


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>8029</p> <p>Accredited to ISO 15189:2022</p>	<p align="center">South Eastern Health & Social Care Trust</p> <p align="center">Issue No: 013 Issue date: 06 August 2025</p> <table border="1"> <tr> <td> Clinical Biochemistry Laboratory Ulster Hospital Upper Newtownards Road Dundonald Northern Ireland BT16 1RH </td><td> Contact: Darren Crawford Tel: +44 (0)28 904 11565 Fax: +44 (0)28 9048 7131 E-Mail: Darren.crawford@setrust.hscni.net Website: www.setrust.hscni.net </td></tr> </table>	Clinical Biochemistry Laboratory Ulster Hospital Upper Newtownards Road Dundonald Northern Ireland BT16 1RH	Contact: Darren Crawford Tel: +44 (0)28 904 11565 Fax: +44 (0)28 9048 7131 E-Mail: Darren.crawford@setrust.hscni.net Website: www.setrust.hscni.net
Clinical Biochemistry Laboratory Ulster Hospital Upper Newtownards Road Dundonald Northern Ireland BT16 1RH	Contact: Darren Crawford Tel: +44 (0)28 904 11565 Fax: +44 (0)28 9048 7131 E-Mail: Darren.crawford@setrust.hscni.net Website: www.setrust.hscni.net		
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>Clinical Chemistry examination activities for the purposes of clinical diagnosis:</u>	<u>Documented in house methods and manufacturer's instructions for:</u>
	Quantification of:	Roche Cobas 8000 system
Serum / Plasma	Albumin	LABC AUTO2 & 1 (colorimetric)
Serum / Plasma	Alcohol (ethanol)	LABC AUTO-51 & 1 (enzymatic)
Serum / Plasma	Alkaline Phosphatase (ALP)	LABS AUTO-3 & 1 (colorimetric)
Serum / Plasma	Alpha Feto Protein	LABC AUTO-62 & 1 (immunoassay sandwich)
Serum / Plasma	ALT	LABC AUTO-175 & 1 (enzymatic IFCC)
Serum / Plasma	Ammonia	LABC AUTO-4 & 1 (enzymatic)
Serum / Plasma / urine	Amylase	LABC AUTO-6 & 1 (enzymatic colorimetric assay acc. to IFCC)
Serum / Plasma	AST	LABC AUTO-7 & 1 (enzymatic IFCC)
Serum / Plasma	AST /ALT Ratio	LABC AUTO-7, 175 & 1 (calculation)
Serum / Plasma	β-HcG	LABC AUTO-63 & 1 (immunoassay sandwich)
Serum / Plasma	Beta 2 Microglobulin	LABC AUTO-48 & 1 (immunoturbidimetric assay)



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Clinical Chemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	<u>Documented in house methods and manufacturer's instructions for:</u>
	Quantification of: (cont'd)	Roche Cobas 8000 system
Serum / Plasma	Bilirubin (Total)	LABC AUTO-33, & 1 (colorimetric assay diazo)
Serum / Plasma	CA-125	LABC AUTO-67 & 1 (immunoassay sandwich)
Serum / Plasma / urine	Calcium	LABC AUTO-8 & 1 (colorimetric assay with endpoint method (NM-BAPTA))
Urine	Calcium 24hr	LABC AUTO-8 & 1 (by calculation)
Serum / Plasma	Calcium (adjusted)	LABC AUTO-8 & 1 (by calculation)
Urine	Calcium / Creatinine Ratio	LABC AUTO-8, 11& 1 (by calculation)
Serum / Plasma	Carbamazepine	LABC AUTO-180 & 1 (KIMS)
Serum / Plasma	Carcinoembryonic Antigen (CEA)	LABC AUTO-64 & 1 (immunoassay sandwich)
Serum / Plasma / urine	Chloride	LABC AUTO-9 & 1 Indirect
Urine	Chloride 24hr	LABC AUTO-9 & 1 (by calculation)
Serum / Plasma	Cholesterol	LABC AUTO-10 & 1 (enzymatic, colorimetric method)
Serum / Plasma	Cholesterol / HDL Ratio	LABC AUTO-10, 19 & 1 (by calculation)
Serum / Plasma	Complement C3	LABC AUTO-186& 1 (immunoturbidimetric assay)
Serum / Plasma	Complement C4	LABC AUTO-187 & 1 (immunoturbidimetric assay)



