


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9033 Accredited to ISO 15189:2012	Integrated Pathology Solutions LLP	
	Issue No: 013 Issue date: 29 May 2025	
	Airedale NHS Foundation Trust Skipton Road Steeton Keighley West Yorkshire BD20 6TD United Kingdom	Contact: Jayne Buckley Tel: +44 (0) 1535 293447 Fax: +44 (0) 1535 293431 E-Mail: jayne.buckley4@nhs.net Website: www.airedale-trust.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Pathology Department Airedale General Hospital Skipton Road Steeton Keighley West Yorkshire BD20 6TD	Local contact Jayne Buckley – as above	Histopathology & non-gynae cytology Haematology Blood Transfusion Blood storage and issue Biochemistry Microbiology	AGH
Address Pathology Department Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ	Local contact Jayne Buckley – as above	Histopathology Haematology Blood Transfusion Blood storage and issue Biochemistry	BRI



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Site activities performed away from the locations listed above:

Location details	Activity
<p>HODU Department Airedale General Hospital Skipton Road Steeton Keighley West Yorkshire BD20 6TD</p> <p>Local contact Kevan Leighton Kevan.Leighton1@nhs.net</p>	<p>Blood storage only Management of by Laboratory</p>
<p>Theatres – recovery Airedale General Hospital Skipton Road Steeton Keighley West Yorkshire BD20 6TD</p>	<p>Blood storage only Management of by Laboratory</p>
<p>Ward 7 Pathology Department Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ</p> <p>Local contact Andrew Whittingham-Hirst Andrew.Whittingham-hirst@nhs.net</p>	<p>Blood storage only Management of by Laboratory</p>
<p>Delivery Suite – anaesthetic store Pathology Department Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ</p>	<p>Blood storage only Management of by Laboratory</p>
<p>Ultrasound Clinic – renal biopsy Pathology Department Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ</p> <p>Local contact Jayne Buckley - as above</p>	<p>Suitability of renal biopsy glomeruli (carried out by laboratory staff)</p>



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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
<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, endoscopic and needle core biopsies. excision and resection specimens</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis.</p>	<p>In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:</p> <p>Macroscopic and Microscopic examination.</p>	AGH & BRI
		<p>Specimen dissection: Downflow extraction & dissection benches. Cerebro tracking system IPS_Histo_LPT_02 Specimen cut up (dissection and cassetting) IPS_Histo_LPC_01-27 Specimen examination and reporting SOPs IPS_Histo_LPT_03 Examination of high risk specimens IPS_Histo_LPO_35 Use of Histopathology Cerebro Tracking System IPS_Histo_BRI_LPT_05 Organisation of Cut up IPS_Histo_BRI_LPT_06 Specimen Cut up (dissection and cassetting) IPS_Histo_BRI_LPT_04 Taking X-rays of Breast specimens</p>	BRI
		<p>Tissue processing: Manual procedures or using Peloris II tissue processor IPS_Histo_LPT_30 Peloris Tissue Processors</p>	AGH



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below: Decalcification using manual processes: IPS_Histo_LPT_14 Decalcification – end point <u>Tissue embedding</u> Leica HistoCore Arcadia H &C Embedding centre IPS_Histo_LPT_07 Embedding <u>Tissue Sectioning</u> Motorised Microtome: Leica RM2255 Leica RM2235 IPS_Histo_LPT_09 Section Cutting	AGH & BRI
Tissue: Fixed, fresh, paraffin-wax processed and frozen section tissue			
Tissue for frozen sections	Preparation and Routine morphological staining For the detection of: Basophilic and eosinophilic tissue structures. Lipids	Leica Cryostat CM 1950UV for frozen sections : IPS_Histo_BRI_LPT_03 Performance of frozen sections for rapid diagnosis IPS_Histo_LPT_04 Performance of frozen sections IPS_Histo_LPT_27 Use and maintenance of cryostat Leica CM1950 IPS_Histo_LPS_12 HandE Frozen	AGH & BRI



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	
Renal Biopsy FNA	Cellularity assessment (sample adequacy confirmation) followed by processing and analysis in the Histopathology laboratory	Stereo Microscope and IPS_Histo_BRI_LPT_02 performance of frozen sections for immunofluorescence	BRI
Skin and renal frozen sections	Direct immunofluorescent for the detection of: IgA, IgG, IgM, C3c, C1q, Kappa, Lambda	Leica Cryostat CM 1950 for frozen sections Fluorescence microscope IPS_Histo_BRI_LPT_02 Performance of frozen sections for Immunofluorescence Manual staining Dako FITC antibodies	
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides	Routine morphological staining For the detection of: Basophilic and eosinophilic tissue structures. <u>Special staining to detect the following:</u> Acid mucins Acid and neutral mucins Melanin Amyloid Elastic fibres <i>Helicobacter pylori</i> Bacteria	Leica ST5020 autostainers Leica CV5030 Coverslipper IPS_Histo_LPT_10 Autostainer IPS_Histo_LPT_11 Coverslipper IPS_Histo_LPS_13 H&E Manual Manual staining methods with the following stains: IPS_Histo_LPS_01 Alcian blue IPS_Histo_LPS_02 Alcian Blue-PAS IPS_Histo_LPS_03 Bleach for melanin IPS_Histo_LPS_05 Congo red IPS_IPS_Histo_LPS_06 Elastic stain IPS_Histo_LPS_08 Giemsa modified IPS_Histo_LPS_09 Gram stain	AGH



