


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9845</p> <p>Accredited to ISO 15189:2012</p>	<p>Betsi Cadwaladr University Health Board</p> <p>Issue No: 007 Issue date: 31 May 2022</p>	
	<p>Ysbyty Gwynedd Penrhosgarnedd, Bangor Gwynedd LL57 2PW</p>	<p>Contact: Bernadette Astbury Tel: +44 (0) 1978 291 100 E-Mail: bernadette.astbury@wales.nhs.uk Website: http://www.bcu.wales.nhs.uk/</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address Wrexham Maelor Hospital Croesnewydd Road Wrexham LL13 7TD United Kingdom</p> <p>Local contact Paul Jakeways 03000 858093</p>	<p>Haematology Biochemistry Blood Transfusion Andrology Management of five blood fridges:</p> <ul style="list-style-type: none"> • Laboratory blood fridge • Theatre blood fridge • Haemosafe remote issue fridge Erdigg ward annex • A & E blood fridge • Office blood fridge in Pathology laboratory 	WMH
<p>Address Ysbyty Gwynedd Penrhosgarnedd Bangor Gwynedd LL57 2PW</p> <p>Local contact Mrs Vicky Williamson-Hughes 01248 3846277</p>	<p>Haematology Biochemistry Toxicology Immunology Blood Transfusion Management of three lab-based blood fridges</p>	YG
<p>Address Glan Clywd Hospital Sarn Lane Bodelwyddan LL18 5UJ</p> <p>Local contact Joseph Banwell 01745 448788 ext. 2915</p>	<p>Haematology Biochemistry Blood Transfusion Management of three blood fridges:</p> <ul style="list-style-type: none"> • Cancer Centre Enfys ward • Top Floor corridor, between Delivery suite/Cancer centre • Theatres 	YGC



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Location details	Activity		
		Location code	
Renal and Diabetic Unit Gladstone Centre Maelor Hospital Croesnewydd Road Wrexham LL13 7TD United Kingdom	Paul Jakeways 03000 858093	HbA1c analysis	RDU

Site activities performed away from the locations listed above:

Location details	Activity	
Llandudno General Hospital Hospital Road Llandudno Conwy LL30 1LB	Local contact Joe Leung 01248 384521	Management of blood fridge: Ground floor, Rear of Aberconwy Ward
Abergele Hospital Llanfair Road Abergele LL22 8DP	Local contact Luke Hughes 01745 448790 ext. 2959	Management of Ward 6 blood fridge
Denbigh Infirmary Ruthin Road Denbigh LL16 3ES	Local contact Luke Hughes 01745 448790 ext. 2959	Management of ground floor treatment room blood fridge



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Whole blood EDTA	Plasma viscosity	Benson viscometer SOP PTH/HAEE/611	WMH
Whole blood EDTA	Detection of normal and abnormal morphologies	Manual staining by Clin-tech Speedy Diff kit SOP PTH/HAE/107 Examination by light microscopy SOP PTH/HAE/108	WMH YG YGC
Bone Marrow aspirates	Detection of normal and abnormal morphologies	Manual staining by Clin-tech Speedy Diff kit SOP PTH/HAE/107 Manual Perl's stain SOP PTH/HAE/109	WMH YG YGC WMH YG



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Bone Marrow aspirate and stained trephine slides	Detection of normal and abnormal morphologies	Examination by light microscopy SOP PTH/HAE/108 SOP PTH/HAE/109	WMH YG YGC
CSF	Detection of spinal infiltration (residual cells)	Using Cytospin Shandon Cytospin 2 and Sysmex SP1000 automated staining system using May Grunwald – Giemsa SOP PTH/HAEW/98 SOP PTH/HAEW/102	YG
Whole blood	Screening for the detection of Plasmodium spp (Including <i>Plasmodium ovale</i> <i>Plasmodium falciparum</i> , <i>Plasmodium malariae</i> <i>Plasmodium vivax</i>)	Humasis rapid malaria test kit SOP PTH/HAE/102	WMH YG YGC
	Preliminary screening for malaria parasites	Manual thin film staining using Giemsa with Sorensens Buffer – pH 7.2, SOP PTH/HAE/602 SOP PTH/HAE/108 Preparation of thick films to be stained and reported at other sites as below.	WMH
Whole blood	Detection and identification of Plasmodium species: <ul style="list-style-type: none"> • P.falciparum • P.vivax • P.ovale • P.malariae • P knowlesi 	Manual thin film staining using Giemsa with Sorensens Buffer – pH 7.2, and thick films with Field's Stain. Reporting of thick and thin films from across the network SOP PTH/HAEW/95 SOP PTH/HAE/764	YG YGC



