level with the sample and not at an angle.
- ✓ Labels should be placed around 1cm below the tube lid.
- ✓ The tube lid should be to the left of the sample when reading the label.
- ✓ The label should no cover all around the tube, leaving a gap where the contents of the specimen can be viewed.

Every specimen container must be labelled with:

- Patients full name or Proper coded identifier
- Date of Birth
- Hospital number (or Unique Identifier) *

*External contract specimens may not have a unique Identifier number this should not preclude acceptance of samples in such cases where there is no doubt of the identity of the client.

Additional information Required for Blood Transfusion samples:

- Date and time of collection
- Identification of person who took the sample

Each specimen must be labelled beside the patient.

In **no** circumstances should a specimen container be pre-labelled

In **no** circumstances should blood samples be transferred from one tube to another

Addressograph labels for Blood Transfusion tests will be rejected.

2 Sample Rule for Blood Transfusion

Nuffield Health pathology require 2 samples from the patient must be tested, before the issuing of blood products. A second sample should be requested for confirmation of the ABO group of a first-time patient prior to transfusion where this does not impede the delivery of urgent red cells or components.

To comply with the British Committee for Standards in Haematology BCSH Guidelines these samples must be taken from different phlebotomy events, ideally by different phlebotomists with a period of 15 minutes between collection.

Request Form Completion

Any specimen sent to pathology for testing must be accompanied with an appropriately completed and legible request form. Nuffield Health provide four different request forms depending on the examinations requested:

- ✓ General Request Form
- ✓ Blood Transfusion Request Form
- ✓ Histology and non-Gynae
- ✓ Gynae cytology request form

Although Nuffield forms are preferable any request form meeting the requirements below will be accepted.

Sites who are live with TrackCare the request is transferred electronically from TrackCare to Ultra.
The information required for TrackCare requests are the same as any paper request form.

General Pathology Request Forms – Required Information

The request form must provide sufficient information to ensure unequivocal traceability of the patient to the request and the sample. The request form should include the following information where available and relevant:

- **Patients full name or coded identifier**
- **Date of birth**
- **Hospital Number (or unique Identifier)**
- Patient's address
- Requester name and contact details.
- Date and time of specimen collection.
- Identification of examinations requested.
- Type of specimen and, where appropriate, anatomical site of origin Investigations requested.
- Relevant clinical information
- Identification of priority status

Request Forms not including the information highlighted in bold above may be rejected.

Blood Transfusion Request Form – Required Information

For blood transfusion samples request forms should include:

- **Patients full name or coded identifier**
- **Date of birth**
- **Hospital Number (or unique Identifier)**
- Patient's address
- Requester name and contact details.
- Date and time of specimen collection.

- Identification of examinations requested.
- Type of specimen and, where appropriate, anatomical site of origin Investigations requested.
- Relevant clinical information
- Identification of priority status
- Group & Save Request and / or number of units for cross matching
- Reason for request
- Number and type of blood components required
- Date and time when units are required
- Indication of any special requirements e.g. irradiated
- Previous transfusion history (if known)
- Details of any known antibodies/bleeding disorder
- Details of who collected the sample

Specimen Rejection

Specimens will be rejected by the Pathology Department if there are any deviations from the collection and handling of primary samples and they do not comply with the labelling criteria detailed above. The final decision to accept or reject a specimen is made by the Pathology Department.

Laboratory staff must not amend details on the sample or request form.

A Specimen Rejection Form will be completed when samples are rejected by Pathology Departments, appropriate clinical teams will be informed of the deviation and rejection of the sample(s)

Where appropriate, e.g. for non-repeatable specimens such as Histology or Cytology samples, the Pathology Department shall seek verification of sample identity from an appropriate clinician or manager.

In cases where an inadequately labelled request form or sample is received from a patient who is not easily accessible for a repeat, then, at the discretion of senior laboratory staff, and after sample verification, the sample is processed with the report showing a clear disclaimer detailing the shortcomings of the sample and/or request. The disclaimer must alert the requesting practitioner to take responsibility for the results and for any action taken as a result of the report.

Note: inadequately labelled samples for blood transfusion testing will not be accepted under any circumstances; samples must be re-taken.

