


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9623 Accredited to ISO 15189:2022	Sheffield Teaching Hospitals NHS Foundation Trust	
	Issue No: 015 Issue date: 07 February 2025	
	Rotherham Hospital Moorgate Road Rotherham S60 2UD	Contact: Natalie Holmes Tel: +44 (0) 1709 424008 E-Mail: sth.sybpqrg@nhs.net Website: http://www.therotherhamft.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	Site Activity
The Rotherham NHS Foundation Trust Moorgate Road Rotherham S60 2UD	Biochemistry Haematology and Blood Transfusion Blood Fridges (Blood Transfusion Laboratory) <ul style="list-style-type: none">• Blood Stock Fridge APL2• Blood Issue Fridge APL3 Immunology Microbiology Cellular Pathology Andrology

Site activities performed away from the locations listed above:

Location details	Activity
Mortuary / Body Store The Rotherham NHS Foundation Trust Moorgate Road Rotherham S60 2UD	Mortuary Services (body receipt, storage, and release)



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> <u>Automated Routine Biochemistry</u> Quantitative determination of:	Documented in house methods and manufacturers' instructions for: Siemens Atellica CH SOP LP-BIO-AL-130 by:
Serum/Plasma	Alpha 1 Antitrypsin	Immunturbidimetric
Serum/Plasma	Albumin	BCG
Serum/Plasma	Alkaline Phosphatase	Enzymatic
Serum/Plasma	ALT	Enzymatic
Lithium heparin plasma	Ammonia	Enzymatic
Serum/Plasma	AST	Enzymatic
Serum/Plasma	Beta-2-Microglobulin	Latex agglutination
Serum/Plasma	Bicarbonate	Enzymatic
Serum/Plasma/Urine	Calcium	Arsenazo III
Serum/Plasma	Carbamazepine	PETINIA
Serum/Plasma	Cholesterol	Chol esterase
Serum/Plasma	Creatine Kinase	Enzymatic
Serum/Plasma/Urine	Chloride	Indirect ISE
Serum	Complement C3	Immunturbidimetric
Serum	Complement C4	Immunturbidimetric
Serum/Plasma	Direct (Conjugated) Bilirubin	Endpoint oxidation
Serum/Plasma	HDL- Cholesterol	Trinder reaction
Serum/Plasma/Urine	Creatinine	Enzymatic
Serum/Plasma	Gentamicin	PETINIA



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturers' instructions for:
	Quantitative determination of: (cont'd)	Siemens Atellica CH SOP LP-BIO-AL-130 by:
Serum/Plasma	Gamma GT	Enzymatic
Serum/Flox Plasma/CSF	Glucose	Enzymatic
Serum	Haptoglobin	PEG enhanced
Serum/Plasma	IgA	PEG enhanced
Serum/Plasma	IgG	PEG enhanced
Serum/Plasma	IgM	PEG enhanced
Serum/Plasma/Urine	Inorganic phosphorus	Molybdate
Serum/Plasma	Iron	Ferrozine
Serum/Plasma	Paracetamol	Enzymatic
Serum/Plasma/Urine	Potassium	Indirect ISE
Serum/Plasma	LDH	Enzymatic
Flox Plasma/CSF	Lactate	Enzymatic
Serum/Plasma	Lipase	Enzymatic
Serum/Plasma	Lithium	Colorimetric endpoint
Serum/Plasma/Urine	Magnesium	Xylidyl blue
Serum/Plasma/Urine	Sodium	Indirect ISE
Serum/Plasma	Phenytoin	PETINIA
Serum/Plasma	Salicylate	Enzymatic
Serum/Plasma	Total Bilirubin	Vanadate oxidation
Serum/Plasma	Theophylline	PETINIA
Serum/Plasma	Total protein	Biuret



