

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9550</p> <p>Accredited to ISO 15189:2022</p>	<h3>Sheffield Teaching Hospitals NHS Foundation Trust</h3> <p>Issue No: 016 Issue date: 09 April 2026</p>	
	<p>Doncaster & Bassetlaw NHS Foundation Trust Pathology Services Doncaster Royal Infirmary Armthorpe Road Doncaster DN2 5LT</p>	<p>Contact: Mr Andrew Wood Tel: +44 (0)1302 644749 Extn. 644749 E-Mail: andrew.wood24@nhs.net Website: www.dbth.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
<p>Address Pathology Department Doncaster Royal Infirmary Armthorpe Road Doncaster DN2 5LT</p>	<p>Local contact Mr Andrew Wood Tel: +44 (0)1302 644749 E-Mail: andrew.wood24@nhs.net</p>	<p>Andrology Blood Transfusion Haematology Clinical Biochemistry Immunology Microbiology Virology Cellular Pathology Phlebotomy Mortuary Services Body Storage Facilities Blood Issue fridge</p> <p>Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme as defined in the laboratory QA evidence requirements:</p> <ul style="list-style-type: none"> • Review of Family Origin Questionnaire and Full Blood Count screen • Subsequent testing at a laboratory accredited to ISO 15189 for detection of haemoglobin variants 	DRI



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Location details		Activity	Location code
Address Bassetlaw District General Hospital Blyth Road Worksop S81 0BD	Local contact Mr Andrew Wood Tel: +44 (0)1302 644749 E-Mail: andrew.wood24@nhs.net	Phlebotomy Body Storage Facilities Haematology Blood Transfusion Clinical Biochemistry Microbiology	BDGH
Address Montagu Hospital Mexborough Adwik Road Mexborough S64 0AZ	Local contact Mr Andrew Wood Tel: +44 (0)1302 644749 E-Mail: andrew.wood24@nhs.net	Phlebotomy Specimen Reception Body Storage Facilities Blood issue fridge	MMH



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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>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	
	Chemistry Assays	Abbott Alinity c (CLS-SOP-932) analyser with specific reference to:	
	Quantification of		
Serum / Urine	Sodium	Ion selective electrode PATH-IFU-705	DRI BDGH
Serum / Urine	Potassium	Ion selective electrode PATH-IFU-593	DRI BDGH
Serum / Urine	Urea	Enzymatic PATH-IFU-618	DRI BDGH
Serum / Urine	Creatinine	Enzymatic PATH-IFU-580	DRI BDGH
Serum	eGFR	Calculated eGFR/EPI formula CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Calculated AKI	Nationally mandated algorithm (NHS England Alert 2015) CLS-SOP-701, CLS-R-216	DRI BDGH
Serum / Urine	Creatinine Clearance	Calculated using standard formula CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Total Protein	Colourimetric PATH-IFU-614	DRI BDGH
Serum	Albumin	Colourimetric PATH-IFU-567	DRI BDGH
Serum	Alkaline Phosphatase	Enzymatic PATH-IFU-692	DRI BDGH
Serum	ALT	Enzymatic PATH-IFU-569	DRI BDGH
Serum	Total Bilirubin	Colourimetric PATH-IFU-613	DRI BDGH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Chemistry Assays	Abbott Alinity c (CLS-SOP-932) analyser with specific reference to:	
	Quantification of (cont'd)		
Serum	Conjugated Direct Bilirubin	Colourimetric PATH-IFU-585	DRI BDGH
Serum / Urine	Calcium	Colourimetric PATH-IFU-574	DRI BDGH
Serum / Urine	Phosphate	Colourimetric PATH-IFU-638	DRI BDGH
Serum	Calcium (Albumin Adjusted)	Calculation based on ACB Position paper 2015 equation CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Triglyceride	Enzymatic PATH-IFU-616	DRI BDGH
Serum	Total Cholesterol	Enzymatic PATH-IFU-575	DRI BDGH
Serum	HDL Cholesterol	Accelerator Selective Detergent Enzymatic PATH-IFU-617	DRI BDGH
Serum	LDL Cholesterol	Friedwald Equation CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Non-HDL Cholesterol	As per NICE CG 181 CLS-SOP-701, CLS-R-216	DRI BDGH
Lithium Heparin Plasma	Ammonia	Enzymatic PATH-IFU-570	DRI BDGH
Serum / Urine	Amylase	Enzymatic PATH-IFU-571	DRI BDGH
Serum	AST	Activated Enzymatic PATH-IFU-572	DRI BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Chemistry Assays	Abbott Alinity c (CLS-SOP-932) analyser with specific reference to:	
	Quantification of (cont'd)		
Serum	Bicarbonate	Enzymatic PATH-IFU-579	DRI BDGH
Serum/Urine	Chloride	Ion selective electrode PATH-IFU-593	DRI BDGH
Serum	Creatine Kinase	Enzymatic PATH-IFU-576	DRI BDGH
Serum	C Reactive Protein	Latex immunoassay turbidimetric PATH-IFU-582	DRI BDGH
Serum	Digoxin	Particle enhanced turbidimetric inhibition immunoassay PATH-IFU-584	DRI BDGH
Fluoride Oxalate plasma	Ethanol	Enzymatic PATH-IFU-587	DRI BDGH
Serum	Gamma GT	Enzymatic PATH-IFU-588	DRI BDGH
Fluoride Oxalate Plasma/CSF	Glucose	Enzymatic PATH-IFU-589	DRI BDGH
Serum	Iron	Colourimetric PATH-IFU-688	DRI BDGH
Fluoride Oxalate Plasma	Lactate	Enzymatic PATH-IFU-598	DRI BDGH
Serum	LDH	Enzymatic PATH-IFU-691	DRI BDGH
Serum	Lithium	Colourimetric PATH-IFU-601	DRI BDGH
Serum/Urine	Magnesium	Colourimetric PATH-IFU-602	DRI BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Chemistry Assays	Abbott Alinity c (CLS-SOP-932) analyser with specific reference to:	
	Quantification of (cont'd)		
Serum	Paracetamol	Enzymatic/Colorimetric PATH-IFU-566	DRI BDGH
Serum	Salicylate	Enzymatic/Colorimetric PATH-IFU-606	DRI BDGH
CSF/Urine	Protein	Turbidimetric PATH-IFU-620	DRI BDGH
Serum/Urine	Uric Acid	Enzymatic PATH-IFU-619	DRI BDGH
Serum	Alpha-1 Antitrypsin	Immunoturbidimetric PATH-IFU-695	DRI
Serum	Angiotensin Converting Enzyme	Enzymatic PATH-IFU-414	DRI
Serum	β-2 Microglobulin	Immunoturbidimetric PATH-IFU-707	DRI
Serum	Bile Acids	Enzymatic PATH-IFU-612	DRI BDGH
Serum	Complement C3	Immunoturbidimetric PATH-IFU-697	DRI
Serum	Complement C4	Immunoturbidimetric PATH-IFU-698	DRI
Serum	Haptoglobin	Immunoturbidimetric PATH-IFU-700	DRI
Serum	Immunoglobulins IgG	Immunoturbidimetric PATH-IFU-702	DRI
Serum	Immunoglobulins IgM	Immunoturbidimetric PATH-IFU-703	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Chemistry Assays Quantification of (cont'd)	Abbott Alinity c (CLS-SOP-932) analyser with specific reference to:	
Serum	Immunoglobulins IgA	Immunoturbidimetric PATH-IFU-701	DRI
Serum	Phenobarbitone	Turbidimetric inhibition immunoassay PATH-IFU-728	DRI
Serum	Phenytoin	Enzyme Immunoassay PATH-IFU-704	DRI
Serum	Rheumatoid Factor	Immunoturbidimetric PATH-IFU-535	DRI
Serum	Theophylline	Enzyme Immunoassay PATH-IFU-705	DRI
Serum	Transferrin	Immunoturbidimetric PATH-IFU-615	DRI BDGH
Serum	Valproate	Turbidimetric inhibition immunoassay PATH-IFU-727	DRI