Specimen Rejection due to Poor Sample Quality

Specimens will be rejected due to poor sample quality in certain circumstances if the result produced may be affected by sample quality. Examples of rejection types include:

- ✓ Samples too old to process (i.e. Blood Coagulation samples)
- ✓ Inadequately filled samples (incorrect sample / anticoagulant ratio)
- ✓ Clotted samples where anti-coagulated samples are required.
- ✓ Haemolysed samples
- ✓ Icteric samples
- ✓ Gross lipaemia
- ✓ Inadequately fixed histology samples
- ✓ Incorrect transport medium used – Microbiology.

The degree of the effect various sample artefacts upon test results is subjective and will be based on the clinical judgement of qualified BMS staff and the risk and impact assessed. Where there is a question as to the sample artefact having upon the final test result this shall be notified in the patient report to alert the clinician on the potential impact upon the results.

Specimens may not be accepted for testing if they have been damaged in transit and arrive leaking or damaged.

9. Transportation and Delivery of Samples

It is the responsibility of the sender to identify material that falls within the scope of the Carriage of Dangerous Goods Regulations and ensure that they are correctly packaged and transported.

All specimen containers, request forms, sleeved plastic bags, secure outer containers or rigid transport boxes may be supplied by the laboratory upon request.

All high-risk specimens and their request forms must be labelled with yellow 'Danger of Infection' label. A specimen must be considered **HIGH RISK** if the patient is known to have been tested positive for, or exposed to viral infections such as, but not limited to:

- Hepatitis C
- Hepatitis B
- HIV

Transportation of Specimens to the Laboratory within the hospital environment

- All specimens must be in a primary receptacle (specimen container) that is sealed or closed so as to prevent any leakage. This must be placed in a sealed plastic bag. The form must be placed in the separate plastic pocket, so as not to be in contact with any specimens.

- The specimens must then be placed in a secondary receptacle; this is the specimen transport box and is a rigid container. There must be absorbent material in this box, in sufficient quantity to absorb the entire contents of the primary receptacle(s).

- The specimens must be delivered promptly to the laboratory specimen reception area ensuring that the time between collection and receipt is appropriate and that temperature intervals are maintained.

The safe transport of pathology samples within the hospital is important to ensure that all hospital personnel, patients and visitors are not put at risk of infection. Safe and effective transport of specimens will help to maintain the integrity of the specimen to ensure accuracy of results.

It is the responsibility of everyone who handles pathology specimens to ensure that they are transported in a safe manner. If the integrity of the samples has been compromised the laboratory must be notified immediately so that action can be taken to reduce risk and prevent recurrence.

Spillage kits and protective clothing sufficient to deal with any spillage must be available within the hospital.

Specific Instructions for Histology Samples.

Histology samples contain formalin as a fixative for human tissue and as such pose specific health and safety risks to those individuals involved in their transport. The following instructions are in addition to the general statements above.

Request Forms

Pathology request forms must be transported in a separate plastic bag which will prevent contamination should there be any specimen leakage.

Checks prior to transporting samples.

All histology samples must be double checked to ensure that lids or screw tops are correctly fitted and sealed properly to ensure that leakage of formalin does not occur when being transported around the Hospital.

Sample Bagging and Transport

Due to the varied size and number of Histology samples that can be generated from various departments in Hospitals specific individual guidance cannot be given for all sample types. The table below is based on sample volume, but where multiple samples of small volume cross into the next category then instructions for the larger volume are to be followed.

Sample Container Volume	Sample Bagging Instructions	Sample Transport Instructions
60ml	Samples can be bagged together in a sealable bag (Maximum of 6 per bag)	Placed into Versa pack Type Box with absorbent material in the bottom. Transported by hand
120ml	Samples can be bagged together in a sealable bag (Maximum of 3 per bag)	Placed into Versa pack Type Box with absorbent material in the bottom. Transported by hand
350ml	Samples are to be individually bagged with a sealable bag. (Maximum of 3 per box)	Placed into Versa pack Type Box with absorbent material in the bottom. Transported by hand
500ml	Samples are to be individually bagged with a sealable bag (Maximum of 3 per box)	Placed into Versa pack Type Box with absorbent material in the bottom. Transported by hand
1L	Individually bagged in a sealable bag (Maximum of 2 per box)	Placed into Versa pack Type Box with absorbent material in the bottom. Transported by hand
2.5L	Individually bagged in a sealable bag	Transported by dedicated sample transport trolley*
5L	Samples must be double bagged	Transported by dedicated sample transport trolley*
10L	Samples must be double bagged	Transported by dedicated sample transport trolley*

* Sample trolley must have high sides to prevent samples rolling off during transit.
Example of Versa pack Box

Handling of Large Histology Specimens

Samples of 5L or more should be handled with extra care as the spillage of large samples are potentially very serious. The lids must be secure and double checked.

