

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 5<sup>th</sup> 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 & Waters TQD LCMS/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
Phenylalanine and tyrosine Monitoring	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

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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 & Thalassaemia Screening (Haemoglobin Variants S,C,D,E, O-Arab)		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
Expanded ENBS screening (MCADD, PKU, GA1, IVA, MSUD & HCU)		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
MACDD Screening (C8 & C10)	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
Phenylketouria Screening (PHE & TRY)	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
Glutaric Aciduria Type 1 Screening (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
Isovaleric Acidaemia Screening (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

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Revision	7.0
Issue date	01/03/2024
Review date	On Q Pulse



Homocystinuria Screening (MET)	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
Maple Syrup Urine Disease Screening (Combined XLE)	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
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
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
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

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