


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2012</b>	<b>Viapath Analytics LLP</b>	
	<b>Issue No: 001    Issue date: 27 January 2022</b>	
	<b>Pathology Department Viapath Analytics LLP Princess Royal University Hospital Orpington Kent BR6 8ND</b>	<b>Contact: Julie Jordan Tel: +44 (0) 1689 864291 E-Mail: <a href="mailto:julie.jordan1@nhs.net">julie.jordan1@nhs.net</a> Website: <a href="http://www.viapath.co.uk">www.viapath.co.uk</a></b>
<b>Testing performed at the above address only</b>		

### Supporting activities:

Location details	Activity
Blood Transfusion Laboratory	Storage & issue of blood & blood products



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Serum/Plasma (unless otherwise stated)</p> <p>and Urine</p> <p>and Urine</p> <p>and Urine</p> <p>and Urine</p> <p>and Urine</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u></p> <p>Sodium (Na) Potassium (K) Chloride (Cl)</p> <p>Alkaline phosphatase (ALP) Alanine aminotransferase (ALT) Aspartamine aminotransferase (AST) Total bilirubin Iron Unsaturated iron binding capacity (UIBC) Gamma-glutamyl transferase (GGT) Magnesium Urate Bicarbonate Paracetamol Cholesterol Triglycerides HDL-Cholesterol Amylase Urea Calcium Total Protein Albumin Creatinine Kinase (CK) Salicylate Phosphate Bile Acids (total) Lactate dehydrogenase (LDH) Glucose Conjugated bilirubin Angiotensin Converting Enzyme (ACE) Lactate Ammonia Ethanol Lithium</p>	<p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Roche Cobas 8000: c702 module BB-AP-034 &amp; measurement principles stated</p> <p>Indirect ion selective electrode (ISE)</p> <p>Photometry</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum/Plasma (cont'd) (unless otherwise stated)</p> <p>Urine Cerebrospinal fluid (CSF) CSF CSF</p> <p>Serum/Plasma</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Amikacin Carbamazepine Valproate Theophylline Phenytoin Gentamicin Vancomycin C-Reactive Protein (CRP) C3, C Alpha-1-Antitrypsin Immunoglobulin A Immunoglobulin G Immunoglobulin M Rheumatoid Factor Creatinine Glucose Lactate Protein</p> <p>Calculated parameters: Adjusted Calcium AKI (acute kidney injury) grading eGFR (estimated glomerular filtration rate) Total iron binding capacity (TIBC) Transferrin saturation Globulins Low density lipoprotein (LDL) cholesterol Non-high density lipoprotein (non-HDL) cholesterol</p>	<p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Roche Cobas 8000: c702 module BB-AP-034 &amp; measurement principles stated</p> <p>Photometry</p> <p>By Calculation BB-AP-043</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required
Urine	Albumin:Creatinine ratio (ACR) Protein:Creatinine ratio (PCR) Calcium:Creatinine ratio Calcium excretion Creatinine excretion Phosphate excretion Potassium excretion Total protein excretion Sodium excretion Urea excretion	Roche Cobas 8000: c702 module BB-AP-034 & measurement principles stated  By calculation
Serum/Urine	Creatinine clearance	By calculation
Serum/Plasma (unless otherwise stated)	Vitamin B12 Vitamin D Troponin T N-Terminal-pro B-type Natriuretic Peptide (NT-pre BNP) Digoxin Folate Ferritin Thyroid Stimulating Hormone (TSH) Free T4 (FT3) Free T3 (FT4) Follicle Stimulating Hormone (FSH) Luteinising Hormone (LH) Prolactin Testosterone Oestradiol Progesterone Sex Hormone Binding Globulin (SHBG) Beta-Human Chorionic Gonadotrophin (βHCG) Cortisol	Roche Cobas 8000: c801 module BB-AP-034 & measurement principles stated  Electrochemiluminescence Immunoassay



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions as required
Serum/Plasma (cont'd) (unless otherwise stated)	Prostate Specific Antigen (PSA) Carcinoembryonic hormone (CEA) Alpha-Fetoprotein (AFP) CA-125 CA-153 CA-199 Parathyroid Hormone (PTH) Procalcitonin	Roche Cobas 8000: c801 module BB-AP-034 & measurement principles stated  Electrochemiluminescence Immunoassay
Serum	Free androgen index	By calculation
Serum	Macroprolactin	PEG Precipitation & Roche Cobas 8000: c801 module Electrochemiluminescence Immunoassay BB-AP-004
Serum Urine	Osmolality	Advanced Instruments Vitech 3320 Osmometer Freezing Point Depression BB-AP-006
Haemolysed Whole Blood	HbA1c	Roche Cobas c513 Turbidimetric Inhibition Immunoassay (TINIA) BB-AP-039



