


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <p><b>UKAS</b> MEDICAL</p> <p>9948</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Birmingham Women's and Children's NHS Foundation Trust</b></p> <p>Issue No: 007 Issue date: 14 September 2021</p>	
	<p>Newborn Screening &amp; Biochemical Genetics</p> <p>Birmingham Children's Hospital</p> <p>Steelhouse Lane</p> <p>Birmingham</p> <p>West Midlands</p> <p>B4 6NH</p>	<p>Contact: Adam Gerrard</p> <p>Tel: +44 (0)121 333 9903 / 9942</p> <p>E-Mail: adam.gerrard@nhs.net</p> <p>Website: www.bwc.nhs.uk/newborn-screening-and-biochemical-genetics</p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Blood Science examination activities for the purposes of clinical diagnosis</u>	Documented in-house procedures based on equipment manuals and standard methods as specified below:
Plasma Serum	Transferrin Isoforms	Agilent 1260 Series HPLC: HPLC with UV detection I/S/T/160
Bloodspot	Pterins	HPLC with fluorescence detection N/S/B/009
Plasma, Urine CSF	Amino Acids (Quantitative)	Biochrom 30 Plus Amino Acid Analyser Ion-exchange HPLC, spectrophotometry I/S/144
Plasma, Serum Bloodspot	Nitisinone – NTBC	Waters Acquity UPLC & Xevo TQD: HPLC-MS/MS I/S/N/154
Plasma Bloodspot	Succinylacetone	HPLC-MS/MS I/S/S/155
Plasma, Bloodspot	Total Homocysteine	HPLC MS/MS: I/S/139, I/S/166
Plasma, Serum Urine, Bloodspot	Free & Acyl Carnitines	Waters Acquity UPLC & Xevo TQD FIA-MS/MS I/S/A/130, I/S/130



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Science examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house procedures based on equipment manuals and standard methods as specified below:  Agilent 5975/7890 Series GC/MSD System, GCMS:
Urine	Organic Acids (Qualitative)	I/S/O/016
Plasma	Methylmalonic Acid (micro-molar range)	I/S/M/108
Urine	Orotic Acid	I/S/O/111
Plasma	Very Long Chain Fatty Acids, Pristanic & Phytanic Acid	I/S/V/080
Urine	Amino Acids (Qualitative)	Amersham Mutiphor II, HVE I/S/001
Urine Amniotic Fluid	Glycosaminoglycans (Qualitative)	Scie-Plas Electrophoresis Equipment Electrophoresis (1D & 2D) I/S/G/010  Tecan Infinite F200 PRO Plate Reader Fluorometric:
Leucocytes, Bloodspot Fibroblasts	Lysosomal Acid Lipase (Acid Esterase)	I/S/A/039, I/S/A/143
Leucocytes, Bloodspot Fibroblasts	$\alpha$ -Galactosidase A	I/S/A/043, I/S/141
Plasma, Serum Leucocytes, Fibroblasts	$\alpha$ -Fucosidase	I/S/A/115, I/S/A/088  Tecan Infinite F200 PRO Plate Reader Fluorometric:
Plasma, Serum Leucocytes, Fibroblasts	$\alpha$ -Mannosidase	I/S/A/116, I/S/A/087
Leucocytes, Bloodspot Fibroblasts	$\alpha$ -Glucosidase (Acid Maltase)	I/S/A/124, I/S/140, I/S/A/046
Plasma, Serum	Aspartylglucosaminidase	I/S/A/126



