

# Mass Spectrometry Flexible Scope

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## 1.0 INTRODUCTION

### 1.1 Scope and Purpose

The purpose of this document is to define the boundaries of the flexible scope and describe the process of implementing and managing the flexible scope within sections of Medical Biochemistry, Cardiff and Vale Health Board. The department must demonstrate competency, impartiality and consistency, and comply with ISO-15189:2012 and 15189:2022 in order to maintain a flexible scope.

The flexible scope only applies to mass spectrometry-based techniques which the department has established competence in developing and performing. Flexible scope does not cover new analytical principles which the department has no prior experience in performing. This flexibility can only apply to tests utilising technologies which have previously been successfully validated and introduced within the department in line with ISO 15189:2022 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 well documented and approved.

The flexible scope therefore covers analytes on the following platforms:

- Sciex 5500 LCMC
- Sciex 6500+ LCMS

Analytes currently included within the flexible scope are detailed in Appendix 1

Changes within the flexible scope may include:

- Modification of current test method(s)
- Modification of a previously validated/verified test method(s)
- Changes in the performance of the method for a given analyte (for example measuring range and uncertainty)
- Changes in result interpretations/comments
- Addition of new analyte
- Changes in sample matrix

### 1.2 Responsibility

The departmental Management team are responsible for the implementation of this procedure.

Section Clinical lead is responsible for ensuring staff follow this procedure

### 1.3 Definitions / Abbreviations

#### Scope of accreditation

Conformity assessment activities for which a body holds accreditation.

#### Fixed scope

Clearly defined description of the specific conformity assessment activities for which the body holds accreditation

#### Flexible scope

The scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the

conformity assessment body. This also includes extending the scope of accreditation to introduce new locations.

### Schedule of accreditation

The document that UKAS issues, accompanying the certification of accreditation, to define the scope of accreditation awarded.

## 1.4 References

|                         |                                                                                                            |
|-------------------------|------------------------------------------------------------------------------------------------------------|
| ISO 15189:2022          | Medical laboratories - Requirements for quality and competence                                             |
| ED-LAB-GEN 4            | UKAS policy and general guidance for the implementation and management of flexible scopes of accreditation |
| ED-BIO-EAReqFlexiScopes | EA Requirements for the Accreditation of Flexible Scopes (EA2-15)                                          |

## 1.5 Related Documents

|                                    |                             |
|------------------------------------|-----------------------------|
| Quality manual                     | QM-BIO-QualMan              |
| Schedule of accreditation          | MI-BIO-8989Schedule         |
| Change Control Procedure           | MP-BIO-ChaCont              |
| Change Control form                | MF-BIO-ChaCont              |
| Instructions for Assay Validation  | LI-BIO-AssayVal             |
| Assay Validation record            | LF-BIO-AssayVal             |
| Equipment management procedure     | MP-BIO-EquipMgmt            |
| SOP Guidelines                     | LI-BIO-SOPGuide             |
| Training and Development Procedure | MP-BIO-TTrainProcedure      |
| Lead Staff document                | MI-BIO-LeadStaff            |
| Risk assessment Flexible scope     | QI-BIO-ERiskAssessFlexScope |

## 2.0 Procedure for implementing and managing a flexible scope

The department of Medical Biochemistry, Immunology and Toxicology is a UKAS accredited Medical Laboratory No:8989. The department has a fixed scope of accreditation as detailed in the schedule of accreditation [MI-BIO-8989Schedule]

The Flexible scope for Mass spectrometry covers those platforms and analytes described in Appendix 1

## 2.1 Management Controls

### 2.1.1 Impartiality

The laboratory management strive to ensure that there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity. Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work. Staff are required to have an awareness of the UHB's policy: Standards of Behaviour Framework Policy Incorporating Declarations of Interest, Gifts, Hospitality and Sponsorship [EP-LAB-StdsConduct].

