Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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London

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HSL (Analytics) LLP

Issue No: 026 Issue date: 15 May 2025

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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
	General Biochemistry	
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated)	Quantification of:	Ion Sensitive Electrode method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1- 37
Urine also	Sodium	
Urine also	Potassium	
	Chloride	
	Quantification of:	Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1- 37
	Alanine Aminotransaminase	31
Urine also	Albumin	
	Alkaline Phosphatase	
	Alpha-1 Antitrypsin	
	Amikacin	
Urine also	Amylase	
	Angiotensin Converting Enzyme	
	Aspartate Aminotransferase	
	Bicarbonate	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated) (cont'd)	Quantification of: (cont'd)	Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1- 37
	B2 Microglobulin	
	Bile Acids	
	Bilirubin (total and conjugated)	
	Complement C3	
	Complement C4	
Urine also	Calcium	
	Carbamazepine	
	Caeruloplasmin	
	Cholesterol	
	Cholinesterase	
	Creatine Kinase	
Urine also	Creatinine (Jaffe)	
Urine and Serum	Creatinine (enzymatic)	
	C-Reactive Protein (CRP)	
	CRP (High Sensitivity)	
Urine also	Ethanol	
	Fructosamine	
	Gentamicin	
	Gamma Glutamyl Transferase	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated) (cont'd)	Quantification of: (cont'd)	Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1- 37
	Glutamate dehydrogenase	
CSF & urine also	Glucose	
	Haptoglobin	
	HDL Cholesterol	
	IgG	
	IgA	
	IgM	
	Iron	
CSF & plasma only	Lactate	
	Lactate Dehydrogenase	
	Lipase	
	Lipoprotein (a)	
	Lithium	
Urine also	Magnesium	
	Phenytoin	
Urine also	Phosphate	
	Rheumatoid Factor	
	Theophylline	
Urine and CSF also	Total Protein	

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	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated) (cont'd)	Quantification of: (cont'd)	Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1- 37
	Transferrin	
	Triglyceride	
	Teicoplanin	
Urine also	Urate	
Urine also	Urea	
	Unsaturated Iron Binding Capacity	
	Valproate	
	Vancomycin	
	Examination activities for the purposes of clinical diagnosis.	
Urine	Quantification of:	Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1- 37
	Amphetamine	31
	Barbiturates	
	Benzodiazepine	
	Cannabinoids	
	Cocaine	
	Cotinine	
	Methadone	
	Opiates	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated) (cont'd)	Quantification of: (cont'd)	Immunoassay methods using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37
Plasma only	Adrenocorticotrophic Hormone	
	Alpha-Fetoprotein	
	Anti-Mullerian Hormone	
	Anti-Thyroglobulin antibodies	
	Beta-Human Chorionic Gonadotrophin	
	CA125	
	CA153	
	CA199	
	Calcitonin	
	Carcinoembryonic Antigen	
	Creatine Kinase MB	
	Cortisol	
	Dehydroepiandrosterone Sulphate	
	Digoxin	
	Oestradiol	
	Ferritin	
	Folate	
	Follicle Stimulating Hormone	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated) (cont'd)	Quantification of: (cont'd)	Immunoassay methods using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-
	Human Chorionic Gonadotrophin (free)	37
	Prostate Specific Antigen (free & total)	
	FT3	
	FT4	
	Growth Hormone	
	IgE	
	Insulin	
	Luteinising Hormone	
	Macroprolactin (PEG Precipitation)	SOP BIO-MP1-45
	Myoglobin	
	NT-Pro B-Type Natriuretic Peptide	
	Pregnancy Associated Plasma Protein (PAPP-A)	
	Progesterone	
	Prolactin	
	Parathyroid Hormone	
	Procalcitonin	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated) (cont'd)	Quantification of: (cont'd)	Immunoassay methods using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-
	Sex Hormone-Binding Globulin	37
	T3 (total)	
	T4 (total)	
	Testosterone	
	Thyroglobulin	
	Thyroid Stimulating Hormone	
	Troponin T (High Sensitivity)	
	Vitamin B12	
	25-hydroxy Vitamin D	
	Thyroid Peroxidase Antibody	
	Quantification of:	Immunoassay using Abbott Architect i2000SR; SOPs BIO-MP1-10
	CA125	30F3 BIO-WIF 1-10
	HE4	
Serum/EDTA	Homocysteine	
	ROMA	
Whole Blood EDTA	Red Cell Folate	
	Troponin I (High Sensitivity)	
	Vitamin B12 (Active)	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated)	Biochemistry Calculated Parameters:	By calculation using Cobas c702 SOP-MP1-16-Q-1
Urine	Albumin:Creatinine ratio	
	Anion Gap	
	Corrected Calcium	
Urine also	Creatinine Clearance	
	LDL Cholesterol	
	eGFR	
Urine	Protein : Creatinine Ratio	
Urine also	Renal Tubular reabsorption of Phosphate	
	Total Iron Binding Capacity	
	Transferrin Saturation	
Urine and Serum	Creatinine Clearance	By calculation in Middleware LIMS
Calculation	eGFR	By calculation in Middleware LIMS
Urine also	Osmolality	Freezing Point Depression using Vitech Osmometer SOP BIO-MP1-14
Serum	Amyloid A	Immunoassay using Siemens BNII SOP MCH-MP2-2
	Apolipoproteins A1 & B	SOP MCH-MP2-4

