

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



10641

Accredited to
ISO 15189:2022

Inuvi Diagnostics Limited

Issue No: 015 Issue date: 27 March 2025

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Location details		Activity	Location code
Address Unit E1 Churcham Business Park Churcham Gloucestershire GL2 8AX	Local Contact Sarah Fryer	Biochemistry	E1



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	
	Quantitative analysis of:	Beckman Coulter AU/700 SOP 7.2.1.5	
Venous plasma	Glucose	Hexokinase	
Venous and Capillary Whole Blood (EDTA & Heparin)	HbA1c	Turbidimetric immuno-inhibition	
	Quantitative analysis of:	Cobas c503 analyser SOP 7.5.4	
Venous and Capillary Serum	Albumin	BCG	
Venous and Capillary Serum	ALP	IFCC	
Venous and Capillary Serum	ALT	IFCC	
Venous and Capillary Serum	APOA	Immunoturbidmetric	
Venous and Capillary Serum	APOB	Immunoturbidmetric	
Venous and Capillary Serum	Bilirubin – Total	Diazo	
Venous and Capillary Serum, and Plasma	Cholesterol – Total	Cholesterol oxidase	
Venous and Capillary Serum	Creatinine – Enzymatic	Enzymatic	
Venous and Capillary Serum	CRP – hs	Immunoturbidmetric	
Venous and Capillary Serum	Ferritin	Immunoturbidmetric	
Venous and Capillary Serum	GGT	IFCC	
Venous and Capillary Serum, and Plasma	HDL	Enzymatic	
Venous and Capillary Serum	Iron	Colourmetric	
Venous Serum	LDH	IFCC	
Venous and Capillary Serum	Total Protein	Colourmetric	
Venous and Capillary Serum, and Plasma	Triglyceride	Enzymatic	
Venous and Capillary Serum	Uric Acid	Enzymatic	
Venous and Capillary Serum	UIBC	Ferrozine	
Venous and Capillary Serum	Urea	Kinetic	
Venous Serum	ISE (Cl, Na, K)	Indirect ISE	
Venous Serum	AST	IFCC	
Venous Serum	Calcium	NM-BAPTA	
Venous Serum	Creatine Kinase	UV	
Venous Plasma	Glucose	UV Hexokinase	
Venous Serum	Magnesium	Colourmetric	
Venous and Capillary Serum	Lipoprotein A	Immunoturbidmetric	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum Venous and Capillary Serum	Quantitative analysis of: Vitamin D Active Vitamin B12 Sex Hormone Binding Globulin (SHBG) Oestradiol Prolactin Follicle Stimulating Hormone (FSH) Luteinising Hormone (LH) Vitamin B12 Progesterone Free T3 Testosterone (including dilution) Folate TSH Free T4 Thyroglobulin Antibodies Thyroid Peroxidase Antibodies Total T4 ProBNP	Cobas e801 analyser SOP 7.5.4 Electrochemiluminescence Immunoassay (ECLIA)	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Venous Serum Venous and Capillary Serum Venous and Capillary Serum	Quantitative analysis of: (cont'd) Cortisol DHEA-S PSA	Cobas e801 analyser SOP 7.5.4 Electrochemiluminescence Immunoassay (ECLIA)	
Venous and Capillary Serum	Quantitative analysis of: AMH	Beckman Access 2 analyser SOP 7.3.1 Immunoenzymatic Chemiluminescent	
Venous and Capillary Serum	Flexible Scope Biochemical compounds	Flexible scope protocols: Biochemistry analytes and cancer markers using Roche Cobas e503 and e801. Materials or products tested: Serum (venous and/or capillary) using manufacturer validated and CE marked kits. As limited by Document ID 2.02.	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	By calculation	
Venous & Capillary Serum	Globulins LDL Cholesterol Non-HDL Cholesterol Total Iron Binding Capacity (TIBC) Transferrin Saturation Estimated Glomerular Filtration Rate (eGFR) (CK-EPI) Adjusted Calcium Free Testosterone Free Androgen Index		
	<u>Serological examination activities for the purpose of clinical diagnosis:</u>		
	<u>Virology</u> HIV I and II and P24 Ag	Beckman Access 2 analyser SOP 7.3.1 Immunoenzymatic Chemiluminescent	
	Hep C Antibodies Hep B surface Antigen Hep B Surface Antibodies Hep B Core Antibodies		
Venous Serum	Rubella IgG Antibodies	Roche Cobas e801 analyser SOP 7.5.4	
Venous Serum	Measles IgG Antibodies Mumps IgG Antibodies Varicella Zoster IgG Antibodies	Dynex DS2 ELISA platform SOP 7.6.1	



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Venous and Capillary Serum	Flexible Scope Virology/serology analytes	Flexible scope protocols: Virology/serology analytes using Beckman Access 2, Roche Cobas c503 and e801 and Dynex DS2. Materials or products tested: Serum (venous and/or capillary) using manufacturer validated and CE marked kits. As limited by Document ID 2.02.	
Whole Blood, Venous and Capillary	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> Full Blood Count Haemoglobin White Blood Cell Count Red Blood Count Platelet Count Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Corpuscular haemoglobin concentration Red cell distribution width-CV Mean Platelet Volume Platelet Distribution Width Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count	Horiba Yumizen 1500/550 Analyser using impedance, cytochemistry and absorbance SOPs: 7.2.3.3 and 7.2.3.4	
END			