Serum	Carbamazepine	1-step Chemiluminescence Immunoassay PATH-IFU-696	DRI
Serum	Gentamicin	Turbidimetric inhibition immunoassay PATH-IFU-699	DRI
Urine	Microalbumin	Immunoturbidimetric PATH-IFU-623	BDGH
Serum	Vancomycin	Turbidimetric inhibition immunoassay PATH-IFU-706	DRI
EDTA Whole Blood	Haemoglobin A1c	Enzymatic PATH-IFU-824	BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Chemistry Assays Quantification of (cont'd)	Abbott Alinity c (CLS-SOP-932) analyser with specific reference to:	
Serum	Anion Gap	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Calculated Osmolality	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Globulin	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	HDL Ratio	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Total iron binding Capacity	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Serum	Transferrin Saturation	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	Albumin / Creatinine Ratio	Calculated CLS-SOP-701, CLS-R-216	BDGH
Urine	Protein / Creatinine Ratio	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	Calcium / Creatinine Ratio	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	Phosphate / Creatinine Ratio	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	Urate / Creatinine Ratio	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Protein Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Creatinine Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturer's instructions for:	
	Chemistry Assays	Abbott Alinity c (CLS-SOP-932) analyser with specific reference to:	
	Quantification of (cont'd)		
Urine	24hr Urea Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Sodium Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Potassium Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Chloride Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Phosphate Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Magnesium Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH
Urine	24hr Urate Excretion	Calculated CLS-SOP-701, CLS-R-216	DRI BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Immunoassay: Detection & Quantitative Determination of:	Documented procedures & manufacturer's instructions for Abbott Alinity i (CLS-SOP-932) analyser with specific reference to:	
Serum	Total β HCG	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-610	DRI BDGH
Lithium Heparin Plasma	hs Troponin I	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-592	DRI BDGH
Serum	25-Hydroxy-Vitamin D	1-Step Competitive Chemiluminescent Immunoassay PATH-IFU-708	DRI
EDTA Plasma	NT pro B-Type Natriuretic Peptide (BNP)	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-721	DRI
Serum	Cortisol	1-Step Competitive Chemiluminescent Immunoassay PATH-IFU-649	DRI BDGH
Serum	DHEAS	1-Step Competitive Chemiluminescent Immunoassay PATH-IFU-714	DRI
Serum	Ferritin	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-647	DRI BDGH
Serum	Folate	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-645	DRI BDGH
Serum	FSH	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-716	DRI
Serum	Free T3	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-715	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Immunoassay: Detection & Quantitative Determination of: (cont'd)	Documented procedures & manufacturer's instructions for Abbott Alinity i (CLS-SOP-932) analyser with specific reference to:	
Serum	LH	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-717	DRI
Serum	Oestradiol	1-Step Competitive Chemiluminescent Immunoassay PATH-IFU-725	DRI
Serum	Progesterone	1-Step Competitive Chemiluminescent Immunoassay PATH-IFU-718	DRI
Serum	Prolactin	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-719	DRI
Serum	Post-PEG monomeric prolactin	PEG Precipitation CLS-SOP-315, PATH-IFU-719	DRI
Serum	Prostate Specific Antigen	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-723	DRI
EDTA Plasma	Parathyroid Hormone	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-726	DRI
Serum	Sex Hormone Binding Globulin	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-720	DRI
Serum	Testosterone	1-Step Competitive Chemiluminescent Immunoassay PATH-IFU-722	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Immunoassay: Detection & Quantitative Determination of: (cont'd)	Documented procedures & manufacturer's instructions for Abbott Alinity i (CLS-SOP-932) analyser with specific reference to:	
Serum	TSH	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-651	DRI BDGH
Serum	Free T4	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-641	DRI BDGH
Serum	Active Vit B 12	2-Step Competitive Chemiluminescent Immunoassay PATH-IFU-643	DRI BDGH
Serum	Thyroid Peroxidase Antibodies	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-724	DRI
Serum	AFP	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-709	DRI
Serum	CA125	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-712	DRI
Serum	CA153	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-710	DRI
Serum	CA19-9	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-711	DRI
Serum	CEA	2-step Non-competitive Chemiluminescent Immunoassay PATH-IFU-713	DRI
Serum	Free Androgen Index (FAI)	Calculated CLS-SOP-701, CLS-R-216	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Specialist Chemistry Tests:	Documented procedures & manufacturer's instructions for Sebia Capillary S Electrophoresis System (Capillary Zone Electrophoresis) with specific reference to:	
Serum	Serum Protein Electrophoresis (Qualitative report with semi-quantitative measurement of paraproteins)	CLS-SOP-40	DRI
Serum	Protein Immunotyping (Qualitative report with semi-quantitative measurement of paraproteins)	Automated Immunological Identification of bands. CLS-SOP-40	DRI
		Documented procedures & manufacturer's instructions for Capillarys 3 TERA (Sebia) Electrophoresis System with specific reference to:	
Serum	Alkaline Phosphatase Isoenzymes (Reported qualitatively with approximate proportions)	Electrophoresis with/without lectin treatment CLS-SOP-61	DRI
Serum / Urine	Protein Immunofixation (Qualitative report with semi-quantitative measurement of paraproteins)	Electrophoresis and Immunofixation CLS-SOP-57	DRI