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum	Alpha-1 Antitrypsin Phenotyping	SOP MCH-MP2-42 (focussing method)
	Alkaline Phosphatase Isoenzymes	SOP MCH-MP2-10
Faeces	Calprotectin	Latex agglutination turbidimetric assay using OC-Sensor Pledia SOP BIO-MP1-48
Plasma	Chromogranin A	ELISA using Dynex DS2 and Euro Diagnostica kit SOP MCH-MP2-46
EDTA Whole Blood	Ciclosporin A Tacrolimus Sirolimus	LCMSMS using Shimadzu 8050 SOP MCH-MP2-13
Serum/urine	Trace Metals Copper Zinc Selenium	NexION 1000 ICP-MS SOP MCH-MP2-68
Whole Blood Whole Blood	Chromium Cobalt	NexION 1000 ICP-MS SOP MCH-MP2-69
Urine	Metanephrines / Metadrenalines: Metanephrine Normetanephrine 3-Methoxytyramine	HPLC using Shimadzu Prominence SOP MCH-MP2-6
	5-Hydroxyindoleacetic acid (5HIAA)	SOP MCH-MP2-7

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	General Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum	IgG Subclasses (IgG 1-4)	Immunoassay using Binding Site Optilite SOP MCH-MP2-55 & MCH-MP2-31
Serum	Enhanced Liver Fibrosis: Procollagen 3 Amino terminal peptide (P3NP) Hyaluronic acid (HA) Tissue inhibitor of metalloproteinase (TIMP-1)	Siemens Atellica IM analyser using chemiluminescent technology SOP BIO-MP1-51
Serum	Erythropoietin	Siemens Atellica IM analyser using chemiluminescent technology SOP BIO-MP1-51
Serum/ Plasma / Whole Blood	Active B12	Immunoassay on Abbott Alinity I using CMIA SOP BIO-MP1-55
	CA 125	
	HE4	
	Homocysteine	
	High sensitivity Troponin I	
	Red Cell Folate	
	ROMA Score (calculated using HE4 and CA 125)	

