


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>8833</p> <p>Accredited to ISO 15189:2012</p>	<b>Northern Lincolnshire and Goole NHS Foundation Trust</b>	
	<b>Issue No: 005    Issue date: 19 August 2021</b>	
	<b>Path Links NHS Pathology Service</b> Diana Princess of Wales Hospital Scartho Road Grimsby DN33 2BA	<b>Contact: Mick Chomyn</b> <b>Tel: +44 (0)1476 464704</b> <b>E-Mail: Michael.chomyn@nhs.net</b>
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code	
<b>Address</b> Pathology Diana Princess of Wales Scartho Road Grimsby DN33 2BA	<b>Local contact</b> See Above	<ul style="list-style-type: none"> <li>• Routine Haematology</li> <li>• Blood Transfusion</li> <li>• Biochemistry</li> <li>• Andrology</li> <li>• Phlebotomy</li> <li>• Blood Fridges</li> <li>• Blood issue/electronic issue</li> <li>• Serology</li> </ul>	A
Pathology Scunthorpe General Hospital Cliff Gardens Scunthorpe DN15 7BH	See above	<ul style="list-style-type: none"> <li>• Routine Haematology</li> <li>• Blood Transfusion</li> <li>• Biochemistry</li> <li>• Immunology</li> <li>• Microbiology</li> <li>• Serology</li> <li>• Molecular</li> <li>• Phlebotomy</li> <li>• Blood fridges</li> <li>• Blood issue/electronic issue</li> </ul>	B
Pathology Lincoln County Hospital Greetwell Road Lincoln LN2 5QY	See above	<ul style="list-style-type: none"> <li>• Routine Haematology</li> <li>• Blood transfusion</li> <li>• Biochemistry</li> <li>• Histology</li> <li>• Non gynae cytology</li> <li>• Phlebotomy</li> <li>• Blood Fridges</li> <li>• Blood issue/electronic issue</li> </ul>	C



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Location details	Activity	Location code
<p><b>Address</b> Pathology Boston Pilgrim Hospital Sibsey Road Boston PE21 9QS</p> <p><b>Local contact</b> See above</p>	<ul style="list-style-type: none"> <li>• Routine haematology</li> <li>• Blood transfusion</li> <li>• Biochemistry</li> <li>• Andrology</li> <li>• Microbiology</li> <li>• Phlebotomy</li> <li>• Blood fridges</li> <li>• Blood issue/electronic issue</li> </ul>	D
<p>Pathology Grantham and District General hospital Manthorpe Road Grantham NG21 8DG</p> <p>See Above</p>	<ul style="list-style-type: none"> <li>• Routine Haematology</li> <li>• Blood Transfusion</li> <li>• Biochemistry</li> <li>• Phlebotomy</li> <li>• Blood Fridges</li> <li>• Blood issue/electronic issue</li> </ul>	E
<b>Phlebotomy and blood fridges only :</b>		
<p>Goole and district Hospital Woodland Avenue Goole DN14 6RX</p> <p>See above</p>	<ul style="list-style-type: none"> <li>• Phlebotomy</li> <li>• Blood fridges- Laboratory</li> </ul>	F
<p>Louth County Hospital High Holme Road Louth LN11 0EU</p> <p>See above</p>	<ul style="list-style-type: none"> <li>• Phlebotomy</li> <li>• Blood Fridges- Laboratory</li> </ul>	G
<p>HMT St Hughs Peaks Lane Grimsby DN32 9RP</p> <p>See above</p>	<ul style="list-style-type: none"> <li>• Blood fridges</li> </ul>	H
<p>Lincoln BMI Nettleham Road Lincoln LN2 1QU</p> <p>See above</p>	<ul style="list-style-type: none"> <li>• Blood fridges- Maternity and main theatres</li> </ul>	I
<p>Diana Princess of Wales Scarho Road Grimsby DN33 2BA</p> <p>See Above</p>	<ul style="list-style-type: none"> <li>• Blood fridges- main theatres</li> </ul>	J



