

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Accredited to
ISO 15189:2012

Great Ormond Street Hospital for Children NHS Foundation Trust

Issue No: 001 Issue date: 23 August 2018

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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	<u>Routine Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Serum / plasma / urine	Quantitative determination of: Sodium Potassium Chloride Urea Creatinine Urate Calcium Phosphate Total Protein Magnesium	Vitros 5600 Microslide using documented procedure CSOP A058 Dry slide technology
Serum / plasma	Albumin Alanine transaminase (ALT) Alkaline Phosphatase (ALP) Ammonia Amylase Aspartate transaminase (AST) Bilirubin Bicarb BuBc Carbamazepine Cholesterol Creatine Kinase (CK) CKMB CRP / C Reactive Protein Digoxin Gamma GT Glucose Carbamazepine Cholesterol	Vitros 5600 Microslide using documented procedure CSOP A058 Dry slide technology



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HUMAN BODY FLUIDS (cont'd)	<u>Routine Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Serum / plasma	Creatine Kinase (CK) CKMB CRP / C Reactive Protein Digoxin Gamma GT Glucose HDL / HDL Cholesterol Iron LDH Lipase Phosphate	Vitros 5600 Microslide using documented procedure CSOP A058 Dry slide technology
Serum / plasma	Phenytoin Phenobarbitone TIBC Total protein Triglyceride	Vitros 5600 Microslide using documented procedure CSOP A058 Dry slide technology
Serum/Plasma/CSF/Fluid	Glucose Lactate Protein	Vitros 5600 Microslide using documented procedure CSOP A058 Dry slide technology
Serum / plasma	aFP hCG Troponin 1	Immunoassay using Vitros 5600 microwell following documented procedure CSOP



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HUMAN BODY FLUIDS (cont'd)	<u>Routine Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Serum / plasma	TSH FT3 FT4 cortisol androstenedione testosterone DHEA LH FSH GH IGF BP3 prolactin PTH Insulin C-peptide ferritin vitamin B12 folate ACTH NT-proBNP	Immunoassay using Siemens Immulite 2000 XP following documented procedure CSOP A059
Serum / plasma	Tacrolimus Ciclosporin Sirolimus	AB Sciex 3200 LC-MS using documented procedure CSOP N056
Serum / plasma	IgA IgG IgM C3 C4 A1AT Caeruloplasmin	Protein nephelometry using Siemens BNII analyser using documented procedure CSOP N009
Urine	Albumin RBP	Protein nephelometry using Siemens BNII analyser using documented procedure CSOP N009



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HUMAN BODY FLUIDS (cont'd)	<u>Routine Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Serum / plasma	NEFA BOHB ACE Protein (BCP)	IL650 photometry. End point assay/ kinetic assays using documented procedures CSOP N057
Urine	NAG	IL650 photometry. End point assay/ kinetic assays using documented procedures CSOP N057
Serum / plasma	Proteins CK isoenzymes Amylase isoenzymes LDH isoenzymes ALP isoenzymes cryoproteins	Protein electrophoresis/isoenzymes Electrophoresis (Helena Biosciences) using documented procedures CSOP N037, CSOP N058, CSOP N060
Serum / plasma	Inhibin B AMH	ELISA using documented procedures CSOP N047, CSOP N048, CSOP N034, CSOP N035
Serum / plasma	GFR estimation (using Iohexol)	Waters HPLC using documented procedures CSOP N051
Whole Blood	Blood Gas Analysis (pH & ionised calcium) iCa pH	Rapid 348 Blood gas analyser - using using documented procedure CSOP N027
Serum/Plasma/Urine	Osmolality	Osmometer 800 (freezing point depression) using using documented procedure CSOP A038
Blood / CSF	Lactate Pyruvate	Cobas Bio fluorometry using documented procedure CSOP N012, CSOP N030
Blood	Acetoacetate	Cobas Bio fluorometry using documented procedure CSOP N012, CSOP N030
Faeces	Occult blood	Guaiac dye kit method using manufacturers kit and documented procedure CSOP N033



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HUMAN BODY FLUIDS (cont'd)	<u>Routine Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Urine	hCG (pregnancy test)	Using manufacturers kit and documented procedure CSOP N036
Sweat	Sweat Test - Chloride conductivity	Wescor conductivity meter using coulometry and documented procedures CSOP N055, CSOP N054
Blood	Manganese	Thermo-Fisher ICP-MS Mass spectrometry following documented procedure CSOP N069
Plasma / serum	Copper Selenium Zinc	Thermo-Fisher ICP-MS Mass spectrometry following documented procedure CSOP N069
Plasma / serum	Biotinidase	LC-tandem Mass Spectrometry (AP4000 Sciex) following documented procedure CSOP N052
	<u>Metabolic Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Urine	Organic Acids, VMA/HVA	Gas Chromatography - Mass Spectrometry Agilent 7890A, GC-MS CSOP M007, CSOP M006, CSOP M030, CSOP M009, CSOP M010
Plasma / serum	Very Long Chain Fatty Acids C26, C24, C22, Phytanate, Pristanate, C26/C22, C24/C22 Busulphan	Gas Chromatography - Mass Spectrometry Agilent 7890A, GC-MS CSOP M007, CSOP M006, CSOP M030, CSOP M009, CSOP M010