Personnel holding responsibility for the development, validation and review process for new tests to be included in the flexible scope must be impartial and act independently i.e must not be involved in other key elements of the process. For example, the Quality Manager/Quality

officer will perform an examination/vertical audit and review the full change control prior to the test being added to the flexible scope as they are independent to the development and validation of the assay.

### 2.1.2 Resource

Management will ensure the availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities. Where an insufficiency is identified, an action is produced and progress reviewed at Section and/or Quality Group Meetings.

#### Personnel

To ensure the department has trained and competent staff to assess the activities required to implement any changes to the flexible scope the departmental procedure [MP-BIO-PersMan] is followed. It describes the process for staff induction, training/competency and staff records. Management ensure that all personnel are competent to perform their assigned activities including the development/review, validation and the authorisation of modified or new processes/procedures.

There is a departmental document to describe the training process within the department [MP-BIO-TTrainProcedure] with training manuals for each staff grade and each section/subsection on Q Pulse. These outline the learning outcomes and the method used to determine competency.

Senior staff in the section (Clinical scientists/Senior Biomedical scientists) have demonstrated competence to select, validate and authorise new activities under the flexible scope.

The Quality manager/Quality officer have demonstrated competence in performing independent audits and review of change controls which allow additions to the flexible scope.

#### Facilities

The section related to this flexible scope is situated at the UHW site, the environment is suitable to facilitate the correct performance of all activities within the bounds of the flexible scope. Audits and workplace inspections highlight any deficiencies.

#### Equipment

The section is well equipped with platforms to enable the implementation of a flexible scope using mass spectrometry

The procedure for the Management of Equipment [MP-BIO-EquipMgt] outlines equipment acceptance testing, equipment instructions, equipment calibration and traceability, equipment maintenance, equipment incident reporting and equipment records

### 2.1.3 Selection, verification and validation of methods

The selection and validation of examination procedures is done in conjunction with clinical colleagues through the attendance of staff at multidisciplinary meetings and the Standing Specialist Advisory Groups (SSAG). Details of areas of development, including those involving mass spectrometry, are included in the section's quality plans (located on Q-pulse) and reviewed every quarter. Any changes in procedures follow the departmental change control process [MP-BIO-ChaCont] [MF-BIO-ChaCont] and are managed using the CA/PA module of Q Pulse. Clinicians are notified via the intranet, website, letters and laboratory reports of changes made.

The departmental change control process will include all steps for implementation, risk assessment, approval and evaluation following implementation. It will ensure that any changes made for analytes that fall within the bounds of the flexible scope follow this process.

The procedure for the validation / verification of a new examination procedure is available in the document module of Q Pulse [LI-BIO-AssayVal]. Validation/verification is documented using the form [LF-BIO-AssayVal] and forms part of the change control implementation stage.

All verification documents are signed by the technical lead, clinical lead and the Quality manager.

The validated state will be maintained through proficiency testing and internal quality control.

#### **2.1.4 Quality Management System**

The department has a well-established Quality management system which ensures adequate records are maintained of any changes that would affect the Mass spectrometry flexible scope. These are held on Q Pulse using the Document module, CAPA module, audit module and supplier module.

All new change controls are raised and discussed at the monthly Quality group meetings.

All changes implemented via the change control procedure are incorporated into the internal audit programme following the procedure for internal audit [QP-BIO-Audit].

#### **Informing UKAS**

The Quality manager/Quality officer is responsible for informing UKAS of any changes made to the flexible scope within 1 month of implementation. This includes but not limited to:

- Changes of methods
- Changes to matrix
- Addition of tests
- Removal of tests
- Changes to key personnel

#### **Informing users**

The test list covering the flexible scope will be updated on Q Pulse and made available on the Endocrine page of the website.

[Medical Biochemistry and Immunology - Cardiff and Vale University Health Board \(nhs.wales\)](https://www.nhs.uk/health-boards/cvuhb/medical-biochemistry-and-immunology)

#### **Review**

Review of all activities under the flexible scope is included within the annual section review which forms part of the departmental annual management review.