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Whole blood	Detection of the presence of sickling haemoglobins	SICKLEDEX solubility test kit SOP PTH/HAE/106	WMH YG
Whole blood	Detection of infectious mononucleosis heterophile antibodies	Accusay Mono kit rapid immunoassay SOP PTH/HAE/104	WMH YG YGC
Whole blood	G6PD screen	G6PD Trinity Biotech using red cell enzyme rate reaction SOP PTH/HAEW/116	YG
Whole blood	Haemoglobinopathy screening: Detection of Haemoglobin variants Hb A Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E	Helena V8 Nexus using capillary electrophoresis SOP PTH/HAEE/604	WMH
Whole blood EDTA	Erythrocyte sedimentation rate (ESR)	Starrsed Auto-Compact analyser (Westergren method) SOP PTH/HAEC/798	YG YGC
Plasma, citrated	Platelet Function Testing	Platelet Aggregometry: Helena Biosciences AggRam using Turbidimetry SOP PTH/HAEW/59	YG



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HUMAN BODY FLUIDS (cont'd)	<u>Blood transfusion examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Blood Grouping by antigen detection <ul style="list-style-type: none"> • A, B and O groups • Rhesus D 	Automated testing using Orthovision, Microcolumns. SOP PTH/TR/845	WMH YG YGC
	Red cell antibody screens (detection and identification) of the following <ul style="list-style-type: none"> • Rhesus: C, c, D, E, e • Kell • Duffy • Kid • Lewis • P • MNS • Lutheran 	Automated testing using Orthovision, Microcolumns. SOP PTH/TR/845 SOP PTH/TR/846	WMH YG YGC
Blood	Antigen phenotyping: <ul style="list-style-type: none"> • Rhesus: C, c, D, E, e • Kell 	Automated testing using Orthovision, Microcolumns. PTH/TR/848	YG YGC WMH
Blood	Compatibility testing of patient's plasma with donor cells	Automated testing using Orthovision, Microcolumns. SOP PTH/TR/847	WMH YG YGC
Blood	Direct antiglobulin test	Automated testing using Orthovision, Microcolumns. SOP PTH/TR/849	WMH YG YGC



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HUMAN BODY FLUIDS (cont'd)	<u>Blood transfusion examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Foetal/maternal haemorrhage screen (Kleihauer)	Source BioScience Foetal red cell detection kit SOP PTH/TRE/13	WMH
		Guest Medical, Fetal red cell detection kit SOP PTH/TRC/020	YGC
Blood	<u>Molecular examination activities for the purpose of clinical diagnosis</u> Detection and identification of the following genetic mutations: <ul style="list-style-type: none"> • Factor V Leiden • Prothrombin gene P20210 • HFE (Haemochromatosis) • HLAB27 	In-house documented procedures based on equipment manuals as relevant Fluorotype Assay using HAIN thermocycler. SOP PTH/HAEC/COAG11	YGC
Urine	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> Detection of human chorionic gonadotropin (hCG)	In-house documented procedures based on equipment manuals as relevant Alere hCG cassette 25 mIU/mL rapid immunoassay pregnancy test SOP:PTH/HAEE/13 <i>NB test is carried out in Haematology department</i>	WMH