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	AGH
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides (cont'd)	<u>Special staining to detect the following:</u> (cont'd)	Manual staining methods with the following stains:	
	Fungi	IPS_Histo_LPS_11 Grocott for fungi	
	Melanin	IPS_Histo_LPS_14 Masson Fontana	
	Connective tissue	IPS_Histo_LPS_15 Masson trichrome	
	Fibrin	IPS_Histo_LPS_18 MSB	
	Glycogen	IIPS_Histo_LPS_21 Periodic acid schiff	
	Ferric Iron	IPS_Histo_LPS_22 Perls'	
	Reticulin fibres	IPS_Histo_LPS_24 Reticulin	
	Hepatitis B inclusion bodies and copper associated protein.	IPS_Histo_LPS_25 Shikata acid orcein	
	Mast cells	IPS_Histo_LPS_26 Toluidine blue for mast cells	
	Connective tissue	IPS_Histo_LPS_27 Van Gieson	
	Calcium salts	IPS_Histo_LPS_28 Von Kossa	
	Acid fast bacilli	IPS_Histo_LPS_29 Ziehl Neelsen (modified) for Leprosy IPS_Histo_LPS_30 Ziehl-Neelsen cold method	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	AGH
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides prepared/stained as above	Morphological assessment and interpretive/diagnostic microscopy	IPS_Histo_LPO_56 Reporting results and giving clinical advice IPS_Histo_LPC-01_27 Specimen examination and reporting SOP's IPS_Histo_LPT_05 Specimen Photography IPS_Histo_LPT_28 VividPath and Micropath Imaging System	
Formalin fixed paraffin embedded slides (FFPE)	Immunohistochemistry to detect the following:	Bond III automated method IPS_Histo_LPT_34 Immunohistochemistry	
	Low and High molecular weight cytokeratins in epithelial cells and carcinomas	AE1/3	
	HGPIN, prostate adenocarcinoma	AMACR (Racemase)	
	Epithelial cell types	BerEp4	
	CA 19.9	Gastrointestinal and pancreatobiliary carcinoma	
	Ovarian cancer	CA125	
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin	
	Epithelial cell types excluding skin and other stratified epithelia	CAM 5.2	
	T Lymphocytes	CD3	
	Granulocytes Reed-Stenberg cells, Renal cell carcinoma	CD10	
	B Lymphocytes	CD20	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	AGH
Formalin fixed paraffin embedded slides (FFPE) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Bond III automated method IPS_Histo_LPT_34 Immunohistochemistry	
	Haematopoietic cells, vascular endothelium.	CD31	
	T cells and some soft tissue, tumour and vascular endothelium	CD34	
	Leukocyte common antigen.	CD45	
	Neuroendocrine cells	CD56	
	Macrophages	CD68	
	GIST, Seminoma	CD117	
	Adenocarcinoma and carcinoid (intestinal epithelium).	CDX2	
	CEA glycoproteins in adenocarcinoma	CEA	
	Tissues of neuroendocrine origin.	Chromogranin	
	Epithelial tissue from glandular to stratified squamous	Cytokeratin (MNF116)	
	High molecular weight cytokeratin in stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5	
	Normal and neoplastic epithelia	Cytokeratin 7	
	High molecular weight cytokeratin in epithelial cells (e.g. squamous)	Cytokeratin 14	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	AGH
Formalin fixed paraffin embedded slides (FFPE) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Bond III automated method IPS_Histo_LPT_34 Immunohistochemistry	
	Lymphatic endothelium	D2-40	
	Colonic and GI Adenocarcinomas, columnar epithelial cells.	Cytokeratin 20	
	Striated and smooth muscle cells	Desmin	
	GIST, Seminoma	DOG 1	
	Normal duct epithelial cell, ductal carcinoma.	E-Cadherin	
	Oestrogen receptor status	ER	
	Normal and neoplastic epithelium	EMA	
	Luminal epithelial cells of breast and urothelial carcinoma	GATA 3	
	Organisms in gastric tissue and biopsies	H.Pylori	
	Melanoma, melanocyte differentiation and perivascular epitheloid cells.	HMB45	
	Nuclear protein in proliferating cells	MIB-1 (Ki67)	
	Lynch Syndrome and cancer predisposition syndromes	MMR proteins	
	Melanoma marker	Melan A	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	AGH
Formalin fixed paraffin embedded slides (FFPE) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Bond III automated method IPS_Histo_LPT_34 Immunohistochemistry	
	Alveolar macrophages, pneumocytes, lung adenocarcinoma.	Napsin A	
	Embryonic cells and germ cell tumours	OCT 3/4	
	Tumour types including thyroid, renal cell and ovarian serous carcinomas	PAX 8	
	P53 mutations in neoplastic cells neoplastic cells in epithelium.	P53	
	HPV infection in dysplastic squamous epithelium	P16	
	Squamous epithelium and myoepithelial cells	P63	
	Nuclei of cells showing expression of progesterone	PR	
	Prostate Specific Antigen in prostate secretory and ductal epithelium	PSA	
	Prostatic acid phosphatase in prostatic epithelium		
	Schwann cells, nerve processes, s100 +ve neoplasms e.g. Melanoma.	S100	
	Smooth muscle cells, myoepithelial cells.	Smooth muscle Actin (SMA)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	AGH
Formalin fixed paraffin embedded slides (FFPE) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Bond III automated method IPS_Histo_LPT_34 Immunohistochemistry	
	Smooth muscle cells myoepithelial cells.	SMM	
	Neuroendocrine cells	Synaptophysin	
	Thyroid transcription factor in lung pneumocytes and thyroid cells	TTF-1	
	Prostate Specific Antigen in prostate secretory and ductal epithelium	PSAP	
	Cells of mesenchymal origin	Vimentin	
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour.	WT-1	
	Morphological assessment and interpretive/diagnostic microscopy	IPS_Histo_LPC_01 to 28 Specimen reporting SOPs IPS_Histo_BRI_LPC_01 to 31 Specimen reporting SOPs	AGH BRI



