


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9623 Accredited to ISO 15189:2012	The Rotherham NHS Foundation Trust	
	Issue No: 004 Issue date: 29 May 2020	
	Rotherham Hospital Moorgate Road Rotherham S60 2UD	Contact: Heather Da Costa Tel: +44 (0) 1709 424008 E-Mail: heather.dacosta@nhs.net Website: http://www.therotherhamft.nhs.uk/
Testing performed at the above address only		

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:
Serum / Plasma	Albumin	Siemens Advia 1800 SOP LP-BIO-AL-104 by: BCG Dye Binding, endpoint
Serum / Plasma	Alkaline Phosphatase	Modified IFCC, kinetic
Serum / Plasma	ALP	Modified IFCC, kinetic
Serum / Plasma	ALT	Modified IFCC, Kinetic
Serum / Plasma	AST	Modified IFCC, kinetic
Serum / Plasma	Bicarbonate	PEPC/MDH, kinetic
Serum / Plasma	Bile Acids	3- α -HSD, kinetic
Serum / Plasma	Bilirubin (Total)	Vanadate oxidation, endpoint
Serum / Plasma	Bilirubin (Conjugated)	Vanadate oxidation, endpoint
Serum / Plasma, Urine	Calcium	Arsenazo III, endpoint
Serum / Plasma, Urine	Chloride	Ion Selective Electrode (ISE), diluted
Serum / Plasma	Cholesterol (Total)	Enzymatic, endpoint
Serum / Plasma	Creatine Kinase	NAC Activated, IFCC, kinetic
Serum / Plasma, Urine	Creatinine	Enzymatic/ Creatinine Deiminase/GLDH, kinetic
Serum / Plasma	CRP	PEG enhanced immunoturbidimetric, endpoint



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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 Advia 1800 SOP LP-BIO-AL-104 (cont') by:
Serum / Plasma	GGT	Modified IFCC, kinetic
Serum / Plasma, CSF	Glucose	Hexokinase, endpoint
Serum / Plasma	HDL	Elimination/catalase, 2 point kinetic
Serum / Plasma	Iron	Ferrozine, endpoint
Serum / Plasma, CSF	Lactate	Lactate Oxidase, endpoint
Serum / Plasma	LDH	Pyruvate/NADH, kinetic
Serum / Plasma	Lipase	DGGMR, kinetic
Serum / Plasma, Urine	Magnesium	Xylidyl Blue, endpoint
Serum / Plasma	Paracetamol	Enzymatic, endpoint
Serum / Plasma, Urine	Phosphate	Phosphomolybdate/UV
Serum / Plasma, Urine	Potassium	Ion Selective Electrode (ISE), diluted
Serum / Plasma	Protein	Biuret, endpoint
Urine, CSF	Protein	Dye binding, endpoint
Serum / Plasma	Rheumatoid Factor	Latex- enhanced immunoturbidimetric, 2-point endpoint
Serum / Plasma, Urine,	Sodium	Ion Selective Electrode, diluted
Serum / Plasma	Salicylate	Enzymatic, endpoint
Serum / Plasma	Transferrin	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma,	Triglyceride	GPO, Trinder without serum blank, endpoint
Serum / Plasma, Urine,	Urea	Urease with GLDH, kinetic



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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 Advia 1800 SOP LP-BIO-AL-104 (cont') by:
Serum / Plasma, Urine	Uric Acid	Uricase/Peroxidase, endpoint
Serum / Plasma	Carbamazepine	EMIT, kinetic
Serum / Plasma	Phenytoin	EMIT, kinetic
Serum / Plasma	Sodium Valproate	EMIT, kinetic
Serum / Plasma	Theophylline	EMIT, kinetic
Serum / Plasma	Lithium	Colorimetric, endpoint
Serum / Plasma	IgG	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma	IgA	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma	IgM	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma	C3	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma	C4	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma	Haptoglobin	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma	Caeruloplasmin	PEG enhanced immunoturbidimetric, endpoint
Serum / Plasma	Alpha-1-antitrypsin	PEG enhanced immunoturbidimetric, endpoint
	<u>Manual Biochemistry</u>	
Serum / Plasma, Urine	Osmolality	Advanced Micro-osmometer 3320 SOP LP-BIO-ODD-009 Depression of freezing point



