Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8833

Accredited to ISO 15189:2022

Northern Lincolnshire and Goole NHS Foundation Trust

Issue No: 013 Issue date: 15 January 2025

Path Links NHS Pathology Service Diana Princess of Wales Hospital

Scartho Road Grimsby

DN33 2BA

Contact: James Maclean Tel: +44 (0)1536 493368

E-Mail: James.maclean@nhs.net

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Pathology Diana Princess of Wales Scartho Road Grimsby DN33 2BA	Local contact See above	 Routine Haematology Blood Transfusion Biochemistry Andrology Phlebotomy Blood Fridges Blood issue/electronic issue Serology 	A
Pathology Scunthorpe General Hospital Cliff Gardens Scunthorpe DN15 7BH	See above	 Routine Haematology Blood Transfusion Biochemistry Immunology Microbiology Serology Molecular Phlebotomy Blood fridges Blood issue/electronic issue 	В
Pathology Lincoln County Hospital Greetwell Road Lincoln LN2 5QY	See above	 Routine Haematology Blood transfusion Biochemistry Histology Non gynae cytology Phlebotomy Blood Fridges Blood issue/electronic issue 	С

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Location details		Activity	Location code
Address Pathology Boston Pilgrim Hospital Sibsey Road Boston PE21 9QS	Local contact See above	 Routine haematology Blood transfusion Biochemistry Andrology Microbiology Phlebotomy Blood fridges Blood issue/electronic issue Molecular 	D
Pathology Grantham and District General hospital Manthorpe Road Grantham NG21 8DG	See above	 Routine Haematology Blood Transfusion Biochemistry Phlebotomy Blood Fridges Blood issue/electronic issue 	Е
Phlebotomy and blood fridges only :			
Goole and district Hospital Woodland Avenue Goole DN14 6RX	See above	PhlebotomyBlood fridges- Laboratory	F
Louth County Hospital High Holme Road Louth LN11 0EU	See above	PhlebotomyBlood Fridges- Laboratory	G
HMT St Hughs Peaks Lane Grimsby DN32 9RP	See above	Blood fridges	н
Lincoln BMI Nettleham Road Lincoln LN2 1QU	See above	Blood fridges- Maternity and main theatres	I
Diana Princess of Wales Scartho Road Grimsby DN33 2BA	See above	Blood fridges- main theatres	J

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DETAIL OF ACCREDITATION

Type of test/Properties		
measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Haematological examination activities for the purposes of clinical diagnosis:	Documented in house methods and manufacturers instructions for	
Blood Coagulation Routine	ACL TOPS 550(ABCD) ACL TOP 350 (E)	ABCD
NR Activated Partial Thromboplastin Time	Clot detection by optical rate of change of absorbance end point being the maximum rate of change	E
Fibrinogen estimationClaussDerived	SOP;- INT SOP 82	
D-Dimers	Latex method SOP;- INT SOP 82	С
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	С
• FVIII • FIX		
 FXI FXII Free protein S Protein C Von Williebrand Factor Antigen Activity 		
AntiThrombin III	Chromogenic end point	С
	measurement Haematological examination activities for the purposes of clinical diagnosis: Blood Coagulation Routine Prothrombin time INR Activated Partial Thromboplastin Time Fibrinogen estimation Clauss Derived D-Dimers Special Coagulation APTT-SP APTT-2 APTT mixing studies APCR FVIII FIX FXI FXI FXI FXI Free protein S Protein C Von Williebrand Factor Antigen Activity	Haematological examination activities for the purposes of clinical diagnosis: Blood Coagulation • Prothrombin time • INR • Activated Partial Thromboplastin Time • Fibrinogen estimation • Clauss • Derived D-Dimers D-Dimers Latex method SOP;- INT SOP 82 Special Coagulation • APTT-SP • APTT-2 • APTT mixing studies • APCR • FVIII • FIX • FXI • FXI • FXI • FXI • FXI • FXI • Free protein S • Protein C • Von Williebrand Factor • Antigen • Activites of the purposes of clinical in house methods and manufacturers instructions for ACL TOPS 550(ABCD) ACL TOP 350 (E) Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change SOP;- INT SOP 82 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