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified below:	AGH
Serous fluids (pleural, peritoneal and pericardial) Sputum Urine Cerebrospinal fluid Fine needle aspirations Bronchoscopy specimens Head and neck specimens	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Cytospin 3,4– Thermo Scientific Leica Autostainer XL Leica Autostainer ST 5020 Leica CV5030 Coverslipper	AGH
Slides prepared as above	Identification of malignant and premalignant cell changes. Characterisation of cell and tumour types. Differential of cell types	IPS_Histo_LPT_13 Cytology IPS_Histo_LPT_10 Autostainer IPS_Histo_LPT_11 Coverslipper IPS_Histo_LPO_05 Reporting results and giving clinical advice IPS_Histo_LPS_16 May-Grunwald Giemsa	
	Morphological assessment and interpretation/diagnosis	IPS_Histo_LPO_05 Reporting results and giving clinical advice IPS_Histo_LPC_01-27 Specimen examination and reporting SOPs	



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HUMAN BODY FLUIDS	<u>Haematological examination for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions:	AGH &BRI
Venous whole Blood: EDTA	Full Blood Count (FBC): WBC RBC Haemoglobin Mean cell volume (MCV) Mean cell haemoglobin (MCH) Mean corpuscular haemoglobin concentration (MCHC) Red cell distribution width (RDW) Packed cell volume (PCV) Platelets Neutrophils Lymphocytes Monocytes Eosinophils Basophils Reticulocyte count	Sysmex XN 9000 tracked system using Hydrodynamic focussing, impedance flow cytometry and Spectrophotometry. IPS_Haem LPT 01 Sysmex XN 9000 FBC analyser	
Ascitic and pleural fluids	White blood cell count	Sysmex XN 9000 tracked system using Hydrodynamic focussing, impedance flow cytometry: IPS_Haem LPT 01 Sysmex XN 9000 FBC analyser	
	Erythrocyte Sedimentation Rate (ESR)	Beckman Alifax using fluorescence flow kinetic analysis: IPS_Haem LPT 17 Test 1 ESR	
	Infectious Mononucleosis screen	Launch Accusay Mono kit using direct solid phase immunoassay: IPS Haem LPT13 Screen for Infectious Mononucleosis using Accusay Mono kit	



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination for the purpose of clinical diagnosis (cont'd)</u>	Documented -in-house methods to meet the requirements of the Sick cell and Thalassaemia (SCT) screening programme laboratory QA evidence requirements	
Venous whole blood: EDTA	Haemoglobinopathy Screening: Detection of haemoglobin variants: HbA, HbA2, HbF, HbS	Sebia Capillarys 3 Octo IPS Haem LPT_03 Haemoglobinopathy Screening using the Sebia Capillary 3 Octa	AGH
Venous whole blood: EDTA	Detection of haemoglobin S	Test kit TCS Biosciences using qualitative solubility/turbidity principle with reference to: PS_Haem_LPT_12 Sicklecheck Haemoglobin S Screening	
Venous whole blood: EDTA	Malarial screening for: <i>Plasmodium falciparum</i> antigen <i>Plasmodium vivax</i> antigen <i>Plasmodium PAN</i> antigen Detection and Identification of Plasmodium species: <i>P.falciparum</i> <i>P.vivax</i> <i>P.ovale</i> <i>P.malariae</i> <i>P. knowlesi</i> Blood film assessment (peripheral) for detection of abnormalities.	Launch Humasis immunochromatographic assay: IPS Haem LPT 02 Malarial Parasite Testing using Launch Humasis Screening Kit Automated SP10 staining machine and manual staining: Giemsa stained blood films (thick and thin) with reference to: IPS_Haem_LPT_04 Selection and Reporting of Blood Films Automated slide preparation using manufacturers analyser Sysmex XN 9000 tracked system and Automated SP10 staining machine or by manual preparation/microscopy with reference to: IPS_Haem_LPT_18 Blood Film Examination	AGH & BRI