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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Virology	
Examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
	Documented in-housed methods to meet the requirements of the of Infectious Diseases in Pregnancy Screening programme as defined in the 'Infectious Diseases in Pregnancy Screening Programme: laboratory QA evidence requirements'
Quantification of:	Immunoassay using Roche Cobas e801
Hepatitis A Total & IgM	SOPs BIO-MP1-8, BIO-MP1-7, BIO-MP1-37
Hepatitis B Core Total Antibody	
Hepatitis B Envelope Antigen	
Hepatitis B Envelope Antibody	
Hepatitis B Surface Antigen	
Hepatitis B Surface Antibody	
Hepatitis C antibody	
HIV 1 & 2 Antibody and p24 Antigen	
Syphilis Total Antibody	
SARS-CoV-2 (COVID-19) spike total antibody (quantitative)	Elecsys SARS-CoV-2 S kit using Roche Cobas e801 SOP BIO-MP1-8
HIV 1 & 2 Antibody and p24 Antigen	Multiplex Flow Immunoassay using Bio-Rad Bioplex SOP IMM-MP1-17
	Measured/Range of measurement Virology Examination activities for the purposes of clinical diagnosis. Quantification of: Hepatitis A Total & IgM Hepatitis B Core Total Antibody Hepatitis B Envelope Antigen Hepatitis B Envelope Antibody Hepatitis B Surface Antigen Hepatitis B Surface Antibody Hepatitis C antibody Hepatitis C antibody HIV 1 & 2 Antibody and p24 Antigen Syphilis Total Antibody SARS-CoV-2 (COVID-19) spike total antibody (quantitative) HIV 1 & 2 Antibody and p24

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Virology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / plasma (unless otherwise stated)	Detection of:	Immunoassay using Abbott Architect i2000SR
	Cytomegalovirus (CMV) IgM & IgG	SOPs BIO-MP1-10
	Hepatitis B Core IgM	
	Hepatitis B Surface Antigen (quantitation)	
Serum & plasma	Hepatitis C antigen	
	Human T-Cell Lymphotropic Virus (HTLV) I / II Antibody	
	Rubella IgM & IgG	
	Toxoplasma IgM & IgG	
Serum & plasma	HIV-1 p24 Antigen and HIV-1 / HIV-2 Antibodies	Abbott Architect HIV Ag/Ab Combo
Serum & plasma	ТРНА	New Bio Manual Agglutination SOP IMM-MP2-46
Serum & plasm	ТРНА	Fortress Diagnostics Manual Agglutination SOP IMM-MP2-46
Plasma	TB Interferon Gamma	TB Quantiferon assay using commercial kits and DiaSorin Liasion analyser SOP IMM-MP1-8, IMM-MP1-18

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Virology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / Plasma (unless	Borrelia IgM & IgG	Chemiluminescence using Diasorin Liaison
otherwise stated) (cont'd)	Epstein Barr Virus VCA IgM	SOP IMM-MP1-8,
	EBNA IgG	SOP IMM-MP1-23
	EBV VCA-IgG	SOP IMM-MP1-24
	Hepatitis B Core Antibody	SOP IMM-MP1-35
	Hepatitis B Surface Antigen	SOP IMM-MP1-25
	Hepatitis Delta Total Antibodies	SOP IMM-MP1-22
	Herpes Simplex Virus (HSV) 1 & 2 IgG (combined)	SOP IMM-MP1-27
	Herpes Simplex Virus (HSV) 1 & 2 IgM (combined)	SOP IMM-MP1-27
	Herpes Simplex Virus (HSV) 1 IgG	SOP IMM-MP1-28
	Herpes Simplex Virus (HSV) 2 IgG	SOP IMM-MP1-28
Faeces	Helicobacter Pylori Antigen	SOP BIO-MP1-50
Plasma / Serum	Rapid Plasma Reagin (RPR)	Manual RPR flocculation test using New Bio commercial kit SOP IMM-MP2-46

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Virology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / Plasma (unless otherwise stated) (cont'd)	Detection of:	Chemiluminescence using Diasorin Liaison XL SOP IMM-MP1-8
	Insulin-Like Growth Factor 1	SOP IMM-MP1-8
	Measles IgM & IgG	SOP IMM-MP1-30
	Mumps IgM & IgG	SOP IMM-MP1-31
	Mycoplasma IgM & IgG	SOP IMM-MP1-32
	Parvovirus IgM & IgG	SOP IMM-MP1-33
	Varicella Zoster Virus IgM & IgG	SOP IMM-MP1-34
	CMV IgG Avidity	SOP IMM-MP1-37
	Hepatitis C Antibody	SOP IMM-MP1-26
Serum only	CMV Avidity	Immunoassay using Biomerieux Vidas 3 SOP IMM-MP2-25, IMM-MP2-69
Serum only	Borrelia IgM & IgG	SOP IMM-MP2-61
	HIV 1 & 2 Antibody and p24 Antigen	HIV 6 Duo Quick assay SOP IMM-MP2-43
Serum only	Syphilis	RPR using AIX-1000 SOP IMM-MP2-4, IMM-MP2-46

