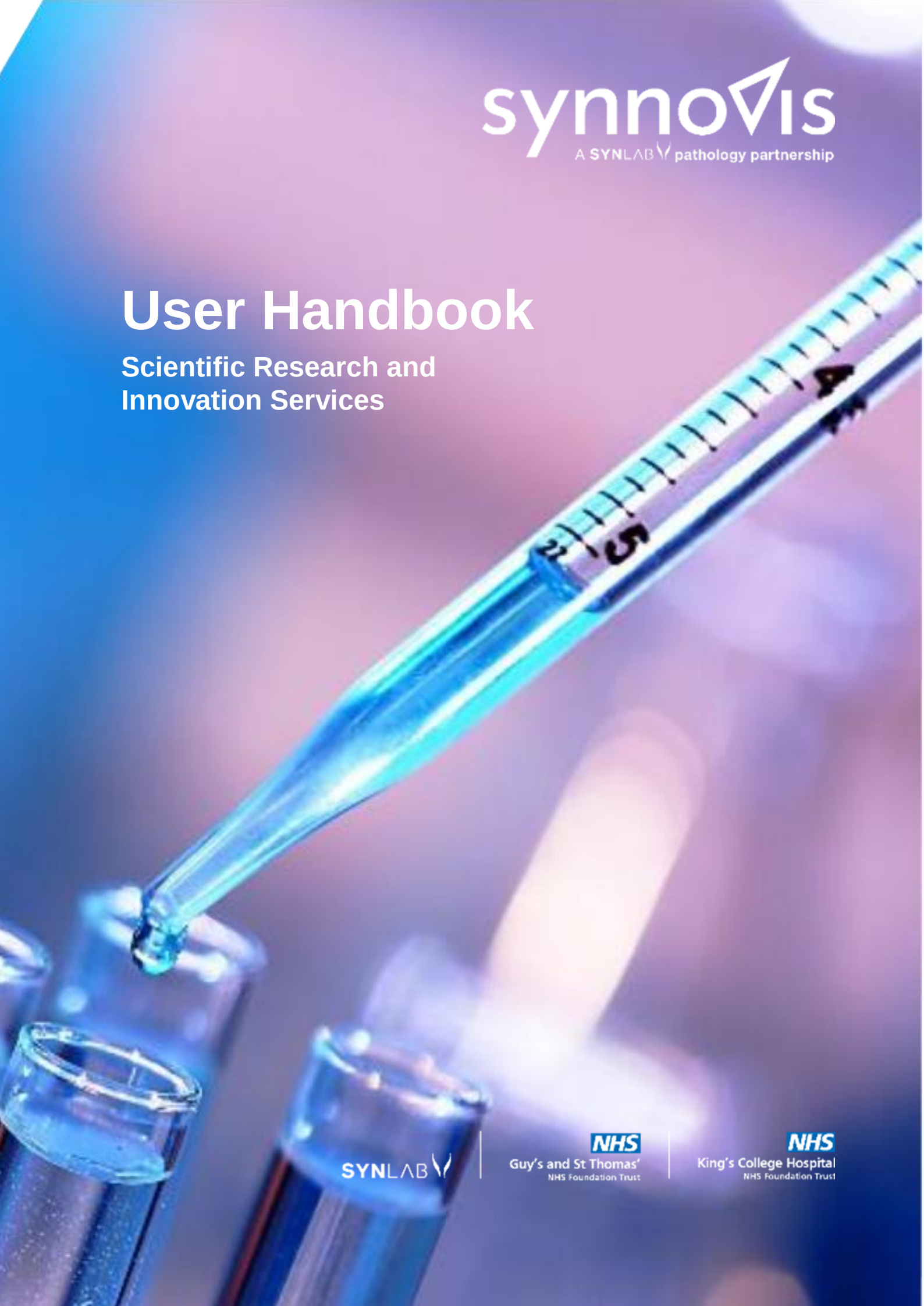
synnovis
A SYNLAB pathology partnership

User Handbook

Scientific Research and Innovation Services



SYNLAB | NHS Guy's and St Thomas' NHS Foundation Trust | NHS King's College Hospital NHS Foundation Trust

Contents

1. Introduction

This document aims to provide users with clear information about how to access our services within the Scientific Research and Innovation Services Department (SR&I) (formally Contract Research and Development) at King's College Hospital NHS Foundation Trust. The document is structured to reflect the flow of a sample, from the point-of-care through to provision of results and clinical advice.

This is a controlled document. Please visit Scientific Research and Innovation Services | Synnovis for the latest version as well as other useful links and information.

