Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Site activities performed away from the locations listed above:

Location details		Activity
Address Body Store West Cumberland Hospital Whitehaven CA28 8JG	Local Contact Karen Simpson	Storage of bodies
Address Mortuary Cumberland Infirmary Carlisle CA2 7HY	Local Contact Karen Simpson	Storage of bodies and mortuary services



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North Cumbria Integrated Care NHS Foundation Trust

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Testing performed at main address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	Microbiology examinations for the purpose of clinical diagnosis	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
Swabs from wounds, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, CAPD fluids, faeces, bone marrow, tissue.	General isolation and characterisation of micro-organisms of clinical significance	Manual culture and microscopy using SOPs: CSF IS-MIC-SOP-18 CAPD IS-MIC-SOP-21 Fluids from normally sterile sites IS-MIC-SOP-21 MRSA/MSSA - IS-MIC-SOP31 Wound (Skin, superficial, non- surgical) IS-MIC-SOP34 Wound (pus and exudate) IS-MIC-SOP-5 Wound (tissue and biopsies) IS- MIC-SOP-7 Orthopaedic-implant associated infections IS-MIC-SOP-55 Wound (Mucosal) IS-MIC-SOP- 9,11,16,19,20 Genital tract and associated specimen IS-MIC-SOP- 32Bronchoalveolar lavage, Sputum and associated specimens IS-MIC- SOP-40 Gram staining-IS-MIC-SOP29 Characterisation tests IS-MIC-SOP- 37
Skin, nails, hair		Mycology - IS-MIC-SOP-38
Bacterial isolates cultured in- house	Determination of antimicrobial susceptibility	Manual (EUCAST) by disc diffusion and gradient MIC using SOPs': EUCAST Disc Diffusion IS-MIC-SOP-51 MIC gradient test method IS-MIC-SOP-66
Bacterial/fungal isolates and blood (blood cultures)	Identification of bacterial and fungal microorganisms	Brucker MALDI Biotyper Sirus- MALDI-ToF IS-MIC-SOP-78



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
Blood	Detection of microbial growth and general isolation of microorganisms of clinical significance.	BACTEC FX automated system using photometric fluorescent technology IS-MIC-SOP-41 IS-MIC-SOP-77
Urine	Detection of white blood cells, red blood cells, casts, epithelial cells, bacteria	Iris iQ Sprint urine analyser using digital imaging and particle counting IS-MIC-SOP-50
Urine	Culture, identification and susceptibility testing of urine pathogens	MAST Urisystem semi-automated system utilising multipoint technology and breakpoint methodology IS-MIC-SOP-75 IS-MIC-SOP-76
	Isolation of clinically significant organisms	Manual culture IS-MIC-SOP-35
Faeces	Detection of faecal ova, cysts and parasites	Manual concentration method and light microscopy using Parasitology IS-MIC-SOP-33
Faeces	Antigen detection of Cryptosporidium and Giardia lamblia	DS2 automated analyser. IS-MIC-SOP-70 IVD Research INC Giardia/Cryptosporidium Combo Stool Antigen Detection Microwell Confirmed by Alere Giardia/Cryptosporidium Quik Chek Lateral Flow device IS-MIC-SOP-74
Faeces	Antigen detection of rotavirus and adenovirus	Pro Flow (ProLab) Lateral Flow device IS-MIC-SOP-48
		DS2 automated analyser: IS-MIC-SOP-70
Faeces	Detection of antigen of: H. pylori	Premier Platinum HpSA [®] PLUS IS-MIC-SOP-73
	C difficile GDH	PREMIER [®] C.difficile GDH IS-MIC-SOP-71