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Immunology	
HUMAN BODY FLUIDS	Examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / plasma (unless otherwise stated)	Quantification of:	Immunoassay using Thermo Phadia 250 Immunocap SOP IMM-MP1-11
	Specific IgG4	SOP IMM-MP1-15
	Mast Cell Tryptase	SOP IMM-MP1-10
	Specific IgE and IgG	SOP IMM-MP1-11
Serum / plasma (unless otherwise stated)	Quantification of:	Immunoassay using Thermo Phadia 2500 Immunocap
Otherwise stated)	Allergen Specific IgE	SOP IMM-MP1-14
	Gliadin IgG & IgA	SOP IMM-MP1-16
	Tissue Transglutamase IgA	SOP IMM-MP1-1
	Extractable Nuclear Antigen IgG	SOP IMM-MP1-6
	Sm IgG	SOP IMM-MP1-6
	Jo-1 IgG	SOP IMM-MP1-6
	Ro (SSA) IgG	SOP IMM-MP1-6
	La (SSB) IgG	SOP IMM-MP1-6
	CENP-B IgG	SOP IMM-MP1-6
	U1-RNP-lgG	SOP IMM-MP1-6
	Scl-70 IgG	SOP IMM-MP1-6
	Cyclic Citrullinated Protein IgG	SOP IMM-MP1-12
	Myeloperoxidase IgG	SOP IMM-MP1-3
	Proteinase 3 IgG	SOP IMM-MP1-3
	dsDNA IgG	SOP IMM-MP1-2
	Beta-2 Glycoprotein IgM & IgG	SOP IMM-MP1-7

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	<u>l</u> mmunology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / plasma (unless	Quantification of: (cont'd)	Immunoassay using Thermo Phadia 2500
otherwise stated) (cont'd)	Glomerular Basement Membrane IgG	Immunocap SOP IMM-MP1-14 SOP IMM-MP1-13
	Mitochondrial M2 IgG	IMM-MP1-14, IMM-MP1-19
	Fibrillarin (U3RNP) IgG	IMM-MP1-14, IMM-MP1-20
Serum (unless stated)	Quantification of:	Immunofluorescence using Grifols / Aesku Helios SOP IMM-MP2-1 with use of the following kits and SOPs:
	Antinuclear Antibodies - IgG	AESKU (Grifols) – SOP IMM-MP2-2
	Anti-Neutrophil Cytoplasmic Antibodies - IgG	AESKU (Grifols) – SOP IMM-MP2-53
	Endomysial IgA	AESKU (Grifols) – SOP IMM-MP2-20
	ds DNA IgG (Crithidia)	AESKU (Grifols) – SOP IMM-MP2-3
	Gastric Parietal Cell IgG	AESKU (Grifols) – SOP IMM-MP2-3
	Liver Kidney Microsomal IgG	AESKU (Grifols) – SOP IMM-MP2-3
	Mitochondrial IgG	AESKU (Grifols) – SOP IMM-MP2-3
	Skin IgG (Pemphigus & Pemphigoid)	AESKU (Grifols) – SOP IMM-MP2-3
	Smooth muscle IgG	Biodiagnostics – SOP IMM-MP2-3
	Adrenal Gland IgG	Biodiagnostics - SOP IMM-MP2-3
	Chlamydia IgM & IgG	SeroFIA Savyon (Launch) – SOP IMM-MP2- 24
	Islet Cell IgG	Biodiagnostics - SOP IMM-MP2-3
	Legionella IgG	Vircell (Quest Biomedical) – SOP IMM-MP2- 23
	Ovarian IgG	Biodiagnostics - SOP IMM-MP2-3

