

Flexible Scope applies only to mass spectrometry and associated technologies, refer to Flexible Scope SOP SLM-P-3 for more details. Flexible scope only applies to Biochemical Sciences, 4th & 5th Floors North Wing, St. Thomas' Hospital.

Flexible Scope Accreditation was granted on 5th October 2021. The following tests have been included within flexible scope following accreditation.

Analyte/ measurand	Scientific Validation Signed by	Independent review performed by	Date of authorisation into flexible scope	Authorised by	Matrix	Equipment/ technique	SOP reference	Change control CAPA reference number	Date UKAS informed	Go Live Date
Urine Sulphocysteine	Dr R Carling	Dominic Harrington, Fiona Denham	13/11/2023	Dr Rachel Carling	Urine	Waters Xevo TQD LC- MS/MS	SLMP-LP-49	CCR-260	3/7/2023; 7/11/2023	13/11/2023
TPMT (thiopurine methyltransferase)	Dr R Carling	Dominic Harrington, Fiona Denham	13/11/2023	Dr Rachel Carling	Whole blood	Waters Xevo TQD LC-MS/MS	SLMP-LP-21	CCR -259	3/7/2023; 7/11/2023	13/11/2023
Total Homocysteine and Methionine monitoring	Dr R Carling 11/07/2022	Dominic Harrington, Fiona Denham	15/09/2022	Dr Rachel Carling	Dried Bloodspot	Exion UPLC + Sciex 4500 LC-MS/MS	SLMN-LP-25 SLMN-LP-27	CCR-248	12/09/2022	26/09/2022
Mitra Creatinine	Dr R Carling 10/8/2022	Dominic Harrington, Fiona Denham	15/09/2022	Dr Rachel Carling	Capillary whole blood	Waters Acquity UPLC + Xevo TQS LC-MS/MS	SLMM-LP-60	CCR-247	15/08/2022	26/09/2022
Phenylalanine and tyrosine	Kate John	Dominic Harrington, Fiona Denham	04/01/2022	Dr Rachel Carling	Dried bloodspot	Exion UPLC + Sciex 4500 LC-MS/MS	SLMM-LP-64	CCR-240	29/12/2021	17/01/2022

The table below details assays submitted for assessment as part of the flexible scope application. Accredited was granted in conjunction with approval of the application.

File name: SLM-QF-139
Author Malinie Naidoo
Authorised by Rachel Carling

Revision 6.0
Issue date 7.11.2023
Review date 7.11.2024

**SLM-QF-139: Biochemical sciences record of
changes within flexible scope**

Analyte/ measurand	Date of authorisation for flexible scope	Reviewed/ authorised by	Developed/ modified by	Matrix	Equipment/ technique	SOP reference	Change control CAPA reference number	Risk assessment number (where applicable)	Date UKAS informed
Acylcarnitines	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Waters MSMS (Xevo TQ-S)	SLMM-LP-17 SLMM-LP-33	CCR-132	Not applicable (risks already assessed for other procedures)	Assessed as part of the initial application submitted 2017
Sickle cell screening	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Waters FIA- MS/MS (Xevo TQ-S)	SLMN-LP-39	CCR-153	Not applicable (risks already assessed for other procedures)	As above
Thalassaemia screening	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Waters FIA- MS/MS (XevoTQ- S)	SLMN-LP-39	CCR-153	Not applicable (risks already assessed for other procedures)	As above
C8	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA- MS/MS	SLMN-LP-25	CCR-176	Not applicable (risks already assessed for other procedures)	As above
Phenylalanine	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA- MS/MS	SLMN-LP-25	CCR-176	Not applicable (risks already assessed for other procedures)	As above
C5DC	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA- MS/MS	SLMN-LP-25	CCR-176	Not applicable (risks already assessed for other procedures)	As above
C5	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA- MS/MS	SLMN-LP-25	CCR-176	Not applicable (risks already assessed for other procedures)	As above
Methionine	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA- MS/MS	SLMN-LP-25 SLMN-LP-27	CCR-176	Not applicable (risks already assessed for other procedures)	As above