## Appendix 1

### Flexible Scope for Department of Medical Biochemistry applying to mass spectrometry and associated technologies

| Analyte/<br>measurand                       | Matrix                   | Equipment/technique                | SOP reference             | Change control reference number |
|---------------------------------------------|--------------------------|------------------------------------|---------------------------|---------------------------------|
| 5-HIAA                                      | Urine (24 hour)          | Exion LC with Sciex 5500           | LP-BIO-Eu5HIAA            | CC-22-08-BIO                    |
| 17(OH)<br>Progesterone                      | Serum/ Plasma            | Exion LC with Sciex 6500+<br>QTrap | LP-BIO-E17OHPs&s          | CC-21-10-BIO                    |
| 17(OH)<br>Progesterone                      | Serum/ Plasma/<br>Saliva | Exion LC with Sciex 5500           | LP-BIO-E17OHPs&s          | CC-19-21-BIO                    |
| 17(OH)<br>Progesterone                      | Dried Bloodspot          | Exion LC with Sciex 5500           | LP-BIO-E17OHPbs           | CC-19-32-BIO                    |
| Androstenedione                             | Serum/ Plasma            | Exion LC with Sciex 5500           | LP-BIO-<br>EAndroDHEAS    | CC-20-20-BIO                    |
| Catecholamines,<br>paediatric (HVA,<br>VMA) | Urine (random)           | Exion LC with Sciex 6500+<br>QTrap | LP-BIO-EHVAVMA            | CC-20-29-BIO                    |
| Cortisol                                    | Saliva                   | Exion LC with Sciex 5500           | LP-BIO-<br>ESalCortSciex  | CC-20-02-BIO                    |
| Cortisone                                   | Saliva                   | Exion LC with Sciex 5500           | LP-BIO-<br>ESalCortSciex  | CC-24-08-BIO                    |
| Cortisol                                    | Urine (24 hour)          | Exion LC with Sciex 5500           | LP-BIO-EUFCortisol        | CC-20-02-BIO                    |
| Dexamethasone                               | Serum/ Plasma            | Exion LC with Sciex 6500+<br>QTrap | LP-BIO-<br>EDexamethasone | CC-21-16-BIO                    |

|                                                                 |                 |                                    |                         |              |
|-----------------------------------------------------------------|-----------------|------------------------------------|-------------------------|--------------|
| DHEA-S                                                          | Serum/ Plasma   | Exion LC with Sciex 5500           | LP-BIO-<br>EAndroDHEAS  | CC-20-20-BIO |
| Metadrenalines<br>(metadrenaline,<br>normetadrenaline,<br>3-MT) | Urine (24 hour) | Exion LC with Sciex 6500+<br>QTrap | LP-BIO-<br>EUrineMetTMS | CC-21-24-BIO |
| Metadrenalines<br>(metadrenaline,<br>normetadrenaline,<br>3-MT) | Urine (24 hour) | Exion LC with Sciex 5500           | LP-BIO-<br>EUrineMetTMS | CC-19-33-BIO |
| Metadrenalines<br>(metadrenaline,<br>normetadrenaline,<br>3-MT) | Plasma (EDTA)   | Exion LC with Sciex 5500           | LP-BIO-PMETMS           | CC-22-24-BIO |
| Testosterone                                                    | Serum/ Plasma   | Exion LC with Sciex 5500           | LP-BIO-ETest            | CC-20-44-BIO |
| Testosterone                                                    | Serum/ Plasma   | Exion LC with Sciex 6500+<br>QTrap | LP-BIO-ETest            | CC-22-03-BIO |

All validation/verification documents are reviewed and signed by the Quality Manager, Technical and Clinical Section Lead

Plans to implement the following:

11-deoxycortisol  
Renin activity  
Aldosterone