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Immunology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis. (cont'd)	
Serum (unless stated)	Quantification of:	Immunofluorescence using Grifols / Aesku Helios SOP IMM-MP2-1 with use of the following kits and SOPs:
	Striated Muscle IgG	AESKU (Grifols) – SOP IMM-MP2-3
Serum	Scleroderma Immunoblot:	Immunoassay using EuroblotOne analyser with reference to the following SOPs:
	Antibodies against:	SOP IMM-MP2-73, IMM-MP2-21
	ScI-70 CENP A CENP B RP11 RP155 Fibrillarin NOR90 Th/To PM-ScI100 PM-ScI75 Ku PDGFR Ro-52	
	Liver Immunoblot	Immunoassay using EuroblotOne analyser with reference to the following SOPs:
Serum	Antibodies against:	SOP IMM-MP2-54, IMM-MP2-73
	AMA-M2 M2-3E (BPO) Sp100 PML gp120 LKM-1 LC-1 SLA/LP Ro-52	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Immunology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis. (cont'd)	Immunoassay using EuroblotOne analyser with reference to the following SOPs:
	Myositis Immunoblot	
Serum	Antibodies against:	SOP IMM-MP2-58, IMM-MP2-73
	Mi-2 alpha Mi-2 beta TIF1-gamma MDA5 NXP2 SAE1 Ku PM-Scl100 PM-Scl75 Jo-1 SRP PL-7 PL-12 EJ OJ Ro-52	
Serum	Quantification of:	ELISA (automated) using commercial kits and Dynex Agility analyser SOP IMM-MP2-62
	Anti-Cardiolipin IgM & IgG	Orgentec – SOP IMM-MP2-13
	Hepatitis E IgM and IgG	Fortress Diagnostics – SOP IMM-MP2-56
	Helicobacter pylori IgG	Premier – SOP IMM-MP2-26
	Intrinsic Factor IgG	Orgentec – SOP IMM-MP2-8
	TB Interferon Gamma	TB Quantiferon assay - SOP IMM-MP2-27
	Haemophilus influenzae type b antibody	Binding site VaccZyme - SOP IMM-MP2-14
	Pneumococcal C.P. Antibodies	Binding site VaccZyme - SOP IMM-MP2-18

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Immunology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (cont'd)	Quantification of: (cont'd)	ELISA (automated) using commercial kits and Dynex Agility analyser SOP IMM-MP2-62
	Tetanus Toxoid Antibodies	Binding Site VaccZyme – SOP IMM-MP2-19
	RNA Polymerase Antibodies	QUANTA Lite III – SOP IMM-MP2-15
Serum / plasma (unless stated)	Quantification of:	ELISA (manual) using the following kits:
	TSH receptor antibodies	RSR SOP IMM-MP2-22
Serum / plasma (unless stated)	Quantification of:	Radial immunodiffusion (manual) using Binding Site kit
	C1 Esterase Inhibitor	Immunonephelometry on Siemens BNII MCH-MP2-70
Serum	ALEX Allergen Specific IgE	Multi Array Xplorer (MAX) 45K analyser IMM-MP2-68

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Immunology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis (cont'd).	In house documented procedures based on equipment manuals and standard methods as specified:
Serum (unless otherwise stated)	Specific IgE	Immuno Solid Phase Allergy Chip and Luxscan scanner SOP IMM-MP2-6
	Rheumatoid Factor	Latex agglutination using Rheumajet SOP IMM-MP2-28
	Anti-Streptolysin O	Latex agglutination using Rheumajet SOP IMM-MP2-29
	Herpes (HSV) 1& 2 Type specific IgG	Immunoblot using Focus Diagnostics Herpeselect 1&2 immunoblot IgG kit SOP IMM-MP2-10

