

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2022	Sheffield Teaching Hospitals NHS Foundation Trust	
	Issue No: 012 Issue date: 08 May 2025	
	Doncaster & Bassetlaw NHS Foundation Trust Pathology Services Doncaster Royal Infirmary Armthorpe Road Doncaster DN2 5LT	Contact: Mr Andrew Wood Tel: +44 (0)1302 644749 Extn. 644749 E-Mail: andrew.wood24@nhs.net Website: www.dbth.nhs.uk

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 Pathology Department Doncaster Royal Infirmary Armthorpe Road Doncaster DN2 5LT	Local contact Mr Andrew Wood Tel: +44 (0)1302 644749 E-Mail: andrew.wood24@nhs.net	Andrology Blood Transfusion Haematology Clinical Biochemistry Immunology Microbiology Virology Cellular Pathology Phlebotomy Mortuary Services Body Storage Facilities Blood Issue fridge 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: <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 FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> Chemistry Assays Quantification of	Documented in house methods and manufacturer's instructions for: Abbott Architect c16000 (DRI, CLS-SOP-528) analyser with specific reference to:	
Serum / Urine	Sodium	Ion selective electrode CLS-SOP-218	DRI
Serum / Urine	Potassium	Ion selective electrode CLS-SOP-218	DRI
Serum / Urine	Urea	Enzymatic CLS-SOP-227	DRI
Serum / Urine	Creatinine	Enzymatic CLS-SOP-216	DRI
Serum	eGFR	Calculated eGFR/EPI formula CLS-SOP-697	DRI
Serum	Calculated AKI	Nationally mandated algorithm (NHS England Alert 2015) CLS-SOP-697	DRI
Serum / Urine	Creatinine Clearance	Calculated using standard formula CLS-SOP-697	DRI
Serum	Total Protein	Colourimetric CLS-SOP-300	DRI
Serum	Albumin	Colourimetric CLS-SOP-207	DRI
Serum	Alkaline Phosphatase	Enzymatic CLS-SOP-208	DRI
Serum	ALT	Enzymatic CLS-SOP-205	DRI
Serum	Total Bilirubin	Colourimetric CLS-SOP-226	DRI
Serum	Conjugated Direct Bilirubin	Colourimetric CLS-SOP-223	DRI
Serum / Urine	Calcium	Colourimetric CLS-SOP-214	DRI
Serum / Urine	Phosphate	Colourimetric CLS-SOP-225	DRI



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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)	<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 Architect c16000 (DRI, CLS-SOP-528) analyser with specific reference to:	
	Quantification of (cont'd)		
Serum	Calcium (Albumin Adjusted)	Calculation based on ACB Position paper 2015 equation	DRI
Serum	Triglyceride	Enzymatic CLS-SOP-299	DRI
Serum	Total Cholesterol	Enzymatic CLS-SOP-215	DRI
Serum	HDL Cholesterol	Accelerator Selective Detergent Enzymatic CLS-SOP-285	DRI
Serum	LDL Cholesterol	Friedwald Equation CLS-SOP-701	DRI
Serum	Non-HDL Cholesterol	As per NICE CG 181 CLS-SOP-701	DRI
Lithium Heparin Plasma	Ammonia	Enzymatic CLS-SOP-209	DRI
Serum / Urine	Amylase	Enzymatic CLS-SOP-210	DRI
Serum	AST	Activated Enzymatic CLS-SOP-206	DRI
Serum	Bicarbonate	Enzymatic CLS-SOP-373	DRI
Serum/Urine	Chloride	Ion selective electrode CLS-SOP-218	DRI
Serum	Creatine Kinase	Enzymatic CLS-SOP-230	DRI
Serum	C Reactive Protein	Latex immunoassay turbidimetric CLS-SOP-222	DRI
Serum	Digoxin	Particle enhanced turbidimetric inhibition immunoassay CLS-SOP-283	DRI
Fluoride Oxalate plasma	Ethanol	Enzymatic CLS-SOP-231	DRI
Serum	Gamma GT	Enzymatic CLS-SOP-217	DRI



