### **Schedule of Accreditation**

issued by

### **United Kingdom Accreditation Service**

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



8169

Accredited to ISO 15189:2012

WC1H 9AJ

### **HSL (Analytics) LLP**

Issue No: 009 Issue date: 03 December 2021

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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-
Urine also	Sodium	37
Urine also	Potassium	
	Chloride	
	Quantification of:	Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1- 37
	Alanine Aminotransaminase	37
Urine also	Albumin	
	Alkaline Phosphatase	
	Alpha-1 Antitrypsin	
	Amikacin	
Urine also	Amylase	
	Angiotensin Converting Enzyme	
	Aspartate Aminotransferase	
	Bicarbonate	

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HSL (Analytics) LLP

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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)	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)	
	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)	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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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)	Quantification of: (cont'd)	Photometry method using Roche Cobas 702 SOPs WSL-AB-COB-006, TDL-AB-COB-005
	Transferrin	& WSL-QP-B-001
	Triglyceride	
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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#### Testing performed at main address only

Materials/Products tested	Type of test/Properties	Standard specifications/
iviateriais/F10uucts testeu	measured/Range of measurement	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)	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	
	Oeastradiol	
	Ferritin	
	Folate	
	Follicle Stimulating Hormone	

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Issue No: 009 Issue date: 03 December 2021

#### Testing performed at main address only

		Q
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)	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)	
	Myoglobin	
	B-Type and (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)	Quantification of: (cont'd)	Immunoassay methods using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37
	Sex Hormone-Binding Globulin	
	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;
	CA125	SOPs BIO-MP1-10
	HE4	
	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 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 also	Osmolality	Freezing Point Depression using Vitech Osmometer SOP BIO-020
Serum	Amyloid A	Immunoassay using Siemens BNII
	Apolipoproteins A1 & B	SOP MCH-002
EDTA Plasma	Homocysteine	
		Electrophoresis using Sebia Hydrasys 2
Serum	Alpha-1 Antitrypsin Phenotyping	SOP MCH-045 (focussing method)
	Alkaline Phosphatase Isoenzymes	SOP MCH-010

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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:
Faeces	Calprotectin	Immunoassay using Thermo Phadia 2500 and Calpro2 ELIA assay SOP-BIO-028
Plasma	Chromogranin A	ELISA using Dynex DS2 and Euro Diagnostica kit SOP MCH-055
EDTA Blood	Ciclosporin Tacrolimus Sirolimus	LCMSMS using Shimadzu 8050 SOP MCH-013
	Trace Metals	Mass spectrometry using Agilent ICP-MS SOP MCH-030
Serum	Copper Zinc Selenium	SOP INCH-030
Urine	Copper Zinc	
EDTA Blood or hip aspirate	Chromium Cobalt	
Urine	Metanephrines / Metadrenalines: Metanephrine Normetanephrines 3-Methoxytyramine	HPLC using Shimadzu Prominence SOP MCH-006
	5-Hydroxyindoleacetic acid (5HIAA)	SOP MCH-007
Serum	Enhanced Liver Fibrosis: Procollagen 3 Amino terminal peptide (P3NP) Hyaluronic acid (HA) Tissue inhibitor of metalloproteinase (TIMP-1)	Immunoassay using Siemens Advia Centaur SOPs MCH-056 & MCH-057
Serum	Erythropoietin	Immunoassay using Siemens Centaur SOP MCH-MP2-58

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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-047 & MCH-032
	Virology	
HUMAN BODY FLUIDS (cont'd)	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 Roche Cobas e801 SOPs WSL-AB-COB-006, TDL-AB-COB-005 & WSL-QP-B-001
	Hepatitis A IgG & IgM	& WSL-QP-B-001
	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	
	Rubella IgG	
	Syphilis Total Antibody	
Venous samples in serum tube and plasma from EDTA tubes	SARS-CoV-2 (COVID-19) IgM & IgG	Elecsys SARS-CoV-2 kit using Roche Cobas e801 SOP BIO-MP1-08
	HIV 1 & 2 Antibody and p24 Antigen	Multiplex Flow Immunoassay using Bio-Rad Bioplex SOP TDL-MAN-033