Urine	Urine Protein Electrophoresis (Qualitative report with semi-quantitative measurement of paraproteins)	Electrophoresis CLS-SOP-58	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Specialist Chemistry Tests: (cont'd)	Documented procedures & manufacturer's instructions for Sebia Capillary S Electrophoresis System (Capillary Zone Electrophoresis) with specific reference to:	
Serum	Cryoglobulin (Qualitative report)	In-house procedure with specific reference to published method (Ann Clin Biochem 2010; 47: 8-16) Electrophoresis CLS-SOP-145	DRI
EDTA Whole Blood	Haemoglobin A1c (Quantitative)	Cation Exchange HPLC Documented procedures & manufacturer's instructions for Tosoh G11 analyser with specific reference to: CLS-SOP-752	DRI
CSF	Xanthochromia Screen (Qualitative)	Spectrophotometry In-house procedure with specific reference to published method (Ann Clin Biochem 2008; 45:238-244) using Camspec M550 spectrophotometer - CLS-SOP-20	DRI
Lithium heparin plasma	Galactosaemia screen (Qualitative determination of GAL-1-PUT activity)	In-house Beutler screening procedure with specific reference to published method (J Lab Clin Med 1966; 68: 137) - CLS-SOP-28	DRI
Urine	Pregnancy Testing (Qualitative)	Documented procedures & manufacturer's instructions for the Medicekpregnancy kit (Immunoassay) - CLS-SOP-21	DRI
Sweat	Sweat collection	Iontophoresis Documented procedures & manufacturer's instructions for the Wescor Sweat Collection System (Model 3700) - CLS-SOP-338	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Specialist Chemistry Tests: (cont'd)	Documented procedures & manufacturer's instructions for Sebia Capillary S Electrophoresis System (Capillary Zone Electrophoresis) with specific reference to:	
Sweat	Sweat Chloride (Quantitation and Interpretation)	Coulometry Documented procedures & manufacturer's instructions for the Sherwood model 926S Chloride Analyser - CLS-SOP-19	DRI
Serum	Osmolality	Freezing Point Depression using the Advanced Instruments Osmo1 CLS-SOP-27	DRI BDGH
		Roche Cobas e411 Immunoassay CLS-SOP-852	DRI
Serum	Serum Placental Growth Factor (PIGF)		DRI
Serum	Serum soluble fms-like tyrosine kinase-1 (sFlt-1)		DRI
Serum	Serum sFlt-1:PIGF Ratio		DRI
Urine	Drugs of Abuse Screen: Cannabis Opiates Cocaine Benzodiazepines Amphetamines	AccuSign DOA 5 test strips (solid phase chromatographic membrane immunoassay) simultaneous detection. Test strips 'read' using the DXpress reader	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	
EDTA Whole Blood	<p>Full Blood Count Quantification of</p> <p>Haemoglobin White Blood Cell Count Red Blood Count</p> <p>Platelet Count</p> <p>Red cell distribution width</p> <p>Haematocrit</p> <p>Mean Cell Volume Mean Cell Haemoglobin Mean Cell Haemoglobin Concentration Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Nucleated Red Cells Reticulocyte count</p>	<p>Sysmex XN instrument enables quantitative and identification of tangible components of blood by means of electrical impedance, laser light scatter and dye bonding CLS-SOP-81, CLS-SOP-82 SLS - Haemoglobin Method Fluorescence Flow Cytometry Direct Current Sheath Flow Detection Method (Electrical Impedance) Direct Current Sheath Flow Detection Method (Electrical Impedance) Direct Current Sheath Flow Detection Method (Electrical Impedance) Direct Current Sheath Flow Detection Method (Electrical Impedance) Calculated from the RBC and HCT Calculated from the RBC and HCT Calculated from HCT and HGB</p> <p>Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry</p>	DRI BDGH
EDTA Whole Blood	Blood film assessment for identification of morphological abnormalities and to confirm analyser findings	Blood film assessment using SP10 automated slide maker stainer or Haematek stainer utilising a May Grunwald and Giemsa stain examined by light microscopy. CLS-SOP-104, CLS-SOP-587	DRI BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
EDTA Whole Blood	Blood Film Parasites to identify and speciate malarial parasites, microfilaria or trypanosomes	Microscopic analysis of thick films and thin blood films Utilising a Giemsa staining method for thin and thick films, SP10 automated slide maker stain or Haematek stainer utilising a May Grunwald and Giemsa stain for thin films CLS-SOP-118	DRI
EDTA Plasma	Infectious Mononucleosis Screening (detection of EBV)	Latex agglutination test principle using non-automated Monogen Bio-kit commercial kit CLS-SOP-111	DRI
EDTA Whole Blood	Malaria screen for detection of Plasmodium species, including P. falciparum, P. knowlesi, P. vivax, P. ovale and P. malariae	Enzymatic detection using non – automated TCS Biosciences DiaMed OptiMAL-IT Rapid Malaria commercial kit - CLS-SOP-120	DRI BDGH
EDTA Whole Blood	Sickle Screen	Clin-Tech Sickle Screen Kit Relative insolubility of HbS when combined with high concentration buffer containing the reducing agent sodium dithionite CLS-SOP-112	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Citrated Plasma	Coagulation	Documented procedures & manufacturer's instructions for TOP550/350 analysers (Werfen) using immunological, turbidimetric, and chromogenic methods:	
	Prothrombin Time (PT)	Using RecombiPlastin 2G for turbidimetric quantitative determination of PT CLS-SOP-69	DRI BDGH
	INR	Calculated parameter - INR = (Patients PT/Mean of PT normal range) ISI	DRI BDGH
	Activated Partial Thromboplastin Time (APTT)	SynthASil reagents for turbidimetric quantitative determination of APTT CLS-SOP-68	DRI BDGH
	Activated Partial Thromboplastin Time Ratio	Calculated parameter - ratio of APPT: Normal APTT	DRI BDGH
	Fibrinogen	Using Q.F.A Thrombin For the quantitative determination of fibrinogen, based on the Clauss method - CLS-SOP-71	DRI BDGH
	D-Dimer	Using a latex-enhanced turbidimetric immunoassay CLS-SOP-75	DRI BDGH
	Thrombin Time	Using purified bovine thrombin for turbidimetric quantitative determination of TT CLS-SOP-72	DRI BDGH
	Anti-Phospholipid Antibodies (Lupus Screen)	Using HemosIL screen and confirm assays are qualitative assays for detection of lupus anticoagulants by the diluted Russell's Viper Venom method - CLS-SOP-73	DRI
	Anti-Xa Assays: LMWH Apixaban Rivaroxaban	Chromogenic assay CLS-SOP-819	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
EDTA Whole Blood	Erythrocyte Sedimentation Rate	Automated Interrliner or Inversa analyser utilising an extrapolation method of the Westergren technique CLS-SOP-103, CLS-SOP-573	DRI
