### **Schedule of Accreditation**

issued by

## **United Kingdom Accreditation Service**

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



Accredited to ISO 15189:2012

### **The Doctors Laboratory Limited**

Issue No:001 Issue date: 27 March 2018

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WC1H 9AX Website: www.tdlpathology.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 The Doctors Laboratory (Manchester) Michigan Avenue Salford Quays Greater Manchester M50 2GY	Local contact Sally Curtis	Haematology Blood Transfusion Biochemistry Microbiology Molecular Biology	A
Pathology Laboratory BMI Alexandra Hospital Mill Lane Cheadle Cheshire SK8 2PX	Sally Curtis	Haematology Biochemistry Blood Fridge	В

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#### Site activities performed away from the locations listed above:

Location details	Activity	Location code
BMI Highfield Hospital Manchester Road Rochdale Lancashire OL11 4LZ	Blood issue fridge for storage of blood products only; no testing occurs at this site	С
BMI Beardwood Hospital Preston New Road Blackburn Lancashire BB2 7AE	Blood issue fridge for storage of blood products only; no testing occurs at this site	D
BMI Beaumont Hospital Old Hall Clough Chorley New Road Bolton Lancashire BL6 4LA	Blood issue fridge for storage of blood products only; no testing occurs at this site	E
BMI Huddersfield Hospital Birkby Hall Road Huddersfield HD2 2BL	Blood issue fridge for storage of blood products only; no testing occurs at this site	F
Ramsay Renacres Hall Hospital Renacres Lane Ormskirk Lancashire L39 8SE	Blood issue fridge for storage of blood products only; no testing occurs at this site	G

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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	Haematology examination activities for the purposes of clinical diagnosis:	In-house documented procedures based on equipment manuals and standard methods as specified below:	
EDTA Blood	Full Blood Count (red blood cells, Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils),	SOP TDL-H-EQPT-007 using Sysmex XT1800i and SOP TDL-H- EQPT-001 using XS1000i	A
	Haemoglobin, HCT, MCV, MCH, MCHC, RDW, Platelet Count, White Cell Count).	SOP TDL-H-EQPT-001 using Sysmex XS1000i	В
Citrated Sample	Coagulation		
	Prothrombin time	SOP TDL-H-EQPT-009 using Sysmex CA540	A
	Activated Partial Thromboplastin time	SOP TDL-H-EQPT-011 using Syxmex C660	В
	Fibrinogen		
EDTA Blood	Blood film assessment & cell differential	SOP TDL-H-004 by Speedy-diff staining and light microscopy	A & B
EDTA Blood	Sickle Cell Haemoglobin Screening Test	SOP TDL-MAN-025 by qualitative solubility using TCS Biosciences Sickle-Check Hb-S Test Kit	A
EDTA Blood	Detection of Infectious Mononucleosis heterophile antibodies	SOP TDL-H-008 using Accusay Mono	A
Blood	Erythrocyte sedimentation rate (automated)	SOP TDL-MAN-032 using Starrsed Auto-Compact	A
Blood	Erythrocyte sedimentation rate (manual)	SOP TDL-H-010 using Westergren	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)	Blood Transfusion  General examination activities for the purposes of clinical diagnosis:	In house documented procedures in conjunction with equipment manuals and standard methods as specified below:	
EDTA Blood	Automated Blood Group: A Rh D negative/Positive O Rh D negative/Positive B Rh D Negative/Positive AB Rh D Negative/Positive	SOP TDL-BT-021using Diamed GelStation	А
EDTA Blood	Automated Antibody detection:  Antibody screening: (D,C,E,c,e,C <sup>w</sup> ,K,k,Kp <sup>b</sup> ,Fy <sup>a</sup> ,Fy <sup>b</sup> , Jk <sup>a</sup> ,Jk <sup>b</sup> ,Le <sup>a</sup> ,Le <sup>b</sup> ,P <sub>1</sub> ,M,N,S,s,Lu <sup>b</sup> , Xg <sup>a</sup> )	SOP TDL-BT-021 using Diamed GelStation and the following panels	A
	Antibody detection: (D, C, E, c, e & Kell)	using Bio-Rad Dia-Panel	
	Antibody detection: (D, C, E, c, e & Kell)	using Bio-Rad Dia-Panel-P (enzyme treated) and NHSBT IAT panel	
	Direct Anti-Globulin test (DAT) (IgG Antibody)	SOP TDL-BT-024 using Diamed Gel cards	A
	Manual Group & antibody screen	SOP-TDL-BT-025 using Diamed Gel cards	А
	Manual Groups	SOP-TDL-BT-030 using manual tube grouping method	A
	Manual crossmatch	SOP-TDL-BT-087 using Diamen Gelcards	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)	General Biochemistry  Biochemical examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum / Plasma (unless otherwise stated)	Quantification of:  Sodium  Potassium  Chloride	SOP TDL-MAN-COB-006 using Roche Cobas 6000 (Location A) and TDL-B-EQPT-001 using Cobas c111 (Location B) by ISE	A & B A & B A & B
Serum / Plasma (unless otherwise stated)		SOP TDL-MAN-COB-006 using Roche Cobas 6000 (Location A) and TDL-B-EQPT-001 using Cobas c111 (Location B) by photometry	
	Albumin	photometry	A & B
	Alkaline Phosphatase (ALP)		A & B
	Alanine Transaminase (ALT)		A & B
	Amylase		A & B
	Asparate Transaminase (AST)		A & B
	Bilirubin (total)		A & B
	Calcium		A & B
	Cholesterol		А
	Creatine Kinase		A & B
	Bicarbonate		А