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturers' instructions for:
	Quantitative determination of: (cont'd)	Siemens Atellica CH SOP LP-BIO-AL-130 by:
Serum/Plasma	Transferrin	PEG- enhanced immunoturbidimetric
Serum/Plasma	Triglycerides	Enzymatic
Serum/Plasma	Caeruloplasmin	Turbidimetric
Serum/Plasma	Bile acids	Enzymatic
Serum/Plasma/Urine	Uric acid	Enzymatic
Serum/Plasma/Urine	Urea	Enzymatic
Urine/CSF	Protein	Pyrogallol red
Serum/Plasma	Valproic acid (Valproate)	PETINIA
Serum/ Plasma	C-reactive protein	Latex agglutination
	Calculated Tests	Results from Siemens Atellica CH SOP LP-BIO-AL-130 and calculations by WinPath Enterprise
Serum/Plasma	Osmolar gap	
Serum/Plasma	Globulin	
Serum/Plasma	Adjusted calcium	
Serum/Plasma	Cholesterol: HDL ratio	
Serum/Plasma	LDL	
Serum/Plasma	Non-HDL	
Serum/Plasma	Iron binding capacity	
Serum/Plasma	Transferrin saturation	
24h Urine	Sodium	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturers' instructions for:
	Calculated Tests (cont'd)	Results from Siemens Atellica CH SOP LP-BIO-AL-130 and calculations by WinPath Enterprise
24h Urine	Potassium	
24h Urine	Chloride	
24h Urine	Creatinine	
24h Urine	Urea	
24h Urine	Calcium	
24h Urine	Phosphate	
24h Urine	Urate	
24h Urine	Magnesium	
24h Urine	Protein	
Urine	Protein: Creatinine Ratio	
Urine	Calcium: Creatinine Ratio	
Urine	Calcium Clearance	
Urine	Calcium Excretion	
Urine/Serum/Plasma	24- hour Creatinine Clearance	
Serum	eGFR	
Serum	CKD Status	
Serum	AKI	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u> Quantitative determination of:	Documented in house methods and manufacturers' instructions for: Siemens Atellica IM SOP LP-BIO-AL-130 by immunoassay
Serum/Plasma	Cortisol	
Serum	Digoxin	
Serum/Plasma	Erythropoietin	
Serum/Plasma	Ferritin	
Serum	Folate	
Serum/Plasma	FSH	
Serum/Plasma	Free T3	
Serum/Plasma	Free T4	
Serum/Plasma	TPO	
Serum/Plasma	LH	
Serum/Plasma	Progesterone	
Serum/Plasma	Prolactin	
Serum	Macro-Prolactin	
Serum	Total HCG	
Serum/Plasma	Troponin I	
Serum/Plasma	TSH	
Serum/Plasma	Vitamin B12	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u> <u>Manual Biochemistry</u>	Documented in house methods and manufacturers' instructions for:
Serum /Urine	Osmolality	Advanced Instruments Osmo 1 Osmometer SOP LP-BIO-ODD-043 Depression of freezing point
	Blood Gas Profile:	IL GEM 5000 SOP LP-BIO-ODD-0421 by:
Whole Blood	pH	Potentiometric Sensor
Whole Blood	pCO ₂	Potentiometric Sensor
Whole Blood	pO ₂	Potentiometric Sensor
Whole Blood	Carbon Monoxide	Amperometric Sensor
Whole Blood	Carboxyhaemoglobin	Optical measurement following chemical lysing and mixing of whole blood samples
Whole Blood	Methaemoglobin	Optical measurement following chemical lysing and mixing of whole blood samples
Whole Blood	Oxyhaemoglobin	Optical measurement following chemical lysing and mixing of whole blood samples
Whole Blood	Whole Blood Sodium	Potentiometric Sensor
Whole Blood	Whole Blood Potassium	Potentiometric Sensor
Whole Blood	Whole Blood Lactate	Amperometric Sensor
Whole Blood	Whole Blood Glucose	Amperometric Sensor
Whole Blood	Whole Blood Ionised Calcium	Potentiometric Sensor



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u> <u>Specialist Biochemistry</u>	Documented in house methods and manufacturers' instructions for:
CSF	Xanthochromia	Scanning spectrophotometry (UVIKON) SOP LP-BIO-ODD-030
Serum	Vitamin A & E	HPLC UV Detection (Chromsystems) SOP LP-BIO-HPL-001
Serum	Vitamin C	HPLC UV Detection (Chromsystems) SOP LP-BIO-HPL-002
Whole Blood	Vitamin B1	HPLC Fluorimetric Detection (Chromsystems) SOP LP-BIO-HPC-011
Whole Blood	Vitamin B6	HPLC Fluorimetric Detection (Chromsystems) SOP LP-BIO-HPC-010
Urine	Catecholamines	HPLC ECD (Chromsystems) SOP LP-BIO-HPC-005
Urine	Metanephrines	HPLC ECD (Chromsystems) SOP LP-BIO-HPC-007
Urine	5-HIAA	HPLC ECD (Chromsystems) SOP LP-BIO-HPC-018
Faeces	Calprotectin	Double- Sandwich ELISA Dynex DS2 SOP LP-BIO-ODD-035



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HUMAN BODY FLUIDS (cont'd)	<p><u>Haematological examination activities for the purposes of clinical diagnosis:</u></p> <p>Full Blood Count (FBC) Analysis of the following parameters:</p>	<p>Documented in house methods and manufacturer's instructions for:</p>
Blood	Platelets	Siemens ADVIA 2120i SOP LP-HAE-LAB-094 by: Mie Theory of light scatter, Siemens reagent
Blood	Red Blood Cells	Cytochemical method using ADVIA 2120 RBC/PLT reagent
Blood	Haemoglobin Haematocrit MCV MCH MCHC RDW	Cyanide- free haemoglobin method
Blood	White Cell Count Neutrophils Lymphocytes Monocytes Eosinophils Basophils LUCs	Peroxidase (Differential cellular staining and Basophil (lobularity) methods
	Manual differential for:	Blood Film and Manual Diff using:
	Metamyelocytes Myelocytes Promyelocytes Blasts Nucleated RBC	Siemens Hematek Analyser and Wright- Giemsa stained films Manual method using May – Grunwald- Giemsa stained films Examined by microscopy SOP LP-HAE-LAB-088, LP-HAE-LAB-039



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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:
Blood	Reticulocytes	Siemens ADVIA 2120 SOP-LP-HAE-LAB-020 Cytochemical method using ADVIA 120 autoRETIC reagent
Blood	ESR	Vitech Starrsed Compact SOP LP-HAE-LB-071 Westergren method
	<u>Coagulation Studies</u>	
Blood (Plasma)	INR	Stago STA-R Max SOP LP-HAEM-COA-048 Chronometric assay using STA®-Neoplastin® R, Manufacturer's ISI and mean normal Prothrombin Time established from the geometric mean of a minimum of 20 normal subjects
Blood (Plasma)	Activated Partial Thromboplastin Time (APTT) (iv heparin monitoring)	Stago STA-R Max SOP LP-HAEM-COA-048 Chronometric assay using STA®-Cephascreen® and the mean normal Activated Partial Thromboplastin Time established from the geometric mean of a minimum of 20 normal subjects
Blood (Plasma)	Prothrombin Time	Stago STA-R Max SOP LP-HAEM-COA-048 Chronometric assay using STA®-Neoplastin® R
Blood (Plasma)	APTT	Stago STA-R Max SOP LP-HAEM-COA-048 Chronometric assay using STA®-Cephascreen®
Blood (Plasma)	Fibrinogen	Stago STA-R Max SOP LP-HAEM-COA-048 Clauss clotting method using STA®-Fibrinogen 5