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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)	Haematology examination activities for the purpose of clinical diagnosis: (cont'd)	Documented In-house methods using:	
Venous whole blood: EDTA	 FBC Haemoglobin estimation Red cell and platelet counts Haematocrit Differential white cell count Reticulocyte MCV MCH MCHC 	Sysmex XN 10 series Haematology Analysers SOP:INT-SOP-141 Colorimetric Laser light scatter Calculated parameter from Haemoglobin and RBC Laser and light scatter and light absorbance Laser light scatter and absorbance Calculated parameters Calculated parameters Calculated parameters Calculated parameters	ABCDE
	ESR	Visual detection of sedimentation interface by automated photometric detection using Vacuette SRS100/II Greiner SOP: INT-SOP-114	ABCD 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	A B C D E
Whole Blood	Malaria Parasite detection	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	ABCDE

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HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purpose of clinical diagnosis: (cont'd)	Documented In-house methods using:	
Whole Blood	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	ABCD E
	Glucose 6 dehydrogenase (G6PD) detection	Qualitative Fluorescence detection- Trinity Biotech SOP ;- INT SOP 107	В
		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 as defined in the laboratory quality assurance evidence requirements	
		Capillarys3 Tera - Sebia capillary Zone electrophoresis (CZE) SOP: INT SOP 165	
Venous whole blood :EDTA	Haemoglobin analysis by detection of haemoglobin variants: HbA, HbA2,HbF, HbS, HbC, HbD, HbE		В
	Haemglobinopathy screening (Antenatal and non-antenatal)		
Venous whole blood :EDTA	Haemoglobin S	Detection of decreased sickle cell solubility of Haemoglobin S with Streck SickleDEX SOP: INT SOP 61	В
Whole blood	HbA1c	Capillarys3 Tera - Sebia capillary Zone electrophoresis (CZE) SOP: INT SOP 165	ABDE

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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)	Blood Transfusion examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods:	
Venous Blood	Blood Grouping A B O Rhesus: C, c, D, E, e, K Jka, Jkb Ss MN Fya, Fyb	BioRad IH500 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	A B C D E (E Manual only)
		BioRad and Manual tube methods using Biovue technology serological methods	A B C D E (E Manual only)
Plasma/EDTA	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	INT-INS-117	Office
	Antibody Detection Direct Anti-Human Globulin (DAGT)	BioRad 3 cell panels, 11 cell panels BioRad DAGT cards Auto BioRad SOP: INT-SOP-93 Manual gel technology SOP:-INT-SOP-35	
	Blood Grouping/Phenotype Fya, Fyb S, s M	Manual procedures by BioRad gel technology and Lorne antisera-red cell agglutination, macroscopic visual detection SOP: INT-SOP-35	
	Blood Grouping • ABO RhD	Manual tube procedures- red cell agglutination, macroscopic visual detection SOP;- INT-SOP-35	

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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations to assist in clinical investigations: (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods:	
Venous Blood	Compatibility testing of patient's plasma with donor cells	Fully automated BioRad cassette technology and manual procedures SOP: INT-SOP-93 SOP: INT-SOP-35 Electronic Issue SOP;-INT SOP21	A B C D E (E Manual only)
Venous Blood	Estimation of Foetal cells	Kleihauer by Acid Elution using Source BioScience kit and Haematoxylin counterstain SOP: INT SOP 28	B D
Venous Blood	FMH	Beckman Coulter Navios Flow Cytometer	В

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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)	Biochemical examination activities for the purposes of clinical diagnosis:	Documented in house methods and manufacturers instructions for	
	Quantitative determination of:	Using Roche Cobas 8000 e602 (C D E) and e801 (A B) 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 Anti-CCP B HCG CA125 CA 153 CA 19-9 CEA Cortisol DHAS Digoxin Ferritin Folate Free T3	Electochemiluminescence assay:	A A D A B B B C C C D D D C D D C D D D C D D D D