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Citrated plasma	Prothrombin time International Normalised Ration (INR) Activated Partial thromboplastin Time (APTT) PT derived fibrinogen (dFIB) Thrombin Time	Werfen ACL TOP 500 using turbidimetry, absorbance and light scatter: IPS_Coag_LPT_01 Routine Coagulation Screening on the ACL TOP IPS_Coag_LPT_06 Coagulation Reference and Therapeutic Ranges	AGH & BRI
	Lupus Anticoagulant Screen	IPS_Coag_LPT_02 Lupus Anticoagulant Screen IPS_Coag_LPT_06 Coagulation Reference and Therapeutic Ranges	AGH
Citrated plasma	Anticoagulant Heparin Test Anticoagulant Heparin/Warfarin test Anticoagulant Warfarin test		
Citrated plasma	D-Dimers	Werfen ACL TOP 500 using turbidimetric immunoassay: IPS_Coag_LPT_01 Routine Coagulation Screening on the ACL TOP IPS_Coag_LPT_06 Coagulation Reference and Therapeutic Ranges	AGH & BRI



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions:	
Citrated plasma	Thrombophilia screen: Protein C Protein S AT III	Werfen ACL TOP 500 using chromogenic assay: IPS_Coag_LPT_04 Protocol for Thrombophilia Screening IPS_Coag_LPT_13 Protein C IPS_Coag_LPT_14 Protein S Free antigen assay IPS_Coag_LPT_12 Anti Thrombin Assay IPS_Coag_LPT_06 Coagulation Reference and Therapeutic Ranges	AGH
	Liquid antiXa assay	IPS_Coag_LPT_01 Routine Coagulation Screening on the ACL TOP IPS_Coag_LPT_06 Coagulation Reference and Therapeutic Ranges	
	Von Willebrands screen	Werfen ACL TOP 500 using immune-turbidimetric assay: IPS_Coag_LPT_02 Factor Assays (including vW screening) IPS_Coag_LPT_06 Coagulation Reference and Therapeutic Ranges IPS_Coag_LPT_16 Von Willebrand Screening (AGH) IPS_Coag_LPT_09_Factor Assays and VW Screens BRI	AGH & BRI



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions:	
Citrated plasma	Intrinsic and Extrinsic Factor assays: XII XI IX VIII II V VII X	Werfen ACL TOP 500 using absorbance and light scatter: IPS_Coag_LPT_01 Routine Coagulation Screening on the ACL TOP IPS_Coag_LPT_17 APTT based Factor Assays V111, IX, X1 and X11 IPS_Coag_LPT_18 PT based Factor Assays 11, V, V11 and X	AGH
	VIII IX XI	IPS_Coag_LPT_06 Coagulation Reference and Therapeutic Ranges	BRI
	Clauss Fibrinogen		
	Factor V Leiden and Prothrombin gene mutation	Cepheid GeneXpert using polymerase chain reaction IPS_COAG_LPT_19 FVL and FII analysis using GeneXpert	AGH



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions:	AGH & BRI
Venous whole blood: EDTA/plasma samples	Blood grouping: ABO Rhesus D status	Column Agglutination Technology using ORTHO BioVue® Cassettes, Ortho Vision Analysers and Ortho Workstation with reference to: IPS_Trans_LPT_20 Routine use of the Ortho Vision analysers IPS_Trans_LPT_06 Provision of blood components for neonates and infants IPS_Trans+LPT_17 Manual testing using the Ortho Workstation	
	Antibody screening Anti-D, Anti-C, Anti-E, Anti-c, Anti-e, Anti-f, Anti-C ^w , Anti-K, Anti-k, Anti-Kp ^a , Anti-Kp ^b , Anti-Fy ^a , Anti-Fy ^b , Anti-Jk ^a , Anti-Jk ^b , Anti-Le ^a , Anti-Le ^b , Anti-S, Anti-s, Anti-M, Anti-N, Anti-P ₁ , Anti-Lu ^a and Anti-Lu ^b	IPS_Trans_LPT_20 Routine use of the Ortho Vision analysers IPS_Trans_LPT_02 Investigation of a positive antibody screen or crossmatch IPS_Trans_LPT_17 Manual testing using the Ortho Workstation	
Venous whole blood: EDTA/plasma samples	Serological crossmatch	Column Agglutination Technology using ORTHO BioVue® Cassettes, Ortho Vision Analysers and Ortho Workstation: IPS_Trans_LPT_20 Routine use of the Ortho Vision analysers IPS_Trans_LPT_23 Serological Crossmatching on the Ortho Vision analysers IPS_Trans_LPT_17 Manual testing using the Ortho Workstation	AGH & BRI