2. General information

SR&I supports investigators from NHS, academic and commercial areas of research requiring pathology services for clinical research studies, scientific research and service evaluations. Each pathology service is outsourced on an individual contractual basis. The scientific team is experienced particularly in delivering routine and bespoke biomarker research with over 300 assays available by immunoassay, including UKAS accredited clinical cytokine panels.

2.1 Location

Scientific Research and Innovation Services is situated at the King's College Hospital NHS Foundation Trust, in Bessemer wing.

2.2 Address

Scientific Research & Innovation Services
C/O Essential Services Laboratory Reception
Ground Floor, Bessemer Wing,
King's College Hospital, Denmark Hill
London, SE5 9RS

2.3 Opening hours

Monday – Friday 09:00 – 17:30 (Excluding public holidays)

2.4 General enquiries

SR&I Laboratory	Telephone	Email
Laboratory & Scientific enquiries	0203 299 5548	synnovis.research@synnovis.co.uk
Contracts enquiries	0203 299 4144	synnovis.researchenquiries@synnovis.co.uk

2.5 Key contacts

Name	Position	Telephone	Email
Dr Royce Vincent	Consultant Chemical Pathologist	0203 299 4100	royce.vincent@nhs.net
Tracey Mare	Head of Scientific Research and Innovation Services	0203 299 3549	tracey.mare@synnovis.co.uk
James Luxton	Senior Biomedical Scientist	0203 299 5548	james.luxton@synnovis.co.uk
David Card	Senior Clinical Scientist - Quality Lead	0203 299 3190	david.card@synnovis.co.uk

3. Test repertoire and information

For the Test Repertoire please follow this link: https://www.synnovis.co.uk/departments-and-laboratories/scientific-research-and-innovation-services.

With the exception of the Cytokine panels (CY19, CY20, CY21 and CY23), tests are not immediately available and are subject to a signed service level agreement before analysis can be carried out.

Please contact synnovis.researchenquiries@synnovis.co.uk if you want to request analysis of any tests from the repertoire. Test information is reviewed annually and updated with any changes in real time. The Scientific Research and Innovation Services Department is a reactive service that adapts to meet the needs of users, therefore if tests are required that do not appear on the repertoire, please contact the Laboratory using the email address above.

4. Contracts and SLAs

Prior to sending clinical trial specimens please contact the clinical trials team with full details of your requirements: synnovis.researchenquiries@synnovis.co.uk.

5. Requesting investigations

All requests are made by using the study specific sample request form, with the exception of the Cytokine panels (CY19, CY20, CY21 and CY23) which are requested by using the Cytokine Referral Sample Request Form (CR&D-LF-61), see https://www.synnovis.co.uk/departments-and-laboratories/scientific-research-and-innovation-services and the Trust EPR system.

5.1 Hospital phlebotomy service

For Synnovis Phlebotomy services please see:
https://www.synnovis.co.uk/departments-and-laboratories/phlebotomy-department

For instructions on blood collection please see:
https://www.kch.nhs.uk/services/services-a-to-z/phlebotomy/

5.2 Request form

For clinical requests, it is essential that requests, forms and samples are completed correctly using a minimum of 3 unique patient identifiers:

- Unique ID number e.g. trial identification, hospital number or NHS number
- Patient name
- Date of Birth

For clinical trials one or two identifiers may be accepted where possible, if there is a unique identifying reference number (e.g. clinical trial participant reference number). The details on the request MUST match the details on the sample or the request cannot be accepted. Hand written sample request forms must be legible.

5.3 Specimen labelling

The person collecting the specimen is responsible for positively identifying the patient and obtaining consent. Specimen tubes must be labelled as soon as the samples are collected. The specimen must be labelled with the patient details, identical to the request form and hazard labels attached where appropriate. Labelling must be clear and legible, and must include the date and time of collection. For the safety of patients and staff, unlabelled or mislabelled specimens cannot be accepted. If EPR barcode stickers are used, please ensure that the sticker is placed on the primary sample in such an orientation that it can be read by a bar code reader.

5.4 Specimen containers

Primary receptacle - a primary watertight leak-proof receptacle containing the specimen (e.g. blood collection tube).

Secondary packaging - a second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s) (e.g. specimen bag). The receptacle must be packaged with enough absorbent material to absorb all fluid in case of leakage. All samples must be placed in individual plastic 'kangaroo' type sample bags to avoid cross contamination. Any documentation (e.g. request forms) are to be placed in the separate pocket on the outside of the bag – not inside with the samples. Sample bags must not be sealed using staples, pins or paperclips. Several cushioned primary receptacles may be placed in the secondary packaging, but sufficient additional absorbent material shall be used to absorb all fluid in case of breakage.

