

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9329

Accredited to
ISO 15189:2022

Randox Laboratories Limited trading as Randox Clinical Laboratory Services (RCLS)

Issue No: 015 Issue date: 03 June 2025

Randox Science Park
Randalstown Road
Antrim
Co. Antrim
BT41 4LP

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Website: www.randox.com

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Randox Science Park Randalstown Road Antrim BT41 4LP	Local contact Emma.mcgoldrick@randox.com	Haematology testing Biochemistry testing Microbiology testing Virology testing Molecular Genetics Supporting technical & management system activities	A
Address Randox Warrington Cube Laboratory Unit 2 Bishops Court Warrington WA2 8QY	Emma.mcgoldrick@randox.com	Haematology testing Biochemistry testing	B



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES	<u>Haematology – Coagulation</u>		
	Examination activities for the purposes of clinical diagnosis		
Plasma	Quantitative measurement of: Concizumab	Manual ELISA using ConcizuTrace ELISA kit using SpectraMax ABS Microplate Spectrophotometer or Biotex ELX 800 Spectrophotometer SOP RCL-3688	A
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		
Serum	Quantification of:	In house method performed on Randox Imola analyser colorimetric, direct ISE and immunoassay detection	
	Albumin		A, B
	HDL-Cholesterol		A, B
	LDL-Cholesterol		A, B
	Total Cholesterol		A, B
	Cystatin C		A, B
	Total Iron Binding Capacity		A, B
	Iron		A, B
	Ferritin		A, B
	Calcium		A, B
	Phosphate		A, B
	Magnesium		A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)		
Serum (cont'd)	Quantification of: (cont'd)	In house method performed on Randox Imola analyser colorimetric, direct ISE and immunoassay detection	
	Total Protein		A, B
	Triglycerides		A, B
	Aspartate Aminotransferase (AST)		A, B
	Alanine Aminotransferase (ALT)		A, B
	Rheumatoid Factor		A, B
	Gamma-Glutamyl transferase		A, B
	Lactate Dehydrogenase (LDH)		A, B
	Creatinine		A, B
	Transferrin		A, B
	Complement 4		A, B
	Urea		A, B
	Uric Acid		A, B
	Lipoprotein A (LPA)		A, B
	Creatinine Kinase - -Nac		A, B
	Apolipoprotein B (APO-B)		A, B
	C-Reactive Protein (CRP)		A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)		
Serum (cont'd)	Quantification of: (cont'd)	In house method performed on Randox Imola analyser colorimetric, direct ISE and immunoassay detection	
	Total Bilirubin		A, B
	Direct Bilirubin		A
Plasma	Quantification of:	In house method performed on Randox Imola analyser by glucose oxidase / dehydrogenase	
	Glucose		A, B
Whole Blood	HbA1c	By high performance liquid chromatography using TOSOH G11 SOP RCL-4199	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u>		
Whole blood	Quantification of Full Blood Count: Basophils Eosinophils HCT Haemoglobin Lymphocytes Mean Cell Haemoglobin Mean Cell Haemoglobin Count Mean Cell Volume Monocytes Neutrophils Platelets Red Blood Cells White Blood Cells	In house method performed on Sysmex XN-550 analyser. Methodologies include flow cytometry and hydrodynamic focussing on	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>		
Urine and Genital swabs	Detection of DNA for: Chlamydia trachomatis Neisseria gonorrhoea Herpes simplex I Herpes simplex II Treponema pallidum Mycoplasma genitalium Mycoplasma hominis Trichomonas vaginalis Ureaplasma urealyticum Haemophilus ducreyi	In house extraction using Kingfisher Flex and Veriti thermal cyclor Analysis performed on Randox Evidence Investigator using STI multiplex PCR array	A
Serum	HIV 1 & 2 antibody & p24 antigen Hepatitis B Surface Antigen Hepatitis C antibody Syphilis antibody	Immunoassay using Roche Cobas 8000 & e801 module SOP RCL-3597	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Genetics</u>		
gDNA extracted externally or gDNA extracted in-house	Examination activities for the purposes of clinical diagnosis Detection of Single Nucleotide Variants (SNVs) and Copy Number Variation (CNVs)	In-house extraction using MagMAX Ultra v 2 kit and Kingfisher Flex Library Preparation using Illumina DNA Prep with Enrichment with TruSight Cancer/Cardio Oligos Sequencing by MiSeq using MiSeq Reagent kit v 2 or Nextseq 2000P1 reagent kit) Analysis of virtual panels using Sopia DDM or Fabric Enterprise bioinformatics software.	A
gDNA extracted externally or gDNA extracted in-house	Generation of QC checked FASTQ files from Whole Exome	In-house extraction using MagMAX Ultra v 2 kit and Kingfisher Flex Library Preparation using Illumina DNA Prep with Enrichment using Twist Bioscience Oligos for Illumina Exome 2.5 Panel (exome). Sequencing by NovaSeq with NovaSeq6000 SP reagent kit. FASTQ file generation using Illumina BaseSpace.	A
gDNA from Fecal or Saliva samples extracted externally or in-house	Generation of QC checked FASTQ files	In-house extraction using MagMAX Ultra v 2 kit and Kingfisher Flex Shotgun Metagenomic Library Preparation using Shotgun Metagenomics Illumina Library Pooling and Next Seq 2000 or Nova Seq 6000. FASTQ file generation using Illumina BaseSpace	A
END			