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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 (cont'd)</u>	Documented in house methods and manufacturers' instructions for:
Serum / Plasma	Ammonia	A. Menarini Diagnostics Blood Ammonia Meter –Ammonia Checker II (model AA-4120) SOP LP-BIO-ODD-004 Alkaline ammonium ions gasified to ammonia and reacts with BCG, microdiffusion
	Blood Gas Profile:	IL GEM 4000 SOP LP-BIO-NPT-007 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>Automated Immunoassay</u> Quantitative determination of:	Documented in house methods and manufacturers' instructions for:
Serum	Digoxin	Siemens Centaur XP SOP LP-BIO-AL-112 by: Competitive Immunoassay
Serum	Gentamicin	Competitive Immunoassay
Serum	B12	Competitive Immunoassay
Serum	Folate	Competitive Immunoassay
Serum	Ferritin	2 Site Sandwich Immunoassay
Serum	HCG	2 Site Sandwich Immunoassay
Serum	Cortisol	Competitive Immunoassay
Serum	Progesterone	Competitive Immunoassay
Serum	FSH	2 Site Sandwich Immunoassay
Serum	LH	2 Site Sandwich Immunoassay
Serum	Prolactin	2 Site Sandwich Immunoassay
Serum	Macroprolactin	2 Site Sandwich Immunoassay following PEG extraction SOP LP-BIO-AL-012
Serum	TSH-Ultra	Sandwich Immunoassay
Serum	Free T3	Competitive Immunoassay
Serum	Free T4	Competitive Immunoassay
Serum	Troponin I	3 Site Sandwich Immunoassay
Serum	Hs Troponin-T	Sandwich Immunoassay



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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
Serum	Vitamin B1	HPLC Fluorimetric Detection (Chromsystems) SOP LP-BIO-HPC-011
Serum	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)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturers' instructions for:
	Calculation of:	Calculated Tests using Siemens Advia 1800 and Clinisys WinPath
Serum	Serum Osmolar Gap	
Serum / Plasma	Globulin	
Serum / Plasma	Adjusted Calcium	
Serum / Plasma	Cholesterol: HDL ratio	
Serum / Plasma	LDL	
Serum / Plasma	Non-HDL cholesterol	
Serum / Plasma	Iron binding capacity	
Serum / Plasma	Transferrin saturation	
Urine	24-hour urine sodium	
Urine	24-hour urine potassium	
Urine	24-hour urine chloride	
Urine	24-hour urine urea	
Urine	24-hour urine creatinine	
Urine	24-hour urine calcium	
Urine	Calcium: creatinine ratio	
Urine	Urine calcium excretion	
Urine	Calcium clearance	
Urine	24-hour urine phosphate	
Urine	24-hour urine urate	
Urine	24-hour urine magnesium	



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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:
	Calculation of:	Calculated Tests using Siemens Advia 1800 and Clinisys WinPath
Urine	24-hour urine protein	
Urine	Protein: creatinine ratio	
Urine	Urate: creatinine ratio	
Serum	Macroprolactin recovery	
Urine	24-hour urine noradrenaline	
Urine	24-hour urine adrenaline	
Urine	24-hour urine dopamine	
Urine	24-hour urine nor metadrenaline	
Urine	24-hour urine metadrenaline	
Urine	24-hour urine 5HIAA	
Serum	Vitamin E lipid correction	
Serum	Vitamin E lipid correction ratio	
Urine	Overnight noradrenaline	
Urine	Overnight metadrenaline	
Urine	Overnight adrenaline	
Urine	Overnight normetadrenaline	
Urine	Overnight dopamine	
Urine	Noradrenaline: creatinine ratio	
Urine	Adrenaline: creatinine ratio	
Urine	Dopamine: creatinine ratio	



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HUMAN BODY FLUIDS (cont'd) Urine Urine Urine Urine Serum / Plasma Serum / Plasma Serum / Plasma / Urine	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u> Calculation of: (cont'd) Metadrenaline: creatinine ratio Normetadrenaline: creatinine ratio VMA: creatinine ratio HVA: creatinine ratio Estimated Glomerular Filtration Rate (eGFR) Acute Kidney Injury (AKI) 24-hour Creatinine Clearance	Documented in house methods and manufacturers' instructions for: Calculated Tests using Siemens Advia 1800 and Clinisys WinPath