Outer packaging - The secondary packaging is placed in outer shipping packaging with suitable cushioning material. For postal specimens this will be a UN3373 box and for cross-site or GP transport this will be a Daniels box or appropriate Igloo (white polystyrene box).

Needles and other sharps must never be sent to the laboratory. Any specimens that are received leaking or in a dangerous condition will not be processed but will be discarded. In this event the clinician will be informed via a report generated electronically on the pathology IT system.

5.5 Specimen collection

Order of draw:

VACUETTE® SELECTION CHART

Kings College Hospital NHS Foundation Trust

Blood Cultures; Aerobic followed by Anaerobic. If insufficient blood for both culture bottles, use aerobic bottle only.

Cap Colour and Volume	Cap Colour and Volume	Tube Type	Tests	Special Instructions
3ml KFK 469	2ml KFK 333	Trisodium Citrate	Coagulation; Coagulation Tests, Heparin & Warfarin Control, Anti-XA, Thrombophilia Screen, Lupus Screen, Confirmation Platelet Clumps	Ensure tube filled to indicated mark
8ml KFK 501		Clot Activator and Separation Gel	Serology; Viral, Bacterial, Parasite, Fungal.	
5ml KFK 304	2.5ml KFK 383	Clot Activator and Separation Gel	Routine Chemistry; Endocrinology, Drug Levels (Vancomycin, Gentamicin, Amikacin, Tobramycin), Immunology, B12, Ferritin, Serum Folate, EPO, Androstenedione, Insulin, C-Peptide, DHEAS, lithium, total bile acids, serum porphyrins, calcitonin, thyroglobulin, chromogranins, fluoride	Insulin / C-peptide must be sent to lab within 30 mins.
6ml KFK 321		Lithium Heparin	Homocysteine, Ammonia (on ice), White cell enzymes (full), Glycogen storage enzyme (full), GIPT.	
6ml KFK 262		Trace Element	Plasma Trace Elements.	
4ml KFK 332	3ml KFK 338	EDTA	FBC, Adult ESR, Sickle, Malaria, Retics, HBA1C, G6PD, DCT, Cyclosporin, GF, Bloodfilm, Red-Cell Folate, Lymphocyte Subsets, HLA, B27, PNH Screen, Red Cell Protoporphyrins, Red Cell PBG-Deaminase, PTHI, ACTH, genetic tests, Viral DNA / RNA (qualitative, quantitative and sequencing), Red Cell Analysis, Gilbert's Testing, plasma metanephrines, aldosterone and renin, Whole Blood Lead, Cobalt, Chromium, Manganese, Cadmium, Arsenic, Thallium	Must send plasma metanephrines, aldosterone and renin within 30 mins.
9ml KFK 076		EDTA	HIV and HCV viral load testing, Virology Molecular PCR	
6ml KFK 339		EDTA for crossmatch	Blood Group and Screen, Cross Match, DAT, Kleihauer, Red Cell Phenotype	
2ml KFK 330		NAF Oxalate	Glucose (blood and CSF), Lactate (blood and CSF)	

Gut Hormones, plasma catecholamines & PTHrP: Sample tube (with trasylol) must be collected from the biochemistry lab

All tubes require immediate mixing following collection. Insufficient mixing can result in inaccurate test results and the need to re-draw

IMPORTANT: Hold tube in place with the thumb until filled to the required level

VACUETTE® products and ordering codes

VAKS01 VERSION 01.
Last updated May. 2012

greiner bio-one

Greiner Bio-One Ltd.
Brunel Way, Stroudwater Business Pk.
Stonehouse. Glos. GL10 3SX
sales@uk.gbo.com . www.vacuette.com

5.6 High risk specimens

Separate procedures are used in the laboratory for the safe handling and examination of samples from patients known, or suspected, to have infection caused by high risk pathogens that pose a risk to laboratory workers and others if handled incorrectly. It is the responsibility of the person taking such a specimen to ensure request forms and specimens are labelled to indicate danger of infection. The request form must give sufficient clinical information to enable experienced laboratory staff know what special precautions are necessary. These specimens must be placed in a Biohazard specimen bag.

5.7 Other sample types

If you require tests to be carried out on other non-high risk sample types not specified in the requirements e.g. CSF, ocular fluid, pericardial fluid etc. please contact the laboratory to discuss sample requirements and result validity.

5.8 Add-on tests

For clinical samples clinicians can contact the laboratory by telephone or email to request additional tests, which can be added on where possible – i.e. sufficient volume, correct sample type, stability.

