

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8029

Accredited to
ISO 15189:2012

South Eastern Health and Social Care Trust

Issue No: 004

Issue date: 08 August 2019

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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>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	Albumin	LABC AUTO2 & 1 (colorimetric)
Urine	Albumin / Creatinine Ratio	LABC AUTO-2, 11 & 1 (calculation)
Serum	Alcohol (ethanol)	LABC AUTO-51 & 1 (enzymatic)
Serum	Alkaline Phosphatase (ALP)	LABS BIO2 52 (colorimetric)
Serum	Alpha Feto Protein	LABC AUTO-62 & 1 (immunoassay sandwich)
Serum	ALT	LABC AUTO-5 & 1 (enzymatic IFCC)
Serum	Amikacin	LABC AUTO-58 & 1 (KIMS)
Serum	Ammonia	LABC AUTO-4 & 1 (enzymatic)
Serum/ urine	Amylase	LABC AUTO-6 & 1 (enzymatic colorimetric assay acc. to IFCC)
Serum	AST	LABC AUTO-7 & 1 (enzymatic IFCC)
Serum	AST /ALT Ratio	LABC AUTO-7 & 1 (calculation)
Serum	β -HcG	LABC AUTO-63 & 1 (immunoassay sandwich)
Serum	Beta 2 Microglobulin	LABC AUTO-48 & 1 (immunoturbidimetric assay)



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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	Bilirubin (Total)	LABC AUTO-33, & 1 (colorimetric assay diazo)
Serum	CA-125	LABC AUTO-67 & 1 (immunoassay sandwich)
Serum/ urine	Calcium	LABC AUTO-8 & 1 (colorimetric assay with endpoint method (NM-BAPTA))
Urine	Calcium 24hr	LABC AUTO-8 & 1 (by calculation)
Serum	Calcium (adjusted)	LABC AUTO-8 & 1 (by calculation)
Urine	Calcium / Creatinine Ratio	LABC AUTO-8, 11 & 1 (by calculation)
Serum	Carbamazepine	LABC AUTO-68 & 1 (KIMS)
Serum	Carcinoembryonic Antigen (CEA)	LABC AUTO-64 & 1 (immunoassay sandwich)
Serum / urine	Chloride	LABC AUTO-9 & 1 Indirect
Urine	Chloride 24hr	LABC AUTO-9 & 1 (by calculation)
Serum	Cholesterol	LABC AUTO-10 & 1 (enzymatic, colorimetric method)
Serum	Cholesterol / HDL Ratio	LABC AUTO-10, 19 & 1 (by calculation)
Serum	Complement C3	LABC AUTO-49 & 1 (immunoturbidimetric assay)
Serum	Complement C4	LABC AUTO-50 & 1 (immunoturbidimetric assay)



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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	Cortisol	LABC AUTO-65 & 1 (immunoassay competition)
Serum	C-Reactive Protein	LABC AUTO-12 & 1 (immunoturbidimetric assay)
Serum/ 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	Creatine Kinase	LABC AUTO-14 & 1 (IFCC UV-test enzymatic IFCC)
Serum	Digoxin	LABC AUTO-66 & 1 (immunoassay competition)
Serum	Direct Bilirubin	LABC AUTO-16 & 1 (diazo method)
Serum	Estimated GFR	LABC AUTO-11 & 1 (by calculation)
Serum	Ferritin	LABC AUTO-69 & 1 (immunoassay sandwich)
Serum	Folic Acid	LABC AUTO-70 & 1 (immunoassay competition)
Serum	Follicle Stimulating Hormone (FSH)	LABC AUTO-71 & 1 (immunoassay sandwich)
Serum	Free T3	LABC AUTO-72 & 1 (immunoassay competition)
Serum	Free T4	LABC AUTO-73 & 1 (immunoassay competition)
Serum	Gentamicin	LABC AUTO-42 & 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	GGT	LABC AUTO-17 & 1 (enzymatic colorimetric assay)
Serum	Globulins	LABC AUTO-53, 52, 54 & 1 by calculation
Plasma / Cerebrospinal fluid (CSF)	Glucose	LABC AUTO-18 & 1 (enzymatic hexokinase)
Serum	HDL	LABC AUTO-19 & 1 (homogeneous enzymatic colorimetric test)
Serum	Hydroxybutyrate	LABC AUTO-20 & 1 (enzymatic)
Serum	Immunoglobulins G, A & M	LABC AUTO-53, 52, 54 & 1 (immunoturbidimetric assay)
Serum	Iron	LABC AUTO-21 & 1 (colorimetric assay)
Serum	% Iron saturation	LABC AUTO-21 & 1 (by calculation)
Plasma/ Cerebrospinal fluid (CSF)	Lactate	LABC AUTO-23 & 1 (colorimetric)
Serum	LDH	LABC AUTO-22 & 1 (enzymatic)
Serum	Lithium	LABC AUTO-24 & 1 (colorimetric)
Serum	Low density lipoprotein (LDL)	LABC AUTO-19 & 1 by calculation
Serum	Luteinising Hormone (LH)	LABC AUTO-75 & 1 (immunoassay sandwich)
Serum/ urine	Magnesium	LABC AUTO-25 & 1 (colorimetric end point)
Urine	Microalbumin	LABC AUTO-26 & 1 (turbidimetric)
Serum	Oestradiol	LABC AUTO-76 & 1 (immunoassay competition)