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum	Paraprotein bands identification and clarification	Helena V8 Nexus SOP PTH/BIO/206 /195	WMH YG YGC
Serum	Protein abnormalities screening	Helena V8 Nexus SOP PTH/BIO/195	WMH YG YGC
Urine	Bence Jones confirmation and typing	Sebia Hydrasys 2 SOP PTH/BIO/207	WMH YG YGC
Serum, Urine	Immunofixation	Helena SA 3&4 SOP PTH/BIOE/60 SOP PTH/BIOW/118 SOP PTH/BIOC/538	WMH YG YGC
Blood	Glycated Haemoglobin (HbA1c)	Tosoh G11 SOP PTH/BIO/187	WMH YG YGC
Blood	Glycated Haemoglobin (HbA1c)	Tosoh GX SOP PTH/BIO/187	RDU
CSF	Xanthochromia	Jasco V-730 spectrophotometer SOP PTH/BIO/148	WMH YGC
CSF	Xanthochromia	Beckman Coulter DU800 Spectrophotometer SOP PTH/BIOW/128 SOP PTH/BIOW/129	YG



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum, urine	Osmolality	Freezing point depression osmometry using Advanced instruments 3320 Osmometer SOP PTH/BIO/210	WMH YGC
Serum, urine	Osmolality	Freezing point depression osmometry using Advanced instruments Osmo 1 SOP PTH/BIO/210	YG
Renal calculi	Determination of the composition of renal calculi	JASCO FT/IR 4100 spectrometer Spectra Manager Software, including Spectra measurement and Spectra Analysis programmes SOP PTH/BIOE/40	WMH
Urine	Screening for carcinoid syndrome and phaeochromocytoma:	High Performance Liquid Chromatography using Waters 2695 HPLC Analyser SOP PTH/BIOW/125 SOP PTH/BIOW/126 SOP PTH/BIOW/127	YG
Serum	5HIAA VMA Metadrenalines Normetadrenalines Cryoglobulin screening and detection	Visual detection SOP PTH/BIOW/132 SOP PTH/BIOC/517	YG YGC



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Sweat	Screening for cystic fibrosis: chloride concentration	Using Wescor Macroduct sweat collection system followed by analysis on the Beckman Coulter AU5800 using ion selective electrode SOP PTH/BIOW/4 SOP PTH/BIOW/124	YG
Whole blood	Immunosuppressant monitoring: Cyclosporin Tacrolimus Sirolimus	Using Waters Acquity UPLC/MS/MS SOP PTH/BIOW/88 SOP PTH/BIOW/90	YG
Whole Blood, Urine, Serum	Confirmation of drugs of abuse and screening for drugs in Post-mortem analysis (for Coroner only). Detected drugs are then quantified. 6MAM Acebutolol Acepromazine Alimemazine Alprazolam Ambroxol Amiodarone Amisulpride Amitriptyline Amoxapine Amphetamine Amylobarbitone Atenolol Atropine	Waters Acquity UPLC/MS/MS AGILENT 5975 GC/MS analyser SOP PTH/BIOW/88 Waters LC/MS/MS SOP PTH/BIOW/135 Agilent GC/MS SOP PTH/BIOW/78	YG



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Whole Blood, Urine, Serum	Confirmation of drugs of abuse and screening for drugs in Post-mortem analysis (for Coroner only). Detected drugs are then quantified. Benzoyllecgonine Betaxolol Bisoprolol Bromazepam Brompheniramine Buflomedil Bupivacaine Buprenorphine Bupropion Butobarbitone Caffeine Carbamazepine Celiprolol Chlordiazepoxide Chlormethiazole Chloroquine Chlorpheniramine Chlorpromazine Citalopram Clenbuterol Clobazam Clomipramine Clonazepam Clonidine Clotiazepam Cloxazolam Clozapine Cocaine Codeine Colchicine Cyclizine	Waters Acquity UPLC/MS/MS AGILENT 5975 GC/MS analyser SOP PTH/BIOW/88 Waters LC/MS/MS SOP PTH/BIOW/135 Agilent GC/MS SOP PTH/BIOW/78	YG



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Whole Blood, Urine, Serum	Confirmation of drugs of abuse and screening for drugs in Post-mortem analysis (for Coroner only). Detected drugs are then quantified. Desalkyl flurazepam Desipramine Dextromethorphan Dextromoramide Diazepam Diclofenac Dihydrocodeine Diltiazem Diphenhydramine Doxapram Doxepine Doxylamine Droperidol Ecgonine methyl ester EDDP Ephedrine Estazolam Ethenzamide Ethosuximide Fenspiride Fentanyl Flecainide Flumazenil Flunitrazepam Fluoxetine Fluphenazine Flurazepam Fluvoxamine Gabapentin Haloperidol Heroin	Waters Acquity UPLC/MS/MS AGILENT 5975 GC/MS analyser SOP PTH/BIOW/88 Waters LC/MS/MS SOP PTH/BIOW/135 Agilent GC/MS SOP PTH/BIOW/78	YG