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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:
Blood (Plasma)	D-Dimer	Stago STA-R Max SOP LP-HAEM-COA-048 Immunturbidimetric method using STA®-Liatest®
Blood (Plasma)	Mixing Studies	Stago STA-R Max SOP LP-HAEM-COA-010 STA®-Cephascreen® and/or Chronometric assay using STA®-Neoplastin® R
Blood (Plasma)	Actin FS APTT	Stago STA-R Max SOP LP-HAEM-COA-048 Chronometric assay using Sysmex Actin FS
Blood (Plasma)	<u>Lupus Testing:</u> Dilute Russell Viper's Venom Screen	Stago STA-R Max SOP LP-HAEM-COA-053 Chronometric assay using snake venom to activate phospholipid-dependent part of coagulation cascade
Blood (Plasma)	Dilute Russell Viper's Venom Confirm	Stago STA-R Max SOP LP-HAEM-COA-053 Chronometric assay using snake venom to activate phospholipid-dependent part of coagulation cascade and excess phospholipid to neutralise LA
Blood (Plasma)	PTTLA (Lupus sensitive APTT reagent)	Stago STA-R Max SOP LP-HAEM-COA-053 Chronometric assay using LA-sensitive STA®-PTTLA reagent
Blood (Plasma)	Actin FS (Lupus insensitive APTT reagent)	Stago STA-R Max SOP LP-HAEM-COA-053 Chronometric assay using LA-insensitive Sysmex Actin FS reagent



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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:
Blood	<u>Manual Testing</u> Glandular Fever Screen for IM heterophile antibodies	Accusay Mono IM SOP LP-HAE-LAB-065 Bovine erythrocyte extract (immunoassay)
Blood	<i>Plasmodium falciparum</i> HRP2 & <i>P. falciparum</i> , <i>P. vivax</i> , <i>P. ovale</i> , <i>P. malariae</i> Pan LDH	Apacor CareUS Rapid Malaria Test (RDT) SOP LP-HAE-LAB-038 Immuno-chromatographic method
Blood	Thick and thin blood film for detection of malarial parasite stages	SOP LP-HAE-LAB-038 Manual staining at pH 7.2, Giemsa Stain and microscopy
Blood	Sickle Test for detection of HbS	Microgen m96-50 S-test kit SOP LP-HAE-LAB-001 Qualitative method using phosphate buffer and sodium dithionate (reducing agent)
		Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia Screening Programme as defined in the July 2018 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements (Provisional Screen)
	<u>Haemoglobinopathy Investigation</u> Haemoglobinopathy Investigations to determine HbA2 and HbF levels and the presence of abnormal haemoglobins	TOSOH G11 HPLC technology to determine with reference to:
Blood		SOP LP-HAE-HBO-094 (Routine)
Blood		SOP LP-HAEHBO-003 (Ante-natal Haemoglobinopathy Screening Programme)



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HUMAN BODY FLUIDS (cont'd)	<p><u>Haematological examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p><u>Lymphocyte Subsets</u></p> <p>Determination of lymphocyte subsets in GUM and Paediatric patients: Reported for all: CD3 % AND ABSOLUTE CD3+CD4+ % AND ABSOLUTE CD3+CD8+ % AND ABSOLUTE CD4:8 RATIO</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>BD FACS Canto II SOP LP-HAEM-FC-024 Using flow cytometry and relevant fluorochrome- conjugated monoclonal antibodies to detect specific lymphocyte populations</p>
HUMAN BODY FLUID	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>Group and Save (including antibody screen)</p> <p>Adult/Paediatric patients (>4 months) Neonates (<4 months) Automated Blood Groups</p> <ul style="list-style-type: none"> - ABO and RhD systems: - RhD positive - A RhD positive - B RhD positive - AB RhD positive - RhD negative - A RhD negative - B RhD negative <p>AB RhD negative</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>IH-1000 Analyser, using DiaMed Gel Column Technology, Routine Grouping SOP LP-BB-LAB-098</p> <p>DiaMed Banjo Card Reader SOP LP-BB-LAB-101</p>



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HUMAN BODY FLUID (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u>	Documented in house methods and manufacturer's instructions for:
Blood	Group and Save Adult/Paediatric patients (>4 months) Neonates (<4 months) <ul style="list-style-type: none"> - ABO and RhD systems: - RhD positive - A RhD positive - B RhD positive - AB RhD positive - RhD negative - A RhD negative - B RhD negative AB RhD negative	Manual Grouping, using DiaMed Gel Column Technology SOP LP-BB-LAB-100 DiaMed Banjo Card Reader SOP LP-BB-LAB-101
Blood	Group and Save Adult/Paediatric patients (>4 months) Neonates (<4 months) <ul style="list-style-type: none"> - ABO and RhD systems: - RhD positive - A RhD positive - B RhD positive - AB RhD positive - RhD negative - A RhD negative - B RhD negative AB RhD negative	Urgent Requests SOP LP-BB-LAB-060 Tube agglutination and DiaMed Gel Column Technology, Emergency Grouping and Issue of Group Compatible Blood SOP LP-BB-LAB-015 DiaMed Banjo Card Reader SOP LP-BB-LAB-101