EDTA Whole Blood	Automated Direct Coombs Test To detect red cells that are coated in vivo with immunoglobulin and/or complement	Documented procedures & manufacturer's instructions for the IH-1000 analyser (DIAMED ID-Card System) using column agglutination technology, Polyspecific AHG and monospecific AHG reagents anti-IgG, anti-IgA, anti-IgM, anti-C3c, anti-C3d with specific reference to - CLS-SOP- 3	DRI BDGH
EDTA Whole Blood	Automated Blood Group: To determine ABO and RhD type with reverse group	Documented procedures & manufacturer's instructions for the IH-1000 analyser (DIAMED ID-Card System & ID-Diacell) using column agglutination technology and monoclonal anti-A, anti-B and anti-D (DV1-) to determine the antigens A, B, D with specific reference to - CLS-SOP- 3	DRI BDGH
EDTA Whole Blood	Automated Blood Group: To confirm ABO and RhD group	Documented procedures & manufacturer's instructions for the IH-1000 analyser (DIAMED ID-Card System) using column agglutination technology and monoclonal anti-A, anti-B and anti-D (DV1-) to determine the antigens A, B, D, with specific reference to: CLS-SOP- 3	DRI BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for:	
EDTA Whole Blood	Automated Blood Group: To determine the ABO and RhD group of a Neonate	Documented procedures & manufacturer's instructions for the IH-1000 analyser (DIAMED ID-Card System) using column agglutination technology and monoclonal anti-A, anti-B, anti-AB and anti-D (DV1-) to determine the antigens A, B, D, with specific reference to - CLS-SOP- 3	DRI BDGH
EDTA Whole Blood	Automated Antibody Screen To screen for the presence atypical antibodies, to the antigens present from the following blood group systems: Rh: D, C, D, E, C, e, Cw Kell: K, k Kidd: Jka, Jkb Duffy: Fya, Fyb MNS: M, N, S, s Lewis (Lea, Leb) & Kpa are present when possible	Documented procedures & manufacturer's instructions for the IH-1000 analyser (DIAMED ID-Card System & ID-Diacell) using column agglutination technology. The screening cells have double dose expression of Rh, Duffy, Kidd and MNS antigens, with specific reference to - CLS-SOP- 3	DRI BDGH
EDTA Whole Blood	Automated Prophylax Screen: The 6 cells show the following Rh expression: R1R2 r'r r''r rr rr rr The panel of 6 cells has antigens present from the following blood group systems: Kell: K, k Kidd: Jka, Jkb Duffy: Fya, Fyb MNS: M, N, S, s Lewis: Lea, Leb	Documented procedures & manufacturer's instructions for the IH-1000 analyser (DIAMED ID-Card System & ID-DiaScreen Prophylax) using column agglutination technology. Used as an adjunct to the antibody screen on pregnant women having received anti-D prophylaxis or other patients allo-immunised with anti-D, with specific reference to: CLS-SOP- 3	DRI BDGH



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
EDTA Whole Blood	Manual Direct Coombs test: To detect red cells that are coated in vivo with immunoglobulin and/or complement	Using the DIAMED ID-Card System (column agglutination technology, Polyspecific AHG and monospecific AHG reagents anti-IgG, anti-IgA, anti-IgM, anti-C3c, anti-C3d) – CLS-SOP-306	DRI BDGH
EDTA Whole Blood	Manual Blood Group: To determine ABO and RhD type with reverse group	Using the DIAMED ID-Card System & ID-Diacell (column agglutination technology and monoclonal anti-A, anti-B and anti-D (DV1-) to determine the antigens A, B, D. A1 and B cells are used to indicate the presence or absence of anti-A and anti-B isoagglutinins) – CLS-SOP-397	DRI BDGH
EDTA Whole Blood	Manual Blood Group: To confirm ABO and RhD group	Using the DIAMED ID-Card System (column agglutination technology and monoclonal anti-A, anti-B and anti-D (DV1-) to determine the antigens A, B, D) – CLS-SOP-397	DRI BDGH
EDTA Whole Blood	Manual Blood Group: ABO/Rh Newborn group	Using the DIAMED ID-Card System (column agglutination technology and monoclonal anti-A, anti-B, anti-AB and anti-D (DV1-) to determine the antigens A, B, D) – CLS-SOP-397	DRI BDGH



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>EDTA Whole Blood</p> <p>EDTA Whole Blood</p> <p>EDTA Whole Blood</p>	<p><u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Manual Antibody Screen To screen for the presence atypical antibodies, to the antigens present from the following blood group systems: Rh: D, C, D, E, C, e, Cw Kell: K, k Kidd: Jka, Jkb Duffy: Fya, Fyb MNS: M, N, S, s Lewis (Lea, Leb) & Kpa are present when possible</p> <p>Manual Prophylax Screen: The 6 cells show the following Rh expression: R1R2 r'r r''r rr rr rr The panel of 6 cells has antigens present from the following blood group systems: Kell: K, k Kidd: Jka, Jkb Duffy: Fya, Fyb MNS: M, N, S, s Lewis: Lea, Leb</p> <p>Manual Rh and K Type For profiling of the Rh phenotype and K typing</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Using the DIAMED ID-Card System & ID-Diacell (column agglutination technology). The screening cells have double dose expression of Rh, Duffy, Kidd and MNS antigen CLS-SOP-303</p> <p>Using the DIAMED ID-Card System & ID-DiaScreen Prophylax (column agglutination technology). Used as an adjunct to the antibody screen on pregnant women having received anti-D prophylaxis or other patients allo-immunised with anti-D. These cells meet the criteria for double dose expression of the Duffy, Kidd and MNS antigens – CLS-SOP-303.</p> <p>Using the DIAMED ID-Card System (column agglutination technology and monoclonal anti-C, anti-c, anti-E, anti-e and anti-K to determine the antigens C, c, E, e, K) – CLS-SOP-392</p>	<p>DRI BDGH</p> <p>DRI BDGH</p> <p>DRI BDGH</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
EDTA Whole Blood	Manual IAT Antibody Identification: To identify atypical antibodies detected in the antibody screen. Antigens are present on the panel cells from the following blood group systems: Rh: D, C, D, E, C, e, Cw Kell: K, k, Kpa Kidd: Jka, Jkb Duffy: Fya, Fyb MNS: M, N, S, s Lewis: Lea, Leb	Using the DIAMED ID-Card System & ID-DiaPanel (column agglutination technology). For the Rh system, MNSs, Duffy and Kidd, the antigens must be in homozygous form. The Lewis antigens must be present, as should the rare antigen Kpa – CLS-SOP-304	DRI BDGH
