Title:	**UKAS Flexible Scope**
Subject:	**Management of UKAS Flexible Scope**

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Each document has an individual record of amendments. The current amendments are listed below.

Amendment Number: Date	Insert Issue no	Section involved	Amendment
23/01/2024	9.0	1.1, 1.2.4	Inclusion of the MS satellite site located at DH. Review and update in-line with ISO15189:2022
02/10/2022	8.0	All	Update following the Synnovis Group rebrand
21/06/2022	7.0	2.1	Trust sign off not a requirement for UKAS accreditation
30/03/2022	6.0	2.2	RA incorporated as an action within the template
		2.3	Inclusion of the validation template SLM-QF-158
21/09/2022	8.0		Logo change
27/08/2024	10	2	General update of section and addition of suggested CCR actions under 2.3. DA

Contents

1. Introduction

1.1 Principle

This document describes the processes for applying for, and maintaining, the accreditation of pathology tests to ISO-15189:2022 standards which fall within flexible scope for Biochemical Sciences, Synnovis Analytics (UKAS accreditation reference 9093).

Biochemical Sciences is based on the 4th and 5th floors of St. Thomas' Hospital, London and has a satellite Mass Spectrometry (MS) laboratory, located off-site at Kings College Hospital, London, from which the immunosuppressant drug monitoring (IDM) service is provided.

Biochemical Sciences, as the managing entity, is responsible and accountable for the IDM service and ensures that all processes align with the quality management system in accordance with the department's accreditation to ISO15189:2012.

See Biochemical Sciences Quality Manual (SLM-QM-1) for further details.

The department must demonstrate competency, impartiality and consistency, and comply with ISO15189 and UKAS GEN-1 principles in order to maintain flexible scope accreditation.

The flexible scope detailed herein applies only to mass spectrometry based techniques which the department has established competence in developing and performing (see section 2). Flexible scope does not cover new analytical principles which the department has no prior experience in performing. Flexible scope is set out within the bounds of ISO/IEC 17025 and provides a basis for ensuring tests which have been transferred to an alternative analytical instrument remain within the scope of accreditation during the transfer, subject to processes described in this document. It also applies to new tests developed using the same technology or new analytes added to existing assays.

This flexibility can only apply to tests utilising technologies which have previously been successfully validated and introduced within the department in line with ISO15189:2012 and have successfully been accredited within the scope of the standard. For a test to be successfully accredited via the flexible scope, the process must be documented and controlled to ensure a full audit trail. Only those activities and locations listed under the flexible scope will be covered.

1.2 Limitations to the Flexible scope

Only tests utilising MS and associated technologies previously validated within Biochemical Sciences at St. Thomas' Hospital and accredited to ISO15189:2012 may be accredited via flexible scope. Tests can only be accredited under flexible scope if they include established mass spectrometry based techniques.

Examples of MS technologies which have never been utilised in the department include time of flight (TOF) analysis and accelerator mass spectrometry (AMS).

1.2.1 Activities covered:

Flexible scope covers areas where the department has established expertise and a track record of successfully establishing methods which meet IS015189 standards and have been granted accreditation by UKAS. All tests must utilise MS technologies to be covered under flexible scope.

Flexible scope covers tests falling in to the following categories

- New analytes not previously measured within the Biochemical Sciences department;
- Analytes detectable during analysis using established assays but not previously quantified/reported;
- Analytes already measured and reported within Biochemical Sciences but which have been transferred to a different mass spectrometer
- Analytes already measured within the department but measured in a different matrix i.e. serum, blood, urine etc.

The flexible scope covers the following:

1.2.2 Mass spectrometry technologies

- Single quadrupole mass spectrometry (MS)
- Triple quadrupole mass spectrometry (MS/MS)

1.2.3 Associated technologies

- Flow injection analysis (FIA)
- Liquid chromatography (LC)
- Ultra and high performance liquid chromatography (UHPLC and HPLC)
- Gas chromatography (GC)
- Automated sample preparation technologies

1.2.4 Locations

- The flexible scope covers established and/or new tests that are provided by Biochemical Sciences from laboratories based on the 4th and 5th floor of the St. Thomas' Hospital site and the satellite MS laboratory, on the Kings College Hospital site.