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HSL (Analytics) LLP

Issue No: 009 Issue date: 03 December 2021

#### Testing performed at main address only

Materials/Products tested	Type of test/Properties	Standard specifications/
	measured/Range of measurement	Equipment/Techniques used
	Virology (cont'd)	
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purposes of clinical diagnosis. Detection of:	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / plasma (unless otherwise stated)		Immunoassay using Abbott Architect i2000SR
	Cytomegalovirus (CMV) IgM & IgG	SOPs BIO-010 & BIO-010-Q-010
	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	
Venous samples in serum tube and plasma from EDTA tubes	SARS-CoV-2 (COVID-19) IgG	Immunoassay using Abbott Architect i2000SR SOP BIO-MP1-10
Serum / Plasma (unless	Borrelia IgM & IgG	Chemiluminescence using Diasorin Liaison
otherwise stated) (cont'd)	Epstein Barr Virus VCA IgM	XL SOP IMM-080
	EBNA IgG	
	EBV VCA-IgG	
	Hepatitis B Core Antibody	
	Hepatitis B Surface Antigen	
	Hepatitis Delta Total Antibodies	
	Herpes Simplex Virus (HSV) 1 & 2 IgG (combined)	

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### **HSL (Analytics) LLP**

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#### Testing performed at main address only

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.	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / Plasma (unless otherwise stated) (cont'd)		Chemiluminescence using Diasorin Liaison XL SOP IMM-080
	Herpes Simplex Virus (HSV) 1 & 2 IgM (combined)	SOF IIVIIVI-000
	Herpes Simplex Virus (HSV) 1 IgG	
	Herpes Simplex Virus (HSV) 2 IgG	
	Insulin-Like Growth Factor 1	
	Measles IgM & IgG	
	Mumps IgM & IgG	
	Mycoplasma IgM & IgG	
	Parvovirus IgM & IgG	
	Varicella Zoster Virus IgM & IgG	
	CMV IgG Avidity	
Serum only	CMV Avidity	Immunoassay using Biomerieux Vidas 3
	Hepatitis C Antibody	SOP IMM-042
Serum only	Borrelia IgM & IgG	
	HIV 1 & 2 Antibody and p24 Antigen	HIV 5 Duo Ultra SOP IMM-081
	HIV 1 & 2 Antibody and p24 Antigen	HIV 6 Duo Quick assay SOP IMM-062
Serum only	Syphilis	RPR using AIX-1000 SOP IMM-014

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### **HSL (Analytics) LLP**

Issue No: 009 Issue date: 03 December 2021

#### Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	<u>Immunology</u>	
Serum / plasma (unless otherwise stated)	Examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / plasma (unless stated)	Quantification of:	Immunoassay using Thermo Phadia 250 Immunocap SOP IMM-007
	Specific IgG4	
	Mast Cell Tryptase	
	Specific IgE and IgG	
Serum / plasma (unless stated)	Quantification of:	Immunoassay using Thermo Phadia 2500 Immunocap SOP IMM-007
	Allergen Specific IgE	GOT IIVIIVI GOT
	Gliadin IgG & IgA	
	Tissue Transglutamase IgA	
	Extractable Nuclear Antigen IgG	
	Sm IgG	
	Jo-1 IgG	
	Ro (SSA) IgG	
	La (SSB) IgG	
	CENP-B IgG	
	U1-RNP-IgG	
	Scl-70 lgG	
	Cyclic Citrullinated Protein IgG	
	Myeloperoxidase IgG	
	Proteinase 3 IgG	
	dsDNA IgG	