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HUMAN BODY FLUID (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u>	Documented in house methods and manufacturer's instructions for:
Blood	Crossmatch	IH-1000 Analyser using DiaMed Gel Column Technology. Compatibility Testing (Crossmatching) SOP LP-BB-LAB-010 Routine Grouping SOP LP-BB-LAB-098 DiaMed Banjo Card Reader SOP LP-BB-LAB-101 Neonatal cross-match procedure Mother and Baby Crossmatching SOP LP-BB-LAB-031
Blood	Crossmatch	Manual Crossmatching using DiaMed Gel Column Technology Compatibility Testing SOP LP-BB-LAB-010 DiaMed Banjo Card Reader SOP LP-BB-LAB-101 Neonatal cross-match procedure SOP LP-BB-LAB-031
Blood	Red cell Phenotyping (RhK and other antigens) Blood Groups (phenotyping) (C, c, E, e, K, k, Fya, Fyb, Jka, Jkb, S, s, M, N, P1, Lea, Leb, Lu(a), Kp(a))	IH-1000 Analyser using DiaMed Gel Column Technology and Lorne antisera. Red Cell phenotyping procedure using antigen profile cards SOP LP-BB-LAB-108 SOP LP-BB-LAB-098 Routine Grouping Manual Testing using DiaMed Gel Column Technology Identification of Atypical Antibodies SOP LP-BB-LAB-023 using enzyme IAT DiaMed Banjo Card Reader SOP LP-BB-LAB-101



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HUMAN BODY FLUID (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u>	Documented in house methods and manufacturer's instructions for:
Blood	Antibody Identification (C, c, D, E, e, K, k, Fya, Fyb, Jka, Jkb, S, s, M, N, P1, Lea, Leb, Lu(a), Kp(a))	IH-1000 Analyser using DiaMed Gel Column Technology. Identification of Atypical Antibodies SOP LP-BB-LAB-023 using enzyme IAT SOP LP-BB-LAB-098 Routine Grouping Manual Testing Identification of Atypical Antibodies SOP LP-BB-LAB-023 using enzyme IAT Manual Testing SOP LP-BB-LAB-100 DiaMed Banjo Card Reader SOP LP-BB-LAB-101
Blood	Fetomaternal haemorrhage Estimation (Kleihauer)	BD FACS Canto II SOP LP-BB-LAB-038 Flow cytometry. Prevention of Haemolytic Disease of the Newborn due to Anti-D including FMH Testing
Blood	Monospecific DAT (C3d, C3c, IgG, IgA, IgM)	IH-1000 Analyser using DiaMed Gel Column Technology Monospecific Direct Anti-Human Globulin Test SOP LP-BB-LAB-030 Routine Grouping SOP LP-BB-LAB-098 Manual Testing Using DiaMed Gel Column Technology, Monospecific Direct Anti-Human Globulin Test SOP LP-BB-LAB-030 Manual Testing SOP LP-BB-LAB-100 DiaMed Banjo Card Reader SOP LP-BB-LAB-101



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HUMAN BODY FLUID (cont'd)	<p><u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u></p> <p><u>Immunological examinations to assist in clinical investigations:</u></p> <p>Identification of:</p> <p>Antinuclear Antibody</p> <p>Anti- Neutrophil Cytoplasmic Antibody</p> <p>Crithidia Antibody</p> <p>Endomysial Antibody</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Documented in house methods and manufacturers' instructions for:</p> <p>Biosystems IPro Slide Processor/ Immunofluorescence Workstation and microscope Liver/Kidney/Stomach Tissue Block SOP LP-IML-075</p>
Blood	<p>Identification of:</p>	<p>Siemens Immulite Immunoassay Analyser with chemiluminescence detection SOP LP-IML-083</p>
Blood	<p>Total IgE</p>	<p>SOP LP-IML-027</p>



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HUMAN BODY FLUID (cont'd)	<p><u>Immunological examinations to assist in clinical investigations:</u> <u>(cont'd)</u></p> <p>Allergen- specific IgE</p> <p>Cat E1 House dust mite D1 Dog E5 Timothy grass G6 Aspergillus M3 Nut mix FP1 (F13, F17, F18, F20, F36) Peanut F13 Hazelnut F17 Brazil nut F18 Almond F20 Walnut F256 Food Mix FP5 (F1, F2, F3, F13, F14) Egg white F1 Milk F2 Cod fish F3 Wheat F4 Soybean F14 Egg Yolk F75 Fish mix FP2 (F3, F37, F24, F40, F41) Latex K82 Birch T3 Weed Panel WX3 (W6, W9, W10, W12, W20) Tree Panel TP8 (T1, T3, T4, T7, T11) F36 = coconut F37 = Blue mussel F24 = Shrimp/prawn F40 = Tuna F41 = Salmon T1 = Box-elder T2 = Grey alder T4 = Hazel T7 = Oak T11 = London Plane/Maple leaf sycamore W9= Plantain</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Siemens Immulite Immunoassay Analyser with chemiluminescence detection SOP LP-IML-083</p>