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
	C difficile toxin AB	PREMIER [®] TOXINS A & B ELISA IS-MIC-SOP-72
CSF	Enumeration of red and white blood cells	Manual method using modified Fuchs Rosenthal counting chamber IS-MIC-SOP-18
	Molecular examinations for the purposes of clinical diagnosis.	
		Cepheid GeneXpert PCR
Faeces	Gene detection of C. difficile toxin A/B	IS-MIC-SOP-82 IS-MIC-SOP-64
	Detection of Norovirus	IS-MIC-SOP63
Oropharyngeal swabs	Detection of SARS-CoV-2 genes N2 and E	IS-VI-SOP-289
Nose/Throat swabs	SARS-CoV-2/FLU/RSV	IS-COM-SOP-90
Faeces/Rectal swab/ Bacterial isolates	Carbapenem resistance gene Detection	CARBA-R Kit PCR IS-MIC-SOP-79
Swabs/Urine	Mycoplasma resistance	ResistancePlus MG FleXible assay PCR IS-IV-SOP-329
Swabs and CSF	Detection of DNA to the following:	PCR using SeePrep/Arrow extraction and ABI PRISM 7500 amplification. IS-VI-SOP-125 IS-VI-SOP-119
Swabs	Herpes simplex 1 Herpes simplex 2 Varicella zoster	Altona AltoStar Alpha HerpesvirusPCR Kit IS-VI-SOP-317



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
Swabs and CSF	Detection of RNA to the following: Influenza A & B	Altona RealStar Influenza S&T RT- PCR Kit 340 IS-VI-SOP-182
Vaginal, endocervical, throat, eye rectal and urine	Detection of DNA for Chlamydia trachomatis and Neisseria gonorrhoeae	PCR using COBAS 6800 analyser IS-VI-SOP- 273 & 274
Serum	Detection and quantitation of RNA for Hepatitis C virus	PCR using COBAS 6800 analyser IS-VI-SOP-275
Oropharyngeal Swabs	Detection of SARS-CoV2 ORF1ab and E genes	PCR using COBAS 6800 analyser IS-VI-SOP-287
Urine, Vaginal, Cx, Meatal swabs	Detection of Trichomonas vaginalis and Mycoplasma Genitalium	PCR using COBAS 6800 analyser IS-VI-SOP-286
	Serological examinations for the purposes of clinical diagnosis.	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
Serum	Detection of the following:	CMEIA using Roche Cobas e601 analyser and IS-VI-SOP-240
	CMV IgG avidity CMV IgG CMV IgM Hepatitis A IgG Hepatitis B Surface Antigen Hepatitis B core IgG Hepatitis B core IgM Hepatitis B antibody Hepatitis C Antibody HIV ab/ag Rubella IgG Rubella IgM Toxoplasma IgM Syphilis IgG/IgM	IS-VI-SOP-241 IS-VI-SOP-242 IS-VI-SOP-249 IS-VI-SOP-248 IS-VI-SOP-256 IS-VI-SOP-253 IS-VI-SOP-257 IS-VI-SOP-250 IS-VI-SOP-252 IS-VI-SOP-246 IS-VI-SOP-247 IS-VI-SOP-243 IS-VI-SOP-245 IS-VI-SOP-251



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
	Detection of the following:	ELISA using DS2 automated analyser and IS-VI-SOP-193
Serum	Borrelia VIsE/pepC10 IgG/IgM	Accudiag Borrelia IgG IgM kit IS-VI-SOP-306
Serum	Detection of the following:	CLIA using Diasorin Liaison XL analyser and IS-VI-SOP-305
	EBNA IgG EBV VCA IgG EBV VCA IgM Bordetella pertussis toxin IgG Measles IgG VZV IgG Hepatitis E IgM	IS-VI-SOP-310 IS-VI-SOP-312 IS-VI-SOP-311 IS-VI-SOP-307 IS-VI-SOP-321 IS-VI-SOP-328 IS-VI-SOP316
Lithium Heparin	Quantiferon	Using Quantiferon-TB Gold plus assay IS-VI-SOP-309
Serum	Detection of <i>Treponema pallidum</i> IgG and IgM	ASI TPHA kit by haemagglutination IS-VI-SOP-323
Serum	Detection of non-specific antibodies to <i>Treponema pallidum</i> : Rapid Plasma Reagin	ASI RPR Card Test for Syphilis by macroscopic flocculation IS-VI-SOP-324
Urine	Detection of the following: Legionella pneumoniae antigen Strep pneumoniae antigen	Immunochromatographic assay using BINAX NOW IS-VI-SOP-106 IS-VI-SOP-107