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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)	Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
	Quantitative determination of:	Using Roche Cobas 8000 e602 (C D E) module and e801(A B) SOP INT-INS-246 and INT-110	
Serum/Heparinised plasma (unless otherwise stated)		Electochemiluminescence assay:	
	Free T4 FSH IGF-1 Growth Hormone LH Macroprolactin Parathyroid Hormone Pro BNP Progesterone Prolactin Total PSA Rh Factor Testosterone Thyroid Receptor Antibodies Thyroglobulin TPO Troponin T TSH Vitamin B12 PIGF sFlt-1 PIGF/sFlt-1 ratio		AB D D B B C D C D D D B C D C D C D C D

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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)	Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
	Quantitative determination of: (cont'd)	Using Roche Cobas 8000 e602 module and e801 (A) c702 (All) SOP INT-INS 110 and INT-INS-246	
Serum/Heparinised plasma (unless otherwise stated)		Photometric assays:	
(cont'd)	Alcohol		A B C D E
Serum/Plasma/Ascitic Fluid/ PD fluid (C D)/ Pleural Fl. (B	Albumin		ABCD E
C D E), Urine	Alkaline Phosphatase		ABCD
	Alpha-1-Antitrypsin		E B
	ALT		ABCD E
Serum/Plasma/Ascitic Fluid/	Amylase		ABCD
Pleural fluid (BCDE), Urine	AST		E ACD
Office	Beta 2 Microglobulin Bicarbonate		B ABCD
	Bile Acids		E A
	Bilirubin		ABCD
Serum	Ammonia		E ABCD
	C3		В
	C4 Caeruloplasmin		B B
Serum, Plasma, Urine	Calcium		ABCD
			E

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HUMAN BODY FLUIDS (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
	Quantitative determination of: (cont'd)	Using Roche Cobas 8000 e602 module and e801 (A) c702 (All) SOP INT-INS 110 and INT-INS-246	
Serum/Heparinised plasma		Photometric assay:	
(unless otherwise stated) (cont'd)	Carbamazepine Cholesterol		A ABCD E
	СК		ABCD E
	Conjugated Bilirubin		ABCD E
	CRP		ABCD E
Serum, Plasma, PD fluid (C D), Urine	Creatinine		ABCD E
<i>D)</i> , Cimo	Gamma GT		A B C D
Serum, plasma, Sodium Fluoride EDTA plasma, PD	Gentamicin Glucose		ABCD ABCD E
Ascitic Fluid, CSF (B C D), Fluid (C D), Pleural fl. (B C D E)	Haptoglobin HDL cholesterol		C ABCD E
EDTA Plasma	Homocysteine IgA IgG IgM		B B B
Sodium Fluorido FDTA CSF	Iron		A B C D
Sodium Fluoride EDTA, CSF (B C D) Serum, Plasma, CSF (B C D), Pleural Fluid (B C D E)	Lactate		ABCD E ABCD E
Serum Serum, Plasma, Urine (A)	Lithium Magnesium		A D A B C D E
			E

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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)	Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
	Quantitative determination of: (cont'd)	Using Roche Cobas 8000 e602 module and e801 (A) c702 (All) SOP INT-INS 110 and INT-INS-246	
Serum/Heparinised plasma (unless otherwise stated)		Photometric assay:	
(cont'd)	Paracetamol		A B C D E
Serum, Plasma, Urine	Phenytoin Phosphate		A D A B C D E
	Salicylate		ABCD
Serum, Plasma, Ascitic Fluid, CSF (B C D) PD fluid	Theophylline Tobramycin Total Protein		E AD BCD ABCD E
(C D) Pleural FI (B C D E), Urine	Transferrin		ABCD E
Office	Triglycerides		A B C D
Serum, Plasma,Urine	Urate		ABCD
Serum, Plasma, Urine, PD	Urea		E ABCD
fluid (C D)	Vancomycin		E ABCD
		Using Roche Cobas 8000 c702 SOP INT-INS 110 and INT-INS-271 Turbidimetric immunoassay	
Faeces	Faecal immuno elastase Calprotectin	Buhlmann fPELA turbo test Buhlmann fCAL turbo test	B B
		Using Roche Cobas 8000 c801 (A) and c702 (E) module FIT FOB Gold NG Wide homogenous latex based immunoassay	
Faeces	Faecal Haemoglobin measurement (FIT)		ΑE