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HUMAN BODY FLUID (cont'd)	<p><u>Immunological examinations to assist in clinical investigations:</u> <u>(cont'd)</u></p> <p>Allergen- specific IgE (cont'd)</p> <p>W10 = Goosefoot W12 = Golden Rod W20 = Nettle W6 = Mugwort</p> <p>IgG Aspergillus Precipitins</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Siemens Immulite Immunoassay Analyser with chemiluminescence detection SOP LP-IML-083</p> <p>SOP LP-IML-051</p>
Blood	<p>Identification and quantitation of main protein fractions (albumin, alpha 1, alpha-2, , beta-1, beta-2, gamma fractions)</p>	<p>Sebia Capillarys 3 SOP LP-IML-081 Capillary Protein Electrophoresis and serum immunotyping</p>
Serum	<p>Immunotyping for protein characterisation</p>	
Urine	<p>Bence Jones Protein Screen</p> <p>Bence Jones Protein Immunofixation</p>	<p>Sebia Hydrasys 2 Gel Electrophoresis SOP LP-IML-101</p>
Blood	<p>Identification of:</p> <p>Mitochondrial M2 Antibodies</p> <p>ENA Antibody Screen</p> <p>DsDNA Antibodies</p> <p>Anti-Gliadin Antibodies</p>	<p>Alegria Organtec Immunoassay Analyser SOP LP-IML-050 ELISA</p>



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HUMAN BODY FLUID (cont'd)	<u>Immunological examinations to assist in clinical investigations:</u> <u>(cont'd)</u>	Documented in house methods and manufacturer's instructions for:
Blood (cont'd)	Identification of: (cont'd)	Alegria Organtec Immunoassay Analyser SOP LP-IML-050 ELISA
	Centromere B Antibodies	
	Glomerular Basement Membrane Antibodies	
	Intrinsic Factor Antibodies	
	PR3/MPO Antibody	
	IgG Tissue Transglutaminase Antibodies	
Blood	Identification of:	Dynex DS2 Automated ELISA Processing Workstation SOP LP-IML-076
	IgA tTG	
Blood	Cryoglobulin Screen	SOP LP-IML-026 Visual check for precipitation at 40C
Blood	ENA Typing: Anti RNP/Sm Ab Anti Sm Ab Anti-Ro Ab Anti La Ab Anti Scl70 Ab Anti Jo-1 Ab	Euroimmun Immunoblot Kit SOP LP-IML-016



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examinations to assist in clinical investigations</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
	<u>Bacteriology Section</u>	
Blood	Isolation of microorganisms of clinical significance	BacTAlert 3D SOP LP-MIC-BAC-014 Blood Culture
Blood Culture	Sensitivity testing	Rapid Antimicrobial Susceptibility Testing (RAST) SOP LP-MIC-BAC-014
CSF	Isolation of microorganisms of clinical significance and microscopical examination	SOP LP-MIC-BAC-016 Manual culture, cell count and Gram stain
Swabs/ Pus from various anatomical sites	Isolation of microorganisms of clinical significance and microscopical examination	SOP LP-MIC-BAC-015 SOP LP-MIC-BAC-020 Manual culture and Gram staining and microscopy
Ascitic and Joint Fluids	Isolation of microorganisms of clinical significance and microscopical examination	SOP LP-MIC-BAC-023 Manual culture and microscopy including Gram staining
Eye swabs, aspirates and corneal scrapes	Isolation of bacterial and fungal microorganisms of clinical significance and microscopical examination	SOP LP-MIC-BAC-041 Manual culture and Gram stained microscopy
Sputum and bronchial lavage	Isolation of bacterial and fungal microorganisms of clinical significance and microscopical examination	SOP LP-MIC-BAC-002 Manual culture
Sputum, BAL and tissue	Isolation and presumptive Identification of <i>Mycobacterium</i> spp.	AAFB/Auramine staining and microscopy LP-MIC-BAC-005 Culture using Bact/Alert LP-MIC-BAC-038
Liquid mycobacterial culture medium.	Qualitative detection of <i>Mycobacterium tuberculosis</i> complex antigen MPT64	TBCheck MPT64 assay using rapid immunochromatography LP-MIC-BAC-038
Skin and nail scrapes	Microscopy (KOH preps) and culture for dermatophyte fungi	Manual methods LP-MIC-BAC-004



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations to assist in clinical investigations (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Bacterial Isolates	Identification of microorganisms of clinical significance	VITEK: SOP LP-MIC-BAC-001 and Manual conventional methods inc RESIST 3 kit for CPE organisms LP-MIC-BAC-066, 073, 074, 075,076, 077, 078, 079, 081,084
Bacterial, Mould and Yeast Isolates	Identification of microorganisms of clinical significance	Vitek MS (MALDI-Toff) SOP LP-MIC-BAC-088 Mass spectrometry
Bacterial and Yeast Isolates	Sensitivity Testing	SOP LP-MIC-BAC-068 Disc Diffusion Testing - EUCAST VITEK2 Automated System SOP LP-MIC-BAC-001 Vitek compact analyser LP MIC BAC 048 MIC testing for susceptibility to Colistin Bioconnections MIC Strip Colistin Kit
Faeces	<i>Clostridioides</i> (formerly <i>Clostridium</i>) <i>difficile</i> Toxin Detection	Manual test SOP LP-MIC-BAC-051 Enzyme immunochromatographic test R-Biopharm RIDAQuick toxin a/b test
Faeces	<i>Clostridioides</i> (formerly <i>Clostridium</i>) <i>difficile</i> Antigen Detection	SOP - LP MIC BAC 051 using ProFlow GDH kit
Faeces	Rotavirus and Adenovirus Antigens	Manual test SOP LP-MIC-BAC-049 Enzyme immunochromatographic test R-Biopharm QuickStripe Rotavirus/Adenovirus (cassette format)
Faeces	Norovirus Antigen	Manual test SOP LP-MIC-BAC-055 Enzyme immunochromatographic test R-Biopharm RIDAQUICK Norovirus- cassette format