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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)	General Biochemistry  Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum / Plasma (unless otherwise stated) (cont'd)	Quantification of: (cont'd)  Creatinine	SOP TDL-MAN-COB-006 using Roche Cobas 6000 (Location A) and TDL-B-EQPT-001 using Cobas c111 (Location B) by photometry	A & B
	C-Reactive protein  Gamma-glutamyl  Transpeptidase (GGT)		A & B A & B
	Gentamicin		А
	Glucose		A & B
	HDL Cholesterol		А
	Iron		
	Lactate Dehydrogenase		A & B
	Magnesium		A & B
	Phosphate		А
	Phospholipase A2 (PLA2)		А
	Total Protein		A & B
	Transferrin		А
	Triglyceride		А
	Unsaturated Iron Binding Capacity		А

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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)	General Biochemistry	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum / Plasma (unless otherwise stated) (cont'd)	Quantification of: (cont'd)	SOP TDL-MAN-COB-006 using Roche Cobas 6000 (Location A) and TDL-B-EQPT-001 using Cobas c111 (Location B) by photometry	
	Urate		A
	Urea		A & B
	Vancomycin		A
	Vitamin D		Α
	Testosterone (free)	SOP EXT-1034using Accubindon BEST 2000 by ELISA	А
	HbA1c	SOP WSL-AB-TOS-001 using TOSOH G8 by HPLC	
	<u>Immunoassay</u>	In house documented procedures	
	Biochemical examination activities for the purposes of clinical diagnosis.	based on equipment manuals and standard methods as specified below:	
	Quantification of:	SOP TDL-MAN-COB-006 using	A
	CA125	Roche Cobas 6000	
	Carcinoembryonic antigen (CEA)		
	Ferritin		
	Folate		
	Follicle Stimulating Hormone		

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Materials/Products tested		s tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN (cont'd)	BODY	FLUIDS	Immunoassay  Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
			Quantification of: (cont'd)  Human chorionic gonadotrophin (HCG)  Lutenising Hormone  Oestradiol  Progesterone  Prolactin  Prostate specific antigen (free & total)  T3 (free & toal)  T4 (total)  Testosterone  Thyroid Stimulating Hormone  Troponin T (high sensitivity)  Vitamin B12  Testosterone  Thyroid Stimulating Hormone	SOP TDL-MAN-COB-006 using Roche Cobas 6000	A
			Troponin T (high sensitivity) Vitamin B12		

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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)	Viral Serology  Serological examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified below:	
	Quantification of:  Hepatitis A total antibody	SOP TDL-MAN-COB-006 using Roche Cobas 6000 by immunoassay	А
	Hepatitis B surface antigen		
	Hepatitis B surface antibody		
	Hepatitis B core antibody		
	Hepatitis C IgG / IgM antibody		
	HIV p24 antigen & HIV1/2 antibody		
	Syphilis IgG and IgM		
	HIV-1 p24 Ag, HIV-1 Ab (Groups M & O), HIV-2 Ab	SOP EXT-1672 using Bioplex HIV5	А
	Molecular Biology		
	Molecular examination activities for the purposes of clinical diagnosis. Detection of:	In house documented procedures based on equipment manuals and standard methods by polymerase chain reaction as specified below:	
Swabs from nose, groin, axilla	MRSA	SOP CH-M-4-2-17 using Cepheid GeneXpert	А
Urine and Throat, Vaginal and Rectal swabs	Detection of Chlamydia trachomatis and Neisseria gonorrhoea DNA	SOP TDL-I-1-92 using BD Viper XTR and Cepheid GeneXpert	A
	END		

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