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HUMAN BODY FLUIDS (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 Architect c16000 (DRI, CLS-SOP-528) analyser with specific reference to:	
	Quantification of (cont'd)		
Fluoride Oxalate Plasma/CSF	Glucose	Enzymatic CLS-SOP-284	DRI
Serum	Iron	Colourimetric CLS-SOP-219	DRI
Fluoride Oxalate Plasma	Lactate	Enzymatic CLS-SOP-220	DRI
Serum	LDH	Enzymatic CLS-SOP-233	DRI
Serum	Lithium	Colourimetric CLS-SOP-292	DRI
Serum/Urine	Magnesium	Colourimetric CLS-SOP-224	DRI
Serum	Paracetamol	Enzymatic/Colorimetric CLS-SOP-297	DRI
Serum	Salicylate	Enzymatic/Colorimetric CLS-SOP-254	DRI
CSF/Urine	Protein	Turbidimetric CLS-SOP-140	DRI
Serum/Urine	Uric Acid	Enzymatic CLS-SOP-367	DRI
Serum	Alpha-1 Antitrypsin	Immunoturbidimetric CLS-SOP-256	DRI
Serum	Angiotensin Converting Enzyme	Enzymatic CLS-SOP-257	DRI
Serum	β -2 Microglobulin	Immunoturbidimetric CLS-SOP-228	DRI
Serum	Bile Acids	Enzymatic CLS-SOP-211	DRI
Serum	Complement C3	Immunoturbidimetric CLS-SOP-212	DRI
Serum	Complement C4	Immunoturbidimetric CLS-SOP-213	DRI
Serum	Haptoglobin	Immunoturbidimetric CLS-SOP-232	DRI



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HUMAN BODY FLUIDS (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 Architect c16000 (DRI, CLS-SOP-528) analyser with specific reference to:	
	Quantification of (cont'd)		
Serum	Immunoglobulins IgG	Immunoturbidimetric CLS-SOP-287	DRI
Serum	Immunoglobulins IgM	Immunoturbidimetric CLS-SOP-288	DRI
Serum	Immunoglobulins IgA	Immunoturbidimetric CLS-SOP-286	DRI
Serum	Phenobarbitone	Turbidimetric inhibition immunoassay CLS-SOP-234	DRI
Serum	Phenytoin	Enzyme Immunoassay CLS-SOP-235	DRI
Serum	Rheumatoid Factor	Immunoturbidimetric CLS-SOP-298	DRI
Serum	Theophylline	Enzyme Immunoassay CLS-SOP-253	DRI
Serum	Transferrin	Immunoturbidimetric CLS-SOP-302	DRI
Serum	Valproate	Turbidimetric inhibition immunoassay CLS-SOP-255	DRI



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HUMAN BODY FLUIDS (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 Architect I2000 (DRI, VIR-SOP-20) analyser with specific reference to:	
Serum	Total β HCG	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP-316	DRI
Lithium Heparin Plasma	hs Troponin I	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP-221	DRI
Serum	25-Hydroxy-Vitamin D	1-Step Competitive Chemiluminescent Immunoassay CLS-SOP-512	DRI
EDTA Plasma	NT pro B-Type Natriuretic Peptide (BNP)	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP 786	DRI
Serum	Cortisol	1-Step Competitive Chemiluminescent Immunoassay CLS-SOP-179	DRI
Serum	DHEAS	1-Step Competitive Chemiluminescent Immunoassay CLS-SOP-180	DRI
Serum	Ferritin	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP-182	DRI
Serum	Folate	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP-183	DRI
Serum	FSH	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-184	DRI
Serum	Free T3	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP-185	DRI



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HUMAN BODY FLUIDS (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 Architect I2000 (DRI, VIR-SOP-20) analyser with specific reference to:	
Serum	LH	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-311	DRI
Serum	Oestradiol	1-Step Competitive Chemiluminescent Immunoassay CLS-SOP-181	DRI
Serum	Progesterone	1-Step Competitive Chemiluminescent Immunoassay CLS-SOP-310	DRI
Serum	Prolactin	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-315	DRI
Serum	Macroprolactin	PEG Precipitation CLS-SOP-315	DRI
Serum	Prostate Specific Antigen	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-314	DRI
EDTA Plasma	Parathyroid Hormone	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-312	DRI
Serum	Sex Hormone Binding Globulin	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-313	DRI
Serum	Testosterone	1-Step Competitive Chemiluminescent Immunoassay CLS-SOP-190	DRI



