


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8210</p> <p>Accredited to ISO 15189:2022</p>	<p>Royal Devon University Healthcare NHS Foundation Trust</p> <p>Issue No: 017 Issue date: 09 April 2026</p>	
	<p>Department of Blood Sciences Royal Devon & Exeter Hospital Area A2 Barrack Road Exeter EX2 5DW</p>	<p>Contact: Adrian Cudmore/Mandy Perry Tel: +44 (0) 1392 402461 Fax: +44 (0) 1392 402905 E-Mail: rduh.bloodsciencesadmin@nhs.net Website: www.exeterlaboratory.com</p>
<p>Testing performed at the above address only</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity
Department of Blood Sciences Royal Devon & Exeter Hospital Template A Barrack Road Exeter EX2 5DW	<p>Contact: Adrian Cudmore 01392 402936</p>	Clinical Chemistry including Fetal Anomaly Screening Programme
	<p>Adrian Cudmore 01392 402936</p>	General Haematology including Antenatal Sickle cell and thalassaemia screening
	<p>Jennifer Davies 01392 403363</p>	Blood transfusion including storage & issue of blood and blood products
	<p>Adrian Cudmore 01392 402936</p>	Special Haematology including Molecular Haematology
	<p>Adrian Cudmore 01392 402936</p>	Immunology



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Site activities performed away from the locations listed above:

Location details	Activities
Phlebotomy department Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Venepuncture and collection of blood for diagnostic purposes
Haematology Wards Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Fridge for storage & issue of blood and blood products only
Maternity Ward Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Fridge for storage & issue of blood and blood products only
Main theatre Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	2 Fridges for storage & issue of blood and blood products only
Orthopaedic centre Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Fridge for storage & issue of blood and blood products only
Tiverton Hospital Kennedy Way EX16 6NT	Fridge for storage & issue of blood and blood products only
Sidmouth Hospital Herdons Lane All Saints Road EX10 8EW	Fridge for storage & issue of blood and blood products only
Nightingale Hospital Moor Lane EX2 7JG	Blood fridge for storage & issue of blood and blood products only



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum from venous and capillary collection	Albumin	Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies. CC/SOP/0284 Colourimetric, BCG
	Alkaline phosphatase	Colourimetric, IFCC
	Alanine aminotransferase	Kinetic, IFCC with PP activation
	Aspartate aminotransferase	Kinetic, IFCC with PP activation
	Protein (total)	Colourimetric, Biuret
	Iron	Colourimetric, Ferrozine
	Magnesium	Colourimetric, Xylidyl Blue
	Cortisol	Competitive ECLIA
	Dihydroxyepiandrosterone sulphate	Competitive ECLIA
	Folate	Competitive ECLIA
	FT3	Competitive ECLIA
	FT4	Competitive ECLIA
	Oestradiol	Competitive ECLIA
	Progesterone	Competitive ECLIA
Testosterone	Competitive ECLIA	
Vitamin D total	Competitive ECLIA	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology
Serum from venous and capillary collection (cont'd)	HDL-Cholesterol	Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies
	Cholesterol (total)	CC/SOP/0284
	γ-Glutamyl transferase	Enzymatic Colourimetric, CHER
	Triglycerides	Enzymatic Colourimetric, ID/MS standardisation
	Transferrin	Enzymatic Colourimetric, IFCC
	IgA	Enzymatic Colourimetric, Wahlefeld
	IgG	Immunoturbidimetric
	IgM	Immunoturbidimetric, Tina-quant
	Chloride	Immunoturbidimetric, Tina-quant
	Urea	Immunoturbidimetric, Tina-quant
	hsCRP	Indirect ISE
	Active B12	Kinetic, Urease
	CA 125	Particle enhanced Immunoturbidimetric assay, Latex
	Ferritin	Sandwich ECLIA
IGF-1	Sandwich ECLIA	
FSH	Sandwich ECLIA	
LH	Sandwich ECLIA	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum from venous and capillary collection (cont'd)	Prolactin	Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies. CC/SOP/0284 Sandwich ECLIA
	PSA (total)	Sandwich ECLIA
	SHBG	Sandwich ECLIA
	TSH	Sandwich ECLIA
	Creatine kinase	UV-Test, IFCC
	Anti-SARS-CoV-2	Sandwich ECLIA
	Anti-SARS-CoV-2 S	Sandwich ECLIA (double antigen)
Serum from venous and capillary collection and urine	Creatinine	Enzymatic, Creatininase
	Sodium	Indirect ISE
	Urate	Enzymatic Colourimetric, Uricase
Venous Serum	Bilirubin (total)	Colourimetric, Diazo
	Ethanol	Enzymatic, Alcohol Dehydrogenase
	Paracetamol	Colourimetric, Arylacylamidase
	Bile acids	Colourimetric, HSD
	Lactate	Colourimetric, LOD
	Calcium (total)	Colourimetric, NM-BAPTA
	Lithium	Colourimetric, Porphyrin



