


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|---|--|--|
|  UKAS MEDICAL 8812 Accredited to ISO 15189:2012 | The Doctors Laboratory Limited Issue No: 008 Issue date: 15 September 2021 | |
| | The Halo Building 1 Mabledon Place London WC1H 9AX | Contact: Sally Curtis Tel: +44 (0) 207 307 7342 E-Mail: sally.curtis@tdlpathology.com 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 Regents Place 4 Windsor Street Salford Manchester M5 4HB | Local contact Sally Curtis | Haematology Blood Transfusion Biochemistry Microbiology Molecular Biology | A |



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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 | B |
| 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 | C |
| 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 | D |
| BMI Huddersfield Hospital Birkby Hall Road Huddersfield HD2 2BL | Blood issue fridge for storage of blood products only; no testing occurs at this site | E |
| 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 | F |



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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 | | |
| | Haematology 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 | Full Blood Count | Sysmex XN10 modules in 9100 III system SOP HAE-001 | A |
| | White Blood Cells (Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils) | by fluorescence flow cytometry | A |
| | Red Blood Cells, Platelets | by impedance | A |
| | Haemoglobin | by SLS photometry | A |
| | HCT, MCV, MCH, MCHC, RDW, | by calculation | A |
| | Reticulocytes | by flow cytometry | A |
| | Citrated Sample | <u>Coagulation</u> | |
| Prothrombin time | | By light absorption using Sysmex C660 SOP HAE-LIH-1 | A |
| Activated Partial Thromboplastin time | | | |
| Fibrinogen | | | |
| EDTA Blood | D-Dimer | | |
| | Sickle Cell Haemoglobin Screening | Sickle solubility using Helena Biosciences HbS-Solubility screening kit SOP HAE-PRI-3 | A |
| EDTA Blood | Detection of Infectious Mononucleosis heterophile antibodies | By rapid immunoassay using Accusay Mono SOP TDL-H-008 | A |



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| HUMAN BODY FLUIDS | Haematology Haematology 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 | Blood film assessment & cell differential | By Speedy-diff staining and light microscopy SOP TDL-H-004 | A |
| EDTA Blood | Erythrocyte sedimentation rate | By RAL Automated Stainer & light microscopy SOP HAE-NMRR-4 | A |
| EDTA Blood | Erythrocyte sedimentation rate | Sysmex Interliner XN1 (automated) SOP HAE-NMRR-17 | A |
| EDTA Blood | Erythrocyte sedimentation rate | Westergren method using Dispettes manual) | A |
| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion</u> 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 | Blood group: A Rh D positive A Rh D negative O Rh D positive O Rh D negative B Rh D positive B Rh D negative AB Rh D positive AB Rh D negative | Using Grifols Eflexis analyser and Gel-based microtyping system and reagents (automated) BTF-EAL3-1 | A |
| | | Using Grifols Wadiana analyser, Gel-based microtyping system, screening & panel cells (automated) BTF-EAL3-10 | A |
| | | Using Grifols Gel-based microtyping system and reagents (manual) BTF-EAL3-25 | A |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion</u> 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 | Antibody detection and identification Rh: D,C,E,c,e,Cw Kell: K,k,Kpa,Kpb Duffy: Fya,Fyb Kidd: Jka,Jkb Lewis: Lea,Leb P: P1 MNS: M,N,S,s Lutheran: Lua,Lub Xg: Xga | Using Grifols Eflexis analyser and Gel-based microtyping system and reagents (automated) BTF-EAL3-1 | A |
| EDTA Blood | Antibody detection and identification Rh: D,C,E,c,e Kell: K | Using Grifols Wadiana analyser, Gel-based microtyping system, screening & panel cells (automated) BTF-EAL3-10 | A |
| EDTA Blood | Antigen phenotyping : Rh: D, C, E, c, e, Cw Kell: K | Using Grifols Eflexis analyser and Gel-based microtyping system and reagents (automated) BTF-EAL3-1 | A |
| | | Using Grifols Wadiana analyser, Gel-based microtyping system, screening & panel cells (automated) BTF-EAL3-10 | A |
| | | Using Grifols Gel-based microtyping system and reagents (manual) BTF-EAL3-25 | A |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion</u> 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 | Direct antiglobulin test | Using Grifols Eflexis analyser and Gel-based microtyping system and reagents (automated) BTF-EAL3-1 | A |
| | | Using Grifols Gel-based microtyping system and reagents (manual) BTF-EAL3-25 | A |
| EDTA Blood | Compatibility testing of patient's plasma with donor cells | Using Grifols Gel-based microtyping system and Indirect Antiglobulin test (manual) and electronic issue BTF-EAL3-58 | A |