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
		Documented in-housed methods to meet the requirements of the of Infectious Diseases in Pregnancy Screening programme as defined in the July 2018 'Infectious Diseases in Pregnancy Screening Programme: laboratory QA evidence requirements'
	Hepatitis B Surface Antigen Hepatitis B core IgG Hepatitis B core IgM Hepatitis B antibody HIV 1 / 2 antibody/antigen detection Syphilis IgG/IgM antibodies	cMEIA using Roche Cobas e601 analyser and IS-VI-SOP-240
	Immunology examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
	Detection of the following:	Optilite automated analyser using turbidimetry andIS-VI-SOP-261
Serum	Anti-streptolysin O antibodies	IS-VI-SOP-280
Serum	Beta 2 Microglobulin	IS-VI-SOP-281
Serum	C3 & C4 concentration	IS-VI-SOP-278
Serum	IgG,A,M (Immunoglobulins)	IS-VI-SOP-277
Serum	Rheumatoid factor	IS-VI-SOP-279
Serum/urine	Quantitation of free light chains	IS-VI-SOP-283



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
Serum	Detection of cryoglobulin	Manual method using SOP IS-VI- SOP-152
	Detection of the following:	DS2 automated ELISA analyser using IS-VI-SOP-193
Serum, plasma	Tissue Transglutaminase (tTG) IgA autoantibodies	Organtec TTG IgA IS-VI-SOP-150
Serum, plasma	Intrinsic factor autoantibodies	Organtec Anti-Intrinsic Factor IS-VI-SOP-233
Serum	Haemophilus influenzae type B antibodies (IgG)	The Binding Site IS-VI-SOP-6
Serum	Pneumococcal vaccine antibodies (PPV23) (IgG)	The Binding Site IS-VI-SOP-1
Serum	Tetanus vaccine antibodies (IgG)	The Binding Site IS-VI-SOP-7
Serum	Glutamic acid decarboxylase (GAD) autoantibodies (IgG)	EUROImmun kit IS-VI-SOP-192
	Detection of the following:	iPro immunofluorescence processor and IS-VI-SOP-194
Serum	Anti-nuclear antibody & liver autoantibody screen + titre	Euroimmun Mosaic Basic Profile 3C IFT Slides IS-VI-SOP-4
Serum	Avian immunofluorescence (IFA) titre	Eurommun Pigeon Intestine IFT Slides IS-VI-SOP-95
Serum	Gastric parietal cell autoantibodies (GPC)	Euroimmun Mosaic Basic Profile 3C IFT Slides IS-VI-SOP-4



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
	Immunofluorescence detection of:	iPRO Immunofluorescence processer
Serum	Anti-neutrophil cytoplasmic antibodies (ANCA) and Titre	ANCA Titre Indirect Immunofluorescence IS-VI-SOP-96
Serum	Endomysial (IgA)	Anti Endomysial Indirect Immunofluorescence IS-VI-SOP-3
Serum	Anti-nuclear antibody & liver autoantibody screen + titre	Anti-nuclear antibody & liver autoantibody screen + titre IS-VI-SOP-4
		Manual immunofluorescence using
Serum	Crithidia (Double Stranded DNS Antibodies) (IgG)	Novalite ds Crithidia Iucilliae IS-VI-SOP-2
Serum	Islet cell autoantibodies (IgG)	Novalite ICA Primate Pancreas IS-VI-SOP-214
Serum	Endomysial (IgA)	Novalite Monkey Oesophagus IFA IS-VI-SOP-3
	Detection of the following autoantibodies:	Immunoblot using EUROBlotOne and SOP IS-VI-SOP-314
Serum	Liver Screen (IgG) (Anti-M2, M2- 3E(BPO), Sp100, PML, Gp210, LKM-1, LC-1, SLA/LP & Ro52)	Euroimmun Profile Autoimmun Liver Disease Euroline IS-VI-SOP-212
Serum	Myositis Screen (IgG) (Mi-2α, Mi-2β, TIF1γ, MDA5, NXP2, SAE1, Ku, PM- Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52 and cN-1A)	Euroimmun Myositis Profile 16AgEuroline
Serum	Systemic Sclerosis Screen (IgG) (Anti- Scl70, CENP-A, CENP-B, RP11, RP155, Fibrillarin, NOR-90, Th/To, PM- Scl, Ku, PDGF-R & Ro52)	Euroimmun Systemic Sclerosis Euroline



