Toxicology 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 the Toxicology section, Medical Biochemistry, Cardiff and Vale Health Board. The department must demonstrate competency, impartiality and consistency, and comply with ISO-15189 in order to maintain a flexible scope.
The flexible scope only applies to 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 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 covers drugs of abuse screen on two platforms:

- Thermo Orbitrap Accurate Mass spec which includes the Thermo Orbitrap (Accurate mass) and Thermo Vanquish (UHPLC).
- Waters TQs Micro LCMSMS.

Drugs of abuse 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 drug (for example measuring range and uncertainty)
- Changes in result interpretations/comments
- Addition of a new drug of abuse
- Changes in sample matrix

1.2 Responsibility

The departmental Management team are responsible for the implementation of this procedure.
Toxicology Clinical lead is responsible for ensuring staff in Toxicology 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-EquipMgnt
SOP Guidelines	LI-BIO-SOPGuide
Training and Development Procedure	MP-BIO-TTrainProcedure
Lead Staff document	MI-BIO-LeadStaff
Risk assessment Flexible scope	QI-BIO-TXRiskAssessFlexScope

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 in the Toxicology section covers those platforms and drugs in urine 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 Toxicology department (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 Toxicology department is situated at the UHL site within the Academic building, 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 Toxicology department is well equipped with platforms to enable the implementation of a flexible scope for urine drug screen.

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) 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 the analysis of drugs of abuse in Toxicology falls within the bounds of the flexible scope.

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 Toxicology 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 Toxicology page of the website.

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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 Drugs of abuse

Equipment

Urine Drug Screen on 2 platforms:

- Thermo Orbitrap Accurate Mass spec which includes the Thermo Orbitrap (Accurate mass spectrometer) and Thermo Vanquish (UHPLC).
- Waters Acquity I class (UHPLC) and Waters TQs Micro (LCMSMS).

Parameters

On Thermo Orbitrap Accurate Mass spec which includes the Thermo Orbitrap (Accurate mass spectrometer) and Thermo Vanquish (UHPLC).

- Opiates (Morphine, Codeine, 6MAM, Dihydrocodeine, Fentanyl, Oxycodone, Tramadol)
- Amphetamine (Amphetamine, Methamphetamine and MDMA)
- Benzodiazepines (Diazapam, Nordiazepam, Oxazepam, Temazepam and Alprazolam)
- Norbuprenorpine and Buprenorphine
- Cannabis metabolite (9-carboxy THC)
- Benzoylecognine (cocaine metabolite)
- Methadone Metabolite (EDDP)
- Ketamine
- Pregabalin
- Gabapentin

On Waters TQs Micro (LCMSMS).

- Opiates (Morphine, Codeine, 6MAM, Dihydrocodeine, Fentanyl, Oxycodone, Tramadol)
- Amphetamine (Amphetamine, Methamphetamine, MDMA)
- Benzodiazepines (Diazapam, Nordiazepam, Oxazepam, Temazepam and Alprazolam)
- Norbuprenorpine and Buprenorphine
- Cannabis metabolite (9-carboxy THC)
- Benzoylecognine (cocaine metabolite)
- Methadone Metabolite (EDDP)
- Ketamine
- Pregabalin
- Gabapentin

To follow:

On Thermo Orbitrap Accurate Mass spec and Waters TQs Micro (LCMSMS):

- MDA