Sample pots **must not** be carried around in an unsupported manner.

Large sample pots must be transported around the hospital using appropriate equipment (trolley) to reduce the risk of spillage.

Specimen Transport between Laboratories

Specific UN transport regulations must be met when moving diagnostic and infectious samples. The requirements vary depending on the mode of transportation; classification and conditioning of the specimen. They are designed to ensure that samples arrive at their destination in good condition and present no hazard to individuals during transport.

The packaging shall consist of at least three components:

- ✓ a primary receptacle.
- ✓ a secondary packaging.
- ✓ an outer packaging of which is to be rigid.

There should be a double layer of packaging to help contain samples during transport.

Containers used to transport specimens between hospitals should have a layer of absorbent material sufficient to absorb sample spoilage if a container were to leak in transit.

Containers should also be sealed with a tamperproof seal to ensure the contents remain secure during transit.

To maintain GDPR compliance, all Patient identifiable information must be hidden from sight, samples will be bagged, any patient request forms must be in a sealed envelope or similar covering to ensure that identifiable data is not accidentally compromised.

All packages must use a diamond-on-point label with **'UN3373'** within. The words **Diagnostic Specimens or Clinical Specimens** must be marked adjacent to the label.

Formaldehyde neutralizing materials must be available when specimens in formalin are transported via vehicle

Transportation of Specimens to the Laboratory by post

- ✓ Specimens sent by post must be packaged according to the postal regulations for the transport of pathological specimens.
- ✓ The specimen must be placed in a securely sealed watertight container not exceeding 50ml or 50g. It must be wrapped in enough absorbent material to absorb all leakage in the event of damage.
- ✓ The specimen must be sealed in a plastic bag and placed in a second durable watertight, leak proof container. This must be placed in a strong cardboard box and sealed securely, or alternatively a postal approved padded envelope may be used.
- ✓ The outer packaging must be clearly labelled with a UN3373 sticker that indicates it is a diagnostic specimen. The use of tape with the words "**Pathological Specimens – Fragile Handle with Care**" is recommended. The package must have the senders name and address, and the destination address.
- ✓ All infectious material must be packed in packaging that conforms to UN602. Safebox containers are available from the Royal Mail and can be supplied by the pathology department upon request.
- ✓ Group 4 infectious material MUST NOT be sent through the post.

Transport Via Couriers

- ✓ All specimens must be in a primary receptacle that is sealed or closed so as to prevent any leakage. This must be placed in a sealed plastic bag. The form must be placed in the separate plastic pocket, so as not to be in contact with any specimens.
- ✓ The specimens must then be placed in a secondary receptacle; this is the specimen transport box and is a rigid container. There must be absorbent material in this box, in sufficient quantity to absorb the entire contents of the primary receptacle(s).
- ✓ The specimens must be delivered promptly to the laboratory specimen reception area.
- ✓ Carriage by road is permitted providing the above instructions are adhered to. You must contact the laboratory for advice on the road transport of specimens containing more than 500ml or weighing more than 500g or known to be **High Risk**.

Rules for porters

- ✓ Cover any cuts or grazes on hands with a waterproof dressing
- ✓ Handle all specimens gently to avoid breakage.
- ✓ Handle specimens as little as possible.
- ✓ Place all specimens in designated plastic bags.
- ✓ Carry all specimens in the rigid boxes provided by the laboratory.
- ✓ If you do touch a specimen in error, wash your hands immediately.
- ✓ If a specimen leaks into the box tell the laboratory staff so they can make it safe.
- ✓ If you drop and break a specimen do not touch it or clear up the spillage. Isolate it and send someone to the laboratory for assistance.
- ✓ Never take specimens into the canteen or restroom, do not eat, drink or smoke when carrying specimens.
- ✓ Always wash your hands after handling specimens.