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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>Haematological examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for	
Venous Blood: Citrated	Blood Coagulation	ACL TOPS 500	
	Routine		
	<ul style="list-style-type: none"> <li>• Prothrombin time               <ul style="list-style-type: none"> <li>○ INR</li> </ul> </li> <li>• Activated Partial Thromboplastin Time</li> <li>• Fibrinogen estimation               <ul style="list-style-type: none"> <li>○ Clauss</li> <li>○ Derived</li> </ul> </li> </ul>	Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change  SOP;- INT SOP 82	A B C D E
	D-Dimers	Latex method SOP;- INT SOP 82	C
	Special Coagulation	SOPs;- INT INS 169 and 37 Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change	C
	<ul style="list-style-type: none"> <li>• FVIII</li> <li>• FIX</li> <li>• FXI</li> <li>• FXII</li> <li>• Free protein S</li> <li>• Protein C</li> <li>• Von Williebrand Factor               <ul style="list-style-type: none"> <li>○ Antigen</li> <li>○ Activity</li> </ul> </li> <li>• AntiThrombin III</li> </ul>	Chromogenic end point	C
	<ul style="list-style-type: none"> <li>• PT</li> <li>• APTT</li> </ul>	Manual tube method and waterbath Manual detection of clot INT SOP 82	C



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Documented In-house methods using:	
Venous whole blood: EDTA	<p>FBC</p> <ul style="list-style-type: none"> <li>• Haemoglobin estimation</li> <li>• Red cell and platelet counts</li> <li>• Haematocrit</li> <li>• Differential white cell count</li> <li>• Reticulocyte</li> <li>• MCV</li> <li>• MCH</li> <li>• MCHC</li> </ul> <p>ESR</p>	<p>Sysmex XN 10 series Haematology Analysers SOP:INT-SOP-141 Colorimetric Laser light scatter</p> <p>Calculated parameter from Haemoglobin and RBC Laser and light scatter and light absorbance Laser light scatter and absorbance Calculated parameters Calculated parameters Calculated parameters</p> <p>Visual detection of sedimentation interface by automated photometric detection using Vacuette SRS100/II Greiner SOP: INT-SOP-114</p>	A B C D E
Blood	Identification of normal and abnormal morphologies including WBC differential count	Staining by SP 10 SOP: INT SOP 60 staining by Romanowsky examined by microscopy SOP;-INT SOP 122 microscopy	
Bone marrow aspirate	Identification of normal and abnormal morphologies	Staining by SP 10 SOP: INT SOP 60 staining by Romanowsky examined by microscopy SOP;-INT SOP 122 microscopy	C
Bone marrow and Urine	Iron detection	Perl's Prussian Blue staining Sigma Aldrich kit by Romanowsky stain- SOP;-INT SOP 70 examined by microscopy SOP;-INT SOP 122 microscopy	C



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Documented In-house methods using:	
Whole Blood	Malaria Parasite detection <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• Non-falciparum</li> </ul> Speciation <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• P.Ovale</li> <li>• P.Malariae</li> <li>• P.Vivax</li> <li>• P.Knowlesi</li> </ul>	Antigen testing with CareStart kit by Immunochromatographic interface SOP: INT-SOP-64 And Thick film –Field Stain Thin Film – Giemsa Stain Examined by microscopy SOP: INT SOP 64	A B C D E
	Plasmodium Falciparum parasitaemia	Thin Film – Giemsa Stain. Enumeration by microscopy SOP;-INT SOP 64	A B C D E
Venous whole blood :EDTA	Infectious Mononucleosis screen (EBV) antibody	Clearview II Card Qualitative Immunoassay agglutination interpreted by visual inspection. SOP: INT SOP 48	A B C D E
Venous whole blood :EDTA	Haemoglobin S	Detection of decreased solubility of Haemoglobin S with TCS BioScience kit SOP: INT SOP 61	A B C D E
	Glucose 6 dehydrogenase (G6PD) detection	Quantitative Fluorescence detection- Trinity Biotech SOP ; - INT SOP 107	B
		Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia screening programme, as defined in the as defined in the July 2018 Sickle cell and Thalassaemia screening programme: laboratory QA evidence requirements.	



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Documented In-house methods using:	
Venous whole blood :EDTA	Haemoglobinopathy Screening <ul style="list-style-type: none"> <li>○ HbA2</li> <li>○ HbF</li> <li>○ HbA</li> <li>○ HbS</li> <li>○ HbC</li> <li>○ HbD</li> <li>○ HbE</li> </ul>	TOSOH G8 by HPLC SOP: INT SOP 69	A
Human Body Fluids (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations: (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	A B C D E
Venous Blood	Blood Grouping <ul style="list-style-type: none"> <li>• A B O</li> <li>• Rhesus: C, c, D, E, e,</li> <li>• K</li> <li>• Jka, Jkb</li> </ul>	Ortho Vision analyser and associated testing protocols – fully automated cassette technology including Rh-subgroup and K phenotyping cards SOP: INT-SOP-93 And Jka/Jkb phenotyping cards INT SOP 35  Ortho vision and Manual tube methods using Biovue technology serological methods	A B C D E