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions as required
Blood (Red cells, Plasma)	ABO / RhD typing by detection & identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh D Negative AB Rh D Negative B Rh D Negative O Rh D Negative	Automated using: CAT BioRad IH500 BT-PP-041  Manual using: CAT BioRad ABO and reverse grouping cards and A1 & B reagent cells BT-PP-032
Blood (Plasma)	Antibody screen for detection of antibodies: Rh – C, D, E, c, e, Cw K, k, Kpa Fya, Fyb M, N, S, s Jka, Jkb Lea, Leb Lua P, P1	Manual using: CAT BioRad IAT technology, anti-IgG IAT gel cards and BioRad 3 cell antibody screening reagent cells BT-PP-002
Blood (Plasma)	Antibody Identification of antibodies: Rh – C, D, E, c, e, Cw K, Kpa Fya, Fyb M, N, S, s Jka, Jkb Lea, Leb Lua P1	Automated using: CAT BioRad IH500 BT-PP-041  Manual using: CAT BioRad IAT technology, anti-IgG IAT gel cards BT-PP-002
Blood (Red cells)	Direct Antiglobulin Testing (DAT)	Automated using: CAT BioRad IH500 BT-PP-041  Manual using: CAT BioRad polyspecific & monospecific IgG and CD3d DAT cards BT-PP-033



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required
Blood (Red cells)	Rh/K phenotyping of antigens: C, c, E, e, K	Automated using: CAT BioRad IH500 BT-PP-041  Manual using: CAT BioRad Rh/K antigen typing cards BT-PP-006
Blood (Red cells, Plasma)	Compatibility testing (Crossmatch)	Manual using: CAT BioRad Anti-IgG IAT gel cards BT-PP-003
Blood (Red cells)	Foetal Maternal Haemorrhage	Kleihauer Acid Elution & microscopy BT-PP-005
Whole Blood	<u>Haematology examination activities for the purpose of clinical diagnosis</u>  Full Blood Count (FBC) Analysis: Total red cell count Haemoglobin Mean cell volume Mean cell haemoglobin Mean cell haemoglobin concentration Haematocrit Red cell distribution width Total white cell count Absolute neutrophil count Absolute lymphocyte count Absolute monocyte count Absolute eosinophil count Absolute basophil count Platelet count Mean platelet volume	Sysmex XN10 & XN20 Fluorescence Flow Cytometry BH-AP-040
Whole Blood	Nucleated Red Cell Count	Sysmex XN10 & XN20 Fluorescence Flow Cytometry BH-AP-040



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required
Whole Blood	Reticulocytes	Sysmex XN10 & XN20 Fluorescence Flow Cytometry BH-AP-040
Whole Blood (Blood Film)	Red Cell morphology White Cell morphology Platelet morphology White Cell Differential	RAL Stainer Methylene Blue and May-Grünwald stains Methanol Free, Chromatic Detection BH-AP-039  Nikon Eclipse 80i Olympus BX43 Microscopy BH-AP-10 BH-AP-30
Whole Blood	Detection of Malaria antigens: <i>Plasmodium falciparum</i> HRP2 & <i>P. falciparum</i> , <i>P. vivax</i> , <i>P. ovale</i> , <i>P. malariae</i> Pan LDH	CareStart RPYDTEST Immunochromogenic method BH-AP-002
Whole Blood (Blood Film)	Detection & presumptive speciation of Malaria & non-malaria parasites, including: <i>P. falciparum</i> , <i>P. vivax</i> , <i>P. ovale</i> , <i>P. malariae</i> , <i>P. knowlesi</i>  % Parasitaemia for <i>P. falciparum</i> & <i>P. knowlesi</i>	Thick and thin film Giemsa (pH7.2) staining BH-AP-002  Nikon Eclipse 80i Olympus BX43 Microscopy BH-AP-10 BH-AP-30
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	StaRRsed Autocompact Red cell sedimentation BH-AP-011
Whole Blood	Heterophile antibodies (Infectious Mononucleosis screen)	IM Clearview Test kit Latex Agglutination BH-AP-18
Whole Blood	Sickle Cell Solubility	S-Test kit Visual interpretation BH-AP-001





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HUMAN BODY FLUIDS (cont'd)  Whole Blood  Whole Blood  Whole Blood	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)  Clotting Screen: Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT)  Clauss Fibrinogen  D-dimer	In house documented methods incorporating manufacturers' instructions as required  Sysmex CS-2500 Spectrophotometry Correction studies (where required) BH-CP-002  Sysmex CS-2500 Spectrophotometry BH-CP-002  Sysmex CS-2500 Spectrophotometry BH-CP-002
END		