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations to assist in clinical investigations (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Faeces, Rectal Swabs	Isolation of gastro-intestinal microorganisms of clinical significance	SOP LP-MIC-BAC-009 Manual culture
Faeces and Urine	Microscopical identification of ova, cysts and parasites	SOP LP-MIC-BAC-052 using Parasep and Manual microscopy
Genital Tract Samples,	Isolation of genital microorganisms of clinical significance	SOP LP-MIC-BAC-017 Manual culture
	<u>Serology Section</u>	
Blood	Detection of:	Vidas FPIA SOP LP-MIC-VIR-043 Enzyme-linked Fluorescent assay – automated using VIDAS Blue
	Hepatitis Bs Antigen Rubella IgG Rubella IgM HIV Serology CMV IgG CMV IgM CMV Avidity Test Measles IgG Mumps IgG Toxoplasma Screen Helicobacter IgG Antibody Varicella zoster IgG Procalcitonin EBV VCA IgM EBNA IgG	
Blood	Detection of:	Dynex DS2 SOP LP-MIC-BAC-057 SOP LP-MIC-VIR-047 Automated EIA
	Parvovirus IgG Parvovirus IgM	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations to assist in clinical investigations (cont'd)</u>	Documented in house methods and manufacturer's instructions for:
	<u>Serology Section (cont'd)</u>	
Blood	Quantiferon testing	Interferon gamma release test IGRA using Dynex DS2 SOP LP-MIC-BAC-65 Automated EIA
Faeces	Detection of Helicobacter Antigen	Dynex DS2 SOP LP-MIC-BAC-050 Automated EIA
Blood	Anti-DNase B Detection of Anti Streptodornase B	SOP LP-MIC-VIR-016 Manual Streptodornase B Inhibition
Blood	Determination of Anti- Streptolysin O (ASOT)	SOP LP-MIC-VIR-001 Latex Agglutination
Nasopharyngeal Aspirate	Detection of RSV Antigen	SOP LP-MIC-VIR-018 ProFlow lateral flow kit
Urine	Detection of:	Sofia Analyser SOP LP-MIC-VIR-006 Automated Fluorometric EIA
	<i>Legionella pneumophila</i> serogroup 1 Antigen	
	<i>Streptococcus pneumoniae</i> Antigen	