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Human Body Fluids (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations: (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	A B C D E
Plasma/EDTA	<p>Red cell Antibody Screening and identification : Rh- D, C, E, c, e, f and cw Kell K, k, kpa, kpb Duffy Fya and Fyb Kidd Jka and Jkb Lewis Lea and Leb MNS S, s, M, N Lutheran Lua and Lub</p> <p>Antibody Detection</p> <p>Direct Anti-Human Globulin (DAGT)</p> <p>Blood Grouping/Phenotype</p> <ul style="list-style-type: none"> <li>• Fya, Fyb</li> <li>• S, s</li> <li>• M</li> </ul> <p>Blood Grouping</p> <ul style="list-style-type: none"> <li>• ABO</li> </ul> <p>RhD</p>	<p>INT-INS-117</p> <p>Ortho Vision 3 cell panels, 11 cell panels Ortho DAGT cards Auto Ortho Vision SOP: INT-SOP-93 Manual gel technology SOP:-INT-SOP-35</p> <p>Manual procedures by Ortho gel technology and Lorne antisera-red cell agglutination, macroscopic visual detection SOP: INT-SOP-35</p> <p>Manual tube procedures- red cell agglutination, macroscopic visual detection SOP;- INT-SOP-35</p>	



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Human Body Fluids (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations: (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	A B C D E
Venous Blood	Compatibility testing of patient's plasma with donor cells	Fully automated Ortho cassette technology and manual procedures SOP: INT-SOP-93 SOP: INT-SOP-35 Electronic Issue SOP;-INT SOP21	
Venous Blood	Estimation of Foetal cells	Kleihauer by Acid Elution using Source BioScience kit and Haematoxylin counterstain SOP : INT SOP 28	A B C D
HUMAN BODY FLUIDS	<u>Biochemical examination activities for the purposes of clinical diagnosis:</u>  Quantitative determination of	Documented in house methods and manufacturers instructions for  Using Roche Cobas 8000 e602 and e801 (A) module SOP INT-SOP-110 and INT-INS-246	
Serum/Heparinised plasma (unless otherwise stated)	17 Beta Oestradiol 25 Hydroxy Vitamin D  ACTH Alpha fetoprotein B HCG  CA125 CA 153 CA 19-9 CEA Cortisol DHAS Digoxin Ferritin Folate Free T3	Electrochemiluminescence assay:	A B D A B C D E D A C A B C D E A C A C A C A B C D A B C D A A B C D A B C D E







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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
		Using Roche Cobas 8000 e60 module and e801 (A) SOP INT-INS 110 and INT-INS-246	
		Photometric assays:	
	Alcohol		A B C D E
Serum/Plasma/Ascitic Fluid/ PD fluid (C D)/ Pleural Fl. (B C D E), Urine	Albumin		A B C D E
	Alkaline Phosphatase		A B C D E
	Alpha-1-Antitrypsin		B
	ALT		A B C D E
Serum/Plasma/Ascitic Fluid/ Pleural fluid ( B C D E), Urine	Amylase		A B C D E
	AST		A C D
	Beta 2 Microglobulin		B
	Bicarbonate		A B C D E
	Bile Acids		A
	Bilirubin		A B C D E
Serum	Ammonia		A B C D
	C3		B
	C4		B
	Caeruloplasmin		B
Serum, Plasma, Urine	Calcium		A B C D E



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
Serum/Heparinised plasma (unless otherwise stated)	Quantitative determination of	Using Roche Cobas 8000 e602 module and e801 (A) SOP INT-INS 110 and INT-INS-246	
	Carbamazepine	Photometric assay:	A
	Cholesterol		A B C D E
	CK		A B C D E
	Conjugated Bilirubin		A B C D E
	CRP		A B C D E
Serum, Plasma, PD fluid (C D), Urine	Creatinine		A B C D E
	Gamma GT		A B C D E
Serum, plasma, Sodium Fluoride EDTA plasma, Ascitic Fluid, CSF (B C D), PD Fluid (C D), Pleural fl. (B C D E)	Gentamicin		A B C D
	Glucose		A B C D E
	Haptoglobin		C
	HDL cholesterol		A B C D E
EDTA Plasma	Homocysteine		B
	IgA		B
	IgG		B
	IgM		B
	Iron		A B C D E
Sodium Fluoride EDTA, CSF (B C D)	Lactate		A B C D E
Serum, Plasma, CSF ( B C D), Pleural Fluid (B C D E)	LDH		A B C D E