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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 manufacturers instructions for:</p> <p>Siemens ADVIA 2120 SOP LP-HAE-LAB-018, LP-HAE-LAB-031 by:</p>
Blood	Platelets	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	<p>White Cell Count Neutrophils Lymphocytes Monocytes Eosinophils Basophils LUCs</p> <p>Manual differential for:</p> <p>Metamyelocytes Myelocytes Promyelocytes Blasts Nucleated RBC</p>	<p>Peroxidase (Differential cellular staining and Basophil (lobularity) methods</p> <p>Blood Film and Manual Diff using:</p> <p>Siemens Hematek Analyser and Wright- Giemsa stained films</p> <p>Manual method using May – Grunwald- Giemsa stained films</p> <p>Examined by microscopy</p> <p>SOP LP-HAE-LAB-088, LP-HAE-LAB-039</p>



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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 manufacturers 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 Evolution 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 Evolution 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 Evolution SOP LP-HAEM-COA-048 Chronometric assay using STA®-Neoplastin® R
Blood (Plasma)	APTT	Stago STA-R Evolution SOP LP-HAEM-COA-048 Chronometric assay using STA®-Cephascreen®
Blood (Plasma)	Fibrinogen	Stago STA-R Evolution 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 manufacturers instructions for:
Blood (Plasma)	D-Dimer	Stago STA-R Evolution SOP LP-HAEM-COA-048 Immunoturbidimetric method using STA®-Liatest®
Blood (Plasma)	Mixing Studies	Stago STA-R Evolution SOP LP-HAEM-COA-010 STA®-Cephascreen® and/or Chronometric assay using STA®-Neoplastin® R
Blood (Plasma)	Actin FS APTT	Stago STA-R Evolution SOP LP-HAEM-COA-048 Chronometric assay using Sysmex Actin FS
	<u>Lupus Testing:</u>	
Blood (Plasma)	Dilute Russell Viper's Venom Screen	Stago STA-R Evolution 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 Evolution 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 Evolution SOP LP-HAEM-COA-053 Chronometric assay using LA-sensitive STA®-PTTLA reagent
Blood (Plasma)	Actin FS (Lupus insensitive APTT reagent)	Stago STA-R Evolution 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 manufacturers instructions for:
	<u>Manual Testing</u>	
Blood	Glandular Fever Screen for IM heterophile antibodies	Accusay Mono IM SOP LP-HAE-LAB-065 Bovine erythrocyte extract (immunoassay)
Blood	Malarial Parasite Screen for <i>P. falciparum</i> <i>P. vivax</i> <i>P. ovale</i> <i>P. malariae</i>	Diamed OptiMAL-IT Rapid Malaria Test (RDT) SOP LP-HAE-LAB-072 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
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 dithionite (reducing agent)
	<u>Haemoglobinopathy Investigation</u>	
	Haemoglobinopathy Investigations to determine HbA2 and HbF levels and the presence of abnormal haemoglobins	Arkray HA8180T HPLC technology to determine with reference to:
Blood		SOP LP-HAE-HBO-002 (Routine)
Blood		SOP LP-HAEHBO-003 (Ante-natal Haemoglobinopathy Screening Programme)



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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 manufacturers instructions for:
Blood	<u>Lymphocyte Subsets</u> 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	BD FACS Canto II SOP LP-HAEM-FC-024 Using flow cytometry and relevant fluorochrome- conjugated monoclonal antibodies to detect specific lymphocyte populations
HUMAN BODY FLUID	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Documented in house methods and manufacturer's instructions for:
Blood	Group and Save (including antibody screen) Adult/Paediatric patients (>4 months) Neonates (<4 months) Automated Blood Groups <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 	IH-1000 Analyser, using DiaMed Gel Column Technology, Routine Grouping SOP LP-BB-LAB-098 DiaMed Banjo Card Reader SOP LP-BB-LAB-101