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HUMAN BODY FLUIDS (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 Architect I2000 (DRI, VIR-SOP-20) analyser with specific reference to:	
Serum	TSH	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-189	DRI
Serum	Free T4	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP-188	DRI
Serum	Vit B 12	2-Step Competitive Chemiluminescent Immunoassay CLS-SOP-174	DRI
Serum	Thyroid Peroxidase Antibodies	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-173	DRI
Serum	AFP	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-172	DRI
Serum	CA125	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-177	DRI
Serum	CA15-3	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-773	DRI
Serum	CA19-9	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-176	DRI
Serum	CEA	2-step Non-competitive Chemiluminescent Immunoassay CLS-SOP-178	DRI
Serum	Carbamazepine	1-step Chemiluminescence Immunoassay CLS-SOP-229	DRI



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HUMAN BODY FLUIDS (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 Diasorin Liaison XL analyser (VIR-SOP-33) with specific reference to	
EDTA Plasma	ACTH	Sandwich chemiluminescence immunoassay CLS-SOP-162	DRI
Serum	Growth Hormone	Sandwich chemiluminescence immunoassay CLS-SOP-163	DRI
Serum	IGF-1	Sandwich chemiluminescence immunoassay CLS-SOP-164	DRI
Serum	Tumour Marker hCG	Sandwich chemiluminescence immunoassay CLS-SOP-165	DRI



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HUMAN BODY FLUIDS (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 FLUIDS (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 FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Sweat	Specialist Chemistry Tests: (cont'd) Sweat Chloride (Quantitation and Interpretation)	Documented procedures & manufacturer's instructions for Sebia Capillary S Electrophoresis System (Capillary Zone Electrophoresis) with specific reference to: Coulometry Documented procedures & manufacturer's instructions for the Sherwood model 926S Chloride Analyser - CLS-SOP-19	DRI



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HUMAN BODY FLUIDS (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	Full Blood Count Quantification of Haemoglobin White Blood Cell Count Red Blood Count Platelet Count Red cell distribution width Haematocrit 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	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 Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry Fluorescence Flow Cytometry	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 FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis: (cont'd)</u>	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



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HUMAN BODY FLUIDS (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



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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 FLUIDS (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 FLUIDS (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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HUMAN BODY FLUIDS (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 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	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	DRI BDGH
EDTA Whole Blood	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	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.	DRI BDGH
EDTA Whole Blood	Manual Rh and K Type For profiling of the Rh phenotype and K typing	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	DRI BDGH



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HUMAN BODY FLUIDS (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	Using the acid elution method - Source Bioscience Fetal Cell Detection kit – CLS-SOP-388	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 FLUIDS (cont'd)	<u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Fixed, fresh tissue samples and cell blocks (biopsy, excision, resection and post-mortem specimens) (cont'd)	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	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	
		<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)	DRI
		<u>Embedding:</u> Specimen embedding (HIS-SOP-4) Using: ThermoShandon Histostar (HIS-SOP-247) embedding consoles	DRI
Formalin fixed paraffin wax blocks of processed tissue		<u>Microtomy:</u> Section cutting - (HIS-SOP-5 and HIS-SOP-6) Using: Leica and ThermoShandon microtomes – (HIS-SOP-5; HIS-SOP-6)	DRI
FFPE (formalin fixed paraffin embedded) tissue on glass slides		<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)	DRI