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HUMAN BODY FLUIDS (cont'd	Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
Serum, Plasma, Urine Serum/Plasma, Urine Serum, plasma, Urine	Chloride Potassium Sodium	Roche Cobas 8000 ISE module ISE principles INT-INS-250 AND INT-INS-246	ABCD E ABCD E ABCD E
		Northstar (Uvikon) Spectrophotometer	
CSF	Xanthochromia	INT-SOP-126	BCD
		Advance instruments Osmometer using Freezing point depression	
Serum, Plasma, Urine	Osmolality	INT-SOP-26	ABCD
		Sherwood Scientific Chloride Meter (Macroduct Iontophoresis System)	
Sweat	Chloride	INT-INS-243 INT-SOP-84	ABCD
		Roche Cobas b123 Blood gas analyser using POCT-2:	
Heparinised Blood	pH Glucose Sodium Potassium Ionised Calcium Lactate	Sensor Sensor	AB D
	Haemoglobin Haematocrit	Spectrophotometry	
	Chloride Carboxyhaemoglobin Methaemoglobin pCO2	Sensor Co-oximetry Sensor	
	pO2 pO2	CCTISOT	

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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)	Immunological examination activities for the purposes of clinical diagnosis:	Documented in house methods and manufacturers instructions for	
		Electrophoresis and immunofixation using Helena SAS-3 and SAS-4 systems INT-SOP-136 and 137:	
Urine Serum	Bence Jones protein Cryoglobulins	Electrophoresis using Helena Nexusanalyser:	ВВ
Serum	Abnormal proteins detected from above methods	INT-SOP-137	В
Serum	Serum Free Kappa Light chains Serum Free Lambda light chains Light chains ratio	Optilite Analyser (binding site) INT-SOP-131	В
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	В

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HUMAN BODY FLUIDS (cont'd)	Immunological examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
		Manual immunoblotting method using Euroblot Assays INT-SOP-22:	В
Serum	Confirmatory tests: ENA antibodies LKM antibodies Mitochondrial antibodies Purkinje antibodies Neuronal antibodies		
Whole blood	Detection of the following: ENA blot: Ro60, Ro52, La, Sm, RNP, SCI-70 and Jo-1 Liver blot: SLA/LP, M2, LC-1 and LKM Mito blot: M2, M4 and M9 Neuronal blot: Yo, Hu, Amphiphysin, CV2, Ri and Ma2/Ta	Immunoblotting using Euroline Blotmaster INT-SOP-161	В
Serum	Functional abs: Haemophilus IgG Neumococcal IgG Tetanus IgG Intrinsic factor antibodies	Best 2000 using ELISA INT-SOP-42:	В
Whole Blood	Lymphocyte subsets: CD4 CD8 CD19 CD56	Beckman Coulter Navios and TQ Prep analysers using Flow cytometry: INT-SOP-40INT-SOP-79	В
	CD3 Memory B Cell test Neutrophil function test (DHR)		
	HLA B27	INT-SOP-42	

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HUMAN BODY FLUIDS (cont'd)	Immunological examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/Plasma	Autoantibodies: 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) Total IgE Mast cell tryptase 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) Rat epithelium (e73) Budgie droppings (e77) (e200)	Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41	B

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HUMAN BODY FLUIDS (cont'd)	Immunological examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/Plasma (cont'd)	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 (fx22) Meat mix 2 (fx23) Citrus fruit mix (fx71) 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)	Immunological examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/Plasma (cont'd)	Specific IgE: (cont'd) 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)	Immunological examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/Plasma (cont'd)	Specific IgE: (cont'd) 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 Ovomucoid (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)	Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41	В

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HUMAN BODY FLUIDS (cont'd)	Immunological examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/Plasma (cont'd)	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)	Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41	В
Whole blood	Endo IgA and IgG, crithidia, skin, paraneoplastic, islet cell, adrenal, and ovarian antibodies.	Indirect Immunofluorescence (IIF) using Quantalyser QL3000 INT-SOP-162	В