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Science examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house procedures based on equipment manuals and standard methods as specified below:
Leucocytes Fibroblasts	$\beta$ -Galactocerebrosidase (Galactosylceramidase)	I/S/B/119  Tecan Infinite F200 PRO Plate Reader Fluorometric:
Leucocytes, Bloodspot Fibroblasts	$\beta$ -Galactosidase	I/S/B/045, I/S/B/049
Leucocytes, Fibroblasts	$\beta$ -Glucosidase (Glucocerebrosidase)	I/S/B/047
Plasma, Serum Leucocytes, Fibroblasts	$\beta$ -Glucuronidase	I/S/B/117, I/S/B/048
Plasma, Serum Leucocytes, Fibroblasts	$\beta$ -Mannosidase	I/S/B/118, I/S/B/051
Plasma, Serum	Chitotriosidase	I/S/C/099
Plasma, Serum Leucocytes, Fibroblasts	Hexosaminidase A	I/S/H/073, I/S/H/049
Plasma, Serum Leucocytes, Fibroblasts	Hexosaminidase (Total)	I/S/H/073, I/S/H/050
Leucocytes, Fibroblasts	Palmitoyl Protein Thioesterase 1	I/S/133
Leucocytes, Fibroblasts	Sphingomyelinase	I/S/S/053
Leucocytes, Fibroblasts	Steroid Sulphatase (aryl sulphatase C)	I/S/S/085
Leucocytes, Fibroblasts	Tripeptidyl Peptidase 1	I/S/132
Duodenal tissue	Duodenal Disaccharidases	I/S/D/037  Agilent Cary 60, spectrophotometric:
Leucocytes, Fibroblasts	$\alpha$ -Galactosidase B ( $\alpha$ -N-Acetyl-galactosaminidase)	I/S/A/044
Leucocytes, Fibroblasts	Arylsulphatase A	I/S/A/040



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Science examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house procedures based on equipment manuals and standard methods as specified below:
Plasma	Biotinidase	Agilent Cary 60, spectrophotometric: I/S/B/028
Leucocytes, Fibroblasts Liver, CVS	Fumarylacetoacetate Lyase	I/S/F/041
Leucocytes, Liver	Fructose 1,6 Bisphosphatase	I/S/F/127
Plasma Serum	7-Dehydrocholesterol Screen	I/S/D/064  Thermo Indiko: I/S/159  Spectrophotometric
Dried Blood Spot	Dihydropteridine Reductase	N/S/D/001
Urine	Glycosaminoglycans (Quantitative)	I/S/163
Erythrocytes	Galactose-1-Phosphate (Quantitative)	Enzymatic I/S/161
Plasma Urine	Oxalate	I/S/162, I/S/164  Roche Cobas 6000 Enzymatic:
Results from associated laboratory	Free Fatty Acids	I/S/F/029
Results from associated laboratory	3-Hydroxybutyrate	I/S/H/024
Liver Chorionic villus	Glycine Cleavage Enzyme System	Packard Tricarb 1900CA Scintillation Counter, radiochemical: I/S/G/113, I/S/G/114



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Science examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house procedures based on equipment manuals and standard methods as specified below:
Urine	Detection of nitrite, blood, ketones, glucose, protein, pH	Siemens Clinitek Status +, colourimetric:  Using Multistix® I/S/143
Urine	Reducing substances	Manual, colourimetric I/S/137
Urine	Sugar chromatography	Manual, thin-layer chromatography I/S/S/021
Erythrocytes Bloodspot	Galactose-1-phosphate uridyl transferase screen	Manual, Fluorescence I/S/G/031, I/S/G/032
Plasma Serum	I-Cell Screen	Manual, colourimetric I/S/I/034
	<u>Molecular Genetics examination activities for the purposes of clinical diagnosis</u>	Documented -in-house methods to meet the requirements of the NHS Newborn Blood Spot Screening Programme as defined in the NHS Newborn Blood Spot Screening Programme: laboratory quality assurance evidence requirements
Bloodspot		DNA Extraction Promega Maxwell® 16 DNA extractor: Silica coated paramagnetic particles. NSBGM/SOP/3
	Detection of four common CFTR mutations for newborn screening	Qiagen Rotor-gene Q PCR machine M/S/C/062
Bloodspot	Sickle Cell Disease Haemoglobin Variants	Perkin Elmer Migele, IEF: HPLC, UV detection. Bio-Rad Variant NBS. N/S/S/015, N/S/S/007



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Genetics examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house procedures based on equipment manuals and standard methods as specified below:  Documented -in-house methods to meet the requirements of the NHS Newborn Blood Spot Screening Programme as defined in the NHS Newborn Blood Spot Screening Programme: laboratory quality assurance evidence requirements  Waters Acquity UPLC & Xevo TQD
Bloodspot	Phenylalanine Tyrosine Methionine Leucine Octanoyl carnitine (C8) Decanoyl carnitine (C10) Glutaryl carnitine (C5DC) Isovaleryl carnitine (C5)	FIA-MS/MS N/S/1
Bloodspot	Phenylalanine / Tyrosine Monitoring	FIA-MS/MS N/S/P/010
Bloodspot	TSH IRT	Perkin Elmer Autodelfia: Immunoassay, fluorometric N/S/T/012 N/S/T/017
END		