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Chemistry examination activities for the purposes of clinical diagnosis</u> (cont'd):	<u>Documented in house methods and manufacturer's instructions for:</u>
	Quantification of: (cont'd)	Roche Cobas 8000 system
Serum / Plasma	Cortisol	LABC AUTO-65 & 1 (immunoassay competition)
Serum / Plasma	C-Reactive Protein	LABC AUTO-179 & 1 (immunoturbidimetric assay)
Serum / Plasma / urine	Creatinine	LABC AUTO-11 & 1 (enzymatic)
Urine	Creatinine 24hr	LABC AUTO-11 & 1 (by calculation)
Urine	Creatinine Clearance	LABC AUTO-11 & 1 (by calculation)
Serum / Plasma	Creatine Kinase	LABC AUTO-14 & 1 (IFCC UV-test enzymatic IFCC)
Serum / Plasma	Digoxin	LABC AUTO-66 & 1 (immunoassay competition)
Serum / Plasma	Direct Bilirubin	LABC AUTO-16 & 1 (diazotization method)
Serum / Plasma	Estimated GFR	LABC AUTO-11 & 1 (by calculation)
Serum / Plasma	Ferritin	LABC AUTO-69 & 1 (immunoassay sandwich)
Serum / Plasma	Folic Acid	LABC AUTO-70 & 1 (immunoassay competition)
Serum / Plasma	Follicle Stimulating Hormone (FSH)	LABC AUTO-71 & 1 (immunoassay sandwich)
Serum / Plasma	Free T3	LABC AUTO-72 & 1 (immunoassay competition)
Serum / Plasma	Free T4	LABC AUTO-73 & 1 (immunoassay competition)
Serum / Plasma	Gentamicin	LABC AUTO-169 & 1 (KIMS)



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Chemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	<u>Documented in house methods and manufacturer's instructions for:</u>
	Quantification of: (cont'd)	Roche Cobas 8000 system
Serum / Plasma	GGT	LABC AUTO-17 & 1 (enzymatic colorimetric assay)
Serum / Plasma	Globulins	LABC AUTO-2, 34, 176, 177, 178 by calculation
Serum / Plasma / Cerebrospinal fluid (CSF)	Glucose	LABC AUTO-18 & 1 (enzymatic hexokinase)
Serum / Plasma	HDL	LABC AUTO-19 & 1 (homogeneous enzymatic colorimetric test)
Serum / Plasma	Hydroxybutyrate	LABC AUTO-20 & 1 (enzymatic)
Serum / Plasma	Immunoglobulins G, A & M	LABC AUTO-176, 177, 178 & 1 (immunoturbidimetric assay)
Serum / Plasma	Iron	LABC AUTO-21 & 1 (colorimetric assay)
Serum / Plasma	% Transferrin saturation	LABC AUTO-21, 35 & 1 (by calculation)
Serum / Plasma / Cerebrospinal fluid (CSF)	Lactate	LABC AUTO-23 & 1 (colorimetric)
Serum / Plasma	LDH	LABC AUTO-22 & 1 (enzymatic)
Serum / Plasma	Lithium	LABC AUTO-24 & 1 (colorimetric)
Serum / Plasma	Low density lipoprotein (LDL)	LABC AUTO-19, 10, 36 & 1 by calculation
Serum / Plasma	Luteinising Hormone (LH)	LABC AUTO-75 & 1 (immunoassay sandwich)
Serum / Plasma / urine	Magnesium	LABC AUTO-25 & 1 (colorimetric end point)
Urine	Microalbumin	LABC AUTO-26, 11 & 1 (turbidimetric)



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Chemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	<u>Documented in house methods and manufacturer's instructions for:</u>
	Quantification of: (cont'd)	Roche Cobas 8000 system
Serum / Plasma	Oestradiol	LABC AUTO-76 & 1 (immunoassay competition)
Serum / Plasma	Paracetamol	LABC AUTO-188 & 1 (enzymatic)
Plasma	Para Thyroid Hormone	LABC AUTO-74 & 1 (immunoassay sandwich)
Serum / Plasma	Phenytoin	LABC AUTO-78 & 1 (KIMS)
Serum / Plasma / urine	Phosphate	LABC AUTO -28 & 1 (phosphomolybdate)
Urine	Phosphate 24hr	LABC AUTO-28 & 1 (by calculation)
Serum / Plasma / urine	Potassium	LABC AUTO-29 & 1 Indirect
Urine	Potassium 24hr	LABC AUTO-29 & 1 (by calculation)
Serum / Plasma	Progesterone	LABC AUTO-79 & 1 (immunoassay competition)
Serum / Plasma	Prolactin	LABC AUTO-80 & 1 (immunoassay sandwich)
Serum / Plasma	Prostatic Specific Antigen (PSA)	LABC AUTO-81 & 1 (immunoassay sandwich)
Urine / Cerebrospinal fluid (CSF)	Protein	LABC AUTO-38 & 1 (turbidimetric)
Urine	Protein 24hr	LABC AUTO-38 & 1 (by calculation)
Urine	Protein / Creatinine ratio	LABC AUTO-38, 11 & 1 (by calculation)
Serum / Plasma	Rheumatoid factor	LABC AUTO-143 & 1 (immunoturbidimetric assay)
Serum / Plasma	Salicylate	LABC AUTO-37 & 1 (enzymatic)