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
	Detection of the following autoantibodies: (cont'd)	Immunoblot using EUROBlotOne and SOP IS-VI-SOP-314
Serum	Extended ANA Screen (IgG) (Mi-2, Ku, nRNP/Sm, Sm, SS-A, Ro-52, SS-B, ScI-70, PM-ScI100, Jo-1, CENP B, PCNA, dsDNA, nucleosomes, histones, ribosomal P-protein, AMA-M2 and DFS70)	Euroimmun ANA Profile et Mi-2 Euroline
	Detection of the following:	Manual CCIE precipitation using:
Serum	Aspergillus precipitating antibodies	Microgen Aspergillus Kit (somatic & filtrate antigen) IS-VI-SOP-159
Serum	Avian precipitating antibodies (Pigeon and Budgie serum/faeces, Fowl serum)	Microgen Avian Allergens Kit IS-VI-SOP-171
Serum	Farmers' Lung precipitating antibodies (M.faeni)	Microgen M.faeni Kit IS-VI-SOP-159
Serum	IgG, IgA, IgM, IgD, IgE, Kappa, Lambda	Serum immunofixation using Sebia Hydrasys 2 IS-VI-SOP-244
Urine	Electrophoresis	Urine immunofixation using Sebia Hydrasys 2 IS-VI-SOP-244
Urine	Immunofixation of GAM, K free, L free, Kappa, Lambda	Urine immunofixation using Sebia Hydrasys 2 IS-VI-SOP-244
Serum	Electrophoretic separation and quantitation of paraprotein	Electrophoretic separation of protein using Sebia Capillarys 2 Flex IS-VI-SOP-254
		Phadia 250 analyser using FEIA IS-VI-SOP-139
Serum	Tissue Transglutaminase (tTG) IgG autoantibodies	IS-VI-SOP-262



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
Serum	Beta 2 glycoprotein 1 autoantibodies (IgG)	IS-VI-SOP-165
Serum	CCP autoantibodies (IgG)	IS-VI-SOP-10
Serum	dsDNA autoantibodies (IgG)	IS-VI-SOP-147
Serum	ENA symphony screen includes Ro (52/60), La, Sm D₃, U1-RNP, CENP-B, Jo1, Scl70 (IgG)	IS-VI-SOP-264
Serum	ENA profile: Ro (combined 52/60 and individual antigens) La, SmD ^{p5} , U1RNP, CENP-B, Jo1, Scl- 70 (IgG)	IS-VI-SOP-264
Serum	GBM autoantibodies (IgG)	IS-VI-SOP-265
Serum	Myeloperoxidase (MPO) autoantibodies (IgG)	IS-VI-SO9-265
Serum	Proteinase 3 (PR3) autoantibodies (IgG)	IS-VI-SOP-265
Serum	Quantification of total IgE	IS-VI-SOP-263
Serum	Quantification of Mast Cell Tryptase	IS-VI-SOP-154