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HUMAN TISSUES AND FLUIDS (cont'd)	<p><u>Microbiological examinations to assist in clinical investigations (cont'd)</u></p> <p><u>Molecular Section</u></p> <p>Detection of:</p>	<p>Documented in house methods and manufacturer's instructions for:</p>
Faeces	<i>Clostridioides</i> (formerly <i>Clostridium</i>) <i>difficile</i> toxin gene	BD Max SOP LP-MIC-VIR-049 Nucleic Acid Amplification
Nasal Swabs	MRSA	BD max <i>C. difficile</i> toxin gene SOP LP-MIC-BAC-080
Nasal and/or throat swabs in VTM/UTM and NPAs	<p>Detection of: Sars- Cov- 2 Virus RNA (Covid 19) Target E gene and Orf1ab gene and Respiratory Panel (<i>Influenza A</i>, <i>Influenza A subtype H1N1/2009</i>, <i>Influenza A subtype H1</i>, <i>Influenza A subtype H3</i>, <i>Influenza B</i>, <i>Coronavirus 229E</i>, <i>Coronavirus HKU1</i>, <i>Coronavirus NL63</i>, <i>Coronavirus OC43</i>, <i>Parainfluenza virus 1</i>, <i>Parainfluenza virus 2</i>, <i>Parainfluenza virus 3</i>, <i>Parainfluenza virus 4</i>, <i>Respiratory Syncytial virus A/B</i>, <i>human Metapneumovirus A/B</i>, <i>Adenovirus</i>, <i>Bocavirus</i>, <i>Rhinovirus/Enterovirus</i>, <i>Mycoplasma pneumoniae</i>, <i>Legionella pneumophila</i>, <i>Bordetella pertussis</i>)</p>	<p>QIAGEN QIAstat-Dx Analyser using QIAstat-Dx Respiratory 2019-nCoV Panel (PCR) Ip mic vir 057</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Nose/throat swabs in VTM/UTM and NPAs</p> <p>Genital Tract Specimens and Urine</p> <p>Genital swabs</p> <p>Genital swabs and urine</p>	<p><u>Microbiological examinations to assist in clinical investigations (cont'd)</u></p> <p><u>Molecular Section</u></p> <p>Detection of SARS-CoV- 2 Virus RNA (COVID-19) Target Orf1ab gene</p> <p><i>Chlamydia trachomatis and Neisseria gonorrhoea</i></p> <p>HSV 1</p> <p>HSV 2</p> <p><i>Trichomonas vaginalis</i></p> <p><i>Mycoplasma genitalium</i></p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Hologic Panther SARS-CoV-2 TMA Assay testing (RT-PCR):</p> <p>LP-MIC-VIR-058</p> <p>LP-MIC-VIR-059</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue including biopsies and surgical resection specimens</p> <p>Fresh tissue</p> <p>Fixed and fresh tissue including biopsies and surgical resection specimens</p> <p>Formalin- fixed and processed tissue (to paraffin wax) including biopsies and surgical resection specimens</p> <p>Formalin- fixed paraffin embedded tissue blocks</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u></p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Specimen Dissection SOP LP-HCU-026 Histology Specimen Cut Up SOP LP-HCU-047 Bowel Cancer Screening Polyps- Cut Up and Reporting SOP LP-HCU-045 Cervical Specimens Cut Up and Reporting SOP LP-HCU-028 Breast Specimens Cut Up and Reporting SOP LP-HCU-048 Specimen Dissection</p> <p>Frozen Sections and H&E staining. SOP LR-HP-6 Frozen Section Procedure SOP LP-HP-055 Histopathology: Embedding, Microtomy, Staining and Coverslipping RC0201 Leica CM1860 Cryostat</p> <p>Tissue Processing SOP LP-HP-056 Histopathology Tissue Processing Leica Peloris II Sakura VIP5 RC0202 Histocore Peloris 3</p> <p>Embedding SOP LP-HP-055 Histopathology: Embedding, Microtomy, Staining and Coverslipping Sakura TEC V Embedder</p> <p>Microtomy SOP LP-HP-055 Histopathology: Embedding, Microtomy, Staining and Coverslipping RC0197 & RC0198 Leica Histocore Biocut Microtomes</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin- fixed paraffin embedded tissue sections or cytological preparations on microscope slides</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p>For demonstration of general tissue architecture</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>RC0199 Leica Autostainer XL ST5010 with attached RC0200 Leica CV5030 CoverslipperHaematoxylin and Eosin staining and coverslipping LR-HP-055</p>
<p>Stained formalin- fixed paraffin embedded tissue sections or cytological preparations on microscope slides</p> <p>Formalin- fixed paraffin wax-embedded tissue sections or cytological preparations on microscope slides</p>	<p>Morphological assessment and interpretation/ Diagnosis</p> <p><u>Special Stains</u></p> <p>For demonstration of:</p> <p>Acid and neutral mucins</p> <p>Amyloid</p> <p>Elastic fibres</p> <p>Gram positive and negative bacteria</p> <p>Fungi</p> <p>Connective Tissue</p> <p>Fibrin</p> <p>Protozoa/ Helicobacter</p> <p>Removal of melanin</p> <p>Glycogen/Neutral mucin</p> <p>PAS positive substance/ fungi</p> <p>Iron</p> <p>Reticulin fibres</p> <p>Amyloid</p>	<p>Interpretative/ diagnostic Microscopy and Reporting LP-HIS-ADM-039</p> <p>SOP LP-HIS-HS-109 Histology Staining Manual Manual Staining</p> <p>Alcian Blue/PAS</p> <p>Congo Red</p> <p>Elastic Van Gieson (EVG)</p> <p>Gram Stain</p> <p>Methenamine Silver (MST)</p> <p>Masson Trichrome</p> <p>MSB</p> <p>Giemsa</p> <p>Melanin Bleach</p> <p>Period Acid Schiff's (PAS)</p> <p>Diastase (PAS)</p> <p>Perls Prussian Blue</p> <p>Reticulin</p> <p>Sirius Red</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin- fixed paraffin wax-embedded tissue sections or cytological preparations on microscope slides (cont'd)</p> <p>Formalin- fixed paraffin wax-embedded tissue sections or cytological preparations on microscope slides</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p><u>Special Stains</u> (cont'd)</p> <p>For demonstration of:</p> <p>Hep B, Cu - associated protein</p> <p><i>Mycobacterium leprae</i> (leprosy)</p> <p>Acid alcohol fast bacilli (TB)</p> <p><u>Immunohistochemistry</u></p> <p>For demonstration of:</p> <p>Adenocarcinoma (breast/ pancreas/bile duct/salivary gland/transitional cell carcinoma)</p> <p>Smooth muscle</p> <p>Epithelial cells. Pan cytokeratin</p> <p>Epithelial cells</p> <p>Lymphocytes. Used in lymphoma</p> <p>Epithelial cells</p> <p>Differentiation of mesothelioma from adenocarcinoma. Demonstration of mesothelial cells</p> <p>Cytokeratin 8 and 18</p> <p>T cells</p> <p>Germinal