10. Spillage Procedures

Blood spillages

- ✓ A risk assessment should be taken prior to using chlorine on carpets.
- ✓ Any person can clean a blood spill, provided they have been trained in the following procedure:
- ✓ Disposable gloves and apron should be worn.
- ✓ Dissolve an Acticlor 1.7g tablet in 100ml water to give a 1% hypochlorite solution (10.000ppm).
- ✓ Cover the spill completely, leave for 10 minutes, do not leave unattended.
- ✓ Rinse with warm water.
- ✓ Place all disposable equipment into an orange clinical waste bag.
- ✓ Wash hands

Note:

Chlorine gas may be generated when hypochlorite's are used, they should only be used in well-ventilated areas. Avoid use on acids, e.g. urine spills.

Body fluid spills (except blood)

- ✓ The routine management of spillages (excluding diarrhoea, blood and suspected infections) can be managed using general-purpose detergents.
- ✓ Disposable gloves and plastic aprons must be worn.
- ✓ Always use freshly prepared solutions in clean containers. Discard after use.
- ✓ Dilute general-purpose detergent by adding approximately 5ml to a standard polypropylene bowl filled with hand hot water.
- ✓ Use disposable wipes or paper towels. Discard after use into yellow clinical waste bags.
- ✓ If a mop is used change mop head
- ✓ If a spillage has occurred from a patient with a suspected or confirmed infection use disinfectant.

Formalin Spillage

If there is a spillage of formalin whilst samples are being transported between departments and Pathology, individuals **Must Not** attempt to clear up any spillage without first contacting Pathology for advice.

There are specific formalin spill kits available to be used in the event of a spillage. These will be available from Pathology. Ask for assistance to contact Pathology and ask anyone in the vicinity to vacate the area. Prevent access to the area whilst waiting for the spill kit to arrive, open windows and if possible close the door on the spill until PPE, including face masks, have been donned.

Transport of Blood and Blood Components

Transport of blood and blood components must comply with MHRA guidelines and the local laboratory procedures that will ensure blood and blood products are transported in accordance with the Blood Safety and Quality
Regulations 2005 requirement thus maintaining the 'cold chain'.

The cold chain for the hospital transfusion laboratory starts from the receipt of the blood from the blood supplier to the time the unit is transfused or otherwise disposed of.

11. Factors Affecting Test Results

Factors affecting analysis of individual assays can be **found in Appendix 2** of this laboratory user guide. To minimize the risk of factors affecting interpretation clinical details/history of the patient should always be provided to the laboratory.

When carrying out procedure's SOPs should always be followed, the procedures described in these documents have been designed to minimize risk of interferences and ensure continuity in testing procedures.

Factors affecting interpretation can be extensive and the list below is not exhaustive. If in doubt over interpretation or if advice is required, please contact the laboratory for guidance.

The calculation and interpretation of the uncertainty of measurement for laboratory tests is readily available and can be viewed upon request at your individual testing laboratory.

Pre-Analytical

Please note that there are a number of factors that interfere with some sample analysis therefore precaution must be taken to ensure sample integrity to avoid unnecessary delays. Below is a list of inferences and this list are not limited to:

- ✓ Haemolysis in the sample
- ✓ A tourniquet falsely elevates calcium (always remove tourniquet when performing venipuncture).
- ✓ Under filled citrate (9:1 ratio of blood to anticoagulant), under filled samples cannot be used for analysis as they give erroneous results.
- ✓ EDTA contamination causing problems with potassium, calcium, magnesium and ALP (caused by tipping samples from an EDTA to a plain tube). Samples must never be transferred from one tube to another.
- ✓ Collection of samples should follow the correct order of draw to reduce risk of cross-contamination of additives.
- ✓ Collection of samples from a drip arm (cannulated arm) dilutes samples giving falsely low results or falsely elevated levels. Collect samples from an un-cannulated arm.
- ✓ Always use the designated commercial urine containers, using any other container may introduce contaminants that result in interference.
- ✓ Please refer to SOPs for phlebotomy for further considerations to reduce pre-analytical interferences.

Microbiology

Samples for bacterial/fungal examination can be subject to overgrowth if left untested for extended periods, especially if left un-refrigerated, resulting in false negative or false positive results.

To minimise the risk of this samples should be processed as soon as possible and stored within the fridge until tested. Suitability of sample age and storage conditions and add an appropriate comment warning of interpretation if there is suspicion of these factors affecting the analysis.