EDTA Whole Blood	Manual Enzyme Antibody Identification: To support the IAT panel in identifying atypical antibodies detected in the antibody screen. Antigens are present on the enzyme treated panel cells from the following blood group systems: Rh: D, C, D, E, C, e, Cw Kell: K, k, Kpa Kidd: Jka, Jkb Duffy: Fya, Fyb MNS: M, N, S, s Lewis: Lea, Leb	Using the DIAMED ID-Card System & ID-DiaPanel P (column agglutination technology). For the Rh system, MNSs, Duffy and Kidd, the antigens must be in homozygous form. The Lewis antigens must be present, as should the rare antigen Kpa - CLS-SOP-305	DRI BDGH
EDTA Whole Blood	Manual IAT Crossmatch	Using the DIAMED ID-Card System (column agglutination technology) - CLS-SOP-307	DRI BDGH
EDTA Whole Blood	Kleihauer Film For screening of Feto-maternal Haemorrhage	Kleihauer techniques fetal cells stained in maternal sample if present to enable quantification. Using Clin-Tech Shepard's Stain (Modified Kleihauer) Kit CLS-SOP- 387, CLS-SOP-388 and CLS-SOP-790	DRI BDGH



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fixed, fresh tissue samples and cell blocks (biopsy, excision, resection and post-mortem specimens)</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis. Including identification of basophilic and eosinophilic structures</p>	<p>In House documented methods for preparation and staining all supported by SOPs and, where relevant, manufacturer's instructions for cutting up, processing, embedding dehydration, clearing and mounting, and microscopy</p> <p><u>Tissue dissection:</u> BMS cut up manual (HIS-SOP-1), BMS category A samples (HIS-SOP-248), BMS category B samples (HIS-SOP-249), BMS category C samples (HIS-SOP-250), BMS extended (HIS-SOP-251) and BMS loading (HIS-SOP-27).</p> <p><u>Decalcification:</u> Decalcification (HIS-SOP-35)</p>	<p>DRI</p> <p>DRI</p> <p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fixed, fresh tissue samples and cell blocks (biopsy, excision, resection and post-mortem specimens) (cont'd)</p> <p>Formalin fixed paraffin wax blocks of processed tissue</p> <p>FFPE (formalin fixed paraffin embedded) tissue on glass slides</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis. Including identification of basophilic and eosinophilic structures</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>In House documented methods for preparation and staining all supported by SOPs and, where relevant, manufacturer's instructions for cutting up, processing, embedding dehydration, clearing and mounting, and microscopy</p> <p><u>Tissue processing:</u> Excelsior processor (HIS-SOP-43, HIS-SOP-44, HIS-SOP-45 and HIS-SOP-61) Excelsior AS processor (HIS-SOP-260, HIS-SOP-261, HIS-SOP-262)</p> <p><u>Embedding:</u> Specimen embedding (HIS-SOP-4) Using: ThermoShandon Histostar (HIS-SOP-247) embedding consoles</p> <p><u>Microtomy:</u> Section cutting - (HIS-SOP-5 and HIS-SOP-6) Using: Leica and ThermoShandon microtomes – (HIS-SOP-5; HIS-SOP-6)</p> <p><u>Automated/ manual staining:</u> Gemini autostainer (HIS-SOP-9 and HIS-SOP-10) – H&E & PAP Coverslipping (HIS-SOP-11) QA in routine histology – (HIS-SOP-13) Using: ThermoShandon Gemini autostainer (HIS-SOP-201), Leica CV5030 coverslipper (HIS-SOP-224), Microscopes (HIS-SOP-221)</p>	<p>DRI</p> <p>DRI</p> <p>DRI</p> <p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fresh and Frozen tissue/ Frozen sections on glass slides</p> <p>Fixed tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis. Including identification of basophilic and eosinophilic structures</p> <p>Special Stains for the detection / identification of:</p> <p>Acid mucins</p> <p>Mucins (acid, neutral, mixed)</p> <p>Amyloid</p> <p>Elastic fibres and connective tissue</p> <p>Gram positive and negative organisms</p> <p>H. pylori, mast cells, basophil granules</p> <p>Nuclei and connective tissue</p> <p>Fibrin and connective tissue</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Frozen sections: Use of cyrostat (HIS-SOP-36) in conjunction with manufacturer's instructions for Leica Cryostat CM1860 (HIS-SOP-256)</p> <p>Manual rapid (frozen sections): Urgent frozen section: (HIS-SOP-37)</p> <p>Documented methods (reference in parentheses) using manual special stain techniques as indicated and to include: Special stains overview (HIS-SOP-112) Quality assurance in special stains (HIS-SOP-113)</p> <p>Alcian Blue (HIS-SOP-114)</p> <p>Alcian Blue - Periodic acid Schiffs (HIS-SOP-115)</p> <p>Congo red (HIS-SOP-116)</p> <p>Elastic Van Gieson (HIS-SOP-117)</p> <p>Gram (HIS-SOP-120)</p> <p>Giemsa (modified) (HIS-SOP-118)</p> <p>Haematoxylin van Gieson (HIS-SOP-121)</p> <p>Martius yellow - Brilliant crystal scarlet - Soluble blue (MSB) (HIS-SOP-124)</p>	<p>DRI</p> <p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fixed, fresh tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Special Stains for the detection / identification of: (cont'd)</p> <p>Removal of melanin pigment</p> <p>Fungi, glomerular basement membrane, P. carinii, glycogen</p> <p>Melanin, argentaffin and chromaffin cells</p> <p>Connective tissue</p> <p>Hepatitis B surface antigen and copper associated protein</p> <p>PAS - polysaccharides including: glycogen, neutral mucins, fungi PAS-D - removal of glycogen</p> <p>Haemosiderin (ferric iron salts) and asbestos bodies</p> <p>Reticulin fibres</p> <p>Amyloid, elastic and eosinophils</p> <p>Calcium deposits</p> <p>Mycobacterium spp, including Mycobacterium tuberculosis</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Documented methods (reference in parentheses) using manual special stain techniques as indicated and to include: Special stains overview (HIS-SOP-112) Quality assurance in special stains (HIS-SOP-113)</p> <p>Melanin bleach (HIS-SOP-126)</p> <p>Methenamine silver (Grocott) (HIS-SOP-125)</p> <p>Masson Fontana (HIS-SOP-122)</p> <p>Masson Trichrome (HIS-SOP-123)</p> <p>Orcein (HIS-SOP-127)</p> <p>Periodic acid Schiffs (PAS) and Diastase - Periodic acid Schiffs (PAS-D) (HIS-SOP-129)</p> <p>Perls (HIS-SOP-128)</p> <p>Reticulin (HIS-SOP-131)</p> <p>Sirius red (HIS-SOP-133)</p> <p>Von Kossa (HIS-SOP-135)</p> <p>Ziehl Neelson (HIS-SOP-138)</p>	<p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fixed, fresh tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides (cont'd)</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Immunohistochemistry to detect / identify the following:</p> <p>Cytokeratins: 1, 5, 10 & 14 (high molecular weight cytokeratins)</p> <p>Broad range cytokeratin</p> <p>Fetal liver cells</p> <p>Mesenchymal marker</p> <p>T-cells, B-cells in mantle zone</p> <p>Epithelial cells</p> <p>Luminal cells of the fallopian tube</p> <p>Mesothelial cell lining</p> <p>Low molecular weight marker (anti cytokeratin)</p> <p>Follicular centre B cells</p> <p>B-cell marker</p> <p>T-cell marker</p> <p>Hodgkin and Reed-Sternberg cells</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Documented in-house methods (HIS-SOP-63, HIS-SOP-65, HIS-SOP-238, HIS-SOP-239, HIS-SOP-240, HIS-SOP-241) used in accordance with Dako's operating instructions for the use of Omnis automated immunostainer (HIS-SOP-236 & 237).