

Flexible Scope applies only to mass spectrometry and associated technologies, refer to Flexible Scope SOP SLM-P-3 for more details. UKAS will be updated every three months with status of assays within flexible scope, the review date of this this document is set to 3-month intervals to reflect this. 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
Phenylalanine and tyrosine by LC-MSMS	Kate John	Dominic Harrington, Fiona Denham	04/01/2022	Dr Rachel Carling	Dried bloodspot	AB Sciex – 4500MD 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.

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

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Author Fiona Denham/Malinie Naidoo
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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
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

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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
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
TPMT	02/11/2021 (previously in accredited fixed scope)	Dr Rachel Carling	Dr John Duley, Prof Neil Dalton, Charles Turner	Whole blood	Waters Acquity UPLC + Waters TQD MS/MS	SLMP-LP-21 SLMP-LP-44	Retrospective assay validation – SLMP-QR-154	Not applicable (risks already assessed for other procedures)	As above

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			Dr Lynette Fairbanks						
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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