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<p>HUMAN BODY FLUID (cont'd)</p> <p>Blood</p> <p>Blood</p>	<p><u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u></p> <p>Group and Save</p> <p>Adult/Paediatric patients (>4 months)</p> <p>Neonates (<4 months)</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 -AB RhD negative <p>Group and Save</p> <p>Adult/Paediatric patients (>4 months)</p> <p>Neonates (<4 months)</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 -AB RhD negative 	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Manual Grouping, using DiaMed Gel Column Technology SOP LP-BB-LAB-100</p> <p>DiaMed Banjo Card Reader SOP LP-BB-LAB-101</p> <p>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</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	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 SOP LP-BB-LAB-023 SOP LP-BB-LAB-098 Routine Grouping Manual Testing using DiaMed Gel Column Technology Identification of Atypical Antibodies SOP LP-BB-LAB-023 DiaMed Banjo Card Reader SOP LP-BB-LAB-101



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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 SOP LP-BB-LAB-098 Routine Grouping Manual Testing Identification of Atypical Antibodies SOP LP-BB-LAB-023 Manual Testing SOP LP-BB-LAB-100 DiaMed Banjo Card Reader SOP LP-BB-LAB-101
Blood	Fetomaternal hemorrhage 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
Blood	NaOH test for differentiation between maternal and cord blood	NaOH manual testing using denaturation technique Manual Testing SOP LP-BB-LAB-100



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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 manufacturers instructions for:
Blood	Anti-D Quantification Screen	Manual Testing - using DiaMed Gel Column Technology Antenatal Serology SOP LP-BB-LAB-001 DiaMed Banjo Card Reader SOP LP-BB-LAB-101
Blood	<u>Immunological examinations to assist in clinical investigations:</u> Identification of:	Documented in house methods and manufacturers instructions for:
	Antinuclear Antibody	Biosystems IPro Slide Processor/ Immunofluorescence Workstation and microscope Liver/Kidney/Stomach Tissue Block SOP LP-IML-075
	Anti- Neutrophil Cytoplasmic Antibody	
	Crithidia Antibody	
	Endomysial Antibody	
Blood	Identification of:	Siemens Immulite Immunoassay Analyser with chemiluminescence detection
	Anti TPO Antibodies	SOP LP-IML-083 SOP LP-IML-069
	Erythropoietin	SOP LP-IML-087
	Total IgE	SOP LP-IML-027



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<p>HUMAN BODY FLUID (cont'd)</p>	<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> (cont'd)</p> <p>Allergen- specific IgE (cont'd)</p> <p>W10 = Goosefoot W12 = Golden Rod W20 = Nettle W6 = Mugwort</p> <p>B2 Microglobulin</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-074</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 SOP LP-IML-081 Capillary Protein Electrophoresis and serum immunotyping SOP LP-IML-081</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-10</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> (cont'd)	Documented in house methods and manufacturers 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	
	Anti- Cardiolipin Antibodies (IgG and IgM)	
Blood	Cryoglobulin Screen	SOP LP-IML-026 Visual check for precipitation at 4oC
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
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
Urine	Isolation of microorganisms of clinical significance and microscopical examination	UF1000i Automated Screen SOP LP-MIC-BAC-061 Manual culture and microscopy using inverted microscope
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 of Mycobacterium	AAFB/Auramine staining LP-MIC-BAC-005 Culture using Bact/Alert 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, 081,084,085
Bacterial 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 Colisitin Kit
Faeces	<i>Clostridium difficile</i> Toxin Detection	Manual test SOP LP-MIC-BAC-051 Enzyme immunochromatographic test R-Biopharm Ridaquick toxin a/b test
Faeces	<i>Clostridium 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
Faeces	Norovirus Antigen	Manual test SOP LP-MIC-BAC-055 Enzyme immunochromatographic test R-Biopharm RIDAQUICK Norovirus



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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: 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	Vidas FPIA SOP LP-MIC-VIR-043 Enzyme-linked Fluorescent assay – automated using VIDAS Blue
Blood	Detection of: Mycoplasma IgG Mycoplasma IgM	Chorus SOP LP-MIC-VIR-040 Automated EIA
Blood	Detection of: Parvovirus IgG Parvovirus IgM	Dynex DS2 SOP LP-MIC-BAC-057 SOP LP-MIC-VIR-047 Automated EIA



