


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 9329 Accredited to ISO/IEC 17025:2017	<b>Randox Laboratories Limited trading as Randox Clinical Laboratory Services (RCLS)</b>	
	Issue No: 009 Issue date: 29 June 2022	
	<b>Randox Science Park Randalstown Road Antrim Co. Antrim BT41 4LP</b>	<b>Contact: Rebecca Ennis Tel: +44 (0) 28 9442 2413 E-Mail: <a href="mailto:Rebecca.ennis@randox.com">Rebecca.ennis@randox.com</a> Website: <a href="http://www.randox.com">www.randox.com</a></b>
<b>Testing performed by the Organisation at the locations specified</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
RCLS Randox Science Park Randalstown Road Antrim Co. Antrim BT41 4LP	Local Contact Rebecca Ennis or  Lauren McDowell <a href="mailto:Lauren.McDowell@randox.com">Lauren.McDowell@randox.com</a>	Testing  A
RCLS Holywood 2 Redburn Square, Holywood, Co. Down, BT18 9HZ	Local Contact Rebecca Ennis or  Lauren McDowell <a href="mailto:Lauren.McDowell@randox.com">Lauren.McDowell@randox.com</a>	Testing  C
RCLS Liverpool, 25-31 Tithebarn Street, Liverpool L2 2QP	Local Contact Rebecca Ennis or  Lauren McDowell <a href="mailto:Lauren.McDowell@randox.com">Lauren.McDowell@randox.com</a>	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 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, D
	HDL-Cholesterol		A, C, D
	LDL-Cholesterol		A, C, D
	Total Cholesterol		A, C, D
	Cystatin C		A
	Total Iron Binding Capacity		A, D
	Iron		A, C, D
	Ferritin		A
	Calcium		A, C, D
	Phosphate		A, C, D
	Magnesium		A,, C
	Sodium		A, C
	Potassium		A, C, D
	Total Protein		A
	Chloride		A, C
	Triglycerides		A, C, D



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		
Serum	Quantification of		
	Asparate Aminotransferase (AST)		A, C, D
	Alanine aminotransferase (ALT)		A, C, D
	Rheumatoid Factor		A, C
	Gamma-Glutamyl transferase		A, C, D
	LDH		A
	Creatinine		A, C, D
	Transferrin		A, D
	Complement 3		A, D
	Complement 4		A, B, D
	IgG		D
	Urea		A, C
	Uric Acid		A, C
	LPA		A
	CK-Nac		A, C
	APO-1		D
	APO-B		A, D



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		
Serum	Quantification of CRP Total Bilirubin Direct Bilirubin		A, C A, D A,
Serum	<u>Quantitative endocrinology</u>  Cortisol Thyroid Stimulating Hormone	In house method performed on Immulite analyser. Using immunoassay detection	A
Plasma	Quantification of  Glucose	In house method performed on Randox Imola analyser by glucose oxidase / dehydrogenase	A, C



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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  Urine	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>  <u>In vitro semiquantitative determination of</u>  <u>Bilirubin</u>  <u>Glucose</u>  <u>Ketones</u>  <u>Nitrite</u>  <u>pH</u>  <u>Protein</u>  <u>Red Blood Cells</u>  <u>Leucocytes</u>  <u>Urobilinogen</u>  <u>White Blood cells</u>  <u>Specific Proteins</u>	In house method using the Roche Urisys 1100 instrument using reflectance photometry	A, C, D



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUID	<u>Haematology examination activities for the purpose of clinical diagnosis</u>		
Whole blood	Full blood count (FBC)	In house method performed on Sysmex analyser. Methodologies include flow cytometry and hydrodynamic focussing on C, D - Sysmex XN-550 A, B - Sysmex XS-1000i	A, C, D
	Basophils		
	Eosinophils		
	HCT		
	Haemoglobin		
	Lymphocytes		
Whole blood	Mean Cell Haemoglobin		
	Mean Cell Haemoglobin Count		
	Mean Cell Volume		
	Monocytes		
	Neutrophils		
	Platelets		
	Red Blood Cells		
	White Blood Cells		
	Red Cell Distribution Width	A	



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### Radox Laboratories Limited trading as Radox Clinical Laboratory Services (RCLS)

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUID  Urine and Genital swabs	Microbiological examination activities for the purpose of clinical diagnosis  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  Virology examination activities for the purpose of clinical diagnosis	In house method performed on Radox Evidence Investigator using STI multiplex PCR array – Maxwell 48 extraction platforms and veriti thermal cycler  Documented in-house methods including DHSC requirements for private providers of COVID-19 testing, to include: - General Population testing - Test to Release testing - Day 2 & 8 international arrival testing	A
Nasopharyngeal and/or Oropharyngeal swabs in Viral Transport Media (VTM), saline, PBS or similar.	Detection of SARS-CoV-2 (COVID-19) virus specific gene sequences (ORF1ab and E gene)	Extraction: ThermoFisher MagMax Viral/Pathogen extraction kit using KingFisher Flex system with or without EAST sample transfer platform.  Detection: Radox COVID qPCR kit using QuantStudio 5	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Extracted RNA from the samples listed above	Whole genome sequencing SARS-CoV-2 genome sequencing	Manual and Automated selection of RT-PCR positive SARS-CoV-2 samples for Whole genome Next Generation Sequencing (NGS)  <b>Kits/Equipment:</b> Manufactured Next-Generation SARS-Cov-2 whole genome sequencing kit Illumina Inc. sequencers using the MiSeq and NovaSeq. Analytes 98 SARS-CoV-2 amplicons and 11 Human amplicons (for QC) using the in house and Basespace pipelines	A
END			