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
	Quantitative determination of	Using Roche Cobas 8000 e602 module and e801 (A) SOP INT-INS 110 and INT-INS-246	
Serum/Heparinised plasma (unless otherwise stated)		Photometric assay:	
Serum	Lithium		A D
Serum, Plasma, Urine (A)	Magnesium		A B C D E
	Paracetamol		A B C D E
Serum, Plasma, Urine	Phenytoin		A D
	Phosphate		A B C D E
	Salicylate		A B C D E
	Theophylline		A D
Serum, Plasma, Ascitic Fluid, CSF (B C D) PD fluid (C D) Pleural FI (B C D E), Urine	Tobramycin		B D
	Total Protein		A B C D E
	Transferrin		A B C D E
	Triglycerides		A B C D E
Serum, Plasma,Urine	Urate		A B C D E
Serum,Plasma,Urine, PD fluid (C D)	Urea		A B C D E
	Vancomycin		A B C D



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
Serum	Thyroglobulin antibodies	Siemens Immulite SOP- INT-SOP-57 and EXT-GUI-490 Chemiluminescent Immunoassay	D
Serum, Plasma, Urine	Chloride	Roche Cobas 8000 ISE module ISE principles INT-INS-250 AND INT-INS-246	A B C D E
Serum/Plasma, Urine	Potassium		A B C D E
Serum, plasma,Urine	Sodium		A B C D E
CSF	Xanthochromia	Northstar (Uvikon) Spectrophotometer INT-SOP-126	B C D
Faeces	Calprotectin	Phadia 250 Immunocap using Fluorescent Enzyme immunoassay Calprotectin II INT-INS-271 INT-SOP-41	B
Faeces	Occult blood	Hemascreen Guaic- Peroxidase card method INT-SOP-23	A B D E
Whole blood	HbA1c	TOSOH G11 and GX(C) using HPLC INT-SOP-143 INT-SOP-133	A B C D E
Urine, Plasma Plasma	Copper Zinc	Perkin Elmer (PinAAcle 990T) using Atomic absorption spectrometer INT-SOP-20	C C



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
Serum, Plasma, Urine	Osmolality	Advance instruments Osmometer using Freezing point depression INT-SOP-26	A B C D
Sweat	Chloride	Sherwood Scientific Chloride Meter (Macroduct Iontophoresis System) INT-INS-243 INT-SOP-84	A B C D
Heparinised Blood	pH Glucose Sodium Potassium Ionised Calcium Lactate Haemoglobin Haematocrit Chloride Carboxyhaemoglobin Methaemoglobin pCO <sub>2</sub> pO <sub>2</sub>	Roche Cobas b123 Blood gas analyser using POCT-2:  Sensor Sensor  Spectrophotometry  Sensor Co-oximetry  Sensor	A B C D



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for	
Urine	Bence Jones protein	Electrophoresis and immunofixation using Helena SAS-3 and SAS-4 systems INT-SOP-136 and 137:	B
Serum	Cryoglobulins	Electrophoresis using Helena Nexusanalyser:	B
Serum	Abnormal proteins detected from above methods	INT-SOP-137	B
serum	Serum Free Kappa Light chains Serum Free Lambda light chains Light chains ratio	Optilite Analyser (binding site) INT-SOP-131	B
Serum	Adrenal Antibodies ANA (Hep2) ANCA Crithidia Endomysial antibodies IgG/IgA Mitochondrial antibodies SM Antibodies GPC antibodies LKM antibodies Ovarian antibodies Phemphigus/phemgoid antibodies Purkinje cell antibodies Ribosomal antibodies Striated muscle antibodies	Manual method using indirect Immunofluorescence and microscopy INT-SOP-21	B



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
Serum	Confirmatory tests : ENA antibodies LKM antibodies Mitochondrial antibodies Purkinje antibodies Neuronal antibodies	Manual immunoblotting method using Euroblot Assays INT-SOP-22:	B
Serum	Functional abs: Haemophilus IgG Neumococcal IgG Tetanus IgG Intrinsic factor antibodies	Best 2000 using ELISA INT-SOP-42:	B
Whole Blood	Lymphocyte subsets: CD4 CD8 CD19 CD56 CD3 HLA-B27 expression Memory B Cell test Neutrophil function test (DHR)	Beckman Coulter Navios and TQ Prep analysers using Flow cytometry: INT-SOP-40 INT-SOP-79	B