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Whole Blood, Urine, Serum	Confirmation of drugs of abuse and screening for drugs in Post-mortem analysis (for Coroner only). Detected drugs are then quantified. Hydrocodone Hydromorphone Hydroquinidine Hydroxy Alprazolam Hydroxyzine Ibuprofen Imipramine Ketamine Labetalol Lamotrigine Levetiracetam Levomepromazine Lidocaine Loprazolam Lorazepam Lormetazepam Loxapine LSD Maprotiline MBDB MDA MDEA MDMA Meloxicam Meperidine Meprobamate Methadone Methamphetamine Methaqualone Methocarbamol Methyl Clonazepam	Waters Acquity UPLC/MS/MS AGILENT 5975 GC/MS analyser SOP PTH/BIOW/88 Waters LC/MS/MS SOP PTH/BIOW/135 Agilent GC/MS SOP PTH/BIOW/78	YG



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Whole Blood, Urine, Serum	Confirmation of drugs of abuse and screening for drugs in Post-mortem analysis (for Coroner only). Detected drugs are then quantified. Methylphenidate Metoclopramide Metoprolol Mianserine Midazolam Milnacipran Mirtazapine Molsidomine Morphine Nadolol Nalbuphine Nalorphine Naltrexone Naproxen Nicotine Nitrazepam Norbuprenorphine Nordiazepam Norketamine Nortriptyline Olanzapine Orphenadrine Oxazepam Oxcarbazepine Oxprenolol Oxycodone Paracetamol Paroxetine PCP Pentobarbitone Perphenazine	Waters Acquity UPLC/MS/MS AGILENT 5975 GC/MS analyser SOP PTH/BIOW/88 Waters LC/MS/MS SOP PTH/BIOW/135 Agilent GC/MS SOP PTH/BIOW/78	YG



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Whole Blood, Urine, Serum	Confirmation of drugs of abuse and screening for drugs in Post-mortem analysis (for Coroner only). Detected drugs are then quantified. Pethidine Phenacetin Phencyclidine Pheniramine Phenobarbitone Phenylpropanolamine Phenytoin Pindolol Piroxicam Prazepam Pregabalin Primidone Procaine Procyclidine Promazine Promethazine Propafenone Propoxyphene Propranolol Pseudoephedrine Quetiapine Quinidine Ranitidine Reserpine Risperidone Salbutamol Salicylate Scopolamine Secobarbitone Sertraline Sotalol	Waters Acquity UPLC/MS/MS AGILENT 5975 GC/MS analyser SOP PTH/BIOW/88 Waters LC/MS/MS SOP PTH/BIOW/135 Agilent GC/MS SOP PTH/BIOW/78	YG



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Whole Blood, Urine, Serum</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u></p> <p>Confirmation of drugs of abuse and screening for drugs in Post-mortem analysis (for Coroner only). Detected drugs are then quantified.</p> <p>Strychnine Sulindac Sulpiride Temazepam Tetracaine Tetrazepam Theophylline Thioridazine Tianeptine Tiapride Tofisopam Topiramate Tramadol Trazadone Triazolam Trifluoperazine Trimipramine Triprolidine Valproate Venlafaxine Venlafaxine Odesmethyl Verapamil Vigabatrin Zolpidem Zopiclone</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Waters Acquity UPLC/MS/MS AGILENT 5975 GC/MS analyser</p> <p>SOP PTH/BIOW/88 Waters LC/MS/MS SOP PTH/BIOW/135 Agilent GC/MS SOP PTH/BIOW/78</p>	<p>YG</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Whole Blood	Carboxyhaemoglobin	Beckman Coulter DU800 Spectrophotometer SOP PTH/BIOW/138	YG
Whole Blood, urine, serum, plasma	Ethanol Methanol Isopropanol Acetone	Shimadzu GC Analyser SOP PTH/BIOW/136 SOP PTH/BIOW/91 SOP PTH/BIOW/91 SOP PTH/BIOW/91	YG
Serum, plasma	Screening and quantification of ethylene glycol	SOP PTH/BIOW/89	YG