Biotin Interference

The laboratory performs immunoassay testing using Roche Elecsys technology. This methodology utilises biotin in the determination of assay values. Biotin, also known as vitamin B7, is increasingly found in vitamin supplements in small doses (5-10mg) as well as being prescribed to treat metabolic diseases in higher doses (100mg). This has the potential to interfere with immunoassay based tests performed by the laboratory.

Where a patient is taking Biotin this should be recorded in the clinical details of the request form. Samples should not be taken from patients receiving therapy with high doses of biotin (>5mg/day) until at least 8 hours following the last biotin administration.

The following table lists potentially affected tests and details the level of biotin that does not interfere with the test:

Assay	No Biotin Interference Up to:	Assay	No Biotin Interference Up to:	Assay	No Biotin Interference Up to:
E2	<36 ng/mL	CEA	< 120 ng/mL	PROG	< 30 ng/mL
AFP	< 69 ng/mL	CORS II	< 30 ng/mL	PROL	< 40 ng/mL
CCP	< 30 ng/mL	FSH	< 60 ng/mL	TPSA	< 60 ng/mL
C199	< 100 ng/mL	FT3	< 70 ng/mL	FPSA	< 30 ng/mL
C153	< 100 ng/mL	FT4	< 20 ng/mL	SHBG	< 60 ng/mL
C125	< 35 ng/mL	HCGP	< 80 ng/mL	TEST	< 30 ng/mL
B12	< 50 ng/mL	VITD	< 70 ng/mL	TSH	< 25 ng/mL
LH	< 50 ng/mL				

12. Telephone Action Limits

When phoning results Pathology will ask for and record the name of the individual to whom the results have been given to, this maintains an audit trail of communications and is a n accreditation requirement.

Nuffield Health Laboratories will telephone abnormal results in accordance with the guidelines from Royal College of Pathologists. The action limits criteria are set out in the table below:

Analyte	Units	Action Limits Low	Action Limits High	Comments
BIOCHEMISTRY				
Serum Sodium	mmol/l	120 (130 if <16 yrs)	160	
Serum Potassium	mmol/l	2.5	6.5	
Serum Urea	mmol/l		30 (≥10 if <16 yrs.)	

Serum Creatinine	µmol/l		354 µmol/L (≥ 200 µmol/L if <16 yrs.)	
Plasma Glucose	mmol/l	2.5	25 (≥15 if <16 yrs.)	
Serum Calcium (Adjusted)	mmol/l	1.8	3.5	
Magnesium	mmol/l	0.4		
Phosphate	mmol/l	0.3		
AST	U/L		15 x upper end of Normal	
ALT	U/L		15 x upper end of Normal	
Total CK	U/L		5000 (Unless? MI)	
Amylase	U/L		5 x upper end of Normal	
Triglyceride	mmol/l		20	
Serum Lithium	mmol/l		1.5	
Serum Digoxin	ug/L		2.5	
Theophylline	mg/L		25	
Phenytoin	Mg/L		25	
CRP	mg/L		300	
TSH	miU/L	0.005	100	
FT4	pmol/L		50	
FT3	nmol/L		20	
Troponin (I or T)			Local cut off for MI	
AKI			AKI-3 & AKI-2 – All new Occurrences AKI-1 (Only if K >6.0 mmol/L)	
Ammonia	µmol/L		100	
Bicarbonate	mmol/l	10		
Cortisol	nmol/L	50 nmol/L (Unless part of overnight dexamethasone suppression test)		
Cortisol (SST 30 min)	nmol/L	250		As part of short synacthen test
Ethanol	mg/L		4000	
Paracetamol	mg/L		See Comment	All detectable levels agree local levels
Salicylate	mg/L		300	

Urate	µmol/L		340	Ante-natal indications only
PSA	ng/ml	PSA result >10ng/ml (Wellbeing Only)		