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HUMAN BODY FLUIDS Haematology / Flow Cytometry Haematology / Immunology examination activities for the purposes of clinical diagnosis. Peripheral Blood Peripheral Blood Bone Marrow, Peripheral Blood, CSF, Pleural Fluid, Ascitic Fluid Bone Marrow, Peripheral Blood, CSF, Pleural Fluid, Ascitic Fluid Detection of: Acute Leukaemia Screen: Detection of: Acute Primary CD3 CD7 Haematology / Flow Cytometry dequipment manuals and stand as specified: Flow cytometry using Beckman Aquios SOP FFC-MP2-3 Flow cytometry using DuraClo Beckman Coulter T-Q Prep, N microscopy SOP FFC-MP2-24, FFC-MP2-24 FFC-MP2-4	ndard methods nan Coulter Clone kit with
examination activities for the purposes of clinical diagnosis. Peripheral Blood Peripheral Blood CD19 Natural Killer cells Bone Marrow, Peripheral Blood, CSF, Pleural Fluid, Ascitic Fluid Detection of: CD3 CD3 CD7 equipment manuals and stand as specified: Flow cytometry using Beckman Aquios SOP FFC-MP2-3 Flow cytometry using DuraClo Beckman Coulter T-Q Prep, N microscopy SOP FFC-MP2-24, FFC-MP2-24 FFC-MP2-4	ndard methods nan Coulter Clone kit with
Bone Marrow, Peripheral Blood, CSF, Pleural Fluid, Ascitic Fluid Detection of: CD19 Natural Killer cells Aquios SOP FFC-MP2-3 Flow cytometry using DuraClo Beckman Coulter T-Q Prep, N microscopy SOP FFC-MP2-24, FFC-MP2-24 CD3 CD7	Clone kit with
CSF, Pleural Fluid, Ascitic Fluid Detection of: Acute Primary CD3 CD7 Beckman Coulter T-Q Prep, N microscopy SOP FFC-MP2-24, FFC-MP2- FFC-MP2-4	
CD34 CD33 CD10 CD117 CD20 CD19 HLADR CD45 Acute Intracellular TPT MPO CD34 CD79a CD3 CD45 Acute Myeloid CD11b CD18 CD34 CD13 CD34 CD13 CD33 CD13 CD33 CD17 CD56 CD2	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Haematology / Flow Cytometry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Haematology / Immunology examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Bone Marrow, Peripheral Blood, CFS, Pleural Fluid, Ascitic Fluid (cont'd)	Acute Leukaemia Screen: (cont'd) Detection of: (cont'd) Acute B-Lymphoid Kappa Lambda CD34 CD13 CD10 CD79b CD38 CD19 CD22 Chronic B-Lymphoid Kappa Lambda CD10 CD25 (stacked tube)	Flow cytometry using DuraClone kit with Beckman Coulter T-Q Prep, Navios & microscopy SOP FFC-MP2-24, FFC-MP2-8, FFC-MP2-6, FFC-MP2-4
	CD103 CD5 CD19 FMC7 CD45 CD22 CD79b Chronic T-Lymphoid	
	CD4 CD8 CD3 CD56 CD7 CD16 CD2 CD57 CD45	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Haematology / Flow Cytometry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Haematology / Immunology examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Bone Marrow, Peripheral Blood, CFS, Pleural Fluid, Ascitic Fluid (cont'd)	Acute Leukaemia Screen: (cont'd) Detection of: (cont'd) Chronic Screen CD8/Kappa CD4/Lambda CD5 CD14 CD33 CD23 CD20 CD56 CD34 CD19 CD10 CD3 CD45 Acute T lymphoid CD1a CD7 CD34 CD13 CD16 CD4 CD5 CD2 CD8 CD45	Flow cytometry using DuraClone kit with Beckman Coulter T-Q Prep, Navios & microscopy SOP FFC-MP2-24, FFC-MP2-8, FFC-MP2-6, FFC-MP2-4