For clinical trial samples the analysis (and any reflex testing) is set out in the contract and so requests for add on tests outside the scope of the study cannot be processed.

6. Transport to the laboratory

6.1 General health & safety requirements

Please note:

- Specimens must only be submitted to the laboratory in approved containers.
- The outside of containers must be free from contamination by potentially infectious material.

Each specimen container should be sent in a sealed plastic specimen bag. If a request form is sent with the specimen, it should be kept separate from the specimen within the specimen bag. Samples must be delivered to the department in a way to protect the integrity of the sample. Samples must not be exposed to extreme temperature or prolonged transport. If samples are in danger of being exposed to conditions where sample integrity can be compromised, please contact the laboratory to discuss the most appropriate method of transport.

6.2 Pneumatic Air Tube Transport System (PATTS)

The King's College Hospital NHS Trust policy for use of the PATTS can be viewed on the Kings Intranet, instructions are also available at each work station.

6.3 Receipt of specimens

During normal working hours, specimens are to be delivered to the Synnovis Specimen Reception, Ground floor, Bessemer Wing, KCH. Specimens requiring urgent sample processing are to be delivered directly to the SR&I laboratory, Ground floor, Bessemer Wing.

6.4 Courier and postal deliveries

When sending samples to Scientific Research and Innovation Services, it is the responsibility of the requesting laboratory to ensure that the samples are packed in accordance with the current postal regulations, contain appropriate paperwork and are labelled correctly (sender and recipient). Courier/taxi suitable transport should be arranged by the sender.

6.5 Transport by road

Samples transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the 'The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, as amended (CDG Regs)' – ADR regulations.

The following must be adhered to:

- The box must not be transported in the same compartment as passengers – but must be placed in the boot of any vehicle or the rear compartment of any van used and firmly secured.
- Mail must not be transported in the same carrier box as specimens.
- The container must be secured using appropriate means whilst being transported in the vehicle.
- Specimens must be transported in a secure transport box with a fastened leak proof lid. (Compliant with IATA Packaging Instruction 650 or 621 and UN3373 or UN3291)
- Each box must display a biohazard warning sign and must also state that the box must not be tampered with or opened and a telephone contact number included for emergency purposes.

6.6 Inter-hospital transport

For details of inter-site couriers please contact Synnovis Central Specimen Reception: https://www.synnovis.co.uk/departments-and-laboratories/central-specimen-receptions

6.7 Specimen transport bags

Service users can contact Synnovis Customer Services customerservices@synnovis.co.uk to request specimen transport bags.

7. Results

All results should be interpreted in conjunction with clinical presentation and findings.

7.1 Electronic reporting of results

All results will be accessible via EPR or Cyberlab following authorisation.

7.2 Results enquiries

All results enquiries should be sent to: synnovis.research@synnovis.co.uk

7.3 Clinical advice

Please contact the Consultant Chemical Pathologist for clinical advice, see key contacts (section 2.5).

7.4 Erroneous results

Pre-analytical factors are an important cause of erroneous test results and are largely under the control of the requester. Results may not be reported if it is suspected that they are invalid. The table below gives common causes of erroneous results and the effects seen, this list is not exhaustive.

Problem	Cause	Effect
Delay in sample processing	Delay in transport/processing	Sample degradation, haemolysis, activation of some biomarkers
Storage temperature	Samples stored at incorrect temperature	Sample degradation, haemolysis, activation of some biomarkers
Haemolysis	Traumatic bleed, vibrations during transport, extreme temperature, frozen as whole blood and delayed processing.	Analytical interferences
Lipaemic sample	Non-fasting, with recent ingestion of lipid-containing meal. Condition causing hyperlipidaemia (e.g. alcohol, diabetes, inherited metabolic disease etc.) or recent intravenous infusion of a lipid emulsion	Analytical interferences
Multiple freeze-thaws	Incorrect storage, repeat testing e.g. due to assay failure.	Sample degradation, haemolysis, activation of some biomarkers
Incorrect sample volume	Insufficient sample to perform test, incorrect filling of blood collection tubes e.g. citrate tubes not filled to line.	Inaccurate test results
Incorrect sample tube	Incorrect primary tubes selected at phlebotomy, test added on to another which has different sample requirements	Assays are validated using particular sample types, using a different sample type invalidate the result
Serum tubes centrifuged prior to clot formation	Not allowing the sample to completely clot for 15 - 60 minutes at room temperature before centrifuging	Fibrin will form in the serum, sometimes leading to haemolysis. For SST tubes the gel barrier may not be intact and could cause improper separation
Cross-reactivity	Interfering exogenous or endogenous substances e.g. antibodies (very rare)	Falsely elevated or lowered results
Sample mismatch	Incorrect labelling by sender	Sample not processed

8. Quality assurance

8.1 Commitment to quality

Synnovis management systems support the business vision to be the leading Pathology provider of high quality, cost effective pathology services. A statement of Purpose constitutes the Quality Policy for Synnovis Group LLP and is applicable to both Synnovis Analytics and Synnovis Services. The Statement of Purpose can be found at https://www.synnovis.co.uk/our-quality-policy. Synnovis is an independent pathology provider registered with the Care Quality Commission.