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current PHE SMIs as relevant
	Detection of specific IgG to the following antigens:	Phadia 250 analyser using FEIA IS-VI-SOP-139
Serum	Alternaria alternata specific IgG (ImmunoCAP IgG m6) Aspergillus fumigatus specific IgG (ImmunoCAP IgG m3) Aspergillus flavus specific IgG (ImmunoCAP IgG m228) Aspergillus niger specific IgG (ImmunoCAP IgG m207) Aspergillus terreus specific IgG (ImmunoCAP IgG m36) Budgerigar specific IgG (ImmunoCAP IgG Ge90) Candida specific IgG (ImmunoCAP IgG m5) Cephalosporium (Acremonium kiliense) specific IgG (ImmunoCAP IgG m202) Cladosporium specific IgG (ImmunoCAP IgG m2) Micropolyspora faeni specific IgG (ImmunoCAP IgG Gm22) Fusarium specific IgG (ImmunoCAP IgG Ge92) Parrot Mix specific IgG (ImmunoCAP IgG Ge92) Penicillium chrysogenum specific IgG specific IgG (ImmunoCAP IgG m1) Penicillium glabrum (ImmunoCap M209) Pigeon serum specific IgG (ImmunoCAP IgG Ge93) Rhizopus nigricans (ImmunoCAP IgG Gm24) Thermoactinomyces vulgaris IgG (ImmunoCAP IgG Gm23)	IS-VI-SOP-177



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant
	Detection of specific IgE to the following antigens:	Phadia 250 analyser using FEIA IS-VI-SOP-139
Serum	Almond (RAST f20) Alternaria alternata (RAST m6) Apple (RAST f49) Aspergillus flavus (RAST m228) Aspergillus tumigatus (RAST m3) Aspergillus niger (RAST m207) Aspergillus terreus (RAST m36) Aspergillus mix (RAST mx4) Banana (RAST f92) Brazil nut (RAST f18) Candida (RAST m5) Cashew nut (RAST f202) Cat dander (RAST e1) Celery (RAST f85) Cheese (cheddar type) (RAST f81) Cladosporium(RAST m2) Cocoa (cacao) (RAST f93) Coconut (RAST f36) Cow's milk (RAST f2) Cow's milk casein Bos d8 (RAST f78) Crab (RAST f23) Dog dander (RAST e5) Egg (Hen's) ovomucoid Gal d1 (RAST f233) Egg white (Hen's) (RAST f1) Egg yolk (Hen's) (RAST f75) Feather mix 71 (goose, chicken, duck, turkey) (RAST ex71) Feather mix 72 (budgerigar, canary, parakeet, parrot, finch) (RAST ex72) Fish (cod) (RAST f3) Fish Mix (cod, shrimp, blue mussel, tuna) (RAST fx2) Gluten (RAST f79) Grass pollen mix (cocksfoot, meadow fescue, rye-grass, timothy grass, meadow grass – Kentucky blue) (RAST gx1) Guinea Pig (RAST e6)	IS-VI-SOP-263



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant
	Detection of specific IgE to the following antigens: (cont'd)	Phadia 250 analyser using FEIA IS-VI-SOP-139
Serum (cont'd)	Hay dust - storage (grain/flour) mite (Acarus siro) (RAST d70) Hazelnut (RAST f17) Honey Bee venom (RAST i1) Horse dander (RAST e3) House dust mite (RAST d1) Kiwi fruit (RAST f84) Latex (RAST k82) Mould mix 1 (Penicillium chrysogenum, Cladosporium herbarum, Aspergillus fumigatus) (RAST mx1) Mould mix 4 (A.fumigatus, A.niger, A.terreus, A.flavus) (RAST mx4) Mussel (blue) (RAST f37) Nut Mix 1 (Peanut, Hazel nut, Brazil nut, Almond, Coconut) (RAST fx1 Nut Mix 2 (Pecan nut, Cashew nut, Pistachio, Walnut) (RAST fx22) Orange (RAST f33) Peanut (RAST f13) Peanut rAra h 1 (RAST f422) Peanut rAra h 2 (RAST f423) Peanut rAra h 3 (RAST f424) Peanut rAra h 8 PR10 (RAST f352) Peanut rAra h 8 PR10 (RAST f352) Peanut rAra h 9 nsLTP (RAST f427) Pecan nut (RAST f201) Penicilloyl G (RAST c1) Penicilloyl G (RAST c2) Pine nuts (RAST f203) Rabbit Fur (RAST f203) Rabbit Fur (RAST f424) Sesame seed (RAST f10) Shrimp Mix (Pandalus borealis, Penaeus monodon, Metapenaeopsis barbata, Metapenaeus joyneri) (RAST f24), Silver Birch pollen (RAST t3) Soybean (RAST f14)	IS-VI-SOP-263