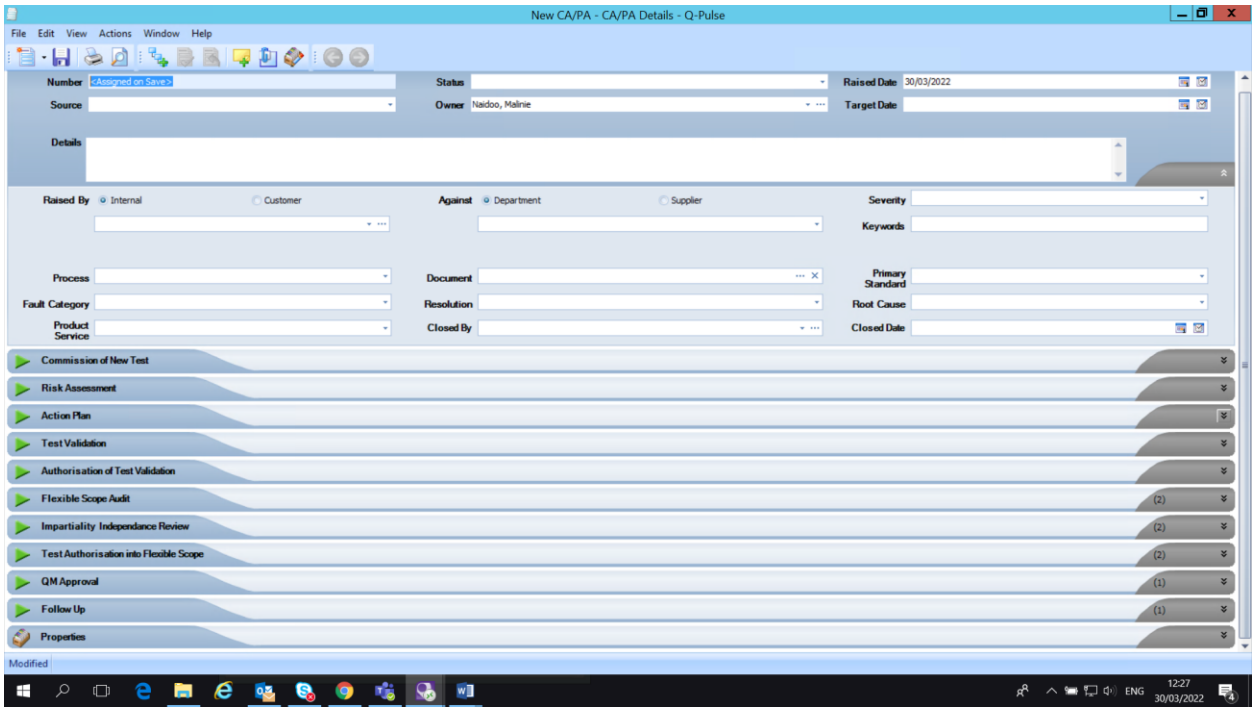
1.2.5 Matrices

- Human serum/plasma
- Human whole blood
- Human dried blood (dried blood collected onto filter paper or with a dried blood collection device as described in the method validation document SLM-QR-55)
- Human urine
- Human cerebrospinal fluid
- Human faeces

2. Flexible Scope Process

The flexible scope process will be managed using a specific change control template under the QPulse CAPA module, and is designed to facilitate delivery of the agreed process for including a new test under UKAS flexible scope accreditation. Staff managing the change control must be signed off as competent against the Review and Authorisation of Validation within Flexible Scope Competency Assessment SLMM-CAF-45. The individual stages of the change control template are detailed below.

Figure 1: Flexible Scope Change Control Template



2.1 Commissioning of New Test:

Changes in repertoire outlined as stated above are validated according to established procedures (refer to SLM-MP-13). Justification of new tests introduced is included on the Synnovis New Test Form on ServiceNow and changes to IT are requested through the ICT requests section on ServiceNow.