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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum/Plasma</p>	<p><u>Immunological examination activities for the purposes of clinical diagnosis: (cont'd)</u></p> <p>Autoantibodies:</p> <p>ANCA (MPO/PR3) Cardiolipin IgG CCP antibodies ENA antibodies Gliadin IgG/IgA GBM antibodies Tissue Transglutaminase ab Ribosomal P ab Ds DNA IgG precipitans to: Farmers Lung A.fumigatus (m3) Avain (Ge90,Ge91,Ge92) Budgie (Ge90) C.albicans (m5) M.faeni (Gm22) Parrot (Ge92) Pigeon (Ge91) T.vulgaris (Gm23)</p> <p>Total IgE Mast cell tryptase</p> <p>Specific IgE as follows: Grass (g6) Grass Mix (gx 3) Rape Pollen (w207) Lupin (w207) Weed mix (wx3) Silver birch (t3) Olive (t9) Tree pollen mix (tx8) House dust mite (d1) Cat (e1) Horse (e3) Dog (e5) Guinea pig (e6)</p> <p>Rat epithelium (e73) Budgie droppings (e77) (e200)</p>	<p>Documented in house methods and manufacturers instructions for</p> <p>Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41</p>	<p>B</p>



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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>Immunological examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
Serum/Plasma	Specific IgE: Budgie feathers (e78) (e201) Rabbit (e82) Hamster (e84) Chicken feathers (e85) Mouse epithelium (e88) Parrot feathers (e213) Pigeon feathers (e215) Chicken droppings (e218) Poultry feather mix (ex17) Caged bird feather mix Nut mix (fx1) Seafood mix (fx2) Cereal mix (fx3) Food mix (fx5) Fruit mix (fx17) Nut mix 2 (fx22) Meat mix 2 (fx23) Citrus fruit mix (fx29) Spice mix (fx71) Spice mix 2 (fx72) Meat mix 1 (fx73) Egg white (f1) Milk (f2) Cod (f3) Wheat (f4) Rye (f5) Barley (f6) Oat (f7) Corn-Maize (f8) Rice (f9) Sesame seed (f10) Pea (f12) Peanut (f13) Soya bean (f14) White bean (f15) Hazelnut (f17) Brazil nut (f18) Almond (f20) Crab (f23) Shrimp (f24)	Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41	B



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
Serum/Plasma	Specific IgE: Tomato (f25) Pork (f26) Beef (f27) Carrot (f31) Orange (f33) Potato (f35) Coconut (f36) Blue Mussel (f37) Tuna (f40) Salmon (f41) Haddock (f42) Strawberry (f44) Yeast (f45) Garlic (f47) Onion (f48) Apple (f49) Egg yolk (f75) Hard cheese (f81) Chicken meat (f83) Kiwi (f84) Celery (f85) Melon (f87) Mustard (f89) Mango (f91) Banana (f92) Cacao (f93) Pear (f94) Peach (f95) Avocado (f96) Pecan nut (f201) Cashew nut (f202) Pistachio nut (f203) Lemon (f208) Pineapple (f210) Blackberry (f211) Mushroom (f212) Paprika/sweet pepper/capsicum (f218) Coffee (f221) Lentil (f235)	Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41	B



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HUMAN BODY FLUIDS (cont'd)  Serum/Plasma	<u>Immunological examination activities for the purposes of clinical diagnosis: (cont'd)</u>  Specific IgE: Cherry (f242) Pine nut (f253) Plum (f255) Walnut (f256) Grape (f259) Chilli pepper (f279) Curry-Santa Maria (f281) Turkey meat (f284) Sweet chestnut (f299) Lime (f306) Green bean (f315) Rape seed (f316) Raspberry (f343) Omega-5-gliadin (f416) Honey Bee (i1) Common Wasp (i3) Mosquito (i71) Bumblebee (i205) A.fumigatus (m3) Mould mix (mx1) Latex (k82) Sunflower seed (k84) Maxitase (k204) Savinase (k205) Penicillin G (c1) Penicillin V (c2) Amoxicillin (c6) Chlorohexidine (c8) Gelatin (c74) Suxamethonium (c202) Morphine (c260) nGal d 2 Ovalbumin (f232) nGal d 1 Ovomuroid (f233) nGal d 3 Conalbumin (f323) rAra h 8 Peanut (f352) rGly m 4,soya (f353) rAra h 1 Peanut (f422) rAra h 2 Peanut (f423) rAra h 3 Peanut (f424) cCor a 8 Hazelnut (f428)	Documented in house methods and manufacturers instructions for  Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41	B



