

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8692

Accredited to
ISO 15189:2022

Great Ormond Street Hospital for Children NHS Foundation Trust

Issue No: 007 Issue date: 28 November 2024

Chemical Pathology

Level 5

Camelia Botnar Laboratories

London

WC21N 3JH

Contact: Helen Aitkenhead

Tel: +44 (0) 20 7813 8318

Fax: +44 (0) 20 7829 8624

E-Mail: Helen.Aitkenhead@gosh.nhs.uk

Website: <https://www.gosh.nhs.uk/wards-and-departments/departments/laboratory-medicine/>

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	Ortho Vitros XT 7600 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	Ortho Vitros XT 7600 Microslide using documented procedure CSOP A058 Dry slide technology



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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)	Ortho Vitros XT 7600 Microslide using documented procedure CSOP A058
	CRP / C Reactive Protein	Dry slide technology
	Digoxin	
	Gamma GT	
	Glucose	
	HDL / HDL Cholesterol	
	Iron	
	LDH	
	Lipase	
	Phosphate	
Serum / plasma	Phenytoin	Ortho Vitros XT 7600 Microslide using documented procedure CSOP A058
	Phenobarbitone	Dry slide technology
	TIBC	
	Total protein	
	Triglyceride	
Serum/Plasma/CSF/Fluid	Glucose	Ortho Vitros XT 7600 Microslide using documented procedure CSOP A058
	Lactate	Dry slide technology
	Protein	
Serum / plasma	aFP	Immunoassay using Ortho Vitros XT 7600 microwell following documented procedure CSOP A058
	hCG	
	Troponin 1	
	Vitamin D	
	Thyroid stimulating hormone (TSH), free T4, free T3,	
	Insulin	
	c-peptide	
	ferritin	
	LH	
	FSH	
	Folate	
	vitamin B12	
	cortisol, prolactin, oestradiol, testosterone	
	NT-proBNP	
Whole Blood	Folate	
Serum / Plasma	PTH, androstenedione, DHEAS, Growth hormone, ACTH	Immunoassay using Diasorin Liaison following documented procedure CSOP A073
Serum / Plasma	IGF1, IGF-BP3	Immunoassay using IDS iSYS following documented procedure CSOP N064



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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	androstenedione t DHEA GH IGF BP3 PTH ACTH	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



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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	Inhibin B AMH	ELISA using documented procedures CSOP N047, CSOP N048, CSOP N034, CSOP N035
Serum / plasma	GFR estimation (using Iohexol)	ThermoFischer HPLC following 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	Advanced Instruments OSMO PRO (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	Guaiaac dye kit method using manufacturers kit and documented procedure CSOP N033



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
Feaces	Faceal haemoglobin	Qualitative faecal immunochemical tesing following documented procedure CSOP N033
	<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
Urine	Sialic acid (free and total)	LC – mass spectrometry using Waters Xevo TQ-S following documented procedure ESOP O042
Plasma / serum	17-hydroxy-progesterone	ABSciex API3200 tandem mass spectroscopy using CSOP N072



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
Urine	Glucose Tetrasaccharide	M031 High Performance Liquid Chromatography using Thermo (Dionex) ICS 5000 +, CSOP M031
Dried blood spot / urine	Acylcarnitines	Tandem Mass Spectrometry, API4000 CSOP M028, CSOP M034, CSOP S013
Urine and plasma	Guanidinoacetate Creatine Creatinine	Tandem Mass Spectrometry, API4000 CSOP M028, CSOP M034, CSOP S013
Faeces / urine	Reducing substances	Benedicts Test - Manual 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 to meet the requirements of the NBS screening programme as defined in the current version of 'Newborn Screening laboratory QA evidence requirements'
	Newborn Screening for Metabolic disorders and PKU Clinic Patient monitoring	Documented in house methods to meet the requirements of the NHS Newborn Blood Spot Screening Programme laboratory quality assurance evidence requirements
Blood spot	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



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>New Born Screening Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods to meet the requirements of the 9 screening programme as defined in the current version of 'Newborn Screening laboratory QA evidence requirements'
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
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 Fluoroimmuno-metric assay CSOP S007 Newborn Screening for congenital hypothyroidism Perkin Elmer Panthera puncher 9 CSOP S028
Blood spot	clinical diagnosis of Severe Combined Immunodeficiency (SCID)	ImmunoIVD SpotIT method polymerase chain reaction (PCR). Bloodspot punching using DBS single puncher Sample preparation and analysis carried out using Proflex and QuantStudio 5DX CSOP S045 - Newborn screening for SCID SOP CSOP RP12 Referral of Severe Combined Immune Deficiency (SCID) Suspected SOP



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
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
Serum	Asparaginase	Tecan Infinite M200 spectrophotometry using ESOP B077
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



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
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
Urine	Glycosaminoglycans	Spectrophotometry Cobas Bio
Leucocyte, cultured fibroblasts (CSK), cultured chorionic villi (CCV), cultured amniotic cells (CAC)	Sphingomyelinase	Radioactive assays using Perkin-Elmer Tri-Carb 2910TR ESOP B014C022, 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



8692
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Great Ormond Street Hospital for Children NHS Foundation Trust
Issue No: 007 Issue date: 28 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
	<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	Phosphofructokinase	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	Debrancher	ESOP B006, O014, O015
Liver Biopsy, muscle biopsy	Acid maltase	ESOP O031
		Phosphate based Phosphate (1) ESOP O029,
Leucocyte, muscle / liver biopsy	Phosphorylase	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
	Phosphate (2)	Phosphate (2) ESOP O028
Liver biopsy	Glucose-6-phosphatase	ESOP O013
END		