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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	Paracetamol	LABC AUTO-27 & 1 (enzymatic)
Plasma	Para Thyroid Hormone	LABC AUTO-74 & 1 (immunoassay sandwich)
Serum	Phenytoin	LABC AUTO-78 & 1 (KIMS)
Serum/ urine	Phosphate	LABC AUTO -28 & 1 (phosphomolybdate)
Urine	Phosphate 24hr	LABC AUTO-28 & 1 (by calculation)
Serum/ urine	Potassium	LABC AUTO-29 & 1 Indirect
Urine	Potassium 24hr	LABC AUTO-29 & 1 (by calculation)
Serum	Progesterone	LABC AUTO-79 & 1 (immunoassay competition)
Serum	Prolactin	LABC AUTO-80 & 1 (immunoassay sandwich)
Serum	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	Rheumatoid factor	LABC AUTO-143(immunoturbidimetric assay)
Serum	Salicylate	LABC AUTO-37 & 1 (enzymatic)
Serum	Sex Hormone Binding Globulin	LABC AUTO-82 & 1 (immunoassay sandwich)



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	Quantification of: (cont'd)	Roche Cobas 8000 system
Serum/ urine	Sodium	LABC AUTO-30 & 1 Indirect
Urine	Sodium 24hr	LABC AUTO-30 & 1 (calculation)
Serum	Teicoplanin	LABC AUTO-144 (turbidimetric)
Serum	Testosterone	LABC AUTO-83 & 1 (immunoassay competition)
Serum	Testosterone (Free)	LABC AUTO-83 & 1 (calculation)
Serum	Theophylline	LABC AUTO-84 & 1 (KIMS)
Serum	Thyroid Stimulating Hormone (TSH)	LABC AUTO-85 & 1 (immunoassay sandwich)
Serum	Tobramycin	LABC AUTO-59 & 1 (enzyme immunoassay)
Serum	Total Bile Acids	LABC AUTO-32 & 1 (enzymatic)
Serum	Total Carbon Dioxide	LABC AUTO-31 & 1 (enzymatic)
Serum	Total Protein	LABC AUTO-134,34 & 1 (colorimetric)
Urine	Total Protein	LABC AUTO-38 & 1 (turbidimetric)
Serum	Transferrin	LABC AUTO-35 & 1 (immunoturbidimetric assay)
Serum	Triglycerides	LABC AUTO-36 & 1 (enzymatic colorimetric test)
Serum	Troponin T (High Sensitivity)	LABC AUTO-87 & 1 (immunoassay sandwich)
Urine	Urate 24hr	LABC AUTO-55 & 1 (calculation)



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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/ urine	Urea	LABC AUTO-39 & 1 (enzymatic)
Urine	Urea 24 hr	LABC AUTO-39 & 1 (by calculation)
Serum	Uric acid	LABC AUTO 55 & 1 (enzymatic)
Serum	Valproic Acid	LABC AUTO-47 & 1 (enzyme immunoassay)
Serum	Vancomycin	LABC AUTO-46 & 1 (enzyme immunoassay)
Serum	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
Whole Blood	Blood Gas Analysis	Documented in-house procedure LABC BIO2-42 & manufacturer's instructions for IL GEM analyser:
	<ul style="list-style-type: none"> ➤ Blood Gas Base Excess ➤ Bicarbonate ➤ Carboxy haemoglobin ➤ Oxygen content ➤ Oxygen saturation ➤ pCO₂ ➤ pH ➤ PO₂ 	Spectrophotometry & calculation Spectrophotometry & calculation Spectrophotometry & calculation Spectrophotometry & calculation Spectrophotometry & calculation Electrode Electrode Electrode
Cerebrospinal fluid (CSF)	Xanthochromia (Bilirubin and oxyhaemoglobin)	Documented in-house procedure LABC BIO2-28 & manufacturer's instructions for Uvikon XS - spectrophotometry



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Faeces	Faecal Occult Blood	Documented in-house procedure LABC BIO2-2 & manufacturer's instructions for Seracult card – application of the Guauac test - colour change end point
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 HBA1C-1 & manufacturer's instructions Biorad variant II Turbo - HPLC
Whole blood	Met Haemoglobin	Documented in-house procedure LABC BIO2-42 & manufacturer's instructions for GEM 4000 analyser (spectrophotometry & calculation)
Serum / urine	Osmolality	Documented in-house procedure LABC BIO2-5 and manufacturer's instructions for analysis using the Advanced Microsmometer 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		