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Haematology	
HUMAN BODY FLUIDS (cont'd)	Haematological examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
EDTA Blood	Full Blood Count:	Sysmex XN10 & XN20 with reference to the following methods: SOP HAE-MP1-2, HAE-60RR-3,
	White blood cells, neutrophils, lymphocytes, eosinophils, monocytes, basophils, nucleated red blood cells	by fluorescence flow cytometry
	Red blood cells, platelets	by impedance
	Haemoglobin	by SLS photometry
	Mean cell volume, mean cell haemoglobin, mean cell haemoglobin concentration, red cell distribution width, immature platelet fraction	by calculation
EDTA Whole Blood	Reticulocytes	Flow cytometry using Sysmex XN10 SOP HAE-60RR-3
EDTA Blood	Blood film morphology (including malaria)	Sysmex SP50 Automated Blood Film Maker and Stainer using May Grunwald Giemsa stain SOP HAE-60RR-50, HAE-MP1-7, HAE-MP1- 8, HAE-MP1-1
EDTA Blood	Erythrocyte sedimentation rate	Starrsed Interrliner (automated) SOP HAE-MP1-9
EDTA Blood	Erythrocyte sedimentation rate	Manual method using Dispettes SOP HAE-60RR-16
EDTA Blood	Glycated Haemoglobin HbA1c	Ion-exchange HPLC using TOSOH G11 SOP HAE-60RR-4
EDTA Blood	Glycated Haemoglobin (Boronate Affinity A1c)	Boronate Affinity using Menarini Hb9210 SOP SHAE-MP2-6

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Haematology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Haematological examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
		Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia screening programme, as defined in the as defined in the Sickle cell and Thalassaemia screening programme: laboratory QA evidence requirements
Serum / Plasma	Detection of Infectious Mononucleosis Heterophile Antibody	Agglutination using BioKit Monolatex Rapid test SOP HAE-60RR-14
Plasma	Coagulation: Prothrombin Time International Normalised ratio Activated Partial Thromboplastin Time (APTT) APTT ratio Fibrinogen Thrombin D-Dimer	By light absorption using Sysmex CS5100 SOPs COAG-RF-1-113, HAE-MP1-3
Bone Marrow & Urine	Haemosiderin	Sigma Iron Stain kit followed by microscopy SOP FFC-MP2-7
Bone marrow aspirate	Film assessment & cell differential	MGG Staining kit with Sysmex RAL Stainer followed by microscopy SOP FFC-MP2-6
EDTA Blood	Detection of Sickle Cell Abnormal haemoglobin	Manual method using which Helena HBS Solubility kit SOP HAE-60RR-13
EDTA / Lithium Heparin	Identification and quantitation of Haemoglobin variants	Capillary electrophoresis using Sebia Capillarys 2 SOP SHAE-MP2-2
	Identification of Haemoglobin variants	HPLC using Menarini Hb9210 SOP SHAE-MP2-3
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procedures based on
procedures based on
nd standard methods
Beckman Coulter
sing Pointe Scientific kit 00 Spectrophotometer
sing Shimadzu UV-1800

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
LILIMANI DODY ELLIDO (contid)	Manual Biochemistry		
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified below:	
	Quantification of:	Gas chromatography mass spectrometry using Shimadzu TQ 8040 with reference to:	
Urine	Steroid profile:	SOP MCH-MP2-41	
	Androsterone (5a) Aetiocholanolone (5b) Dehydroepiandrosterone 11-hydroxyandrosterone 11-hydroxyaetiocholanolone 16-hydroxy-DHA (Pk 1) 16-hydroxy-DHA (Pk 1) Pregnanediol (Progesterone) Pregnanetriol (17-OH-Prog) Androstenetriol Tetrahydrocortisone Allo-Tetrahydrocorticosterone Tetrahydrocortisol Allo-THF Cortolone Cortolone + cortol Cortol 17-hydroxypregnanolone Pk1 17-hydroxypregnanolone Pk2 11-oxo-pregnanetriol Tetrahydro-11-Deoxycortisol Hexahydro-11-deoxycortisol 1 Hexahydro-11-deoxycortisol 2 Androstenediol Pregnenediol Pregnenetriol 16β-hydroxy-DHA (16-oxo-androstenediol) and 15,16-dihydroxy-DHA (16,18 dihydroxy-DHA (Pk 1) 16,18 dihydroxy-DHA (Pk 2) 16-hydroxy-THE 20beta-cortolone		