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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.	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / plasma (unless	Quantification of:	Immunoassay using Thermo Phadia 2500
stated)	Glomerular Basement Membrane IgG	Immunocap SOP IMM-007
	Beta-2 Glycoprotein IgM & IgG	
Serum (unless stated)	Quantification of:	Immunoassay using Grifols / Aesku Helios with use of the following kits and SOPs:
	Antinuclear Antibodies - IgG	AESKU (Grifols) – SOP IMM-012
	Anti-Neutrophil Cytoplasmic Antibodies - IgG	AESKU (Grifols) – SOP IMM-001
	Endomysial IgA	AESKU (Grifols) – SOP IMM-036
	Gastric Parietal Cell IgG	AESKU (Grifols) – SOP IMM-013
	Liver Kidney Microsomal IgG	AESKU (Grifols) – SOP IMM-013
	Mitochondrial IgG	AESKU (Grifols) – SOP IMM-013
	Skin IgG (Pemphigus & Pemphigoid)	AESKU (Grifols) – SOP IMM-013
	Smooth muscle IgG	Biodiagnostics – SOP IMM-013
	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) – IMM-MP2-23
	Ovarian IgG	Biodiagnostics - SOP IMM-MP2-3
	Striated Muscle IgG	AESKU (Grifols) – SOP IMM-MP2-3
	Testicular IgG	Biodiagnostics - IMM-MP2-3

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**HSL (Analytics) LLP** 

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#### 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)	Immunology (cont'd)  Examination activities for the purposes of clinical diagnosis.	Immunoassay using Manual & Helmed with EUROIMMUN immunoblot kit and Euroline scanner with reference to the following SOPs
	Scleroderma Immunoblot:	
Serum	Antibodies against:	SOP IMM-MP2-58
	ScI-70 CENP A CENP B RP11 RP155 Fibrillarin NOR90 Th/To PM-ScI100 PM-ScI75 Ku PDGFR Ro-52 Liver Immunoblot	
Serum	Antibodies against:  AMA-M2 M2-3E (BPO) Sp100 PML gp120 LKM-1 LC-1 SLA/LP Ro-52	SOP IMM-MP2-54

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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.	Immunoassay using Manual & Helmed with EUROIMMUN immunoblot kit and Euroline scanner with reference to the following SOPs
	Myositis Immunoblot	
Serum	Antibodies against:	SOP IMM-MP2-21
	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:
	Anti-Cardiolipin IgM & IgG	Orgentec – SOP IMM-MP2-13
	Hepatitis E IgM and IgG	Fortress Diagnostics – SOP IMM-MP2-62
	Helicobacter pylori IgG	Premier – SOP IMM-MP2-62
	Intrinsic Factor IgG	Orgentec – SOP IMM-MP2-8
	TB Interferon Gamma	TB Quantiferon assay - SOP IMM-MP2-27

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### **HSL (Analytics) LLP**

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#### Testing performed at main address only

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	In house documented procedures based on equipment manuals and standard methods as specified:
Serum / plasma (unless	Quantification of:	ELISA (manual) using the following kits:
stated)	Haemophilus influenzae type b antibody	Binding site – SOP IMM029
	Mannose Binding Lectin	Bioporto – SOP IMM-032
	Pneumococcal C.P. Antibodies	Binding Site – SOP IMM-033
	RNA Polymerase Antibodies	QUANTA Lite – SOP IMM-030
	Tetanus Toxoid Antibodies	Binding Site – SOP IMM-034
	TSH receptor antibodies	RSR – SOP IMM-039
Serum / plasma (unless stated)	Quantification of:	Radial immunodiffusion (manual) using Binding Site kit
	Alternative pathway (AP50)	IMM-026
	Classical Pathway (CH10)	IMM-031
	C1 Esterase Inhibitor	IMM-027

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#### Testing performed at main address only

Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Immunology (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:
Specific IgE	Immuno Solid Phase Allergy Chip and Luxscan scanner IMM-016
Syphilis antibody	Manual TPPA using Serodia kit and UV microscopy SOP IMM-077 and IMM-015
HIV 1 & 2 Antibody and p24 Antigen	Immunoassay using Geenius SOP IMM-064
HIV 1 & 2 Antibody and p24 Antigen	Immunoassay using Determine SOP IMM-063
Rheumatoid Factor	Latex agglutination using Rheumajet SOP IMM-048
Anti-Streptolysin O	Latex agglutination using Rheumajet SOP IMM-050
Herpes (HSV) 1& 2 Type specific IgG	Immunoblot using Focus Diagnostics Herpeselect 1&2 immunoblot IgG kit SOP IMM-077
	measured/Range of measurement  Immunology (cont'd)  Examination activities for the purposes of clinical diagnosis (cont'd).  Specific IgE  Syphilis antibody  HIV 1 & 2 Antibody and p24 Antigen  HIV 1 & 2 Antibody and p24 Antigen  Rheumatoid Factor  Anti-Streptolysin O  Herpes (HSV) 1& 2 Type

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#### Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Haematology / Flow Cytometry	
HUMAN BODY FLUIDS (cont'd)	Haematology / Immunology examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
Peripheral Blood	Lymphocyte subsets CD19 Natural Killer cells	Flow cytometry using Beckman Coulter Aquios SOP FFC-003
Bone Marrow, Peripheral Blood, CFS, Pleural Fluid, Ascitic Fluid	Acute Leukaemia Screen:  Detection of:  Acute Primary  CD3 CD7 CD34 CD33 CD10 CD117 CD20 CD19 HLADR CD45  Acute Intracellular  TPT MPO CD34 CD79a CD3 CD45  Acute Myeloid  CD11b CD18 CD34 CD13 CD33 CD17 CD56 CD2 CD15 CD45	Flow cytometry using DuraClone kit with Beckman Coulter T-Q Prep, Navios & microscopy FFC-002, FFC-004, FFC-008

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# United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

### **HSL (Analytics) LLP**

Issue No: 009 Issue date: 03 December 2021

#### Testing performed at main address only

Materials/Products tested	Type of test/Properties	Standard specifications/
Materials/1 reducte teeted	measured/Range of measurement	Equipment/Techniques used
	Haematology / Flow Cytometry	
HUMAN BODY FLUIDS (cont'd)	Haematology / Immunology examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
	Acute B-Lymphoid	
	Kappa Lambda CD34 CD13 CD10 CD79b CD38 CD19 CD22	
	Chronic B-Lymphoid	
	Kappa Lambda CD10 CD25 (stacked tube) CD103 CD5 CD19 FMC7 CD45 CD22 CD79b	
	Chronic T-Lymphoid	
	CD4 CD8 CD3 CD56 CD7 CD16 CD2 CD57 CD45	

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	Haematology / Flow Cytometry	
HUMAN BODY FLUIDS (cont'd)	Haematology / Immunology examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:
	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	

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	<u>Haematology</u>	
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-001
	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 WSL-AH-027
EDTA Blood	Blood film morphology (including malaria)	Sysmex SP50 Automated Blood Film Maker and Stainer using May Grunwald Giemsa stain SOP 3139
EDTA Blood	Erythrocyte sedimentation rate	Starrsed Interrliner (automated) SOP WSL-AH-006
EDTA Blood	Erythrocyte sedimentation rate	Manual method using Dispettes WSL-AH-021
EDTA Blood	Glycated Haemoglobin HbA1c	Ion-exchange HPLC using TOSOH G8 SOP WSL-AB-TOS-007
EDTA Blood	Glycated Haemoglobin (Borronate Affinity A1c)	Borronate Affinity using Menarini Hb9210 SOP SHAE-006

