

# 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: 017 Issue date: 01 October 2025

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

Contact: Emma McGoldrick  
Tel: +44 (0) 28 9442 2413  
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 |
|--|--|--|---------------|
| <b>Address</b><br>Randox Science Park<br>Randalstown Road<br>Antrim<br>BT41 4LP                            | <b>Local contact</b><br>Emma.mcgoldrick@randox.com | Haematology testing<br>Biochemistry testing<br>Microbiology testing<br>Virology testing<br>Molecular Genetics<br>Supporting technical & management system activities | A             |
| <b>Address</b><br>Randox Warrington Cube Laboratory<br>Unit 2<br>Bishops Court<br>Warrington<br>WA2 8QY    | Emma.mcgoldrick@randox.com                         | Haematology testing<br>Biochemistry testing<br>Microbiology testing  | B             |
| <b>Address</b><br>Randox Laboratories<br>Unit D&E<br>Time Place<br>21 Corrig Road<br>Dublin 18<br>D18 R89T | Emma.mcgoldrick@randox.com                         | Haematology testing<br>Biochemistry testing<br>Virology testing  | C             |
| <b>Address</b><br>Randox Laboratories<br>143-149 Great Portland Street<br>London<br>W1W 6QN                | Emma.mcgoldrick@randox.com                         | Haematology testing<br>Biochemistry testing<br>Virology testing  | D             |



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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, C, D    |
|                           | HDL-Cholesterol  |  | A, B, C, D    |
|                           | LDL-Cholesterol  |  | A, B, C, D    |
|                           | Total Cholesterol  |  | A, B, C, D    |
|                           | Cystatin C   |  | A, B, C, D    |
|                           | Total Iron Binding Capacity  |  | A, B, C, D    |
|                           | Iron   |  | A, B, C, D    |
|                           | Ferritin   |  | A, B, C, D    |
|                           | Calcium  |  | A, B, C, D    |
|                           | Phosphate  |  | A, B, C, D    |
|                           | Magnesium  |  | A, C, D       |



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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 Protein   |   | A, B          |
|                            | Triglycerides   |   | A, B, C, D    |
|                            | Aspartate Aminotransferase (AST)  |   | A, B, C, D    |
|                            | Alanine Aminotransferase (ALT)  |   | A, B, C, D    |
|                            | Rheumatoid Factor   |   | A, B, C, D    |
|                            | Gamma-Glutamyl transferase  |   | A, B, C, D    |
|                            | Lactate Dehydrogenase (LDH)   |   | A, B          |
|                            | Creatinine  |   | A, B, C, D    |
|                            | Transferrin   |   | A, B, C, D    |
|                            | Complement 4  |   | A, B, C, D    |
|                            | Urea  |   | A, B, C, D    |
|                            | Uric Acid   |   | A, B, C, D    |
|                            | Lipoprotein A (LPA)   |   | A, B, C, D    |
|                            | Creatinine Kinase - -Nac  |   | A, B, C, D    |
|                            | Apolipoprotein B (APO-B)  |   | A, B, C, D    |
|                            | C-Reactive Protein (CRP)  |   | A, B, C, D    |



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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 | A, B, C, D    |
|                            | Total Bilirubin   |   | A             |
|                            | Direct Bilirubin  |   | A             |
| Plasma                     | Quantification of:  | In house method performed on Randox Imola analyser by glucose oxidase / dehydrogenase                 | A, B, C, D    |
|                            | Glucose   |   | A, B, C, D    |
| Whole Blood                | HbA1c   | By high performance liquid chromatography using TOSOH G11<br>SOP RCL-4199                             | A             |
| Serum                      |   | Immunoassay using Roche Cobas 8000 & e801 module<br>SOP RCL-3597                                      | A, B, C, D    |
|                            | Oestradiol  |   |               |
|                            | Follicle Stimulating Hormone (FSH)  |   |               |
|                            | Luteinising Hormone (LH)  |   |               |
|                            | Progesterone  |   |               |
|                            | Prolactin   |   |               |
|                            | Testosterone  |   |               |
|                            | Sex Hormone Binding Globulin (SHBG)   |   |               |
|                            | Thyroid Stimulating Hormone (TSH)   |   |               |
|                            | Free Triiodothyronine (FT3)   |   |               |
|                            | Free Thyroxine (FT4)  |   |               |
|                            | Anti-Thyroglobulin Antibodies   |   |               |
|                            | Anti-Thyroid Peroxidase Antibodies  |   |               |



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



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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:<br><br>Chlamydia trachomatis<br>Neisseria gonorrhoea<br>Herpes simplex I<br>Herpes simplex II<br>Treponema pallidum<br>Mycoplasma genitalium<br>Mycoplasma hominis<br>Trichomonas vaginalis<br>Ureaplasma urealyticum<br>Haemophilus ducreyi | In house extraction using Kingfisher Flex and Veriti thermal cycler<br><br>Analysis performed on Randox Evidence Investigator using STI multiplex PCR array | A             |
| Serum                      | HIV 1 & 2 antibody & p24 antigen<br>Hepatitis B Surface Antigen<br><br>Hepatitis C antibody<br><br>Syphilis antibody   | Immunoassay using Roche Cobas 8000 & e801 module<br>SOP RCL-3597  | A, C, D       |
| Urine                      | Detection of DNA for Chlamydia trachomatis & Neisseria gonorrhoea  | PCR using Roche Cobas 6800<br>SOP RCL-4208  | B             |



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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<br><br>Detection of Single Nucleotide Variants (SNVs) and Copy Number Variation (CNVs) | In-house extraction using MagMAX Ultra v 2 kit and Kingfisher Flex<br><br>Library Preparation using Illumina DNA Prep with Enrichment with TruSight Cancer/Cardio Oligos<br><br>Sequencing by MiSeq using MiSeq Reagent kit v 2 or Nextseq 2000P1 reagent kit)<br><br>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<br><br>Library Preparation using Illumina DNA Prep with Enrichment using Twist Bioscience Oligos for Illumina Exome 2.5 Panel (exome).<br><br>Sequencing by NovaSeq with NovaSeq6000 SP reagent kit. FASTQ file generation using Illumina BaseSpace.  | A             |
| gDNA from Faecal 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<br><br>Shotgun Metagenomic Library Preparation using Shotgun Metagenomics Illumina Library Pooling and Next Seq 2000 or Nova Seq 6000.<br><br>FASTQ file generation using Illumina BaseSpace  | A             |
| END   |  |  |               |