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HUMAN BODY FLUIDS (cont'd)	<u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Fresh and Frozen tissue/ Frozen sections on glass slides	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	Frozen sections: Use of cyrostat (HIS-SOP-36) in conjunction with manufacturer's instructions for Leica Cryostat CM1850 (HIS-SOP-256) Manual rapid (frozen sections): Urgent frozen section: (HIS-SOP-37)	DRI
Fresh and Frozen tissue/ Frozen sections on glass slides	Direct Immunohistochemistry to detect / identify the following:	Documented in-house manual methods (HIS-SOP-36, HIS-SOP-38) in conjunction with manufacturer's instructions for Leica Cryostat CM1850 (HIS-SOP-256)	DRI
Fixed tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides	Special Stains for the detection / identification of:	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)	DRI
	Acid mucins	Alcian Blue (HIS-SOP-114)	
	Mucins (acid, neutral, mixed)	Alcian Blue - Periodic acid Schiff's (HIS-SOP-115)	
	Amyloid	Congo red (HIS-SOP-116)	
	Elastic fibres and connective tissue	Elastic Van Gieson (HIS-SOP-117)	
	Gram positive and negative organisms	Gram (HIS-SOP-120)	



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HUMAN BODY FLUIDS (cont'd)	<u>Histopathological examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	DRI
Fixed, fresh tissue samples and cell blocks / FFPE (formalin fixed paraffin embedded) tissue on glass slides	Special Stains for the detection / identification of: (cont'd)	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)	
	H. pylori, mast cells, basophil granules	Giemsa (modified) (HIS-SOP-118)	
	Nuclei and connective tissue	Haematoxylin van Gieson (HIS-SOP-121)	
	Fibrin and connective tissue	Martius yellow - Brilliant crystal scarlet - Soluble blue (MSB) (HIS-SOP-124)	
	Removal of melanin pigment	Melanin bleach (HIS-SOP-126)	
	Fungi, glomerular basement membrane, P. carinii, glycogen	Methenamine silver (Grocott) (HIS-SOP-125)	
	Melanin, argentaffin and chromaffin cells	Masson Fontana (HIS-SOP-122)	
	Connective tissue	Masson Trichrome (HIS-SOP-123)	
	Hepatitis B surface antigen and copper associated protein	Orcein (HIS-SOP-127)	
	PAS - polysaccharides including: glycogen, neutral mucins, fungi PAS-D - removal of glycogen	Periodic acid Schiffs (PAS) and Diastase - Periodic acid Schiffs (PAS-D) (HIS-SOP-129)	
	Haemosiderin (ferric iron salts) and asbestos bodies	Perls (HIS-SOP-128)	
	Reticulin fibres	Reticulin (HIS-SOP-131)	



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<p>HUMAN BODY FLUIDS (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>Documented in house methods and manufacturer's instructions for:</p>	DRI
	<p>Special Stains for the detection / identification of: (cont'd)</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>Amyloid, elastic and eosinophils</p>	<p>Sirius red (HIS-SOP-133)</p>	
	<p>Calcium deposits</p>	<p>Von Kossa (HIS-SOP-135)</p>	
	<p>Mycobacterium spp, including Mycobacterium tuberculosis</p>	<p>Ziehl Neelson (HIS-SOP-138)</p>	DRI
	<p>Immunohistochemistry to detect / identify the following:</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>Cytokeratins: 1, 5, 10 & 14 (high molecular weight cytokeratins)</p>	<p>34βE12</p>	
	<p>Broad range cytokeratin</p>	<p>Cytokeratin AE1 / AE3</p>	
	<p>Fetal liver cells</p>	<p>Alpha 1 fetoprotein (AFP)</p>	
	<p>Mesenchymal marker</p>	<p>α smooth muscle action (αSMA)</p>	
	<p>T-cells, B-cells in mantle zone</p>	<p>BCL-2</p>	
	<p>Epithelial cells</p>	<p>Ber Ep4</p>	



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<p>HUMAN BODY FLUIDS (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>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>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>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>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>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>DRI</p>



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<p>HUMAN BODY FLUIDS (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>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>Oestrogen receptor</p> <p>Melanosomes</p> <p>Leydig, Steroli cells</p> <p>Proliferation marker</p> <p>Leukocyte common antigen</p> <p>Melanocytes</p> <p>p16 HPV biomarkers</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>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>ER</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>P16</p>	DRI