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HUMAN BODY FLUIDS (cont'd)  Serum/Plasma	<u>Immunological examination activities for the purposes of clinical diagnosis: (cont'd)</u>  Specific IgE:  rAra h 9 Peanut (f427) rCor a 1 Hazelnut (f428) rCor a 14 Hazelnut (f439) rCor a 9 Hazelnut (f440) rJug r 1 Walnut (f441) rJug r 3 LTP Walnut (f442) rAna o 3 Cashew nut (f443) rBet v 2 Profilin Birch (t216) r Bet v 1 PR-10 Birch (t215) rApi m 1 phospholipase A2 Honey bee (i208) rVes v 5 Common Wasp (i209) rVes v 1 phospholipase A1 common wasp (i211) MUXF3 CCD Bromelin (o214)	Documented in house methods and manufacturers instructions for  Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41	B
HUMAN BODY FLUIDS  Semen (fertility investigations)	Andrology examination activities for the purposes of clinical diagnosis  pH  Sperm Motility  Sperm Concentration Sperm morphology	Documented in house methods and manufacturers instructions for  Documented in house manual method INT-SOP-37 based on WHO Manual 2010 (5th Edition) or examination carried out under temp controlled conditions using pipette, McolorpHast pH strips, Eosin/Nigrosin stain, Improved Neubauer counting Chamber( motility, Conc, morphology), Papanicolaou stain (morphology) and light microscopy, oil immersion microscopy, heated stage (motility) and phase microscopy.pH using controlled pH strips	A D
Semen (Post Vasectomy)	Detection of Sperm	Documented in house manual method for the examination of preparation based on BAS guidelines using light microscopy INT-SOP-101 INT-INS-115	A D



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE Non-gynae cytology cell blocks</p> <p>Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Basophilic and Eosinophilic structures</p>	<p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Supported by: Tissue Dissection: Manual methods using documented procedures INT-SOP-4, INT-SOP-120, INT-SOP-117, INT-SOP-118, INT-SOP-119, INT-SOP-116, INT-SOP-134</p> <p>Cryotomy: Leica cryostat INT-SOP-8</p> <p>Tissue Processing: Using the Leica Peloris INT-SOP-2</p> <p>Embedding: INT-SOP-3 Using Thermo Histostar</p> <p>Section Cutting: INT-SOP-3 Thermo Paratrimmer Using Leica microtomes</p> <p>Automated H&amp;E staining using Sakura Prism Plus with integrated G2 coverslipper. INT-SOP-6</p>	C



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	C
FFPE and Non-gynae cytology cell blocks	Special staining of histopathology examinations to assist in detection of clinical abnormalities:  Acid Mucins/Neutral Mucins  Carbohydrates and Mucins Amyloid Elastin, Connective tissue Connective tissue, muscle Copper associated Protein Fungi Iron deposition Reticulin  Spirochetes, H.pylori Acid fast bacilli  Bacteria	Special staining In-house manual documented procedures based on manufacturers' manuals as relevant using : Agilant Artisan Link stainer, Thermo Stain Mate stainer INT-SOP-10  Alcian Blue Periodic Acid Schiff (PAS) PAS Congo Red Verhoeffs Elastin van Gieson Masson Trichrome Orcin stain (Shikata) Grocotts Hexamine silver Perl's Prussian Blue Gordon and Sweet's silver impregnation Warthin Starry stain Ziehl Nielsen Manual staining: Gram stain	C
FFPE	<u>Immunohistochemistry examination activities for detection of:</u>  Epithelial Cells Benign and malignant prostate Normal Germinal centre T Cells and Mantle Zone B cells Epithelial cells Ovarian Epithelial cells Smooth muscle cells Mesothelial cells, normal testis	Immunohistochemistry Microscopic examination supported by in-house documented procedures based Leica Bond III: Using SOPs INT-SOP-10  AE1/AE3 AMACR/P63 Bcl2  BerEP4 CA125 Caldesmon Calretinin	C



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	C
FFPE	<u>Immunohistochemistry examination activities for detection of:</u>  Epithelial cells T Cells Germinal centre cells of Tonsil, endometrial stromal cells, normal kidney B Cells Hodgkin cells, Reed-Sternberg cells Endothelial cells Endothelial cells Lymphocytes Neuroendocrine cells Macrophages B cells Mast cells, Stem cells, Cajal cells, melanocytes, basal (skin) and mammary duct epithelial Neuroendocrine cells CEA glycoproteins Squamous epithelium Epithelial cells Thyroid follicular cells Colonic epithelial cells Basal cells, filamentous keratins from glandular to stratified squamous Cytomegalovirus Striated and smooth muscle cells  Gastro Intestinal Stromal tumours (GIST)	Immunohistochemistry Microscopic examination supported by in-house documented procedures based on Leica Bond III: Using SOPs INT-SOP-10  Cam 5.2 CD3 CD10  CD20 CD30  CD31 CD34 CD45 CD56 CD68 CD79a CD117  Chromogranin A CEA CK 5/6 CK7 CK19 CK20 CK34BE12 (HMWCK)  CMV Desmin  DOG-1	