</p> <p>Incorporating the following antibodies:</p> <p>34βE12</p> <p>Cytokeratin AE1 / AE3</p> <p>Alpha 1 fetoprotein (AFP)</p> <p>α smooth muscle action (αSMA)</p> <p>BCL-2</p> <p>Ber Ep4</p> <p>Ca 125</p> <p>Calretinin</p> <p>Cam 5.2</p> <p>CD10</p> <p>CD 20</p> <p>CD 3</p> <p>CD 30 (Ki-1)</p>	<p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fixed, fresh tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides (cont'd)</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Immunohistochemistry to detect / identify the following: (cont'd)</p> <p>Endothelial marker</p> <p>Neuroendocrine</p> <p>Macrophages</p> <p>Mast cells and GIST</p> <p>Intestinal epithelial</p> <p>Carcinoembryonic antigen</p> <p>Neuroendocrine</p> <p>Gastrointestinal epithelia</p> <p>Squamous and myoepithelial</p> <p>Glandular, transitional epithelia</p> <p>Lymphatic endothelium</p> <p>Intermediate filament/ smooth & striated muscle</p> <p>Cell adhesion molecule</p> <p>Epithelial membrane antigen</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Documented in-house methods (HIS-SOP-63, HIS-SOP-65, HIS-SOP-238, HIS-SOP-239, HIS-SOP-240, HIS-SOP-241) used in accordance with Dako's operating instructions for the use of Omnis automated immunostainer (HIS-SOP-236 & 237).</p> <p>Incorporating the following antibodies:</p> <p>CD 34 (Qbend10)</p> <p>CD 56</p> <p>CD 68</p> <p>CD 117 (C Kit)</p> <p>CD X2</p> <p>CEA (mono)</p> <p>Chromogranin A</p> <p>CK 20</p> <p>CK 5/6</p> <p>CK 7</p> <p>D2 40</p> <p>Desmin</p> <p>E-Cadherin</p> <p>EMA</p>	<p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fixed, fresh tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides (cont'd)</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Immunohistochemistry to detect / identify the following: (cont'd)</p> <p>Oestrogen receptor</p> <p>Breast and urothelial carcinoma</p> <p>Melanosomes</p> <p>Leydig, Steroli cells</p> <p>Proliferation marker</p> <p>Leukocyte common antigen</p> <p>Melanocytes</p> <p>Prostate adenocarcinoma</p> <p>Carcinomas of ovary, bladder, lung, and breast.</p> <p>p16 HPV biomarkers</p> <p>Alpha methylacyl coenzyme A racemase</p> <p>Tumour suppressor gene</p> <p>Basal cell marker</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Documented in-house methods (HIS-SOP-63, HIS-SOP-65, HIS-SOP-238, HIS-SOP-239, HIS-SOP-240, HIS-SOP-241) used in accordance with Dako's operating instructions for the use of Omnis automated immunostainer (HIS-SOP-236 & 237).</p> <p>Incorporating the following antibodies:</p> <p>ER</p> <p>GATA3</p> <p>HMB 45 (Anti-human melanosome)</p> <p>Inhibin alpha</p> <p>Ki-67 (MIB-1)</p> <p>LCA (CD 45)</p> <p>Melan A</p> <p>NKX3.1</p> <p>PAX-8</p> <p>P16</p> <p>P504S/ AMACR</p> <p>P53</p> <p>P63</p>	<p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Fixed, fresh tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides (cont'd)</p>	<p><u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Immunohistochemistry to detect / identify the following: (cont'd)</p> <p>Polyclonal Prostate specific antigen</p> <p>Progesterone receptor</p> <p>Prostate specific antigen</p> <p>Renal Cell Marker</p> <p>Melanoma, neuroendocrine</p> <p>Smooth muscle myosin heavy chain</p> <p>Neuroendocrine marker</p> <p>Lymphatic endothelial</p> <p>Lumen of thyroid follicles</p> <p>Thyroid transcription factor</p> <p>Mesenchymal marker</p> <p>Wilms tumour 1 protein</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Documented in-house methods (HIS-SOP-63, HIS-SOP-65, HIS-SOP-238, HIS-SOP-239, HIS-SOP-240, HIS-SOP-241) used in accordance with Dako's operating instructions for the use of Omnis automated immunostainer (HIS-SOP-236 & 237).</p> <p>Incorporating the following antibodies:</p> <p>poly PSA</p> <p>PR</p> <p>PSA</p> <p>RCC</p> <p>S100</p> <p>SMMS 1</p> <p>Synaptophysin</p> <p>Thrombomodulin</p> <p>Thyroglobulin</p> <p>TTF-1</p> <p>Vimentin</p> <p>WT 1</p>	<p>DRI</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>CSF, urine, bronchial brush, bronchial wash, sputum, joint fluid, fine needle aspirate/ aspirate of general body fluids / cytopspin</p> <p>Slides prepared in-house from Synovial and joint fluids</p> <p>Slides prepared in-house from sample types listed above</p> <p>Slides prepared in-house from sample types listed above</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of human body fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis.</p> <p>Detection and identification of crystals</p> <p>Demonstration of cells (nuclei and cytoplasm)</p> <p>Demonstration of cells (nuclei and cytoplasm)</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p><u>Sample preparation:</u> Non gynae specimen receipt (HIS-SOP-76) Fine needle aspiration (HIS-SOP-79) Use of cytopsin (HIS-SOP-82) Use of exhaust protection cabinet (HIS-SOP-84) Preparation of agar clots (HIS-SOP-98)</p> <p>Synovial and joint fluids (HIS-SOP-80)</p> <p><u>Staining: automated:</u> Gemini autostainer (HIS-SOP-9 and HIS-SOP-10) Coverslipping: HIS-SOP-11 QA in routine histology: HIS-SOP-13</p> <p><u>Staining: manual:</u> Giemsa (modified) (HIS-SOP-118) Using: ThermoShandon cytopsin - (HIS-SOP-223) ThinPrep 2000 processor (Hologic) (HIS-SOP-230) ThermoShandon Gemini autostainer (HIS-SOP-201) Leica CV5030 coverslipper - (HIS-SOP-224) Microscopes (HIS-SOP-221)</p>	<p>DRI</p> <p>DRI</p> <p>DRI</p> <p>DRI</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Andrological examination activities for the purposes of clinical diagnosis</u>		
Semen	<u>Post vasectomy:</u> Detection of sperm	2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using low volume fixed depth slides and documented in-house procedure HIS-SOP-287	DRI