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant
	Detection of specific IgE to the following antigens: (cont'd)	Phadia 250 analyser using FEIA IS-VI-SOP-139
Serum (cont'd)	Strawberry (RAST f44) Tomato (RAST f25) Tree pollen mix (Box-elder, Silver Birch, Oak, Elm, Walnut)(RAST tx9) Tuna (RAST f40) Walnut (RAST f256) Wasp venom (RAST i3) Weed pollen mix (Mugwort, Plantain (Ribwort), goosefoot, golder rod, nettle) (RAST wx3) Wheat (RAST f4) Wheat Omega 5 gliadin Tri a 19 (RAST f98)	IS-VI-SOP-263
Serum	EliA Cardiolipin IgG	Phadia 250 analyser using FEIA IS-VI-SOP-315
	Histological examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manual as relevant
Fixed and fresh tissue	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis.	Tissue processing using the following machines: Leica ASP6025, CS-HIS-SOP-211 Menarini Logos Leica Peloris III CS-HIS-SOP-253 Tissue embedding using: Leica Arcadia CS-HIS-SOP-217 Tissue sectioning using manual and automated microtomes and CS-HIS-SOP-72



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Histological examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant
In house preparations of tissue sections	Detection of the following:	Leica XL autostainer using CS-HIS- SOP-94 and Leica CV5030 coverslipper using CS-HIS-SOP- 177
	Basophilic and eosinophilic structures	H&E staining using CS-HIS-SOP-189
	Detection of the following:	Manual staining methods:
	Acid mucopolysaccharides	Alcian blue CS-HIS-SOP-20
	Acid mucins, Neutral mucins, glycoproteins, proteoglycans, hyaluronic acid, glycogen	Alcian blue and PAS using CS-HIS- SOP-46
	Amyloid	Congo red using CS-HIS-SOP-180
	Reticulin Fibres	Gordon & Sweets Reticulin Silver using CS-HIS-SOP-35
	Gram positive and negative bacteria	Gram's stain using CS-HIS-SOP-37
	Fungi	Grocott stain using CS-HIS-SOP-28
	Calcium	Von Kossa stain using CS-HIS- SOP-53
	Helicobacter	Toluidine blue in Sorrenson buffer CS-HIS-SOP-25
	Elastin	Millers Elastic van Gieson using CS-HIS-SOP-161
	Neutral mucins, basement membranes, fungi, glycogen	Periodic acid Schiffs stain using CS-HIS-SOP-76
	Neutral mucins, basement membranes, fungi,	Periodic acid Schiffs Diatase using CS-HIS-SOP-77



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North Cumbria Integrated Care NHS Foundation Trust

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Histological examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant
		Manual special stains
	Haemosiderin	Perls Prussian Blue using CS-HIS-SOP-126
	Mycobacteria	ZN stain using CS-HIS-SOP-38
	Immunocytochemistry staining to detect the following:	Leica Bond III Immuno-stainer using CS-HIS-SOP- 232 and Leica CV5030 coverslipper using CS-HIS- SOP-177, CS-HIS-SOP- 218,220,221,222,224,225,226 and the following antibodies:
	Smooth muscle cells, Myofibroblasts, Myoepithelial cells	Actin
	Neoplastic liver disease, yolk sac tumours, mixed germ cell tumours	AFP
	Follicular lymphoma classification	BCL2
	B-cells	BL26
	Reed Sternberg cells	BERH2 (CD30)
	Gastric, pancreatic and colonic adenocarcinoma	CA19.9
	Ovarian cancer	CA125
	Mesothelial cells	CALRETININ
	T-cells	CD3
	B and T cells	CD5
	B cells	CD10