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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 manufacturers instructions for:
	<u>Serology Section (cont'd)</u>	
Blood	Detection of: EBNA IgG EBV VCA IgM	Dynex DS2 EBV Serology Screen SOP LP-MIC-VIR-048 Automated EIA
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: Legionella pneumophilia serogroup 1 Antigen <i>Streptococcus pneumoniae</i> Antigen	Sofia Analyser SOP LP-MIC-VIR-006 Automated Fluorometric EIA



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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 manufacturers instructions for:
Genital Tract Specimens and Urine	<u>Molecular Section</u> Detection of: nucleic acid <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoea</i> HSV 1 HSV 2	Viper XTR SOP LP-MIC-VIR-042 Nucleic Acid Amplification Test
Faeces	Detection of: <i>Clostridium difficile</i> toxin gene	BD Max SOP LP-MIC-VIR-049 Nucleic Acid Amplification
Nasal Swabs	MRSA	BD Max SOP LP-MIC-VIR-051
Genital swabs and urine	Detection of nucleic acid from <i>Chlamydia trachomatis</i> (confirmation) <i>Neisseria gonorrhoeae</i> confirmation	BD Max SOP LP-MIC-VIR-053 Nucleic acid amplification



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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>Formalin- fixed paraffin embedded tissue sections or cytological preparations on microscope slides</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u></p> <p>For demonstration of general tissue architecture</p>	<p>Documented in house methods and manufacturers 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 LP-HP-015 Frozen Section Procedure SOP LP-HP-055 Histopathology: Embedding, Microtomy, Staining and Coverslipping Thermo Shandon Cryotome E</p> <p>Tissue Processing SOP LP-HP-056 Histopathology Tissue Processing Leica Peloris II Sakura VIP5</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 Leica and Microm Microtomes</p> <p>DRS 2000 Automated Stainer SOP LP-HP-055 Haematoxylin and Eosin staining and coverslipping</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</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><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></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>Copper- associated protein</p> <p>Amyloid</p> <p>Hep B, Cu - associated protein</p> <p>Mast cells</p>	<p>Documented in house methods and manufacturers instructions for:</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 Schiffs (PAS)</p> <p>Diastase (PAS)</p> <p>Perls Prussian Blue</p> <p>Reticulin</p> <p>Rhodanine</p> <p>Sirius Red</p> <p>Orcein</p> <p>Toluidine Blue</p>



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



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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 manufacturers 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 manufacturers 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>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 manufacturers instructions for:</p> <p>Ventana Ultra SOP LP-HIS-HI-011 Automated immunohistochemistry</p> <p>PSA</p> <p>S100</p> <p>Mysosin</p> <p>Synaptophysin</p> <p>TTF1</p> <p>Thyroglobulin</p> <p>Vimentin</p> <p>WT1</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturers instructions for:
Diagnostic Cytology Samples: E.g. Respiratory, Urine, Serous Fluids, Fine Needle Aspirates (FNA), CSF, Synovial Fluids etc.	<u>Diagnostic Cytology</u>	SOP LP-HIS-NG-011 Cytological preparation of body fluids including wet films Thermo Shandon Cytospin 4 Thermo Electron IEC CL10 SOP LP-HIS-NG-002 Use and disinfection of Centrifuge and Cytocentrifuge
Cytological preparations on microscope slides	Differentiation of cell types	Manual Papanicolaou Stain and Microscopy SOP LP-HIS-NG-011 Cytological preparation of body fluids including wet films
Synovial Fluid	Identification of crystals	Wet Film and Microscopy SOP LP-HIS-NG-011 Cytological preparation of body fluids including wet films
Semen Sample	<u>Andrology</u> Fertility Screen and reporting by: Viscosity pH Volume Concentration Motility Morphology	SOP LP-HIS-AND-003 Analysis of fertility samples by: Visual Examination pH Paper Volume/ Weight Counting Chamber Wet Prep- Microscopy Stained Slide- Microscopy
Semen Sample (post vasectomy)	Detection of Spermatozoa and reporting	SOP LP-HIS-AND-004 Analysis of post- vasectomy semen samples by microscopy and centrifugation
END		