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| HUMAN BODY FLUIDS (cont'd) | <u>General Biochemistry</u> Biochemical examination activities for the purposes of clinical diagnosis. | In house documented procedures in conjunction with equipment manuals and standard methods as specified below: | |
| Serum / Plasma (unless otherwise stated) | Quantification of: | By ISE using c702 module on Roche Cobas 8000 system SOP BIO-008 | |
| | Sodium | | A |
| | Potassium | | A |
| | Chloride | | A |
| Serum / Plasma (unless otherwise stated) | | By photometry using c702 module on Roche Cobas 8000 system SOP BIO-008 | A |
| | Albumin | | A |
| | Alkaline Phosphatase (ALP) | | A |
| | Alanine Transaminase (ALT) | | A |
| | Amylase | | A |
| | Asparate Transaminase (AST) | | A |
| | Bilirubin (total) | | A |
| | Calcium | | A |
| | Cholesterol | | A |
| | Creatine Kinase | | A |
| | Bicarbonate | | A |
| | Creatinine | | A |
| | C-Reactive protein | | A |
| | Gamma-glutamyl Transpeptidase (GGT) | | A |



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| HUMAN BODY FLUIDS (cont'd) Serum / Plasma (unless otherwise stated) | <u>General Biochemistry</u> Biochemical examination activities for the purposes of clinical diagnosis. | In house documented procedures in conjunction with equipment manuals and standard methods as specified below: By ISE using c702 module on Roche Cobas 8000 system SOP BIO-008 | |
| | Quantification of: | | |
| | Gentamicin | | A |
| | Glucose | | A |
| | HDL Cholesterol | | A |
| | Iron | | A |
| | Lactate Dehydrogenase | | A |
| | Magnesium | | A |
| | Phosphate | | A |
| | Total Protein | | A |
| | Transferrin | | A |
| | Triglyceride | | A |
| | Unsaturated Iron Binding Capacity | | A |
| | Urate | | A |
| | Urea | | A |
| Vancomycin | A | | |
| Vitamin D | A | | |



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| HUMAN BODY FLUIDS (cont'd) | <u>General Biochemistry</u> | <p>In house documented procedures in conjunction with equipment manuals and standard methods as specified below:</p> <p>By calculation using using c702 module on Roche Cobas 8000 system SOP BIO-008</p> <p>By immunoassay using e801 module on Roche Cobas 8000 SOP BIO-008</p> | |
| | Biochemical examination activities for the purposes of clinical diagnosis. | | |
| | eGFR | | |
| | Globulin | | A |
| | Adjusted calcium | | A |
| | Acute Kidney Alert | | A |
| | Non-HDL Cholesterol | | A |
| | LDL Cholesterol | | A |
| | Total Cholesterol / HDL ratio | | A |
| | Total Iron Binding Capacity | | A |
| | Transferrin Saturation | | A |
| | Quantification of: | | A |
| | CA125 | | |
| | Carcinoembryonic antigen | | |
| | Ferritin | | |
| | Folate | | |
| | Follicle Stimulating Hormone | | |
| Free Thyroxine 4 (FT4) | | | |
| Human chorionic gonadotrophin (HCG) | | | |
| Lutenising Hormone | | | |



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| HUMAN BODY FLUIDS (cont'd) | <u>General Biochemistry</u> Biochemical examination activities for the purposes of clinical diagnosis. | In house documented procedures in conjunction with equipment manuals and standard methods as specified below: By immunoassay using e801 module on Roche Cobas 8000 SOP BIO-008 | A |
| Serum / plasma | Oestradiol Progesterone Prolactin Prostate specific antigen (free & total) T3 (free & total) T4 (total) Testosterone Thyroid Stimulating Hormone Troponin T (high sensitivity) Vitamin B12 HbA1c | By HPLC using TOSOH G11 SOP BIO-BNRR-2 | A |



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| HUMAN BODY FLUIDS (cont'd) | <p><u>Viral Serology</u></p> <p>Serological examination activities for the purposes of clinical diagnosis.</p> <p>Quantification of:</p> <p>Hepatitis A total antibody</p> <p>Hepatitis B surface antigen</p> <p>Hepatitis B surface antibody</p> <p>Hepatitis B core antibody</p> <p>Hepatitis C Ag/Ab (IgG)</p> <p>HIV p24 antigen & HIV1/2 antibody</p> <p>Syphilis IgG and IgM</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>By immunoassay using e801 module on Roche Cobas 8000 SOP BIO-008</p> | A |
| Serum | <p>HIV-1 p24 Ag, HIV-1 Ab (Groups M & O), HIV-2 Ab</p> | <p>HIV5 assay using Bio-Rad Bioplex SOP BIO-MAN-8</p> | A |



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| HUMAN BODY FLUIDS (cont'd) | <u>Molecular Biology</u> 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 | By PCR using Cepheid GeneXpert SOP CH-M-4-2-17 | A |
| Vaginal, rectal and throat swabs, urines | Chlamydia trachomatis & Neisseria gonorrhoea | Aptima Combo 2, Aptima Ct & Aptima GC kits using Hologic Panther SOP IMM-MAN-1 | A |
| Urine | Mycoplasma genitalium | By PCR using Cepheid GeneXpert SOP TDL-I-1-92 | A |
| Urine & vaginal swabs | Trichomonas vaginalis | Aptima assay using Hologic Panther SOP IMM-MAN-1 | A |

END