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Histological examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant
	Immunocytochemistry staining to detect the following: (cont'd)	Leica Bond III Immuno-stainer using CS-HIS-SOP- 232 and Leica CV5030 coverslipper using CS-HIS- SOP-177, CS-HIS-SOP- 218,220,221,222,224,225,226 and the following antibodies:
	Normal Intestinal epithelium	CDX2
	Adenocarcinomas of colon, stomach, lung and breast	CEAM
	Adenocarcinomas of colon, stomach, lung and breast	CEAP
	Epithelial cells	CKAE13
	Normal and abnormal gastric and intestinal epithelium, urothelium and Merkel cells	СК20
	Epithelial cells	CKMNF
	Stratified squamous epithelia	CK5/6
	Basal layer of stratified squamous and non-squamous epithelia	CK14
	Ductal, glandular and non-keratinising epithelia	СК19
	Basal cells and squamous epithelium	CK34BE
	c-kit oncoprotein	СКІТ
	Chromogranin A protein in neuronal and endocrine tissues	CHRG
	Lymphoid tumour cells	CLA
	Cyclin D1 protein expression in breast and bladder tumours and lymphomas	CYCLIN D1



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Histological examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manual as relevant
	Immunocytochemistry staining to detect the following: (cont'd)	Leica Bond III Immuno-stainer using CS-HIS-SOP- 232 and Leica CV5030 coverslipper using CS-HIS- SOP-177, CS-HIS-SOP- 218,220,221,222,224,225,226 and the following antibodies:
	Smooth and striated muscle cells	DESMIN
	Epithelial membrane antigen in glandular epithelia	ЕМА
	Normal epithelial tissues	EP4
	Normal epithelial tissues	ECAD
	Oestrogen receptor	ER
	Human chorionic gonadotrophin producing cells	HCG
	Melanocytic cells	HMB45
	ki-67 antigen in normal and neoplastic cells	KI67
	Identifies breast carcinomas and urothelial carcinomas	GATA-3
	HPV driven tumour	P16
	Macrophages	KP1
	Melanocytic cells	MELA
	Neuroectodermal cells	NCAM
	p53 protein in normal and neoplastic cells	P53
	p63 protein in normal and neoplastic cells	P63



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Histological examinations for the</u> <u>purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manual as relevant
	Immunocytochemistry staining to detect the following: (cont'd)	Leica Bond III Immuno-stainer using CS-HIS-SOP- 232 and Leica CV5030 coverslipper using CS-HIS- SOP-177, CS-HIS-SOP- 218,220,221,222,224,225,226 and the following antibodies:
	Cells expressing prostate specific antigen	PSA
	Endothelial cells	QBEN10
	Neuroectodermal cells	S100
	Smooth muscle cells	SMM
	Neuroectodermal cells	SYNAPTO
	Thyroid transcription factor - 1 protein in normal and neoplastic tissues	TTF1
	Cells of mesenchymal origin in normal and neoplastic tissues	VIMENTIN
	Wilm's tumour protein in proliferative mesothelial cells, mesothelioma, ovarian cystadenocarcinoma, gonadoblastoma, nephroblastoma, desmoplastic small round cell tumour	WT1

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Histological examinations for the purposes of clinical diagnosis (cont'd) Immunocytochemistry staining to detect the following: (cont'd)	In-house documented manual procedures using Leica Bond III Immuno-stainer using CS-HIS-SOP- 232 and Leica CV5030 coverslipper using CS-HIS- SOP-177, CS-HIS-SOP- 218,220,221,222,224,225,226 and
Bronchial washings, urine, CSF, Sputum, clot, fluids, FNA	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities.	the following antibodies: CS-HIS-SOP-5 Cytocentrifuge, CS- HIS-SOP-19 Sigma 2-6E centrifuge CS-HIS-SOP-94 XL Stainer, CS- HIS-SOP-177 Leica Coverslipper, CS-HIS-SOP-83 Microscopes. CS-HIS-SOP-238 Specimen preparation respiratory samples CS-HIS-SOP-21 Urine CS-HIS-SOP-22 CSF CS-HIS-SOP-26 Body fluids CS-HIS-SOP-82 Clot CS-HIS-SOP-82 Clot CS-HIS-SOP-42 FNA CS-HIS-SOP-94 PAP stain CS-HIS-SOP-70 Diff quick stain
END		