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HUMAN BODY FLUIDS (cont'd)	Andrology examination activities for the purposes of clinical diagnosis		
Semen	Post vasectomy Detection of sperm Sperm concentration	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 procedures INT-SOP-101 INT-INS-115	AD
Semen	Fertility testing	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021), manual method / documented in-house procedure INT-SOP-37	A D
	рН	Colorimetric strips	
	Sperm morphology excluding TZI scoring	Stained slides (Papanicolau) microscopy (Bright field)	
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	

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HUMAN BODY TISSUE AND FLUIDS	Histopathological examination activities for the purposes of clinical diagnosis	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	С
FFPE Non-gynae cytology cell Blocks		Supported by: Tissue Dissection: Manual methods using documented proceduresINT-SOP- 4, INT-SOP-120, INT-SOP-117, INT-SOP-118, INT-SOP-119, INT- SOP-116, INT-SOP-134 Cryotomy:	
		Leica cryostat INT-SOP-8 Tissue Processing: Using the Leica Peloris and Epredia Revos INT-SOP-2, INT-SOP-152 Embedding: INT-SOP-3 Using Thermo Histostar Section Cutting: INT-SOP-3 Thermo Paratrimmer Using Leica microtomes	
Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens	Basophilic and Eosinophilic structures	Automated H&E staining using Sakura Prism Plus with integrated G2 coverslipper. INT-SOP-6	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	С
FFPE and Non-gynae cytology cell blocks	Special staining of histopathology examinations to assist in detection of clinical abnormalities:	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	
	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	Alcian Blue Periodic Acid Schiff (PAS) PAS Congo Red Verhoeffs Elastin van Gieson Masson Trichrome Orecin stain (Shikata) Grocotts Hexamine silver Perl's Prussian Blue Gordon and Sweet's silver impregnation Warthin Starry stain Ziehl Nielsen Manual staining: Gram stain	
	Immunohistochemistry examination activities for detection of:	Immunohistochemistry Microscopic examination supported by in-house documented procedures based Leica Bond III: Using SOPs INT-SOP-10	С
FFPE	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, mormal testis Epithelial cells T Cells	AE1/AE3 AMACR/P63 Bcl2 BerEP4 CA125 Caldesmon Calretinin Cam 5.2 CD3	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Immunohistochemistry examination activities for detection of: (cont'd)	Immunohistochemistry Microscopic examination supported by in-house documented procedures based on Leica Bond III: Using SOPs INT-SOP-10	С
FFPE (cont'd)	Germinal centre cells of Tonsil, endometrial stromal cells, normal kidney B Cells Hodgkin cells, Reed-Sternberg cells Endothelial 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 Mesothelioma Cytomegalovirus Striated and smooth muscle cells Gastro Intestinal Stromal	CD10 CD20 CD30 CD31 CD34 CD45 CD56 CD68 CD79a CD117 Chromogranin A CEA CK 5/6 CK7 CK19 CK20 CK34BE12 (HMWCK) Claudin 4 CMV Desmin DOG-1	
	tumours (GIST) Normal duct epithelial cells, ductal carcinoma Normal and neoplastic epithelium Normal Breast, breast carcinoma	D240 ERG E-Cadherin EMA ER (EP1)	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Immunohistochemistry examination activities for detection of: (cont'd)	Immunohistochemistry Microscopic examination supported by in-house documented procedures based on Leica Bond III: Using SOPs INT-SOP-10	С
FFPE (cont'd)	Epithelial cells breast and bladder Placental syncytiotrophoblasts and cytotrophoblasts Hepatocytes Melanocytes Leydig and Sertoli cells in testis Neuroendocrine tumors 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	GATA 3 Glypican HepPar1 HMB45 Inhibin INSM1 Ki-67 (MIB1) Melan A NKX3.1 OCT 3 / 4 PAX 8 P16 P57 P40 P53 P63	
	Breast carcinoma Prostate secretory and ductal epithelium Melanocytes Schwann cells, nerve processes, melanocytes Smooth muscle cells Neuroendocrine cells Thyroid follicular cells Thyroid follicular cells Epithelial cells and mesenchymal cells Fallopian tube epithelial cells, Renal glomeruli	PR PAP SOX 10 S100 SMH Synaptophysin SATB2 SALL4 Thyroglobulin TTF-1 Vimentin WT1	