Suggestions for new tests are often internal and may also be received directly from clinical teams and service users. Any member of staff may make suggestions for new test ideas either by raising at their local section meeting or raising an improvement CAPA on Q-Pulse.

Once approved locally by the Director of Biochemical Sciences, the test goes through the new test commissioning process via ServiceNow. The form details criteria and guidance for requesting a new test.

If the test is to be offered to Trust Clinicians the new test must also be signed off by a representative of the Trust. Sign off by the Trust does not impact UKAS accreditation, nor does it limit the organisation from offering the test to external users. Copies of all test commissioning documentation should be attached to the change control under the Properties.

2.2 Risk Assessment

On completion and approval of new test commissioning via the Synnovis new test process, introduction of the new test will be risk assessed using the Change Control Risk Assessment Form PATH-Q-FORM28 which is incorporated as an action within the template. All risks identified must be mitigated or be able to be managed locally before test development/validation begins. Authorisation to progress will be approved by the Quality Manager and Director of Service. A copy of the risk assessment should be attached to the change control under Properties.

2.3 Action Plan

The action plan is designed to help identify some of the wider aspects required for new test introduction and track who is responsible for completion of the action(s) by a desired target date. Actions included under this section will be specific to the requirements of the test undergoing accreditation, however, they must include any remedial and corrective actions identified as a result of the overarching risk assessment performed in section 2.2. As a general guide, some aspects to consider are:

- Requirement for any additional risk assessments
- Procurement of equipment, reagents and consumables
- Storage of equipment, reagents and consumables
- Preparation and storage of stock, calibration or control materials
- LIMS requirements: test configuration, worklists and outstands, report format, interpretive comment codes and end-to-end testing etc.
- Access to instruments/devices
- Access to software packages
- Specimen receipt and storage logistics
- Generation of COSHH, reagents logs and other routine assay documentation
- Generation of SOPs and training documentation (assay and reporting)
- Update of cross-referenced SOPs
- Subscription to appropriate EQA scheme(s)
- Completion of a BoM (in collaboration with Finance)
- Identification and planning of staff training
- Record keeping / storage of documentation
- Contingency plan agreement in the event of downtime
- Website updates for new test information: specimen requirements, TAT, methodology etc.
- Communication of test go-live with relevant stakeholders

2.4 Test Validation

Development and validation of new tests within flexible scope must be performed by members of staff who have completed and been signed off as competent against the Method Validation Competency Assessment SLMM-CAF-42, and ideally, the Authorisation of Validation within Flexible Scope Competency Assessment SLMM-CAF-45.

Validation of new tests will include successful completion of the Method Validation Plan Template SLM-QF-164, the Method Validation Report Template SLM-QF-158 and the Method Validation Acceptance Form SLM-QF-8. Note - the validation report requires formal sign off as part of test authorisation (section 2.5) and Impartiality and independence (section 2.7).

2.5 Authorisation of Test Validation

The Director of Biochemical Sciences is responsible for authorisation of test validation under flexible scope. The exception to this would be in the event that the Director has personally contributed to the validation process and can no longer be considered independent. In this situation, the test validation will be independently authorised by a Consultant Scientist (BMS or CS).

2.6 Flexible Scope Audit

Once test validation has been authorised, the test will be audited against the flexible scope criteria using the Flexible Scope Audit Checklist SLM-QF-144. Section 1 of the audit will be performed by a Consultant Scientist, Principal Scientist, Advanced Practitioner or Operations Manager who has been independent of the validation process.

Section 2 will be completed by the Quality Manager after the test has been approved for accreditation. Section 2 of the audit is to ensure that key personnel as identified within this document have been responsible for approval of the test into scope. The QM must have completed and been signed off as competent against the Flexible Scope QMS Competency SLMM-CAF-55.

Should any non-conformance(s) be identified at this stage, they must be rectified and closed prior to the impartiality and independence review being performed.