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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	C
FFPE	<u>Immunohistochemistry examination activities for detection of:</u>  Normal duct epithelial cells, ductal carcinoma Normal and neoplastic epithelium Normal Breast, breast carcinoma Epithelial cells breast and bladder Placental syncytiotrophoblasts and cytotrophoblasts Hepatocytes Melanocytes Leydig and Sertoli cells in testis Proliferating cells in germinal centres Melanocytes Germ Cells Epithelial cells of urogenital tract Human Papilloma Virus Squamous epithelium Colonic adenocarcinoma Basal cells and squamous cells Breast carcinoma Prostate secretory and ductal epithelium Melanocytes Schwann cells, nerve processes, melanocytes Smooth muscle cells Neuroendocrine cells	Immunohistochemistry Microscopic examination supported by in-house documented procedures based on Leica Bond III: Using SOPs INT-SOP-10  E-Cadherin  EMA  ER (EP1)  GATA 3  Glypican  HepPar1 HMB45 Inhibin  Ki-67 (MIB1)  Melan A OCT 3 / 4 PAX 8  P16 P40 P53 P63  PR PAP  SOX 10 S100  SMH Synaptophysin	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	C
FFPE	<u>Immunohistochemistry examination activities for detection of:</u>	Immunohistochemistry Microscopic examination supported by in-house documented procedures based on Leica Bond III: Using SOPs INT-SOP-10	
	Thyroid follicular cells Thyroid follicular cells Epithelial cells and mesenchymal cells Fallopian tube epithelial cells, Renal glomeruli	Thyroglobulin TTF-1 Vimentin  WT1	
Bullous/inflammatory lesions from skin and buccal mucosa frozen sections	IgA  IgG IgM C3 Fibrinogen	Manual staining: Direct immunofluorescence	
HUMAN BODY FLUIDS	<u>Diagnostic Cytopathology (Non-Gynaecological) examination activities for the purposes of clinical diagnosis</u>	Macroscopic and microscopic examination	C
Fine needle aspirations (various sites) Serous effusions (pleural, ascetic, pericardial) Urine Cyst Fluids Peritoneal Washings Cerebrospinal Fluid  Air dried prepared slides of above	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Documented in-house procedures In conjunction with manufacturer's instructions for Thermo Cytospin 4 and Sakura Prism PlusStainer with integrated G2 coverslipper Using INT-SOP-62, INT-SOP-6 INT-INS-34 Automated staining PAP and H&E stain Manual staining Giema And light microscopy	



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HUMAN BODY TISSUE AND FLUIDS	<u>Cellular Pathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	C
Slides of stained preparations derived from Human tissue and fluids	Morphological assessment and diagnosis	Olympus / Nikon Microscopes light and fluorescence using INT-SOP-99 Ctology Microscopy and RCPATH guidelines	
HUMAN TISSUES AND FLUIDS	<u>Serological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: 'Documented In-House Methods to meet the requirements of the IDPS Programme handbook as defined in the current version of 'infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening (HIV Antibody/Antigen detection, Hepatitis B surface antigen, Syphilis antibody) Roche Cobas 8000 e801 using electrochemiluminescence immunoassay INT-INS-110 INT-INS-246	A
Serum	Hepatitis B surface Antigen HIV Ab/Ag  Hepatitis B surface antibody Hepatitis B core Antibody Hepatitis C antibody Syphilis Total Antibody		



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Evolis using Enzyme linked immunoassay and SOP INT-SOP-55	B
Serum	HIV Ag/Ab VZ IgG Measles IgG Mumps IgG CMV IgG CMV IgM EBV VCAG EBV CAM EBV NAG Rubella IgG Toxoplasma IgG Mycoplasma IgG Parvovirus IgG Parvovirus IgM Hepatitis E IgG Hepatitis E IgM		
Faeces	C. difficile GDH	Dynex DS2 using Enzyme linked immunoassay: INT-SOP-14	D
Serum	HIV ab/ag	Biorad HIV Geenius using immunochromatography INT-INS-285	B
Serum	Syphilis Ab	Biorad RPR using immunochromatography: INT-INS-258	B
Serum	Syphilis Ab	Biorad TPHA using immunochromatography: INT-INS-258	B



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genital Swab/Urine</p> <p>Plasma</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u></p> <p>Chlamydia DNA N.gonorrhoeae DNA Hepatitis C viral loads Hepatitis C Genotyping HIV 1 viral load</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Abbott m2000 system using PCR: INT-INS-140</p>	B