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)</u> Red cell phenotyping for the following antigens: Rh: C, D, E, c, e Kell: K Direct Antiglobulin Test: Detection of Anti-IgG and C3d	Documented in-house procedures with manufacturer's instructions: IPS_Trans_LPT_20 Routine use of the Ortho Vision analysers IPS_Trans_LPT_17 Manual testing using the Ortho Workstation IPS_Trans_LPT_20 Routine use of the Ortho Vision analysers IPS_Trans_LPT_01 Performance and Investigation of a Direct Antiglobulin Test (DAT) IPS_Trans_LPT_17 Manual testing using the Ortho Workstation Screening by acid elution (AE). Documented in-house procedures with reference to: IPS_Trans_LPT_13 Routine Kleihauer Method	AGH & BRI
Venous whole blood: EDTA/plasma samples	Foetal Cell Count (Kleihauer Test) Four Cell Anti-D Screening Test	Column Agglutination Technology using ORTHO BioVue® Cassettes, Ortho Vision Analysers and Ortho Workstation: IPS_Trans_LPT_20 Routine use of the Ortho Vision analysers IPS_Trans_LPT_24 Selective Antibody Screening on the Ortho Vision™ Using RhD negative cells IPS_Trans_LPT_17 Manual testing using the Ortho Workstation	
EDTA whole blood	Electronic issue	SOP IPS_Trans_LPT_08 Issue of Blood by Electronic Matching	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (AGH) and Beckman AU 680 (BRI):	
Serum/plasma & urine	Calcium	IPs_Chem_TP_09 AU5800 IPs_Chem_TP_08 AU680 Arsenazo	AGH BRI
Serum/plasma, CSF and urine	Total protein	Biuret endpoint	
Serum/plasma	Cholesterol	Cholesterol oxidase	
Serum/plasma	Direct bilirubin	Diazo	
Serum/plasma	Ammonia	Direct enzymatic reaction	
Serum/plasma	Triglyceride	Enzymatic endpoint UV	
Serum/plasma	ethanol	Enzymatic	AGH
Serum/plasma Serum/plasma	Salicylate Creatinine	Enzymatic	AGH & BRI AGH & BRI
Urine	Creatinine		BRI
Serum/plasma & CSF	Lactate		AGH & BRI
Serum/plasma	Paracetamol		
Serum/plasma	Carbamazepine	Enzyme Immunoassay	AGH
Serum/plasma	Phenytoin		
Serum/plasma	Valproate		
Serum/plasma	Gentamicin	Enzyme Immunoassay	
Serum/plasma	Theophylline		
Serum/plasma	Vancomycin		
Serum/plasma,	Amylase	EPS	



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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 manufacturer's instructions for analysis using Beckman AU5800 (AGH) and Beckman AU 680 (BRI):	
Serum/plasma	Albumin	IPS_Chem_TP_08 AU5800 IPS_Chem_TP_08 AU680	AGH BRI
Serum/plasma	Glucose	Direct colorimetric	
Serum/plasma & CSF	Glucose	Hexokinase	
Serum/plasma	Alkaline Phosphatase Isoenzyme	IFCC (heat pre-treatment) IPS_Chem_LPM_33 Alkaline Phosphatase Isoenzyme (ALPI)	BRI
Serum/plasma	Alkaline Phosphatase	IFCC	AGH & BRI
Serum/plasma	GGT	IFCC carboxynitroaniline	
Urine	Amylase	IFCC	
Serum/plasma	HDL	Immunoinhibition	
Urine	Albumin	Immunoturbidimetric	
Serum/plasma, urine,	Chloride	Indirect ISE	
Serum/plasma,	Bicarbonate	PEP carboxylase	AGH & BRI
Serum/plasma, urine, CSF & fluid	Chloride	Indirect ISE	
Serum/plasma, urine,	Potassium		
Serum/plasma, urine,	Sodium		
Urine	Creatinine (Jaffe)	Jaffe	AGH
Serum/plasma	Magnesium	Magon/Xylidyl blue	AGH & BRI
Serum/plasma	Alanine aminotransferase	Modified IFCC without PLP	
Serum/plasma	Aspartate aminotransferase	Modified IFCC without PLP6	
Serum/plasma & Urine	Phosphate	Molybdate UV endpoint	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (AGH) and Beckman AU 680 (BRI): IPS_Chem_TP_09 AU5800 IPS_Chem_TP_08 AU680	AGH BRI
Serum/plasma	Creatine kinase	NAC activated non opt	
Urine	Total Protein	Pyrogallol red	
Serum/plasma	LDH	Pyruvate-Lactate (SCE)	
Serum/plasma	Bile acids	Enzymatic cycling colorimetric	
Serum/plasma	Lithium	Spectrophotometric	
Serum/plasma	Iron	TPTZ	
Serum/plasma	C-reactive protein	Turbidimetric	
Serum/plasma	Immunoglobins		
Serum/plasma	Rheumatoid factor		
Serum/plasma	C3/C4	Turbidimetric	
Serum/plasma, Urine, pleural fluid	Urea	Urase kinetic	AGH & BRI
Urine	Urate	Uricase perox	
Serum/plasma	Urate	Uricase	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman DXI 600 (BRI) and Beckman DXI 800: IPS_Chem_TP_01 Beckman DXI	BRI
Serum/plasma	Alpha-feto protein (AFP)	Chemiluminescence	
Serum/plasma	Beta-human Chorionic Gonadotropin (BHCG)		
Serum/plasma	CA-125		
Serum/plasma	CA 15-3		
Serum/plasma	CA 19-9		
Serum/plasma	Carcinoembryonic antigen (CEA)		
Serum/plasma	Cortisol		
Serum/plasma	Digoxin		
Serum/plasma	Ferritin		
Serum/plasma	Folate		
Serum/plasma	FT 3		
Serum/plasma	FT 4		
Serum/plasma	Luteinizing hormone (LH)		
Serum/plasma	Follicle stimulating hormone (FSH)		
Serum/plasma	hs Oestradiol		
Serum/plasma	hs Troponin 1		
Serum/plasma	Progesterone		
Serum/plasma	Prolactin		