All assays performed in SR&I are validated or verified and conform to the department's quality management system prior to being made available to users. Internal quality control (IQC) and external quality assurance (EQA) are used as part of the overall assurance mechanism along with internal audit to monitor adequacy of operating procedures and effectiveness of the quality systems. Accreditation to ISO 15189 covers the clinical cytokine panels CY19, CY20, CY21 & CY23.

The department monitors quality through monthly quality meetings and completes an Annual Management Review (AMR) to ensure quality objectives are monitored locally and changes or new systems are implemented effectively. Satisfaction of service users is seen as a key indicator of success in improvement of services. Key performance and quality indicators are used to enhance operational performance and remove variation from laboratory processes.

We ensure the confidentiality of information we hold on patients, donors and clients and allow accreditation and regulatory bodies appropriate access to knowledge systems maintained to provide third party assurance to Synnovis and our stakeholders.

8.2 Commitment to meeting the needs and requirements of users

To meet the needs and requirements of our users, the SR&I department:

- Operates a quality management system to integrate the organisation, procedures, processes and resources;
- Establish quality objectives and plans to achieve them; review these objectives periodically;
- Ensure that all personnel are familiar with the Quality Policy, the Quality Manual and related processes to ensure user satisfaction;
- Commit to the health, safety and welfare of staff and visitors to the laboratories;
- Comply with the relevant environmental legislation;
- Is committed to meeting or exceeding the requirements of the standards set for medical laboratories to ensure compliance to ISO 15189, GCP, MHRA, Blood Safety and Quality Regulations (2005), and the Human Tissue Act (2004);
- Uphold professional values and commit to good professional practice and conduct.

8.3 Accredited tests

The following tests are accredited to ISO 15189 by UKAS:

- CY19: IL-1β, IL-6, IL-8, TNFα
- CY20: IL-2ra, IL-10, IL-17, INFγ
- CY21: IL-15, GM-CSF, MCP-1, VEGF-A
- CY23: IL-5, IL-13

For UKAS certificate see:

https://verify.ukas.com/1ac46481-ad60-420c-a43a-ad18395b4c4e#acc.8vZTXAVp

For UKAS schedule of accreditation see:

26342-Medical-Single.pdf (ukas.com)

8.4 Ensuring compliance with accrediting bodies

To meet the requirements of ISO 15189 and GCP Standards, the SR&I department will ensure:

- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users.
- The proper procurement and maintenance of equipment and other resources as are needed for the provision of the service.
- The handling of all specimens in such a way as to ensure the correct and safe performance of laboratory examinations.
- The use of examination procedures that will ensure the highest achievable quality of all tests performed in conjunction with CE or UKCA (UK Conformity Assessment) marked kits and validation of in-house assays.
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.

8.5 Compliments, feedback and complaints

We aim to continuously improve and update our services and to learn from experience. Please get in touch and let us know if you have had any problems in working with the SR&I laboratory. Complaints, errors, mistakes and near misses within the laboratory are logged as non-conformity reports which are investigated by the Quality Lead.

Compliments, feedback or complaints can be made directly to synnovis.researchenquiries@synnovis.co.uk.

For the Synnovis formal complaints procedure see: https://www.synnovis.co.uk/customer-service.

8.6 Data protection

The department complies with the requirements of the General Data Protection Regulation (GDPR) 2018, the Data Protection Act 1998, the Caldicott principles on safeguarding patient confidentiality and patient information and with guidance from the Royal College of Pathologists.

All patient identifiable information is regarded as confidential and is passed on only for official purposes i.e. to professionals with responsibility for patient care or public health. Confidential data is held only as long as necessary and is stored securely. All SR&I Department staff undergo mandatory training in information governance and data protection. Access to the laboratory IT systems is password protected and data is held, processed and transferred in accordance with the UK Data Protection Act.

8.7 Service continuity

In the event that the department is unable to deliver the required service, for example, due to equipment downtime or failure, we will endeavour to contact all relevant users if it impacts on our turnaround times. The department has a business contingency plan in place.