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Chemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	<u>Documented in house methods and manufacturer's instructions for:</u>
	Quantification of: (cont'd)	Roche Cobas 8000 system
Serum / Plasma	Sex Hormone Binding Globulin	LABC AUTO-82 & 1 (immunoassay sandwich)
Serum / Plasma / urine	Sodium	LABC AUTO-30 & 1 Indirect
Urine	Sodium 24hr	LABC AUTO-30 & 1 (calculation)
Serum / Plasma	Teicoplanin	LABC AUTO-174 & 1 (turbidimetric)
Serum / Plasma	Testosterone	LABC AUTO-83 & 1 (immunoassay competition)
Serum / Plasma	Testosterone (Free)	LABC AUTO-83, 82, 2 & 1 (calculation)
Serum / Plasma	Theophylline	LABC AUTO-182 & 1 (KIMS)
Serum / Plasma	Thyroid Stimulating Hormone (TSH)	LABC AUTO-85 & 1 (immunoassay sandwich)
Serum / Plasma	Total Bile Acids	LABC AUTO-172 & 1 (enzymatic)
Serum / Plasma	Total Carbon Dioxide	LABC AUTO-31 & 1 (enzymatic)
Serum / Plasma	Total Protein	LABC AUTO-34 & 1 (colorimetric)
Urine	Total Protein	LABC AUTO-38 & 1 (turbidimetric)
Serum / Plasma	Transferrin	LABC AUTO-35 & 1 (immunoturbidimetric assay)
Serum / Plasma	Triglycerides	LABC AUTO-36 & 1 (enzymatic colorimetric test)
Serum / Plasma	Troponin T (High Sensitivity)	LABC AUTO-87 & 1 (immunoassay sandwich)
Urine	Urate 24hr	LABC AUTO-55 & 1 (calculation)
Serum / Plasma / urine	Urea	LABC AUTO-39 & 1 (enzymatic)



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	Quantification of: (cont'd)	Roche Cobas 8000 system
Urine	Urea 24 hr	LABC AUTO-39 & 1 (by calculation)
Serum / Plasma	Uric acid	LABC AUTO 55 & 1 (enzymatic)
Serum / Plasma	Valproic Acid	LABC AUTO-183 & 1 (enzyme immunoassay)
Serum / Plasma	Vancomycin	LABC AUTO-46 & 1 (enzyme immunoassay)
Serum / Plasma	Vitamin B12	LABC AUTO-61 & 1 (immunoassay competition)
Urine	Bence Jones Protein	Documented in house procedure LABC BIO2-63 and manufacturer's instructions for Helena SAS-3/4 gel electrophoresis
Cerebrospinal fluid (CSF)	Xanthochromia (Bilirubin and oxyhaemoglobin)	Documented in-house procedure LABC BIO2-28 & manufacturer's instructions for Uvikon XS – spectrophotometry and LABC BIO2-75 & manufacturer's instructions for BIO-UV by spectrophotometry
Faeces	Calprotectin	Documented in-house procedure LABC AUTO-153 & manufacturer's instructions Chemiluminescent Immunoassay (CLIA) on the DiaSorin Liaison XL
Whole blood	HbA1c	Documented in-house procedure LABC BIO2-66 & manufacturer's instructions Sebia Capillarys 3 Tera/Octa using capillary zone electrophoresis



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Whole blood	Met Haemoglobin	Documented in-house procedure POCT SOP-56 & manufacturer's instructions for IL GEM 4000 analyser (spectrophotometry & calculation)
Serum / urine	Osmolality	Documented in-house procedure LABC BIO2-5 and manufacturer's instructions for analysis using the Osmo1 depression of freezing point
Serum	Detection of serum proteins <ul style="list-style-type: none">➤ Serum albumin➤ Alpha-1 globulins➤ Alpha-2 globulins➤ Beta globulins➤ Gamma globulins	Documented in-house procedure LABC BIO2 -60 Helena V8 Nexus-capillary zone electrophoresis with LABC BIO2-62 Helena SAS-3/4 serum gel electrophoresis and manufacturer's instructions for V8 Nexus and SAS-3/4.
END		