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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:
Serum / Plasma	Detection of Infectious Mononucleosis Heterophile Antibody	Agglutination using BioKit Monolatex Rapid test SOP WSL-AH-019
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-006, 007 & 008
Bone Marrow & Urine	Haemosiderin	Sigma Iron Stain kit followed by microscopy SOP FFC-007
Bone marrow aspirate	Film assessment & cell differential	MGG Staining kit with Sysmex RAL Stainer followed by microscopy SOP FFC-006
EDTA Blood	Detection of Sickle Cell Abnormal haemoglobin	Manual method using which Helena HBS Solubility kit SOP WSL-AH-018
EDTA / Lithium Heparin	Identification and quantitation of Haemoglobin variants	Capillary electrophoresis using Sebia Capillarys 2 SOP SHAE-002
	Identification of Haemoglobin variants	HPLC using Menarini Hb9210 SOP SHAE-003
EDTA / Lithium Heparin	G6PDH screen	Flourescent Spot Screen test using Trinity Biotech kit and Camag longwave Light Box SOP SHAE-020

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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:
EDTA Blood	Eosin 5-maleimide (Hereditary Spherocytosis Detection)	Flow Cytometry using Beckman Coulter Navios SOP SHAE-005
EDTA / Lithium Heparin	G6PD Quantitation	Spectrophotometry using Pointe Scientific kit and Shimadzu UV-1800 Spectrophotometer SOP SHAE-007
Formalin fixed tissue	Tissue Iron	Spectrophotometry using Labtech Hotblock and Shimadzu UV-1800 Spectrophotometer SOP SHAE-015
EDTA / Lithium Heparin	Pyruvate Kinase	Spectrophotometry using Shimadzu UV-1800 Spectrophotometer SOP SHAE-008

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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)	Manual Biochemistry	
(cont a)	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-044
	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 Tetrahydro-11-deoxycortisol 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-hydroxypregnenolone 6-hydroxy-THE 20beta-cortolone	

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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)	Manual Biochemistry (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-044
	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-071
Plasma	Metanephrines / Metadrenalines: Normetanephrine Metanephrine 3-Methoxytyramine	SOP MCH-026
Serum	Androstenedione	SOP MCH-071
Sonicated Tissue from Liver	Liver enzyme analysis:  Alanine:Glyoxylate aminotransferase (AGT) activity.  AGT immunoreactivity Glyoxylate reductase (GR) activity GR immunoreactivity	Using IL Aries and Shimadzu UV-1800 SOPs 46, 244, 245 & 442
Urine	Urine metabolites: (oxalate, citrate)	Using IL Aries SOPs MCH-020 and 022
Plasma	Oxalate	Using IL Aries SOP MCH-021

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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)	Manual Biochemistry (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:  U glycolate Glycolate: creatinine ratio U glycerate Glycerate:creatine ratio U hydroxyl-oxo—glutarate (HOG) U HOG: creatinine ratio U dihydroxyglutarate (DHG) U DHG:creatinine ratio	SOP MCH-025 by liquid chromatography – mass spectrometry using Shimadzu 8060
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 BIO19
Serum	Quantitation of Paraproteins	SOP BIO-19
		Agarose gel electrophoresis and immunofixation using Sebia Hydrasys 2 with reference to:
Serum / Urine	Detection of paraproteins and bence jones proteins (immunofixation)	SOP MCH-033
Urine	Quantitation of Bence Jones protein (electrophoresis)	SOP MCH-012

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
HUMAN BODY FLUIDS (as stated)	Other Protein Biochemistry  Biochemical examination activities for the purposes of clinical diagnosis.  Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Detection / quantification of cryoproteins	SOP MCH-043	
Serum	Creatine kinase isoenzymes	SOP MCH-011	
Serum	Free light chains	Immunoturbidimetry using Optilite SOP MCH-032 and 034	
Sweat	Chloride	olourimetry using Wescor SOP MCH-037	
Urine	Total porphyrins / porphobilinogen	Spectrophotometry using Shimadzu UV-1800 SOP MCH-038	
CSF	Haem pigments (xanthochromia)	Spectrophotometry using Shimadzu UV-1800 Spectrophotometer SOP MCH-074	
Urine	Reducing substances	SOP 428 by colourimetry using Benedicts solution	
Urine	Cysteine and homocysteine	SOP MCH-014 using manual colourimetric method	
END			

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