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman DXI 600 (BRI) and Beckman DXI 800:	
Serum/plasma	Prostate specific antigen (PSA)	IPS_Chem_TP_01 Beckman DXI Chemiluminescence	BRI
Serum/plasma	Parathyroid Hormone (PTH)		
Serum/plasma	SHBG		
Serum/plasma	Testosterone		
Serum/plasma	Thyroid peroxidase antibody (TPO)		
Serum/plasma	Thyroid stimulating hormone (TSH)		
Serum/plasma	Vitamin B12		
Serum/plasma	Vitamin D		
Serum/plasma	Insulin		
Prepared haemolysate	Red cell Folate		
	Intrinsic factor antibodies	Advanced Instrument Osmometer 2020 (freezing point depression osmometry)	AGH
Serum/plasma/urine	Osmolality	IPS-Chem_LPM_35 Advanced 2020 Osmometer	BRI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions	
Serum/plasma	NT-proBNP	Biomerieux Vidas 3: IPS_Chem_LPM_31 BioMerieux Vidas 3	AGH
Serum	Protein Electrophoresis	Capillary electrophoresis using Sebia Capillarys 2: IPS_Chem_LPM_32 Sebia Capillary Electrophoresis	
	Protein immunotyping	IPS_Chem_LPM_37 Sebia Capillary Immunotyping	
Urine	Bence Jones Protein	Agarose gel electrophoresis using Sebia Hydrasys:	
	Immunofixation	IPS_Chem_LPM_34 Urine protein Electrophoresis and Immunofixation	
	Protein Immunofixation	IPS_Chem_LPM_20 Sebia protein Immunofixation	
Whole Blood	HbA1c	Menarini 9210 Premier affinity chromatography: IPS_Chem_TP_06_Menarini 9210 Premier	AGH
Cerebrospinal fluid	Xanthochromia	Spectronic Camspec M550 bilirubin spectrophotometry: IPS_Chem_LPM_40 Xanthochromia	BRI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)		
	Calculated Tests (data from primary tests, primary test sample requirements listed under that test)		AGH & BRI
Serum	Adjusted calcium	IPS_Chem_TP_09 AU5800 IPS_Chem_TP_08 AU680	
Serum	eGFR (CKD-EPI)		
Serum	LDL-Cholesterol with specific reference to Friedewald formula		
Sweat	Chloride	Sherwood Chloride Analyser IPS_Chem_LPM_36 Sweat Testing	BRI
	<u>Serological/Virology examination activities for the purpose of Clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for analysis using Documented-in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening (IDPS) programme as defined in the laboratory QA evidence requirements (targets marked *) Beckman DXI 800: IPS_Chem_TP_01 Beckman DXI Chemiluminescence	
Serum/plasma	Hepatitis B surface antigen *		AGH, BRI
Serum/plasma	Anti Hepatitis C antibodies		AGH, BRI
Serum/plasma	HIV 1 and 2 antibodies and HIV p24 antigen *		AGH, BRI
Serum/plasma	Rubella IgG		AGH