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Routine samples:</p> <p>Cellular and fluid material contained on swabs, catheter tips and IUCDs Aspirates Fluids Genital samples Pus Samples from sterile sites Semen Tissues/Bone Urine</p> <p>Swabs , Fluids, urines, tips and sputum</p> <p>Urine</p> <p>Blood</p> <p>CSF, CAPD, Ascitic fluid</p> <p>Genital swabs</p>	<p><u>Microbiological examination activities performed for the purpose of clinical diagnosis</u></p> <p>Isolation and characterisation of microorganisms of clinical significance</p> <p>Isolation of MRSA</p> <p>Quantification of white and red blood cells, bacteria and epithelial cells</p> <p>Detection of microbial growth and general isolation and characterisation of microorganisms of clinical significance</p> <p>Detection and identification of White blood cells and red blood cells</p> <p>Trichomonas vaginalis Bacterial vaginosis</p>	<p>In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual inoculation, incubation and culture using:</p> <p>INT-SOP-128 INT-SOP-89 INT-SOP-71 INT-SOP-52 INT-SOP-72</p> <p>Manual culture on chromogenic agar using SOP INT-SOP-29</p> <p>Automated urinalysis, image capture and recognition using: SOP INT-SOP-128 and IRIS IQ 200</p> <p>Liquid media culture using SOP INT-SOP-54 in conjunction with manufacturers instructions for Biomerieux BacTAlert 3D</p> <p>Light microscopy and counting chamber: INT-SOP-50</p> <p>Light microscopy using wet prep and gram stain: INT-INS-263</p>	<p>B D</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	B D
CSF / Ascitic	General isolation and characterisation of micro-organisms of clinical significance	manual inoculation and media culture using SOPs INT-SOP-50, INT-SOP-52	
Respiratory specimens :	General isolation and characterisation of micro-organisms of clinical significance	Manual media culture using SOPs INT-SOP-73	
Sputum Bronchoalveolar lavage Bronchial aspirate, brushings and washings Cellular material contained on swabs Endotracheal tube specimens Nasopharyngeal aspirate Pleural fluid			
Faeces	General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> 0157	Manual culture and using selective agar with SOP INT-SOP-51	
Faeces and bowel contents	Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B	Quik chek tox A/B Immunochromatographic assay using SOP INT-INS-259	
Swabs/Faeces	CPE producing bacteria	Manual culture and using chromogenic agar with SOP INT-SOP-29	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Bacterial cultures (isolated in-house)	Identification and characterisation of micro-organisms	Manual and/or automated identification methods using : SOPs INT-INS-259, INT-SOP-74, INT-SOP-91 Automated methods using Vitek 2 and Vitek compact	B D
Bacterial cultures (isolated in-house) Blood Urine	Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	SOP INT-SOP-67 by manual disk diffusion using EUCAST guidelines and MIC determination using E-Tests Automated testing by Vitek 2 INT-SOP-91 and Vitek Compact. Direct susceptibility testing on Blood cultures and urines by EUCAST methodology	B D
Faeces, fluids, urine & perianal swabs, sellotape slide and suspected parasitic material	Examination for the presence of parasites (ova, cysts, trophozoites and worms including cryptosporidia) of clinical significance	Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: SOPs INT-SOP-51, INT-INS-263	B D
Skin, Hair and nail clippings	Isolation and identification of clinically significant dermatophyte fungi and yeasts	Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) Using INT-SOP-87	B
Sputum, BAL, pleural fluids, tissue	Acid Fast Bacillii	Fluorescent microscopy using Auramine phenol stain and INT-SOP-90 and INT-SOP-263	B D
Sputum, BAL, pleural fluids, tissue	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Liquid culture, auramine phenol staining and incident-light fluorescence microscopy and confirmation ZN staining using light microscopy using: INT-SOP-90, INT-INS-263 in conjunction with Biomerieux BacTAlert 3D and LJ culture slopes	B





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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	B D
Faeces	Detection of Rotavirus	Immunocard Stat RV kit Immunochromatographic assay SOP INT-INS-259	
NPA	Detection of RSV	IBinax NOW RSV mmunochromatographic assay SOP INT-INS-259	
Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues Bone CSF Ascitic fluids Gum Swabs	Detection and identification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae Vincents organisms	Staining (inc. Gram) and microscopic examination using: INT-INS-263	
Urine	Detection of Legionella urinary antigen	Binax NOW Immunochromatographic assay using SOP INT-INS-259	
Urine	Detection of S.pneumoniae urine antigen	Binax NOW Immunochromatographic assay using SOP INT-INS-259	
END			