Analyte	Action Limits
HAEMATOLOGY	
Haemoglobin	<80 g/L , > 190 g/L
Neutrophils	<0.5 x 109/ L >50 x 109/ L
Lymphocytes	>50 x 109/ L , > 50 x 109/ L
Platelets	<30 x 109/ L > 600 x 109/ L
Blood Film	Presence of blasts or other leucocyte precursors
Malaria Parasites Screen	Positive
INR	INR > 5.0
APTT	APTT Ratio > 3.0 (Heparin) or > 1.5 if not on anticoagulant APTT Seconds > 60 sec
BLOOD TRANSFUSION	
Antibody ID	The identification of an antibody that may cause delay in provision of compatible blood to a patient
Blood Group	Unexpected change in Blood Group compared to historic records for the patient. Urgent re-sampling is required in such cases.
MICROBIOLOGY / VIROLOGY	
	All Positive Blood Cultures All Gp A Streptococcus Isolates All Isolates from Sterile Sites All C Difficile Positives All CPE Resistant Organisms MRSA from wound, E. coli 0157, ESBL HIV and other blood borne positive results Acute Hepatitis A, B , C& E
HISTOPATHOLOGY	
	Cases where there is a predictable degree of urgency Cases unexpectedly found to be infectious Expected malignancy cases where no malignancy is found Biopsy or removal of an unexpected organ. Unexpected finding of malignancy Findings that trigger a particular referral pathway
IMMUNOLOGY	

new ANCA anti-PR3 Ab patient	Level Ref A. Only a clearly positive result in a clinical context suggestive of small vessel vasculitis should be telephoned - decision threshold for telephoning to be determined by local agreement with major users.
new ANCA anti-MPO Ab patient	Ref A
new anti-GBM Ab patient	Ref A
Positive LKM/SMA/SLA/LC-1	Children with very high ALT and positive LKM/SMA/SLA/LC-1
Myeloma Investigations Ref B New monoclonal band - any isotype IgG IgA & IgM	>30 g/L >15 g/L > 10 g/L

13. Reference Ranges and Specimen Container Selection

A Specimen bottle types required, instructions for taking samples reference ranges and additional information is shown **see Appendix 2**

14. Access of Results and Additional Testing

- ✓ For Nuffield Health Hospitals that are using Trakcare (electronic patient record system) Pathology results can be accessed 24/7. Please contact Nuffield Health IT for access issues regarding Trakcare.
- ✓ An secure online results portal is available which allows access to results by registered clinical users anywhere where there is internet access. This system allows viewing of results but does not replace printed hard copies issued by the laboratory. Please contact the laboratory to request an account.
- ✓ Wellbeing clinics have their results available by using EMR2 system and they can easily access their patients on this online system. In case of any difficulties of accessing the online results, please contact Pathology for advice.

Add-on Test Procedure

The availability of additional tests is dependent upon sample stability times. Please refer to the laboratory for guidance on sample stability times. If the laboratory still has the sample in storage and sample stability time has not been exceeded additional tests can be requested.

To request additional tests please contact the laboratory to confirm the sample is available and there is sufficient sample volume to perform the additional test. Once the laboratory confirms the test can be added a further request form should be submitted to the laboratory with the additional request and all relevant clinical details. Trakcare users will need to request the addition tests through Trakcare.

14. Laboratory Data Handling and Patient Confidentiality and Complaints

Nuffield Privacy Policy

The Nuffield Health privacy policy can be found on the Nuffield Health Website at:
Privacy Policy

This Privacy Policy sets out the basis on which we collect and process personal data about you including our practices regarding the collection, use, storage and disclosure of personal data that we collect from you and/or hold about you, and your rights in relation to that data.

Complaints Procedures

At Nuffield Health, we're continuing to build a healthier nation by aiming to provide the best possible service. The following link provides the complaint Process and what to expect

Complaints procedure | Nuffield Health

14. References

1. Instructions for use for Sarstedt -S- Monovette Blood collection system
2. Centrifugation recommendations for S-Monovette
3. Preanalytics Manual – greiner BioOne