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HUMAN BODY FLUIDS (cont'd)	<u>Serological/Virology examination activities for the purpose of Clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800:	
Serum	Syphilis total antibody*	IPS_Chem_TP09 AU5800 Immunoturbidimetric AGH and Beckman AU680 BRI	AGH, BRI
Serum	Detection of SARS-CoV-2 IgG antibody	Beckman Coulter Dxl 800 (AGH) and 600 (BRI) Access SARS-CoV-2 IgG assay SOP: IPS_Chem_TP_01 Beckman DXI Biomerieux Vidas 3: ELFA IPS_Chem_LPM_31 BioMerieux Vidas 3	
Serum/plasma	CMV IgG/M		
Serum/plasma	Hepatitis A IgG		
Serum/plasma	Hepatitis A IgM		
Serum/plasma	Hepatitis B core antibody		
		Documented in house methods and manufacturer's instructions for analysis using: Biomerieux Vidas 3: IPS_Chem_LPM_31 BioMerieux Vidas 3	AGH
Serum/plasma	Measles IgG		
Serum/plasma	Toxoplasma IgG/IgA		
Serum/plasma	Varicella Zoster Virus (VZV) IgG		



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<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Routine samples: Cellular and fluid material contained on swabs catheter tips and intrauterine devices. Lines & Intravascular cannulae Fluids Genital samples Pus Samples from sterile sites Semen Tissue Urine</p> <p>Cellular and fluid material contained on swab from genitourinary tract</p> <p>Respiratory fluids (sputum, aspirates and pleural fluid)</p> <p>Joint fluid aspirates</p>	<p><u>Microbiology examination for the purpose of clinical diagnosis</u></p> <p>General isolation of microorganisms of clinical significance</p> <p>Examination for the presence of Trichomonas vaginalis and diagnosis of bacterial vaginosis</p> <p>General isolation of microorganisms of clinical significance</p> <p>Detection and identification of bi-refrangent crystals</p>	<p>In-house documented procedures based on current PHE SMLs and in conjunction with manufacturer's instructions</p> <p>Manual culture methods using various solid agar media: IPS_Micro_LPT_68 ENT and Eye Specimens. IPS_Micro_LPT_03 Investigation of Tissues and Normally Sterile Fluids IPS_Micro_LPT_69 Skin and Wound Swabs and Neonatal Infection Screens IPS_Micro_LPT 67 Investigation of Intravascular cannula IPS_Micro_LPT_10 Investigation of Genital samples</p> <p>Light Microscopy IPS_Micro_LPT_10 Investigation of Genital samples</p> <p>Manual culture methods using various solid agar media: IPS_Micro_LPT_50 Sputum, Bronchial Aspirate and Pleural Fluid.</p> <p>Manual Microscopy: IPS_Micro_LPT_141 Identification of crystals by polarisation</p>	AGH



