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

Co. Antrim

BT41 4LP

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

Issue No: 014 Issue date: 31 March 2025

Randox Science Park Contact: Emma McGoldrick
Randalstown Road Tel: +44 (0) 28 9442 2413

Antrim E-Mail: emma.mcgoldrick@randox.com

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	В

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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	Haematology - Coagulation		
	Examination activities for the purposes of clinical diagnosis		
Plasma	Quantitative measurement of: Concizumab	ELISA testing using Randox Concizumab ELISA and plate reader Biotex ELX 800 SOP RCL- 3688	A
HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis		
Serum	Quantification of:	In house method performed on Randox Imola analyser colorimetric, direct ISE and immunoassay detection	
	Albumin	immunoassay detection	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
			I.

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)		
Serum (cont'd)	Quantification of: (cont'd)	In house method performed on Randox Imola analyser colorimetric, direct ISE and	
	Total Protein	immunoassay detection	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)		А, В
	Creatinine		A, B
	Transferrin		A, B
	Complement 4		A, B
	Urea		A, B
	Uric Acid		А, В
	Lipoprotein A (LPA)		A, B
	Creatinine KinaseNac		A, B
	Apolipoprotein B (APO-B)		A, B
	C-Reactive Protein (CRP)		A, B

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (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	minunoassay detection	A, B
	Direct Bilirubin		А
Plasma	Quantification of:	In house method performed on Randox Imola analyser by glucose	
	Glucose	oxidase / dehydrogenase	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)	Haematology examination activities for the purpose of clinical diagnosis		
Whole blood		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)	Microbiological examination activities for the purpose of clinical diagnosis		
Urine and Genital swabs	Detection of DNA for:	In house extraction using Kingfisher Flex and Veriti thermal cycler	A
	Chlamydia trachomatis	Analysis performed on Randox Evidence Investigator using STI multiplex PCR array	
	Neisseria gonorrhoea Herpes simplex I Herpes simplex II Treponema pallidum Mycoplasma genitalium Mycoplasma hominis Trichomonas vaginalis Ureaplasma urealyticum Haemophilus ducreyi		
Serum	HIV 1 & 2 antibody & p24 antigen	Immunoassay using Roche Cobas 8000 & e801 module SOP RCL-3597	A
	Hepatitis B Surface Antigen Hepatitis C antibody		
	Syphilis antibody		

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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)	Molecular Genetics Examination activities for the purposes of clinical diagnosis		
gDNA extracted externally or gDNA extracted in- house	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			

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