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HUMAN BODY FLUIDS (cont'd)	<u>Metabolic Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Dried Blood spot	Branched Chain Amino Acids <ul style="list-style-type: none"> • Leucine • Isoleucine • Valine • All-isoleucine 	Ultra High Performance Liquid Chromatography. Agilent 1290 Infinity, UHPLC CSOP M027
Plasma / serum / CSF / Urine	Amino acid profile Glycine, Serine, Threonine, Proline, Leucine, Isoleucine, Valine, Allo-isoleucine, Alanine, Glutamine, Arginine, Ornithine, Citrulline, Lysine, Methionine, Taurine, Phenylalanine, Tyrosine, Tryptophan, Histidine, Glutamic acid, Argininosuccinic acid, Total Homocysteine. Cystine (urine) Phosphoethanolamine (urine)	Biochrom 30/30+, Ion Exchange Chromatography. CSOP M020, CSOP M024, CSOP M025
Urine	Sulphocysteine	Biochrom 30/30+, Ion Exchange Chromatography. CSOP M020, CSOP M024, CSOP M025
Plasma / serum / CSF	Amino acid profile: Glycine, Serine, Threonine, Proline, Leucine, Isoleucine, Valine, Allo-isoleucine, Alanine, Glutamine, Arginine, Ornithine, Lysine, Methionine, Taurine, Phenylalanine, Tyrosine, Tryptophan, Histidine, Asparagine, Aspartate, Glutamic acid	High Performance Liquid Chromatography using Waters 2487 HPLC CSOP M002, CSOP M017, CSOP M004, CSOP M031
Urine / Faeces	Sugars: Galactose, Fructose, Sucrose, Glucose, Lactose, Arabinose, Maltose, Sucrose, Xylose, Lactulose, Raffinose, Fucose, Ribose, Isomaltose	High Performance Liquid Chromatography using Waters 2487 HPLC CSOP M002, CSOP M017, CSOP M004, CSOP
Urine	Glucose Tetrasaccharide	M031 High Performance Liquid Chromatography using Thermo (Dionex) ICS 5000 +, CSOP M031



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HUMAN BODY FLUIDS (cont'd)	<u>Metabolic Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Dried blood spot / urine	Acylcarnitines	Tandem Mass Spectrometry, API4000 CSOP M028, CSOP M034, CSOP S013
Urine	Guanidinoacetate	Tandem Mass Spectrometry, API4000 CSOP M028, CSOP M034, CSOP S013
Faeces / urine	Reducing substances	Benedicts Test - mManual colour change using CSOP M026
HUMAN BODY FLUIDS (cont'd)	<u>New Born Screening Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Blood spot	Newborn Screening for Metabolic disorders and PKU Clinic Patient monitoring Phenylalanine Tyrosine Octanoyl Carnitine Decanoyl Carnitine LEUCINE C5 C5 DC Methionine	AB Sciex API3200 Mass Spectrometer CSOP S001 Newborn Screening and Clinic Patient Monitoring by Tandem Mass Spectrometry Perkin Elmer Panthera puncher 9 CSOP S028
Blood spot	Newborn screening for Haemoglobinopathies Haemoglobin F Haemoglobin A Haemoglobin E Haemoglobin C Haemoglobin D Haemoglobin S	AB Sciex API4500 Mass Spectrometer Haemoglobinopathy screening by TMS CSOP S041 Perkin Elmer Panthera puncher 9 CSOP S028



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HUMAN BODY FLUIDS (cont'd)	<u>New Born Screening Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Blood spot	Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)	GSP Neonatal IRT assay Fluorescence DELFIA CSOP S019 Newborn screening for cystic fibrosis Perkin Elmer Panthera puncher 9 CSOP S028
Blood spot	hTSH	GSP Neonatal hTSH Fluoroimmunometric assay CSOP S007 Newborn Screening for congenital hypothyroidism Perkin Elmer Panthera puncher 9 CSOP S028
	<u>Enzyme Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Plasma, leucocyte, cultured fibroblasts (CSK), cultured chorionic villi (CCV), cultured amniotic cells (CAC), chorionic villi (CV)	<u>4 methylumbelliferone assays</u> a-mannosidase b-mannosidase a-fucosidase a-N-acetylgalactosaminidase Hexosaminidase A Total b-hexosaminidase a-galactosidase Iduronate-2-sulphatase b-glucuronidase	Fluorescence - Perkin Elmer LS55 - Tecan Infinite M200 - Tecan freedom Evo SOPs ESOP B005, B022, B023, B024, B025, B026, B027, B032, B033, B034, B035, B038, B039, B040, B041, B042, B048, B049, B064, B066, B068, B069, C008, C009, C010, C014, C015, C017, C018, C019, C024, O006, O007, O009, O010, O011, O045, P007, P008, P009, P011, P014, EEQ002, EEQ006, EEQ008



