

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 21351 Accredited to ISO 15189:2022</p>	<p align="center">Alderley Lighthouse Labs Ltd</p> <p align="center">Issue No: 005 Issue date: 12 March 2025</p>	
	<p>Highfield House Cheadle Royal Business Park Cheadle SK8 3GY</p>	<p>Contact: Kate Elson Tel: +44 (0)777 835 0634 E-Mail: kate@alderleylighthouselabs.com Website: www.alderleylighthouselabs.com</p>
<p align="center">Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Venous and Capillary Serum</p> <p>Combined Nose and Throat Swab in Virus Transport Medium</p> <p>Genital swabs, Urine and Diagnostic Tampons</p>	<p><u>Molecular Virology examination activities for the purpose of clinical diagnosis</u></p> <p>SARS-CoV-2 (COVID-19) total antibody (IgG/IgM)</p> <p>SARS-CoV-2 (COVID-19) spike total antibody (quantitative)</p> <p>Detection of SARS-CoV-2 virus RNA (COVID-19); specific gene sequences ORF1ab, N & S</p> <p>Detection of</p> <p>Neisseria Gonorrhoeae</p> <p>Chlamydia Trachomatis</p> <p>Trichomonas Vaginalis</p> <p>Mycoplasma Genitalium</p>	<p>In-house documented procedures incorporating manufacturers' instructions</p> <p>Using Cobas e801 and Elecsys anti-SARS-CoV-2 S assay and anti-SARS-CoV-2 AB assay SER-SOP-1</p> <p>Automated nucleic acid extraction and Real-Time PCR using: LAB-SOP-003, LAB-SOP-006 and: ThermoFisher Flex extraction platform MagMax viral/pathogen isolation kit Quant Studio7 Real-Time PCR System Applied Biosystems TaqPath COVID-19 CE-IVD RT-PCR kit</p> <p>ThermoFisher Quant Studio 5 PCR multiplex screening utilising Kingfisher extraction method MD-SOP-24 Operation, calibration and maintenance of the QuantStudio 5 thermocycler</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions
Genital swabs, Urine and Diagnostic Tampons	Detection of: Neisseria Gonorrhoeae Chlamydia Trichomonas Vaginalis Mycoplasma Genitalium Ureaplasma Urealyticum Ureaplasma Parvum Mycoplasma Hominis High risk HPV	Thermofisher Quant Studio 7 PCR multiplex screening utilising Kingfisher extraction method MD-SOP-27 PCR Analysis of STI's using Bosphore STD Bundle Kits
Blood Serum/Plasma	Electrochemiluminescence testing for the detection of: Hepatitis B surface antigen (HBsAg) Hepatitis B surface antibody (Anti HBs) Hepatitis B core antibody (Anti HBc) Hepatitis C antibody (Anti HCV) Hepatitis A IgM antibody Hepatitis A total antibody HIV Ag/Ab Combo (Anti HIV1/2 and HIV1p24 Ag) Syphilis total antibody	Roche Cobas Pro e801 analyser. Immunoassay by electrochemiluminescence. BS-SOP-02 Cobas Pro Operational SOP



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Serum/Plasma Venous/Capillary unless otherwise stated	Biochemistry examination activities for the purpose of clinical diagnosis Electrochemiluminescence testing for the quantification of	Roche Cobas Pro analyser. Immunoassay by electrochemiluminescence. BS-SOP-02 Cobas Pro Operational SOP
Venous	TSH FT3 FT4 Folate Vitamin B12 Active B12 Vitamin D Anti TPO Anti Tg Prolactin DHEAS Free PSA Cortisol Free T3 Active B12 Free Androgen Index Free Testosterone	E801
Venous		
Capillary Capillary Capillary Capillary		Calculation Calculation
Serum/Plasma Venous/Capillary unless otherwise stated	Biochemistry examination activities for the purpose of clinical diagnosis Electrochemiluminescence testing for the quantification of	Roche Cobas Pro analyser. Immunoassay by electrochemiluminescence. BS-SOP-02 Cobas Pro Operational SOP
Venous	Testosterone SHBG FSH LH Progesterone AMH Oestradiol TPSA FPSA Cortisol	
Venous		



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Serum/Plasma Venous/Capillary unless otherwise stated	Spectrophotometric testing for the quantification of:	Roche Cobas Pro analyser. Spectrophotometry BS-SOP-02 Cobas Pro Operational SOP ISE
Venous	Sodium Potassium Urea Creatinine Total Bilirubin Albumin Total Protein ALT ALP GGT Cholesterol Triglycerides HDL LDL (Calculated) Calcium Phosphate Magnesium Iron Transferrin Ferretin CRP HS-CRP Apolipoprotein A Apolipoprotein B AST Copper Zinc UIBC Creatine Kinase Uric Acid CRP Hs-CRP eGFR Non-HDL Cholesterol: HDL Ratio Globulin TIBC Transferrin Saturation	C503
Venous/Capillary Blood	Quantitative determination of glycated haemoglobin (HbA1c)	Calculation Calculation Calculation Calculation Calculation Calculation Abbott Afinion 2 HbA1c analyser and Sebia Capillarys Flex 2 BS-SOP-11 Abbott Affinion 2 SOP BS-SOP-13 HbA1c analysis on Sebia Capillarys 2



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Venous and capillary blood	<u>Haematology examination activities for the purpose of clinical diagnosis</u> Full Blood Count testing for the quantification of: White Blood Cells Lymphocyte count Monocyte count Neutrophil count Eosinophil count Basophil count Red Blood Cells Haemoglobin Haematocrit Mean Corpuscular Volume Mean Corpuscular Haemoglobin Mean corpuscular haemoglobin concentration Red blood cell distribution width/SD Platelet count Mean platelet volume	Beckman DX520 FBC analyser BS-SOP-05 Running and maintenance of DX520
END		