

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL <b>25821</b></p> <p>Accredited to ISO 15189: 2022</p>	<h3>Harley Street Pathology Services Limited</h3> <p><b>Issue No: 004    Issue date: 10 June 2025</b></p>	
	<p><b>134-136 Harley Street</b> <b>London</b> <b>W1G 7JY</b></p>	<p><b>Contact: Sonal Parikh</b> <b>Tel: +44 (0) 77 34705973</b> <b>E-Mail: Sonal@hspathology.com</b> <b>Website: <a href="https://hspathology.com/">https://hspathology.com/</a></b></p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:
		Roche Cobas Pure Analyser HS BIO SOP-01
		Roche Cobas Pure c302
		Photometric chemistry methods:
Serum	Alanine Aminotransferase (ALT)	HS BIO SOP-5
Serum	Albumin	HS BIO SOP-2
Serum	Alkaline Phosphatase (ALP)	HS BIO SOP-4
Serum	Aspartate Aminotransferase (AST)	HS BIO SOP-21
Serum	Bilirubin	HS BIO SOP-22
Serum	Calcium	HS BIO SOP-23
Serum	Cholesterol	HS BIO SOP-24
Serum	C-reactive protein	HS BIO SOP-26
Serum	Creatinine	HS BIO SOP-25
Serum	Gamma Glutamyl transferase (GGT)	HS BIO SOP-27
Serum	Glucose	HS BIO SOP-29
Serum	High Density Lipoproteins (HDL)	HS BIO SOP-30
Serum	Immunoglobulin A (IgA)	HS BIO SOP-31
Serum	Immunoglobulin G (IgG)	HS BIO SOP-32
Serum	Immunoglobulin M (IgM)	HS BIO SOP-33
Serum	Iron	HS BIO SOP-34
Serum	Magnesium	HS BIO SOP-36
Serum	Phosphate	HS BIO SOP-37
Serum	Total protein	HS BIO SOP-39
Serum	Transferrin	HS BIO SOP-40
Serum	Triglycerides	HS BIO SOP-41
Serum	Unsaturated Iron-binding Capacity	HS BIO SOP-42
Serum	Urea	HS BIO SOP-43



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:
Serum	Chloride	Roche Cobas Pure c303 Indirect Ion Selective Electrode methods
Serum	Potassium	HS BIO SOP-35
Serum	Sodium	HS BIO SOP-35 HS BIO SOP-35
Serum	Anti-Mullerian Hormone (AMH)	Roche Cobas Pure e402 Electrochemiluminescence (ECL)
Serum	Oestradiol	HS BIO SOP-20
Serum	Ferritin	HS BIO SOP-7
Serum	Folate	HS BIO SOP-8
Serum	Free T3 (FT3)	HS BIO SOP-9
Serum	Free T4 (FT4)	HS BIO SOP-11
Serum	Follicle Stimulating Hormone (FSH)	HS BIO SOP-12
Serum	β HCG	HS BIO SOP-10
Serum	Luteinising Hormone (LH)	HS BIO SOP-13
Serum	Progesterone	HS BIO SOP-14
Serum	Prolactin	HS BIO SOP-16
Serum	Testosterone	HS BIO SOP-15
Serum	Thyroid Stimulating Hormone (TSH)	HS BIO SOP-17
Serum	Vitamin B12	HS BIO SOP-18
Serum	Vitamin D	HS BIO SOP-6 HS BIO SOP-19
EDTA blood	<u>Haematology examination activities for the purposes of clinical diagnosis</u> Full blood count	Manufacturer's instructions and documented In-house methods using:  Sysmex XN-450 Analyser: DC detection, SLS method, flow cytometry & fluorescence flow cytometry HS HAEM SOP-01 HS HAEM SOP-2



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:
High Vaginal Swabs (HVS) Semen Urine	General isolation and characterisation of micro-organisms of clinical significance	Manual culture and Identification of: <ul style="list-style-type: none"> <li>Gram-negative, oxidase-negative bacilli using selective, non-selective and chromogenic culture media, RapID system (Thermo Scientific) and</li> <li>Beta-haemolytic streptococci groups A-G using ProLab Streptococcus grouping kit routine biochemical and latex antigen detection reagents</li> </ul> Manual culture of Candida spp. HS MIC SOP-7 HS MIC SOP-8
Bacterial isolates as isolated above on solid culture medium from HVS, semen and urine samples	Antimicrobial sensitivity testing	EUCAST manual disc sensitivity testing HS MIC SOP-14
HVS	Examination for Bacterial Vaginosis	Light microscopy of Gram-stained slides using Hays criteria HS MIC-SOP-7
Urine	Quantification of white cells, red cells and bacteria	Manual light microscopy HS MIC SOP-8



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HUMAN BODY FLUIDS (cont'd)	<p><u>Virology examination activities for the purposes of clinical diagnosis</u></p> <p><u>Serology:</u></p> <p>Anti-HBc CMV IgG HBsAg HIV-1 Ab HIV-2 Ab HIV Ag (p24) Anti-HCV Syphilis IgG, IgM Toxoplasma IgM Rubella IgG CMV IgM HTLV I and II</p> <p>Molecular virology:</p>	<p>Manufacturer's instructions and documented In-house methods using:</p> <p>Roche Cobas Pure Analyser: Electro-chemiluminescence (ECL) measuring system. HS BIO SOP-1</p> <p>HS SER VIR SOP-13 HS SER VIR SOP-4 HS SER VIR SOP-14 HS SER VIR SOP-11 HS SER VIR SOP-11 HS SER VIR SOP-11 HS SER VIR SOP-12 HS SER VIR SOP-8 HS SER VIR SOP-9 HS SER VIR SOP-6 HS SER VIR SOP-2 HS SER VIR SOP-5</p> <p>Real time PCR using the Hologic Panther</p>
Urine	Detection of <i>Chlamydia trachomatis</i> (CT) and <i>Neisseria gonorrhoea</i> (NG) RNA	HS MOL SOP-01 using the Hologic Aptima Combo II kit
Thin prep liquid-based cytology specimens	Detection of HPV mRNA	HS MOL SOP-5 using the Hologic Aptima HPV Assay kit
END		