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Leucine	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA-MS/MS	SLMN-LP-25	CCR-176	Not applicable (risks already assessed for other procedures)	As above
Total Homocysteine	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA-MS/MS	SLMN-LP-25 SLMN-LP-27	CCR-176	Not applicable (risks already assessed for other procedures)	As above
Branched Chain Amino Acids (Alloisoleucine; Isoleucine; Leucine; Valine)	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots Plasma	Exion UPLC + Sciex 4500 FIA-MS/MS	SLMM-LP-26	CCR-176	Not applicable (risks already assessed for other procedures)	As above
C5 isobars	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Dried bloodspots	Exion UPLC + Sciex 4500 FIA-MS/MS	SLMM-LP-33	CCR-176	Not applicable (risks already assessed for other procedures)	As above
Amino acids (Taurine; Threonine; Serine; Glutamine; Glutamate; Proline; Glycine; Alanine; Citrulline; Cystine; Phenylalanine; Tyrosine; Total; Isoleucine; Leucine; Valine; Methionine; Lysine; Histidine; Ornithine; Arginine)	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Plasma	Waters Acquity UPLC + Xevo LC-MS/MS	SLMM-LP-52	CCR-155	Not applicable (risks already assessed for other procedures)	As above
Immunosuppressant: Sirolimus Everolimus Tacrolimus Cyclosporin	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Blood Sciences (pre-dates current validation process)	Whole blood	Waters TQD LC-MS/MS	SLMM-LP-37	Retrospective assay validation - SLMM-LF-132	Not applicable (risks already assessed for other procedures)	As above
Immunosuppressant: Tacrolimus	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Blood Sciences (pre-dates current validation process)	Whole blood	Waters TQD LC-MS/MS	SLMM-LP-37	Retrospective assay validation - SLMM-LF-132	Not applicable (risks already assessed for other procedures)	As above

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Immunosuppressant: Cyclosporin	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Blood Sciences (pre-dates current validation process)	Whole blood	Waters TQD LC- MS/MS	SLMM-LP-37	Retrospective assay validation - SLMM-LF-132	Not applicable (risks already assessed for other procedures)	As above
Immunosuppressant: Everolimus	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Erin Emmett	Whole blood	Waters TQD LC- MS/MS	SLMM-LP-37	Retrospective assay validation – SLM-QF-54	Not applicable (risks already assessed for other procedures)	As above
Quantitation of Cystine, Ornithine, Arginine and Lysine (COAL)	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Kate John	Urine	Waters Acquity UPLC + Xevo LC- MS/MS	SLMM-LP-49	CCR-146	Not applicable (risks already assessed for other procedures)	As above
Sulphocysteine	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Dr Lynette Fairbanks	Urine	Waters Acquity UPLC + Waters TQD MS/MS	SLMP-LP-49	Retrospective assay validation - SLM-QF-108	SLM-RA-15	As above
Hydroxychloroquine (HCQ)	03/06/2020	Dr Rachel Carling	Donna Austin	Whole blood	Waters Acquity UPLC + Xevo LC- MS/MS	SLMM-LP-58	CCR-187	Not applicable (risks already assessed for other procedures)	UKAS informed as part of flexible scope application process 2021
Tacrolimus using a Mitra® VAMS device	10/09/2021	Dr Rachel Carling	Donna Austin	Capillary whole blood	Waters Acquity UPLC + Xevo-TQS LC-MS/MS	SLMM-LP-60	CCR-207	Attached to CCR-207	UKAS informed as part of flexible scope application process 2021
Mitra Creatinine using a Mitra® VAMS device	10/09/2021	Dr Rachel Carling	Donna Austin	Capillary whole blood	Waters Acquity UPLC + TQD LC- MS/MS	SLMM-LP-60	CCR-207	Attached to CCR-207	UKAS informed as part of flexible scope application process 2021

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