Appendix 1 Laboratory Contact details

Hospital Address	Laboratory Contact Number	Opening Hours	Phlebotomy Location	Phlebotomy Hours	Phlebotomy Contact Number	On site Repertoire
Nuffield Health Brighton Hospital, Warren Rd, Woodingdean, Brighton. BN26DX	01273 627005	Monday to Friday 09:00-17:00	Outpatient Department	Monday to Friday 08:00-20:00	01273 107932	Biochemistry Immunoassay Haematology Blood Transfusion FIT analysis
Nuffield Health Bristol Hospital, 3 Clifton Hill, Clifton, Bristol, BS8 1BN	01179 064876	Monday to Friday 08:00-18:00	Outpatient Department	Monday to Friday 08:00-18:00	01179064875	POCT only
Nuffield Health Brentwood Hospital Shenfield Road, Shenfield, Brentwood CM15 8EH	01277 695663	Monday to Friday 08:00 - 18:00	Willow unit	Monday, Wednesday, Thursday, Friday 08:00 – 16:30 Tuesday 08:00 – 18:30	01277 695724/5663	Biochemistry Immunoassay Haematology Blood Transfusion
Nuffield Health Bournemouth Hospital, 67 Lansdowne Road, Bournemouth, BH1 1RW	01202 702811	Monday to Friday 09:00-17:00	Outpatient Department	Monday to Friday 08:00-20:00	01202 702282	POCT only
Nuffield Health Cambridge Hospital 4 Trumpington Rd, Cambridge CB2 8AF	01223 370921	Monday to Friday 08:00 -18:00	Outpatients Department	Monday to Friday 08:00 - 17:00	01223 485534	Biochemistry Haematology

Cheltenham Nuffield Hospital Hatherly Ln, Cheltenham, GL51 6SY	01242 246516	Monday to Friday 08:00-18:00	Outpatient Department	Monday to Friday 08:00-20:00	01247781169	Biochemistry. Haematology. Blood Transfusion
Nuffield Health Chester hospital The Grosvenor Hospital, Wrexham Road, Chester CH4 7QP	01244 575376	Monday to Friday 09:00 – 17:00	Outpatient Department	Monday to Friday 08:00 - 17:00	01244 680444	POCT only
Nuffield Health Chichester Hospital, 78 Broyle Road, Chichester, PO19 6WB	01243 963351	Monday to Friday 08:00-16:00	Outpatients Department	Monday to Friday 08:00 - 18:00	01243 530600	POCT only
Nuffield Health Derby Hospital Rykneld Road, Littleover, Derby DE23 4SN	01332 540 102	Monday to Friday 09:00 – 17:00	Outpatients Department	Monday to Friday 08:00 - 17:00	01332540139	POCT only
Nuffield Health Exeter Hospital, Wonford Road, Exeter, EX2 4UG	01392 262136	Monday to Friday 08:00-17:00	Outpatient Department	Monday to Friday 08:00-17:00	01392 575378	Biochemistry Haematology Blood Transfusion POCT
Nuffield Health Glasgow Nuffield Hospital 25 Beaconsfield Road Glasgow G120PJ	01415 762762	Monday to Friday 08.00-17.00	Outpatient Department	Monday to Friday 09.00-17.00	01415762736	Biochemistry Haematology Histology MRSA screening
Nuffield Health Guildford Hospital, Stirling Road, Guildford, GU2 7RF	01483 555927	Monday to Friday 08:00-18:00	Outpatient Department	Monday to Friday 08:00 - 18:00	01483 973547	Biochemistry Immunoassay Haematology Blood Transfusion

						Microbiology
Nuffield Health Haywards Heath Hospital, Burrell Rd, Haywards Heath. RH161UD	01444 716870	Monday to Friday 08:30-16:30	Outpatient Department	Monday to Friday 08:00-20:00	01444 476755	POCT only
Nuffield Health Ipswich Hospital Foxhall Rd, Ipswich IP4 5SW	01473277590	Monday to Friday 08:00-16:00	Outpatient Department	Monday to Friday 08:00 - 19:00	01473973341	POCT only
Nuffield Health Leeds Hospital 2 Leighton Street. Leeds LS1 3EB	01133882352	Monday to Friday 09:00 - 17:00	Outpatient Department	Monday to Friday 09:00 - 16:00	01133 227251 Option 1 Option 1	Biochemistry Immunoassay Haematology Blood Transfusion Microbiology Histology
Nuffield Health Leicester Hospital Scraptoft Lane, Leicester LE5 1HY	01162 743 754	Monday to Friday 09:00 – 17:00	Outpatients Department	Monday to Friday 08:00-20:30 Saturday (2nd and 4th in the month) 08:00-13:00	0116 274 3834	POCT only
Nuffield Health Newcastle upon Tyne Clayton Road, Jesmond, Newcastle upon Tyne NE2 1JP	01912 125236	Monday to Friday 08.30-17.00	Outpatients Department	Monday to Friday 09.00-16.00	01912125269	Biochemistry. Haematology. Blood Transfusion