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u></p> <p>Total IgE</p> <p>Specific IgE to:</p> <ul style="list-style-type: none"> Almond Alternaria Tenuis (Alternata) Apple Aspergillus fumigatus Atopic mix Avocado Banana Barley (Food) Beef Birch (silver) Black Currant Blackberry Brazil Nut Broccoli Budgerigar feathers Canary feathers Candida Albicans Cashew Nut Cat Dander Celery Cheese (Cheddar type) Cherry Chestnut (sweet) Chick pea Chicken feathers Chicken Meat Chilli Pepper Chocolate (cacao) Cladosporium Hebarum Coconut 	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Enzyme immunoassay using the Phadia ImmunoCAP 250</p> <p>SOP PTH/IMM/004 SOP PTH/IMM/048 SOP PTH/IMM/REC009</p>	<p>YG</p>



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u></p> <p>Specific IgE to: Coffee Common Wasp (Yellow Jacket) Corn/maize Cow Dander Cow's Milk Crab Cucumber Cultivated rye Dog Dander Duck Egg Egg White Egg Yolk Feather mix (cagebird) Feather Mix (poultry) Finch feathers Fish (Cod) Food Mix (Fruits) Garlic Gerbil epithelium Gluten Goat Milk Gooseberry Grape (red/white wine) Grapefruit Guinea Pig Epithelium Hamster Epithelium Hazel Hazel Nut Honey Bee Venom Horse Dander House Dust Mite</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Enzyme immunoassay using the Phadia ImmunoCAP 250</p> <p>SOP PTH/IMM/004 SOP PTH/IMM/048 SOP PTH/IMM/REC009</p>	<p>YG</p>



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u></p> <p>Specific IgE to: Kiwi Fruit Lactose Lamb (mutton) Latex Lemon Lentil Lettuce Lime Lobster Maxatase Mixed Foods Mixed Moulds Mixed Moulds 2 Mixed Seafood Mugwort Mushroom Mussel (blue) Mustard Nectarine Oat Onion Orange Parakeet feathers Parrot Feathers Pea Peach Peanut Pear Penicilloyl G Penicilloyl V Pineapple Pistachio Pistachio</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Enzyme immunoassay using the Phadia ImmunoCAP 250</p> <p>SOP PTH/IMM/004 SOP PTH/IMM/048 SOP PTH/IMM/REC009</p>	<p>YG</p>



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Betsi Cadwaladr University Health Board

Issue No: 007 Issue date: 31 May 2022

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS Serum	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u> Specific IgE to: Plum Pork Potato Prawn/shrimp Pumpkin seed Rabbit Epithelium Raspberry Rat epithelium Rice Salmon Savinase Sesame Seed Sheep Epithelium Sheep's Wool (Untreated) Soya Strawberry Sunflower seed Sweet Pepper (paprika) Tangerine Timothy-Phleum pratense (grass) Tomato Tuna Turkey meat Vanilla Walnut Wheat White Bean Wine (Red) Yeast	In-house documented procedures based on equipment manuals as relevant Enzyme immunoassay using the Phadia ImmunoCAP 250 SOP PTH/IMM/004 SOP PTH/IMM/048 SOP PTH/IMM/REC009	YG



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Specific IgG to: Apergillus fumigates Budgerigar Micropolyspora faeni Apergillus fumigates Micropolyspora faeni Parrot Pigeon Thermoactinomyces vulgaris Candida Albicans</p> <p>Detection and quantification of Tryptase</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Enzyme immunoassay using the Phadia ImmunoCAP 250</p> <p>SOP PTH/IMM/004 SOP PTH/IMM/048 SOP PTH/IMM/REC009</p>	<p>YG</p>