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<p>HUMAN BODY FLUIDS (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>Alpha methylacyl coenzyme A racemase</p> <p>Tumour suppressor gene</p> <p>Basal cell marker</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>P504S/ AMACR</p> <p>P53</p> <p>P63</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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HUMAN BODY FLUIDS (cont'd)	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for:	
CSF, urine, bronchial brush, bronchial wash, sputum, joint fluid, fine needle aspirate/ aspirate of general body fluids / cytopspin	Examination of human body fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis.	<u>Sample preparation:</u> Non gynae specimen receipt (HIS-SOP-76) Fine needle aspiration (HIS-SOP-79) Use of cytopspin (HIS-SOP-82) Use of exhaust protection cabinet (HIS-SOP-84) Preparation of agar clots (HIS-SOP-98)	DRI
Slides prepared in-house from Synovial and joint fluids	Detection and identification of crystals	Synovial and joint fluids (HIS-SOP-80)	DRI
Slides prepared in-house from sample types listed above	Demonstration of cells (nuclei and cytoplasm)	<u>Staining: automated:</u> Gemini autostainer (HIS-SOP-9 and HIS-SOP-10) Coverslipping: HIS-SOP-11 QA in routine histology: HIS-SOP-13	DRI
Slides prepared in-house from sample types listed above	Demonstration of cells (nuclei and cytoplasm)	<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)	DRI



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HUMAN BODY FLUIDS (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 (Papanicolaou) 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 FLUIDS (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 FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Faeces	Determination of Presence of Clostridium Difficile Toxins	Automated immunoassay for detection of glutamate dehydrogenase and C. difficile toxins using manufacturer's instructions, software and Dynex DS2. Referral to SOP: Clostridium difficile SOP: Clostridium difficile EIA tests MIC-SOP-93 and Quik Chek Complete MIC-SOP-137	DRI
Whole blood (heparinised)	General isolation and characterisation of micro-organisms of clinical significance	Documented procedures & manufacturer's instructions for BacT/Alert 3D 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



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Swabs	Molecular Detection of Herpes Simplex Virus I/II via PCR	Samples are analysed using the HAIN Flurocycler analyser (PCR) according to SOPs (VIR-SOP-67 and VIR-SOP-68), with specific reference to VIR-SOP-70	DRI
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, urethral)	Molecular Detection of Chlamydia & Neisseria gonorrhoea(GC) DNA	Samples are analysed using the Becton Dickinson VIPER analyser (Automated Strand Displacement Amplification) according to manufacturer's instructions (MIC-SOP-125 and MIC-SOP-126), with specific reference to MIC-SOP-39	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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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Cultures isolated in-house from the above samples	Identification of clinically significant bacteria and yeasts	Documented procedures and manufacturers' instructions for Maldi TOF MIC-SOP-122 Biochemical profile determination using VITEK2 Compact MIC-SOP-45 and MIC-SOP-45 The following methods are also used for identification and are described in Identification Methods SOP (MIC-SOP-35): Biochemical profile determination using API Biochemical test strips (BioMerieux)	DRI
		Staphylococci identification using Prolex Staph Xtra latex agglutination test kit	DRI
		Streptococci (Lancefield groups A, B, C, D, F, G) identification using Pro-Lab Prolex Streptococcal Grouping kit	DRI
		E. coli O157 identification using E. coli O157 latex test kit (Oxoid)	DRI
		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	DRI
		Oxidase-positive and –negative isolate determination using Pro-Lab Testoxidase	DRI



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	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 IgM	VIR-SOP-2 - Gel particle agglutination assay (Gelatin particles are coated with Mycoplasma antigen) using Serodia MYCO II commercial kit.	DRI



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
	<u>Serology examination activities for the purpose of clinical diagnosis</u> (cont'd)		
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 VDRL Syphilis Monitoring	VIR-SOP-15 - VDRL (Venereal Disease Reference Laboratory) 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 Axis Shield 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 FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	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



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturer's instructions for:	
Serum	Determination of Procalcitonin Levels	VIR-SOP-16 Chemiluminescent microparticle immunoassay	DRI
		Samples are analysed using the Abbott Architect C16000 analyser (automated chemistry) according to manufacturer's instructions (VIR-SOP-60) and CLS-SOP-528, with specific reference to:	DRI
Serum	Quantitative Determination of Vancomycin	MIC-SOP-8 - Homogeneous particle-enhanced turbidimetric inhibition immunoassay (PETINIA).	DRI
END			