2.7 Impartiality and Independence Review

Personnel accountable for the development, validation, review and authorisation of new tests under flexible scope must be impartial and acting independently, i.e. must not be involved in other key elements of the process. For example, test validation cannot be authorised by the person who has undertaken the analytical process for that validation; the pre-go live audit cannot be performed by an auditor who has been involved in the validation process or authorised the validation. This will be documented in the flexible scope audit conducted.

Prior to final authorisation of the test into flexible scope accreditation, the audit report will be independently assessed alongside the authorised test validation, by the Chief Scientific Officer (CSO) and GSTT Senior Quality Manager (SQM). Both parties must be signed off as competent against the relevant flexible scope competency: SLMM-CAF-45 for the CSO and SLMM-CAF-55 for the SQM.

The CSO and SQM will sign the completed Method Validation Report Template SLM-QF-158 and Flexible Scope Audit Checklist SLM-QF-144 as evidence of review, prior to closing actions set within the impartiality and independence stage.

2.8 Test Authorisation into Flexible Scope

The Director of Biochemical Sciences will be responsible for final sign off and authorisation of the test into accreditation within the flexible scope. This cannot be performed unless stages up to and including the impartiality and independence review have been formally approved and closed.

Once tests have been authorised, they are recorded via update to the Biochemical Sciences Record of Changes within Flexible Scope SLM-QF-139. The record must also be made available on the Synnovis website at http://www.Synnovis.co.uk/departments-and-laboratories/biochemical-sciences.

****** Copies of all signed documentation should be attached to the change control under Properties******

2.9 QM Approval

The SQM is responsible for ensuring all stages have been closed appropriately with all the relevant information and evidence attached.

2.10 Follow Up

New tests included within the testing repertoire will have a vertical audit performed pre-go live (section 2.6) and an examination audit scheduled 3-6months post go live**.**

The change control will remain open until after the follow up audit is conducted and any non-conformance(s) are closed. The Quality Manager is responsible for final closure of the change control.

3. Quality management of the flexible scope

Ensuring completion of the quality management aspects of the flexible scope is the responsibility of the Reference Services Quality Manager. This includes management of the flexible scope process at the satellite location to ensure the established flexible scope processes outlined within policy is maintained. Additional to this is scheduling audits to cover the tests included in the scope; reporting any non-conformances arising from audit, together with proposed actions to the senior management team via the monthly governance report; and updating user information and UKAS, as applicable, once tests have been authorised to be included in the flexible scope as described in Section 2.

3.1 Competency

As with all tests within Biochemical Sciences, only staff signed off as competent can perform assays and authorise results (see SLM-MP-22). All staff involved in development, review, result validation and result authorisation of tests developed within the flexible scope must be authorised as competent to do so. See Policy for Training on Procedures (SLM-MI-13) and Training Policy (SLM-MP-12). Personnel are authorised to develop, review and validate techniques. See assay validation and verification SOP (SLM-MP-13), Quality Improvement SOP (SLM-QP-6) assay development review and validation competency assessment (SLMM-CAF-42). Competency for validation of tests including those within flexible scope is assessed and personnel are authorised. Competency to review and authorise assay validations within flexible scope is assessed using SLMM-CAF-45. Competency for oversight and review of the QMS elements of the process is assessed using SLMM-CAF-55.

3.2 Quality Control

The Biochemical Sciences department ensures the continuing validity of procedures introduced under flexible scope, see Quality Control procedures (SLM-QP-5) for further details.

3.3 External Quality Assessment

Each test within the flexible scope will be subject to EQA and or an alternative approach if there no EQA available for the test. Refer to EQA SOPs SLMM-LP-25, SLMP-LP-50, SLMN-LP-23

for schemes/alternative approach suitability and operational procedures related to EQA participation.

EQA is performed in accordance with the departmental EQA policy, SLM-QP-2.

3.4 Equipment installation and acceptance

Equipment installation and acceptance testing is managed according to procedures in (SLM-MP-18) using the equipment acceptance form, SLM-QF-68.