Semen	<u>Fertility testing:</u> Volume pH Sperm morphology excluding TZI scoring Sperm concentration Sperm motility Sperm vitality	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedures HIS-SOP-86, HIS-SOP-87, HIS-SOP-88, HIS-SOP-91 Volume/weight Colorimetric strips Stained slides (Papanicolau) microscopy (Bright field) Improved Neubauer counting chambers and Microscopy (Phase contrast) Microscopy (Phase contrast) Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)	DRI



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Swabs from eyes, wounds, nose, throat, ears, genital sites, intravascular cannulae, body fluids including CSF, tissues</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis:</u></p> <p>General isolation and characterisation of micro-organisms (bacteria, yeasts) of clinical significance. Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Manual culture, microscopy of wet preparations and stained preparations, cell counts with reference to the following SOPs: Swab Investigations MIC-SOP-14, Investigation of CAPD fluid MIC-SOP-38, Investigation of tissue and Biopsy Specimens MIC-SOP-74, Investigation for MRSA MIC-SOP-19, Investigation of Genital Specimens MIC-SOP-2, Investigation of CSF MIC-SOP-17, Antibiotic Sensitivity Testing MIC-SOP-5, Investigation of fluid samples MIC-SOP-17.</p>	DRI
<p>Respiratory fluids (sputum, bronchial washings, broncho-alveolar lavage)</p>	<p>General isolation and characterisation of micro-organisms of clinical significance</p>	<p>Manual culture of specimens with referral to Respiratory Investigations SOP: MIC-SOP-13.</p>	DRI
<p>Respiratory fluids (sputum, bronchial washings, broncho-alveolar lavage), urine, body fluids & tissue</p>	<p>General isolation and characterisation of Mycobacterium spp. (Note that speciation and antimicrobial susceptibility is tested at Reference laboratory - Birmingham PHE)</p>	<p>Documented Procedures and manufacturer's instructions for MB BacT/Alert automated analyser for liquid culture (MIC-SOP-83). Also use of Lowenstein Jensen slopes for solid culture. Manual light microscopy for examination of stained preparations. Specific reference to Investigations Specimens for Mycobacteria SOP: MIC-SOP-4</p>	DRI
<p>Faeces</p>	<p>General isolation and characterisation of bacteria of clinical significance</p>	<p>Manual culture of specimens with referral to Examination of faeces SOP: MIC-SOP-3.</p>	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Whole blood (heparinised)	Enumeration of TB (<i>Mycobacterium tuberculosis</i> complex) – Specific T-cells	Samples are analysed using the Diasorin Liaison XL (automated chemiluminescence immunoassay) according to manufacturer's instructions (VIR-SOP-38 and VIR-SOP-39) and VIR-SOP-33, with specific reference to: MIC-SOP-90 - Indirect chemiluminescence immunoassay (CLIA).	DRI
Faeces	Determination of presence of Clostridium Difficile Markers (Toxin and GDH)	Samples are analysed using the Diasorin Liaison XL (automated chemiluminescence immunoassay) according to manufacturer's instructions (VIR-SOP-38 and VIR-SOP-39) and VIR-SOP-33, with specific reference to: VIR-SOP-76 - Indirect chemiluminescence immunoassay (CLIA)	DRI
Faeces	H.Pylori stool antigen	Samples are analysed using the Diasorin Liaison XL (automated chemiluminescence immunoassay) according to manufacturer's instructions (VIR-SOP-38 and VIR-SOP-39) and VIR-SOP-33, with specific reference to: VIR-SOP-18 - Indirect chemiluminescence immunoassay (CLIA).	DRI
Faeces	Determination of Presence of genes coding Clostridium Difficile Toxins A & B	Detection of C. difficile toxins using manufacturer's instructions and software on Cepheid GeneXpert®. Referral to SOP: Cepheid Xpert C.Difficile. MIC-SOP-216	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Whole blood (heparinised)	General isolation and characterisation of micro-organisms of clinical significance	Documented procedures & manufacturer's instructions for BacT/Alert VIRTUO Blood culture automated analyser (MIC-SOP-103) with specific reference to Blood Cultures MIC-SOP-15.	DRI BDGH
Urine	Quantification of white and red blood cells, bacteria and epithelial cells. Culture of urine for enumeration and characterisation followed by antimicrobial susceptibility testing of pathogens	Documented procedures & manufacturer's instructions for Iris IQ Sprint automated urine analyser (MIC-SOP-106) with specific reference to Urine SOP: MIC-SOP-1.	DRI
Faeces	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Manual method of light microscopy described within Parasitology SOP: MIC-SOP-34 by wet preparation and concentration using Parasep system using manufacturer's instructions (MIC-SOP-24).	DRI
Skin scrapings, nail clippings, hair	General isolation and characterisation of fungi of clinical significance	Manual method using Mycology SOP: SOP MIC-SOP-42. Samples receive KOH-digest / light microscopy and culture onto fungal selective media	DRI
Urine	Detection of Streptococcus pneumonia antigen	Immunochromatographic membrane device assay using BinaxNOW commercial kit. VIR-SOP-81	DRI
Swabs	Molecular Detection of Herpes Simplex Virus I/II via PCR	Samples are analysed using the HAIN Fluorocycler analyser (PCR) according to SOPs (VIR-SOP-67 and VIR-SOP-68), with specific reference to VIR-SOP-70	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
CSF	Multiplexed nucleic acid molecular detection of the following microorganisms using the Meningitis /Encephalitis panel: Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cytomegalovirus Enterovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Human parechovirus Varicella zoster virus Cryptococcus neoformans/gattii	bioMerieux Biofire Film Array (MIC-SOP-149 and MIC-SOP-148) and in-house SOP MIC-SOP-152	DRI
Swabs in manufacturers sample collection tube (vaginal, endocervical, urethra, rectal, throat and urine)	Molecular Detection of Chlamydia & Neisseria gonorrhoea	Samples are processed using the Abbott Alinity M analyser (Automated PCR) according to manufacturer's instructions (MIC-SOP-225), with specific reference to MIC-SOP-228 and VIR-SOP-89	DRI
Pharmacy Liquids (Broth)	General isolation and characterisation of micro-organisms (bacteria, yeasts) of clinical significance.	Examination of Pharmacy Samples MIC-SOP-53.	DRI