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Plasma, leucocyte, cultured fibroblasts (CSK), cultured chorionic villi (CCV), cultured amniotic cells (CAC), chorionic villi (CV)	B-galactosidase Palmitoyl protein thioesterase I Tripeptidyl peptidase I b-glucosidase a-neuraminidase a-iduronidase Heparin sulphamidase Acetyl-CoA:D glucosamine N-acetyltransferase N-acetylglucosamine-6-sulphatase N-acetylgalactosamine -6-sulphatase a-N-Glucosaminidase	SOPs ESOP B028, B036, B045, B050, B054, B055, B056, B057, B058, B060, B061, B065, C011, C016, C021, C025, C028, C029, C030, C032, C033, C036, C037, P010, P016, P020, P025, P029, P030, P031, P034, P035
Blood spot, leucocyte, cultured fibroblasts (CSK), cultured chorionic villi (CCV), cultured amniotic cells (CAC), chorionic villi (CV)	Acid a-1,4-glucosidase	ESOP B036, B072, C001, C002, P003
Plasma	Chitotriosidase	ESOP B043, B067
Plasma, leucocyte, cultured fibroblasts (CSK), cultured chorionic villi (CCV), cultured amniotic cells (CAC)	Aspartylglucosaminidase	ESOP B043, B067
Leucocyte, cultured fibroblasts (CSK)	6-hexadecanoylamino-4-methylumbelliferyl assay Galactocerebrosidase	Fluorescence technique using Tecan Infinite M200 ESOP B029
Leucocyte, cultured fibroblasts (CSK), cultured chorionic villi (CCV), cultured amniotic cells (CAC)	Arylsulphatase A	Spectrophotometry Cecil CE2041 ESOP B030, B031, B047, B059, C013, C023, C031, C035, O039, O042, P012, P013, P021, P031, P037
Leucocyte, cultured fibroblasts (CSK)	Arylsulphatase B, acid esterase	Spectrophotometry Cecil CE2041
Plasma, Amniotic Fluid	I cell screen	Spectrophotometry Cecil CE2041



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HUMAN BODY FLUIDS (cont'd)	<u>Enzyme Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for
Urine	Glycosaminoglycans	Spectrophotometry Cobas Bio
Urine	Silaic acid	Spectrophotometry Cecil CE2041
Leucocyte, cultured fibroblasts (CSK), cultured chorionic villi (CCV), cultured amniotic cells (CAC)	Sphingomyelinase Galactokinase Glycerol kinase	Radioactive assays using Perkin-Elmer Tri-Carb 2910TR ESOP B014, B046, C022, C038, P022, EEQ007
Leucocyte, Chorionic Villi	Cystine	Mass Spectrometry using API 4000 ESOP B062, P036
Urine	Glycosaminoglycans	Electrophoresis ESOP O041, P033
Leucocyte, cultured fibroblasts (CSK)	Cross reactive immunogenic material	Western Blot Invitrogen i-blot Invitrogen X-cell Surelock ESOP P038
	<u>Carbohydrate metabolism</u>	NADH/NADP based
Erythrocyte	Galactose-1-phosphate, galactose-1-phosphate uridyl transferase	ESOP B013, B016
Liver biopsy	Aldolase	ESOP O024
Liver biopsy, muscle biopsy	Phosphofrutokinase	ESOP O024
Leucocyte, liver biopsy	Fructose-1,6 bisphosphatase	ESOP B011, O023
Leucocyte, muscle / liver biopsy	Phosphoglucomutase	ESOP, B019, O025, Glucose based ESOP O027,
Erythrocyte, muscle / liver biopsy	Glycogen	ESOP B012, O049
Leucocyte, muscle / liver biopsy Liver Biopsy, muscle biopsy	Debrancher Acid maltase	ESOP B006, O014, O015 ESOP O031



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Leucocyte, muscle / liver biopsy	Phosphorylase	Phosphate based Phosphate (1) ESOP O029, ESOP, B009, O019, O020
Erythrocyte, muscle / liver biopsy	Phosphorylase b kinase	ESOP B010, O021, O022,
Leucocyte, muscle biopsy, liver biopsy, CSK, CCV, CAC	Brancher	ESOP B008, O016, O017, O018
Liver biopsy	Phosphate (2) Glucose-6-phosphatase	Phosphate (2) ESOP O028 ESOP O013
END		