3.5 Requests, tenders and contracts

New tests set up at the specific requests of users are recorded as part of the New Tests process (see section 2.3). Usually all requirements of clients are covered through the New Test process except in unusual circumstances e.g. clinical trial work covered under GCP guidelines. In these circumstances requirements are covered by contacts or SLAs, see Synnovis SLA policy (PATH-BD-SOP2) for further details. Clients are routinely informed if the tests performed are within the scope of accreditation.

3.6 Movement to alternative locations

The decision to change the location of a test is the responsibility of the Director of Biochemical Sciences and is recorded in the departmental senior staff meeting minutes (see SLM-MINS-71). Unlike other aspects of flexible scope UKAS must be informed immediately if a test is to be carried out at a new location. These processes also apply to the removal of a location. Biochemical Sciences flexible scope only covers tests carried out at St. Thomas' Hospital, therefore movement to an alternate location constitutes a change outside of flexible scope which would require a formal extension to scope application and approval by UKAS. Refer to section 3.9 if a test is no longer within the scope of accreditation.

3.7 Records

Records of all tests introduced and their validation (including those under flexible scope) are recorded using the Q-Pulse CAPA flexible scope change control record feature according to change control procedures (SLM-MP-13). Records in the form a list of assays introduced under flexible scope are recorded using Biochemical Sciences record of changes within flexible scope (SLM-QF-139) including the following information:

- Analyte/measurand
- Date of authorisation for flexible scope
- Names of staff who have reviewed and authorised the test
- Developed/modified by
- Matrix
- Equipment/technique
- SOP reference
- Change control CAPA reference number (including acceptance form and validation record)
- Risk assessment number (where applicable)
- Date UKAS informed

3.8 Audit Management Review

Methods incorporated under flexible scope are audited according to document Internal Audit Procedures (SLM-QP-4). Updates on audit progress and details of tests included under flexible scope are provided to management via the Governance Report (SLM-GR-2) and reviewed at the Biochemical Sciences Senior Staff Meeting. An audit of assay validation and flexible scope is included in the audit schedule (see SLM-QF-13).

QMS aspects of the flexible scope will be audited annual using SLM-QF-156, and will form a part of the audit schedule for the department.

3.9 Removing a test from scope of accreditation

UKAS will be informed of any changes to tests within the scope of accreditation. The test repertoire must be updated on the website by completion of the form, PATH-Q-FORM23, and submitted to the Quality Manager.

The record of flexible scope (SLM-QF-139) must be updated and made available on the Synnovis website at http://www.synnovis.co.uk/departments-and-laboratories/biochemical-sciences.

Users will be informed of the change to accreditation via a departmental user letter. A CAPA will be raised on QPulse to capture all the changes above.

3.10 Informing UKAS of changes

UKAS will be informed of any changes to methods or scope at regular predefined intervals agreed with UKAS (every three months).

UKAS will be informed of any changes to the key personnel involved in the flexible scope process (as specified in this policy) at the earliest opportunity, i.e. as soon as the change to personnel has been confirmed within Synnovis (this may be before the change actually occurs).

The Operations Managers for each laboratory area will be responsible for informing the Quality Manager of such changes, who will in turn be responsible for updating the test list (if required) and informing the UKAS Senior Assessment Manager.

3.11 UKAS User reports and information

Where tests fall within flexible scope user results reports must include this information where IT systems allow it. The record of flexible scope (SLM-QF-139) must be kept updated on the Synnovis website, see http://www.synnovis.co.uk/departments-and-laboratories/biochemical-sciences. This policy (SLM-P-3) will also be available on the website in the same location as SLM-QF-139, in order for service users to have access to a full description of the extent and management of the flexible scope.

4. References

1. BSI. Medical Laboratories – requirements for quality and competence (ISO15189:2012). November 2012 (incorporating corrigendum October 2014).
2. UKAS. GEN 4 - UKAS policy and general guidance for the implementation and management of flexible scopes of accreditation. Edition 1. October 2019.

3. EA requirements for the accreditation of flexible scopes: https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-15-m.pdf