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Manual Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:
	Quantification of: (cont'd)	Gas chromatography mass spectrometry using Shimadzu TQ 8040 with reference to:
Urine (cont'd)	Steroid profile: (cont'd)	SOP MCH-MP2-41
	6-hydroxy-20alphacortolone 6-hydroxy-20beta-cortolone 1-hydroxy-20beta-cortolone 15,17-dihydroxypregnanolone Oestriol 3,16, 17-trihydroxy-5- pregnane-7,20-dione 6-hydroxy-tetrahydro-11- deoxycortisol	
		Liquid chromatography mass spectrometry using Shimadzu 8060:
Plasma / Serum	17-Hydroxyprogesterone	SOP MCH-MP2-54
Plasma	Metanephrines / Metadrenalines: Normetanephrine Metanephrine 3-Methoxytyramine	SOP MCH-MP2-26
Serum	Androstenedione	SOP MCH-MP2-54

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Manual Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:
Urine	Oxalate & Citrate	Spectrophotometry using Randox RX Daytona SOPs MCH-MP2-61, MCH-MP2-64 & MCH-MP2-65
Urine	Oxalate & Citrate	Spectrophotometry using IL Aries SOPs MCH-MP2-19, MCH-MP2-20 & MCH- MP2-22
Plasma	Oxalate	Spectrophotometry using Randox RX Daytona SOP MCH-MP2-61, MCH-MP2-63,
Plasma	Oxalate	Spectrophotometry using IL Aries SOPs MCH-MP2-19, MCH-MP2-21

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Manual Biochemistry (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:
Urine	Primary hyperoxaluria metabolites:	SOP MCH-MP2-25 by liquid chromatography – mass spectrometry using Shimadzu 8060
	Glycolate Glycolate: creatinine ratio Glycerate Glycerate: creatinine ratio Dihydroxyglutarate (DHG) DHG: creatinine ratio	
Renal calculi	Qualitative and semi- quantitative detection of organic and inorganic compounds	Fourier Transform Infrared Spectroscopy using Thermo Nicolet iS10 SOP MCH-MP2-24
Serum	Detection of normal and abnormal protein fractions and electrophoretic patterns	Capillary zone electrophoresis using Sebia Capillarys 3 SOP BIO-MP1-13
Serum	Quantitation of Paraproteins	SOP BIO-MP1-13
		Agarose gel electrophoresis and immunofixation using Sebia Hydrasys 2 SOP MCH-MP2-9 with reference to:
Serum / Urine	Detection of paraproteins and bence jones proteins (immunofixation)	SOP MCH-MP2-32
Urine	Quantitation of Bence Jones protein (electrophoresis)	SOP MCH-MP2-12
Serum & plasma	Lipoprotein electrophoresis (floating beta)	Lipid gel electrophoresis using Sebia Hydrasys 2 and floating beta-lipoprotein assay SOP MCH-MP2-56

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Other Protein Biochemistry	
HUMAN BODY FLUIDS (as stated)	Biochemical examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified below:
	Quantification of:	
Serum	Detection / quantification of cryoglobulins	SOP MCH-MP2-40
Serum	Creatine kinase isoenzymes	SOP MCH-MP2-11
Serum	Free light chains	Immunoturbidimetry using Optilite SOP MCH-MP2-31 and MCH-MP2-33
Serum	Prealbumin (transthyretin)	Turbidimetry using Optilite MCH-MP2-66
Urine	Total porphyrins / porphobilinogen	Spectrophotometry using Shimadzu UV-1800 SOP MCH-MP2-37, MCH-MP2-38
CSF	Haem pigments (xanthochromia)	Spectrophotometry using Shimadzu UV-1800 Spectrophotometer SOP MCH-MP2-34
Urine	Reducing substances	by colourimetry using Benedicts solution SOP MCH-MP2-39
Urine	Cystine and homocystine	using manual colourimetric method SOP MCH-MP2-14
Faeces	Faecal haemoglobin	Latex-enhanced turbidimetry using OC- Sensor Pledia SOP BIO-MP1-48
END		

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