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Autoimmunity: Detection and monitoring of the following:</p> <p>ANCA Anti-Nuclear Ab (ANA) Anti-Mitochondria Ab (AMA) Smooth Muscle Ab (SMA) Liver Kidney Microsomal Ab (LKM) Gastric Parietal Cell Ab (GPC) Crithidia Ab Skin Ab (Pemphigus/Pemphigoid) Endomysial Ab (IgA and IgG)</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Indirect Immunofluorescence using Werfen ASP 1200 slide processor and NIKON E400 Fluorescence microscope</p> <p>SOP PTH/IMM/008 Werfen ASP1200 Slide Processor Routine Use SOP PTH/IMM/012 Use of Nikon Eclipse E400 UV Microscope SOP PTH/IMM/035 Immunofluorescence slide interpretation SOP PTH/IMM/041 SOP PTH/IMM/REC009</p>	<p>YG</p>



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Quantification of the following: Anti-B2-GP1 Antibodies IgG and IgM Anti-Cardiolipin Ab level IgG and IgM Anti-CCP Antibodies IgG Anti-Centromere Antibodies IgG Anti-IgA TTG Antibodies Anti-IgG TTG Antibodies anti-ds-DNA antibodies IgG ENA Ab screening IgG Anti Ro antibodies IgG Anti La antibodies IgG Anti SMdp antibodies IgG Anti U1 RNP IgG Anti SCL70 IgG Anti Jo-1 IgG Anti-MPO antibodies IgG Anti-PR3 antibodies IgG Anti-GBM Antibodies IgG</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Enzyme immunoassay using the Phadia ImmunoCAP 250</p> <p>SOP PTH/IMM/004 SOP PTH/IMM/048 SOP PTH/IMM/REC009</p>	<p>YG</p>



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HUMAN BODY FLUIDS Serum	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of IgG antibodies against nuclear antigens (nRNP/SM, SM, SSA, Ro52, SSB, Scl-70, PM-scl, Jo-1, CENP B, PCNA, dsDNA, nucleosomes, histones, Ribo-P protein, AMA-M2)</p> <p>Detection of antibodies against Systemic sclerosis specific antigens (Scl-70 Cenp A, Cenp B, RP11, RP155, Fibrillarin, NOR-90, Th/T0, PMscl-100, PMScl-75, KU, PDGFR, Ro52).</p> <p>Detection of antibodies against autoimmune liver diseases IgG (AMA-M2, 3EBPO, SP100, PML, GP210, LKM-1, LC-1, SLA/LP, Ro52)</p> <p>Detection of antibodies against autoimmune inflammatory myopathies 16 ag IgG (Mi2a, Mi2b, TIF1g, MDA-5, NXP-2, SAE-1, KU, PMScl-100, PMScl-75, Jo-1, SRP, PL7, PL12, EJ, OJ, Ro52)</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Immunoblots Methods using Euroimmun profiles</p> <p>Euroline blot Euroblotmaster Method using Euroimmun ANA profile 3 Euroline IgG</p> <p>SOP PTH/IMM/058</p> <p>Euroline blot Euroblotmaster Systemic sclerosis (nucleoli) profile Euroline IgG</p> <p>SOP PTH/IMM/058</p> <p>Euroline blot Euroblotmaster Euroline- autoimmune liver diseases IgG</p> <p>SOP PTH/IMM/058</p> <p>Euroline blot Euroblotmaster Euroline- autoimmune inflammatory myopathies 16 antigen IgG</p> <p>SOP PTH/IMM/058</p>	<p>YG</p> <p>YG</p> <p>YG</p> <p>YG</p>



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HUMAN BODY FLUIDS	<u>Andrology examinations for aid of Clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	WMH
Seminal fluid	Fertility Screening <ul style="list-style-type: none"> • Semen pH • Semen volume • Sperm concentration • Sperm motility • Sperm vitality • Sperm morphology 	Documented in house procedures based on WHO laboratory manual 5 th edition (2010) SOP PTH/AND/001 pH paper Volume/weight Microscopy counting chamber Microscopy using wet prep Stained slide microscopy Stained slide microscopy	
	Post vasectomy seminal analysis	Documented in house procedures based on the Association of Biomedical Andrologists (ABA), the British Andrology Society and the British Association of Urological Surgeons (BSAC) (2016) guidelines SOP PTH/AND/002	
	Detection of sperm	Centrifugation and microscopy	
END			