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Microbiology examination for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on current PHE SMIs and in conjunction with manufacturer's instructions	AGH
Cellular and fluid material contained on swabs	Screening for <i>Methicillin-Resistant Staphylococcus aureus</i> (MRSA)	Manual culture methods using Brilliance MRSA 2 Selective Agar Media (Oxoid) IPS_Micro_LPT_34 Methicillin-Resistant Staphylococcus aureus (MRSA) Screen	
Cerebrospinal fluid	Detection and identification of: White blood cells Red blood cells Bacteria.	Direct manual microscopy using light microscopy and Fuchs Rosenthal counting chamber: IPS_Micro_LPT_140 CSF Gram stain: IPS_Micro_LPT_51 Gram stain manual method Phenylauramine stain: IPS_Micro_LPT_53 Phenylauramine stain for AAFB ZN: IPS_Micro_LPT_58 Cold Ziehl Neelsen stain for AAFB	
Urine	Quantification of White and Red blood cells, Epithelial cells and bacteria.	Automated microscopy using Menarini Sedimax: IPS_Micro_LPT_138 Automated urine microscopy using Menarini Sedimax Manual microscopy	
	General isolation and characterisation of micro-organisms of clinical significance and susceptibility testing of isolates.	Manual culture and use of MAST Urisystem: IPS_Micro_LPT-139 MAST URI System	
	HCG Urine Pregnancy testing	Manual testing chromatographic immunoassay Lab 21 kit: IPS_Micro_LPT-41 Pregnancy Testing	
	Detection of <i>Legionella pneumophila</i> serogroup 1 antigen	Binax NOW kit IPS_Micro_LPT_24 Legionella Urinary Antigen Test	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Microbiology examination for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on current PHE SMIs and in conjunction with manufacturer's instructions	AGH
Urine and Cerebrospinal fluid	Detection of <i>Streptococcus pneumoniae</i> antigen	IPS_Micro_LPT-49 Strep pneumoniae Urinary Antigen Test using Binax NOW kit	
Whole Blood	Isolation of micro-organisms of clinical significance	Automated platform BD BacTec liquid media culture: IPS_Micro_LPT06 Blood Cultures and the BacTec FX	
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: <i>Salmonella spp</i> <i>Shigella spp</i> <i>Campylobacter spp</i> <i>E.coli O157</i> <i>Vibrio spp</i> <i>Aeromonas spp</i>	Manual culture methods using selective Culture Media: IPS_Micro_LPT_15 Investigation of Faeces for Enteric Pathogens	
Bacterial cultures isolated in house from all sample types as listed	Antimicrobial susceptibility testing of clinically significant bacterial	Manual (EUCAST) sensitivity testing using disc diffusion and gradient minimum inhibitory concentration determination: IPS_Micro_LPT_100 Susceptibility Testing Automated sensitivity testing (EUCAST) using Beckman MicroScan WalkAway 96 IPS_Micro_LPT_137 MicroScan	
Bacterial cultures isolated in house from all sample types as listed	Identification of microorganisms of clinical significance.	Automated Bruker Microflex Matrix-assisted laser desorption/ionisation-Time of Flight (MALDI-TOF): IPS_Micro_LPT_136 Bruker Microflex MALDI-TOF	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Microbiology examination for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on current PHE SMLs and in conjunction with manufacturer's instructions	AGH
Cultures isolated in house	Identification of <i>E coli</i> O157	ProLab E.Coli 0157 Latex agglutination kit and: IPS_Micro_LPT_15 Investigation of Faeces for Enteric Pathogens	
Faeces	Detection of <i>Clostridium difficile</i> GDH antigen & Toxin A & B.	Alere Quik Chek Rapid membrane ELISA it and: IPS-Micro_LPT_17 Clostridium difficile Investigation	
Faeces	Detection of <i>Helicobacter.pylori</i>	H.pylori Faecal Antigen Test using Proflow H.pylori rapid membrane immunoassay kit. IPS_Micro_LPT_20 Helicobacter Pylori Faecal Antigen Testing and: IPS-Micro_LPT_08 of Enteric Samples	
Faeces	Detection of Rotavirus	Rotascreen Dipstick Method M580 (Microgen kit) immunochromatographic stick coated with a monoclonal immunoreagent specific for rotavirus and: IPS-Micro_LPT_19 Processing of Faecal samples for Rotavirus	
Faeces	Detection of <i>Cryptosporidia spp</i>	Fluorescent manual microscopy using auramine phenol stain: IPS_Micro_LPT-54 Phenylauramine Stain for Cryptosporidia IPS_Micro_LPT-56 Modified Ziehl-Neelsen Stain for Cryptosporidia and Cyclospora IPS_Micro_LPT_16 Investigation of specimens other than blood for parasites	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Microbiology examination for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of <i>Cyclospora spp</i></p> <p>Detection of parasites- ova, cysts and worms of clinical significance</p>	<p>In-house documented procedures based on current PHE SMLs and in conjunction with manufacturer's instructions</p> <p>Manual Microscopy using modified Ziehl-Neelson stain:OMEGA IPS_Micro_LPT-56 Modified Ziehl-Neelsen Stain for Cryptosporidia and Cyclospora</p> <p>Concentration using Parasep concentration and examination of deposit by light microscopy: IPS-Micro_LPT_08 Processing of Enteric Samples</p> <p>IPS_Micro_LPT_16 Investigation of specimens other than blood for parasites</p>	AGH
Skin Nail Hair	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination IPS_Micro_LPT_36 Mycology processing of samples from Skin, Nails and Hair	
Sputum, aspirates, pleural fluid, swabs	Isolation of <i>Mycobacterium species</i>	<p>Automated platform for culture using the BD MGIT for TB investigation: IPS_Micro_LPT_35 Investigation of Specimens for <i>Mycobacterium species</i></p> <p>Manual culture methods using Löwenstein-Jensen media: IPS_Micro_LPT_35 Investigation of Specimens for <i>Mycobacterium species</i></p>	
Sputum, aspirates, pleural fluid, swabs	Detection of Acid-alcohol fast bacilli	Ziehl-Neelsen staining and light microscopy: IPS_Micro_LPT_58 Cold Ziehl-Neelsen stain for AAFB	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on current PHE SMIs and in conjunction with manufacturer's instructions	
Urine and genital swabs	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> RNA	Automated platform Gen-Probe Panther system using Nucleic acid amplification-based testing (NAAT): IPS_Micro_LPT_11 Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> NAAT using the GenProbe Panther System	AGH
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swabs in VTM Sputum Nasopharyngeal aspirates	Detection of SARS-CoV-2 virus RNA (COVID-19) specifically ORF 1 gene and ORF 8 gene	AusDiagnostics HighPlex 24 Procedure using MT-PCR SOP: IPS_Micro_LPT_90 AusDiagnostics HighPlex 24 Procedure	AGH
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swabs in VTM	Detection of SARS-CoV-2 virus RNA (COVID-19) specifically ORF1ab gene	Aptima SARS-CoV-2 assay on the Hologic Panther Plus System. SOP: IPS_Micro_LPT_93 Detection of SARS-CoV-2 using Hologic Panther System	AGH
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swabs in VTM	Detection of SARS-CoV-2 virus RNA (COVID-19) specifically N2 and E genes	Cepheid GeneXpert using the Xpress SARS-CoV-2/Flu/RSV assay. SOP: IPS_Micro_LPT_92 SARS-CoV-2 SARS CoV2, Influenza A and B and RSV Analysis by GeneXpert	AGH & BRI
END			