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Cultures isolated in-house from the above samples</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Identification of clinically significant bacteria and yeasts</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Documented procedures and manufacturers' instructions for Maldi TOF MIC-SOP-122 Biochemical profile determination using VITEK2 Compact MIC-SOP-45 and MIC-SOP-45</p> <p>The following methods are also used for identification and are described in Identification Methods SOP (MIC-SOP-35):</p> <p>Biochemical profile determination using API Biochemical test strips (BioMerieux)</p> <p>Staphylococci identification using Prolex Staph Xtra latex agglutination test kit</p> <p>Streptococci (Lancefield groups A, B, C, D, F, G) identification using Pro-Lab Prolex Streptococcal Grouping kit</p> <p>E. coli O157 identification using E. coli O157 latex test kit (Oxoid)</p> <p>Determination of antigens of <i>Salmonellae</i>, <i>Shigellae</i>, <i>Bordetellae</i>, <i>Vibrio cholera</i> O1 using slide agglutination tests using commercially-supplied antisera</p> <p>Oxidase-positive and –negative isolate determination using Pro-Lab Testoxidase</p>	<p>DRI</p> <p>DRI</p> <p>DRI</p> <p>DRI</p> <p>DRI</p> <p>DRI</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturer's instructions for:	
Direct specimen testing and cultures isolated in-house from the above samples	Detection and identification of clinically significant bacteria and yeasts	Manual staining and microscopy Identification Methods SOP (MIC-SOP-35): Grams' stain Auramine stains Ziehl Neelson stains Acridine Orange stain	DRI
Cultures isolated in-house from the above samples	Antimicrobial susceptibility testing of clinically-significant bacteria, yeasts (including determination of minimum inhibitory concentration (MIC)	All below follow EUCAST directions and requirements: Documented procedures and manufacturers' instructions for VITEK2 Compact MIC-SOP-45 and MIC-SOP-45 Manual testing by disc-diffusion MIC-SOP-5	DRI
	<u>Serology examination activities for the purpose of clinical diagnosis</u>		DRI
Serum	Semi-quantitative Determination of ASO Antibodies	VIR-SOP-1 - Latex slide agglutination assay (Polystyrene latex particles coated with streptolysin-O antigen in a stabilising buffer) using Bio-kit Rheumajet commercial kit.	DRI
Serum	Detection of Mycoplasma IgG	VIR-SOP-2 - Indirect sandwich chemiluminescence immunoassay (CLIA).	DRI
Serum	Detection of Mycoplasma IgM	VIR-SOP-2 - Indirect sandwich chemiluminescence immunoassay (CLIA).	DRI
Serum	Detection of Measles IgG	VIR-SOP-2 - Indirect sandwich chemiluminescence immunoassay (CLIA).	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Urine	Detection of Legionella pneumophila serogroup 1 Antigen	VIR-SOP-3 - Immunochromatographic membrane device assay using Binax NOW commercial kit.	DRI
Naso-pharyngeal Aspirate	Detection of RSV	VIR-SOP-4 - Immunochromatographic membrane device assay (for the qualitative detection of RSV fusion protein antigen) using Binax NOW commercial kit.	DRI
Serum	Semi-Quantitative Syphilis Monitoring (RPR)	VIR-SOP-15 - VDRL (RPR) reagin slide test (Carbon particles coated with reagin antigen) used to measure the presence of non-treponemal antibodies produced because of syphilitic infection. Performed using the NewBio RPR (Rapid Plasma Reagin) Commercial Kit	DRI
Stool	Detection of Rotavirus & Adenovirus Antigen	VIR-SOP-58 - Immunochromatographic membrane device assay (for the qualitative detection of Rotavirus and Adenovirus antigens in faecal specimens) using Prolab ProFlow™ Rota/Adeno commercial kit.	DRI
Stool	Detection of Norovirus Antigen	VIR-SOP-59 - Immunochromatographic membrane device assay (for the qualitative detection of Norovirus antigens in faecal specimens) using Prolab ProFlow Norovirus kit	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Immunoassay:	Documented procedures & manufacturer's instructions for Abbott Alinity I (VIR-SOP-96) analyser with specific reference to:	DRI
		Documented In-House Methods to meet the requirements of the IDPS Programme handbook as defined in the current version of 'infectious diseases in pregnancy screening: laboratory QA evidence requirements as applicable and noted with an asterisk:	
Serum	Detection of Cytomegalovirus IgG	VIR-SOP-94	DRI
Serum	Detection of Cytomegalovirus IgM	VIR-SOP-94	DRI
Serum	Detection of Hepatitis A IgG	VIR-SOP-99	DRI
Serum	Detection of Hepatitis A IgM	VIR-SOP-101	DRI
Serum	Detection of Hepatitis B Antibody	VIR-SOP-102	DRI
Serum	Detection of Hepatitis B Surface Antigen *	VIR-SOP-92	DRI
Serum	Detection of Hepatitis B Core Antibody	VIR-SOP-91	DRI
Serum	Detection of Hepatitis C Antibody	VIR-SOP-93	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	Immunoassay:	Documented procedures & manufacturer's instructions for Abbott Alinity I (VIR-SOP-96) analyser with specific reference to:	DRI
		Documented In-House Methods to meet the requirements of the IDPS Programme handbook as defined in the current version of 'infectious diseases in pregnancy screening: laboratory QA evidence requirements as applicable and noted with an asterisk:	
Serum	Detection of HIV Antigen/Antibody *	VIR-SOP-90	DRI
Serum	Detection of Rubella IgG	VIR-SOP-97	DRI
Serum	Detection of Rubella IgM	VIR-SOP-95	DRI
Serum	Detection of Syphilis Treponemal Antibody *	VIR-SOP-98	DRI
Serum	Detection of Toxoplasma IgG	VIR-SOP-100	DRI
Serum	Detection of Toxoplasma IgM	VIR-SOP-100	DRI



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	
Serum	Immunoassay (Diasorin):	Samples are analysed using the Diasorin Liaison XL (automated chemiluminescence immunoassay) according to manufacturer's instructions (VIR-SOP-38 and VIR-SOP-39) and VIR-SOP-33, with specific reference to:	DRI
	Detection of EBV VCA IgG	VIR-SOP-35 - Indirect chemiluminescence immunoassay (CLIA).	DRI
	Detection of EBV VCA IgM	VIR-SOP-35 - Indirect chemiluminescence immunoassay (CLIA).	DRI
	Detection of EBV EBNA IgG	VIR-SOP-35 - Indirect chemiluminescence immunoassay (CLIA).	DRI
	Detection of Parvovirus IgG	VIR-SOP-36 - Indirect sandwich chemiluminescence immunoassay (CLIA).	DRI
	Detection of Parvovirus IgM	VIR-SOP-36 - Antibody-capture sandwich chemiluminescence immunoassay (CLIA).	DRI
	Semi-quantitative Determination of Varicella zoster IgG	VIR-SOP-37 - Indirect sandwich chemiluminescence immunoassay (CLIA).	DRI
Faeces	Calprotectin	VIR-SOP-74 Chemiluminescent microparticle immunoassay	DRI
Serum	Determination of Procalcitonin Levels	VIR-SOP-16 Chemiluminescent microparticle immunoassay	DRI

END