Nuffield Health North Staffordshire Clayton Rd, Newcastle-under-Lyme, Newcastle ST5 4DB	01782 382502	Monday to Friday 09:00 – 17:00	Outpatient Department	Monday to Friday 08:00-17:00	01782 625431	POCT only
Nuffield Health Parkside Hospital 53 Parkside, London SW19 5NX	0203 340 3471	Monday to Friday 08:00-20:30	Outpatient Department	Monday to Friday 0830 – 1900 Saturday 0830 - 1300	0203 340 3440 Cancer Centre London 0203 340 3419	Biochemistry Immunoassay Haematology Blood Transfusion
Nuffield Health Plymouth Hospital, Derriford Road, Plymouth, PL6 8BG	01752 761829	Mon-Thursday 08:00-18:00 Friday 08:00-17:00	Pathology Department	Monday to Thursday 08:00-18:00 Friday 08:00-17:00	01752 761829	POCT Only
Nuffield Health Shrewsbury Longden Rd, Shrewsbury SY3 9DP	01743 282569	Monday to Friday 09:00 – 17:00	Outpatient Department	Monday to Friday 08:00-17:00	01743 282500	POCT only
Nuffield Health Taunton Hospital, Staplegrove Elm, Taunton, TA2 6AN	01823 250625	Monday to Friday 09:00-17:00	Outpatient Department	Monday to Friday 09:00-17:00	01823 250616	POCT Only
Nuffield Health Tees Hospital Junction road Norton Stockton on Tees TS20 1PX	01642 367444	Monday to Friday 08.30-16.30	Outpatient Department	09.00-16.00	01642360100	POCT only

Nuffield Health The Holly High Rd, Buckhurst Hill IG9 5HX	0208 936 1204	Monday to Friday 08:00- 18:00	Outpatient Department	8:30 to 4 pm Sat 8:30 to 12:30 pm	0208 143 6430	Biochemistry. Haematology. Blood Transfusion
Nuffield Health The Manor Hospital, Beech Road, Headington, Oxford. OX3 7RP.	01865 307595	Monday to Friday 08:00 – 17:00	Outpatient Department	8am to 8pm Monday to Friday, 8am - 4pm Saturday	01865 307630 Phlebotomy 07787666884	Biochemistry Haematology Blood Transfusion Histology
Nuffield Health Tunbridge Wells Hospital, Kingswood Rd, Tunbridge Wells. TN24UL	01892 356884 01892 356886	Monday to Friday 0900-1700	Outpatient Department	Monday to Friday 08:10 – 14:50	01892 356863	Biochemistry Haematology Histology
Nuffield Health Vale Hospital, Hensol Castle Park, Hensol Rd, Pontyclun, CF72 8JX	011443449291	Monday to Friday 08:30-16:30	Pre-assessment	08:00-16:00	01443443851	POCT only
Nuffield Health Warwickshire Hospital The Chase, Old Milverton Lane, Leamington Spa CV32 6RW	01926 436 338	Monday to Friday 08:00 – 19:30	Pathology	8am to 6pm (Mon-Fri) 8am to 1:00 pm(Sat)	01926 562 614	Biochemistry Immunoassay Haematology Blood Transfusion, Microbiology Virology Cytology Histology
Nuffield Health Wessex Hospital, Winchester Rd, Eastleigh, SO53 2DW	02380258407	Monday to Friday 08:00- 18:00	Outpatients Department	9am to 5pm (Mon-Fri) 9am to 2 pm(Sat)	02380258414	Biochemistry Haematology Blood Transfusion Histology
Nuffield Health Woking Hospital, Shores Road, Woking,	01483 227819	Monday to Friday 08:00- 18:00	Outpatient Department	08:00- 18:00	01483 227800	Immunoassay POCT only

GU21 4BY						
Nuffield Health Wolverhampton Wood Rd, Tettenhall, Wolverhampton WV6 8LE	01902 793280	Monday to Friday 08:00- 18:00	Outpatient Department	08:00- 18:00	01902 7541777	Allergy Biochemistry Immunoassay Haematology Blood Transfusion
York Nuffield Hospital, Haxby Road, York. YO31 8TA	01904715030	Monday to Friday 09:00 - 17:00	Outpatient Department	09:00-15:00	01904715121 or 01904712150	POCT only