Schedule of Accreditation

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Birmingham Women's and Children's NHS Foundation Trust

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Newborn Screening & Biochemical Genetics
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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis	Documented in-house procedures based on equipment manuals and standard methods as specified below:
		Agilent 1260 Series HPLC:
Plasma Serum	Transferrin Isoforms	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
		Waters Acquity UPLC & Xevo TQD:
Plasma, Serum Bloodspot	Nitisinone – NTBC	HPLC-MS/MS I/S/N/154
Plasma Bloodspot	Succinylacetone	FIAMS/MS I/S/S/155
Plasma, Bloodspot	Total Homocysteine	HPLC MS/MS: I/S/166
Bloodspot	Phenylalanine / Tyrosine Monitoring	FIA-MS/MS N/S/P/010

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures based on equipment manuals and standard methods as specified below:
		Waters Acquity UPLC & Xevo TQD/ Xevo TQS:
Plasma, Serum Urine, Bloodspot	Free & Acyl Carnitines	FIA-MS/MS I/S/A/130, I/S/A/168
		Water Acquity UPLC & Xevo TQS
Plasma	Methylmalonic Acid to assess functional B12 deficiency	HPLC MS/MS I/S/M/169
Blood (leucocytes isolation)	White Cell Cystine	HPLC MS/MS I/S/M/168
Urine	Organic Acids (Qualitative)	**Agilent Intuvo GCMS** I/S/170
		Agilent 5975/7890 Series GC/MSD System, GCMS I/P/046
Plasma	Methylmalonic Acid (micro-molar range)	I/S/M/108
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)** I/S/G/010

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures based on equipment manuals and standard methods as specified below: **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	α-Galactosidase A	I/S/A/043, I/S/141
Plasma, Serum Leucocytes, Fibroblasts	α-Fucosidase	I/S/A/115, I/S/A/088
Plasma, Serum Leucocytes, Fibroblasts	α-Mannosidase	I/S/A/116, I/S/A/087
Leucocytes, Bloodspot Fibroblasts	α-Glucosidase (Acid Maltase)	I/S/A/124, I/S/140, I/S/A/046
Plasma, Serum	Aspartylglucosaminidase	I/S/A/126
Leucocytes Fibroblasts	β-Galactocerebrosidase (Galactosylceramidase)	I/S/B/119
Leucocytes, Bloodspot Fibroblasts	β-Galactosidase	I/S/B/045, I/S/B/049
Leucocytes, Fibroblasts	β-Glucosidase (Glucocerebrosidase)	I/S/B/047
Plasma, Serum Leucocytes, Fibroblasts	β-Glucuronidase	I/S/B/117, I/S/B/048
Plasma, Serum Leucocytes, Fibroblasts	β-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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures based on equipment manuals and standard methods as specified below:
		Tecan Infinite F200 PRO Plate Reader Fluorometric:
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	α-Galactosidase B (α-N-Acetyl-galactosaminidase)	I/S/A/044
Leucocytes, Fibroblasts	Arylsulphatase A	I/S/A/040
Plasma	Biotinidase	I/S/B/028
Leucocytes, Fibroblasts Liver, CVS	Fumarylacetoacetate Lyase	I/S/F/041
		Thermo Indiko: I/S/159
		Spectrophotometric
Dried Blood Spot	Dihydropterdine Reductase	N/S/D/001
Urine	Glycosaminoglycans (Quantitative)	I/S/163
		Enzymatic
Erythrocytes	Galactose-1-Phosphate (Quantitative)	I/S/161
Plasma Urine	Oxalate	I/S/162, I/S/164

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures based on equipment manuals and standard methods as specified below:
		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
		Siemens Clinitek Status +, colourimetric:
Urine	Detection of nitrite, blood, ketones, glucose, protein, pH	Using Multistix® I/S/143
Urine	Reducing substances	**Manual, colourimetric** I/S/137
Urine	Sugar chromatography	**Manual, Thin layer chromatography** I/S/S/021
Urine	Oligosaccharides (Qualitative)	**Manual Thin layer Chromatography** I/S/O/015
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures based on equipment manuals and standard methods as specified below:
	Newborn Blood Spot Screening Tests	Documented 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	Newborn screening for qualitative detection of haemoglobin variants	**Sebia Capillarys Zone Electrophoresis, automated** (1st line) N/P/S/050 N/S/C/001 **Bio-Rad Variant NBS** (2nd line). N/P/B/025 N/S/C/002
Bloodspot	Semi-quantitative detection of T-cell Receptor Excision Circles (TREC)	For Severe Combined Immunodeficiency (SCID) with the **Perkin Elmer Victor Enlite using Polmerase chain reaction (PCR) and Time-Resolved Fluorescence Resonance Energy Transfer assay** (TR-FRET) NSBG/SOP/5

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Molecular Genetics examination activities for the purposes of clinical diagnosis (cont'd)	Documented 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	Phenylalanine Tyrosine Methionine Succinylacetone Leucine Octanoyl carnitine (C8) Decanoyl carnitine (C10) Glutaryl carnitine (C5DC) Isovaleryl carnitine (C5)	**Waters Acquity UPLC & Xevo TQD** FIA-MS/MS Neobase 2 NSBGN/SOP/9 N/S/X/2
Bloodspot	Detection of four common CFTR mutations for newborn screening	Manual DNA extraction using **Qiagen Qiagen QIAamp DNA Micro Extraction Kit** NSBGM/SOP/9 Qiagen Rotor-gene Q PCR machine M/S/C/062
END		