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HUMAN BODY FLUIDS	Diagnostic Cytopathology (Non-Gynaecological) examination activities for the purposes of clinical diagnosis	Macroscopic and microscopic examination	С
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	
HUMAN BODY TISSUE AND FLUIDS	Cellular Pathological examination activities for the purposes of clinical diagnosis	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
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	С
Whole slides of stained preparations	Morphological assessment and diagnosis	Digital scanning (Whole Slide Imaging – WSI) using Hamamatsu S360 and S60; Dynamyx software INT-SOP-146	С

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis	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 (relevant targets marked *).	
		Roche Cobas 8000 e801 using electrochemiluminescence immunoassay INT-INS-110 INT-INS-246	В
Serum	Hepatitis B surface Antigen HIV Ab/Ag * Hepatitis B surface antibody * Hepatitis B core Antibody Hepatitis C antibody Syphillis Total Antibody *		

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HUMAN TISSUES AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Diasorin Liaison XL using CLIA and SOP INT-SOP-148	В
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 & IgM Hepatitis B e Antigen (HBeAg) Hepatitis B anti-core IgM		
Serum Plasma Faeces Faeces	Syphilis TPHA and RPR HBsAg Interferon Gamma GDH Helicobacter pylori antigen	Arlington Scientific TPHA and RPR manual kits	В
Faeces	C. difficile GDH	Dynex DS2 using Enzyme linked immunoassay: INT-SOP-14	D
Serum	HIV ab/ag confirmation	Biorad HIV Geenius using immunochromatography INT-INS-285	В

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular examination activities for the purpose of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	В
Genital Swab/Urine Plasma/serum	Chlamydia DNA N.gonorrheae DNA T.vaginalis DNA M.genitalium DNA Hepatitis C viral loads	Abbott AlinityM system using PCR:	В
Nose/Throat swabs	HIV 1 viral load SARS CoV 2 Influenza A Influenza B RSV		
Faeces Genital swabs, Ocular swabs and urine	SARS CoV2 Flu A/B RSV Norovirus N.gonorrhoeae confirmation C.trachomatis confirmatio	Cepheid Genexpert using PCR	ВD
DNA/RNA taken from Nose & Throat swabs in viral transport medium	Extended respiratory PCR – Sars-Cov-2, Influenza A, Influenza B, RSV, Bocavirus, Bordetella pertussis, Legionella pneumophila, Mycoplasma pneumoniae, Rhinovirus/Enterovirus, Chlamydia pneumonia, Adenovirus, Human metapneumovirus, Parainfluenza 1-4; Seasonal coronavirus OC43, NL63, HKU1 and 229E	Qiagen Qiastat PCR INT-SOP-159	В

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

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)	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 : Sputum Bronchoalveolar lavage	General isolation and characterisation of micro-organisms of clinical significance	Manual media culture using SOPs INT-SOP-73	
Bronchial aspirate, brushings and washings Cellular material contained on swabs Endotracheal tube specimens Nasopharyngeal aspirate Pleural fluid			
Faeces	General isolation and characterisation of Salmonella, Shigella, Campylobacter & E. coli 0157	Manual culture and using selective agar with SOP INT-SOP-51	
Faeces and bowel contents	Detection of <i>Clostridium</i> difficile GDH antigen and toxins A & B	Quik chek tox A/B Immunochromatopgraphic assay using SOP INT-INS-259	
Swabs/Faeces	CPE producing bacteria	Manual culture and using chromogenic agar with SOP INT-SOP-29	
Isolates of Enterobacterales	Carbapenemase detection	NG-Biotech Laboratories NG-test Carba5 manual method	BD

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)	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	BD
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	BD
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	BD
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	В
Sputum, BAL, pleural fluids, tissue	Acid Fast Bacillii	Fluorescent microscopy using Auramine phenol stain and INT- SOP-90 and INT-SOP-263	BD
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	В

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	BD
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	Meridian TRUImmunochromatographic assay using SOP INT-INS-259	B D
Urine	Detection of S.pneumoniae urine antigen	Meridian TRU Immunochromatographic assay using SOP INT-INS-259	B D
END			

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