centres of lymph tissue</p> <p>R-S cells in Hodgkin's lymphoma</p> <p>Activated lymphocytes and plasma cells. R-S cells in Hodgkin's lymphoma</p> <p>Endothelial cells</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>SOP LP-HIS-HS-109 Histology Staining Manual Manual Staining</p> <p>Orcein</p> <p>Wade- Fite</p> <p>Ziehl Neelsen (ZN)</p> <p>Ventana Ultra SOP LP-HIS-HI-011 Automated immunohistochemistry</p> <p>34BE12</p> <p>Actin (SMA)</p> <p>AE1/AE3</p> <p>AMACR</p> <p>BCL2</p> <p>BerEP4</p> <p>Calretinin</p> <p>CAM 5.2</p> <p>CD3</p> <p>CD10</p> <p>CD15</p> <p>CD30</p> <p>CD34</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin- fixed paraffin wax- embedded tissue sections or cytological preparations on microscope slides (cont'd)</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry (cont'd)</u></p> <p>For demonstration of: (cont'd)</p> <p>Neural cells adhesion protein in tumours e.g. plasma cell tumours, pancreatic tumour, spindle cell tumours, small cell carcinoma</p> <p>Macrophages</p> <p>Plasma cells</p> <p>Intestinal cells, loss of differentiation in colorectal tumours</p> <p>Normal colonic cells. Found in adenocarcinoma of lung, colon, stomach, oesophagus, pancreas, gall bladder, salivary gland, ovary and endocervix</p> <p>Endocrine cells. Used in neuroendocrine tumours</p> <p>Epithelial cells e.g., ducts, glands, transitional epithelium of urinary tract</p> <p>Epithelial cells. Used in differentiation of mesothelioma and adenocarcinoma</p> <p>Epithelial cells. Found in adenocarcinoma of stomach, colon, pancreas and some reactivity in mucinous ovarian tumours</p> <p>Normal smooth muscle. Soft tissue tumours</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Ventana Ultra SOP LP-HIS-HI-011 Automated immunohistochemistry</p> <p>CD56</p> <p>CD68</p> <p>CD138</p> <p>CDX2</p> <p>CEA</p> <p>Chromogranin A</p> <p>CK7</p> <p>CK5/6</p> <p>CK20</p> <p>Desmin</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin- fixed paraffin wax- embedded tissue sections or cytological preparations on microscope slides (cont'd)</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry (cont'd)</u></p> <p>For demonstration of: (cont'd)</p> <p>Epithelial cell membrane. Used in differentiation of ductal versus lobular carcinoma of the breast</p> <p>Epithelial cell membrane. Used to demonstrate normal and neoplastic epithelial cells</p> <p>Oestrogen receptor. Used in breast cancer and other tumours</p> <p>Trophoblasts of placenta. Used in germ cell tumours</p> <p>Melanoma cells</p> <p>Peptide hormone used in germ cell tumours</p> <p>Proliferating cells. Prognostic marker in tumours</p> <p>B cell lymphocytes</p> <p>Pan leucocytes</p> <p>Melanoma cells</p> <p>Neuroendocrine and neuronal cells</p> <p>Trophoblasts of placenta. Used in germ cell tumours</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Ventana Ultra SOP LP-HIS-HI-011 Automated immunohistochemistry</p> <p>E-Cadherin</p> <p>EMA</p> <p>ER</p> <p>HCG</p> <p>HMB45</p> <p>Inhibin</p> <p>Ki67</p> <p>CD20</p> <p>CD45</p> <p>Melan A</p> <p>NSE</p> <p>PLAP</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin- fixed paraffin wax- embedded tissue sections or cell blocks from cytological preparations on microscope slides (cont'd)</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry (cont'd)</u></p> <p>For demonstration of: (cont'd)</p> <p>Prostate epithelial cells</p> <p>Protein found in normal cells e.g. melanocytes, histiocytes and expressed in some tumours e.g. melanoma</p> <p>Melanocytes and myoepithelial cells</p> <p>Myoepithelial cells. Used in breast to differentiate benign and malignant lesions</p> <p>Neuroendocrine cells</p> <p>Follicular epithelial cells of thyroid. Differentiates primary adenocarcinoma from metastatic carcinoma. Used in lung tumours</p> <p>Follicular epithelial cells of thyroid</p> <p>Mesenchymal cells</p> <p>Mesenchymal cells</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Ventana Ultra SOP LP-HIS-HI-011 Automated immunohistochemistry</p> <p>PSA</p> <p>S100</p> <p>SOX-10</p> <p>Myosin</p> <p>Synaptophysin</p> <p>TTF1</p> <p>Thyroglobulin</p> <p>Vimentin</p> <p>WT1</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Diagnostic Cytology Samples: E.g. Respiratory, Urine, Serous Fluids, Fine Needle Aspirates (FNA), CSF, Synovial Fluids etc.</p> <p>Cytological preparations on microscope slides</p> <p>Synovial Fluid</p> <p>Stained formalin- fixed paraffin embedded tissue sections or cytological preparations on microscope slides</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p><u>Diagnostic Cytology</u></p> <p>Differentiation of cell types</p> <p>Identification of crystals:</p> <ul style="list-style-type: none"> • Monosodium urate • Calcium pyrophosphate <p><u>Home Reporting</u></p> <p>Morphological assessment, interpretation/diagnosis and reporting at home working locations</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>SOP LP-HIS-NG-011 Cytological preparation of body fluids including wet films</p> <p>Thermo Shandon Cytospin 4 Thermo Electron IEC CL10 SOP LP-HIS-NG-002 Use and disinfection of Centrifuge and Cytocentrifuge</p> <p>Manual Papanicolaou Stain and Microscopy SOP LP-HIS-NG-011 Cytological preparation of body fluids including wet films</p> <p>Wet Film and Microscopy SOP LP-HIS-NG-011 Cytological preparation of body fluids including wet films</p> <p>Home Working locations- QI-PPA-006 Risk assessment- Home Working- MR-HIS-HRA-067 Audit Checklist- Home Working- QT-PQ-065</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy:</u> Detection of sperm	Based on 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 large volume chambers/ manual microscopy and documented in-house procedure SOP LP-HIS-AND-004
Semen	<u>Fertility testing:</u> Volume pH Sperm morphology including 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 procedure SOP LP-HIS-AND-003 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)
END		