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies. CC/SOP/0284
Venous Serum (cont'd)	Anti-Thyroglobulin	Competitive ECLIA
	Anti-TPO	Competitive ECLIA
	Cyclosporin	Competitive ECLIA
	Digoxin	Competitive ECLIA
	Tacrolimus	Competitive ECLIA
	Vitamin B12	Competitive ECLIA
	Amylase	Enzymatic Colourimetric, IFCC
	Ammonia	Enzymatic, Glutamate dehydrogenase
	Angiotensin converting enzyme	Enzymatic, KK-ACK
	Complement C3	Immunotubidometric, Tina-quant
	Complement C4	Immunotubidometric, Tina-quant
	Carbamazepine	KIMS
	Phenytoin	KIMS
	Theophylline	KIMS
	Vancomycin	KIMS
	Phosphate	Molybdate UV, Molybdate



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Venous Serum (cont'd)	sFlt-1	Sandwich ECLIA
	Troponin T	Sandwich ECLIA
	Anti-CCP	Sandwich ECLIA (IgG-Capture)
	Lactate dehydrogenase	UV-Test, IFCC
	Bicarbonate	Enzymatic, PEP
	Bilirubin (direct)	Enzymatic, Vanidate Oxidation
	Tobramycin	Enzyme Immunoassay
	Gentamycin	Enzyme Immunoassay, CEDIA
	Methotrexate	Enzyme Immunoassay, EMIT
	Salicylate	Enzyme Mediated Colourimetric, Hydroxylase
	Ceruloplasmin	Immunoturbidometric
	Rheumatoid factor	Immunoturbidometric
	Free kappa light chains	Immunoturbidometric, Freelite
	Free lambda light chains	Immunoturbidometric, Freelite
	Alpha-1-antitrypsin	Immunoturbidometric, Tina-quant
	Beta-2 microglobulin	Immunoturbidometric, Tina-quant
Venous Serum and urine	Amylase	Enzymatic Colourimetric, IFCC



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Venous Serum and urine	Potassium	Indirect ISE
Venous Serum and plasma	Insulin	Sandwich ECLIA
Venous Serum, plasma and urine	C-peptide	Sandwich ECLIA
CSF	Lactate	Colourimetric, LOD
CSF, urine	Protein	Turbidimetric
CSF, urine, venous serum	Glucose	UV-Test, Hexokinase
Urine	Calcium	Colourimetric, NM-BAPTA
	Magnesium	Colourimetric, Xylidyl Blue
	Microalbumin	Immunoturbidometric, Tina-quant
	Amphetamines	KIMS
	Benzodiazepines	KIMS
	Cannabinoids	KIMS
	Cocaine	KIMS
	Methadone	KIMS
	Opiates	KIMS
	Urea	Kinetic, Urease
	Phosphate	Molybdate UV, Molybdate



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Urine	Creatinine Clearance	By calculation CC/SOP/0119
Venous Serum	Adjusted Calcium	
	sFlt-1/PIGF	
	Acute Kidney Injury	Calculated using renal registry national algorithm
	GFR	MDRD EPI calculation
	Urine-C-peptide creatinine ratio	
	Non-HDL cholesterol	
Urine	Albumin/creatinine ratio	
Venous Serum	Free lambda/kappa ratio	
	Free kappa/lambda ratio	
	Schwartz eGFR	
	FIB-4 calculation	
Venous Serum	Adalimumab antibody (total)	Dynex DS2 Automated ELISA system CC/SOP/0279
	Adalimumab drug levels	CC/SOP/0262
	GAD antibody	BS/SOP/0033
	IA2 antibody	BS/SOP/0035
	Infliximab antibody (total)	CC/SOP/0261
	Infliximab drug levels	CC/SOP/0260



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Venous Serum (cont'd)	Ustekinumab drug levels	Dynex DS2 Automated ELISA system CC/SOP/907
	Vedolizumab antibody (free)	CC/SOP/903
	Vedolizumab drug levels	CC/SOP/0262
	Zinc Transporter 8 antibody	BS/SOP/0037
	Lambda light chains (Sebia)	CC/SOP/944
	Kappa light chains (Sebia)	CC/SOP/944
Faeces	Faecal Calprotectin	Mast OC Sensor Pledia CC/SOP/936
	FIT (faecal immunochemical test)	CC/SOP/936
Venous serum and urine	Osmolarity	Osmo 1 Single Sample Micro-osmometer CC/SOP/0025
Sweat	Chloride	Manual method Chloride meter Coulometry CC/SOP/0053



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>EDTA whole blood</p> <p>EDTA whole blood</p> <p>Bone marrow</p>	<p><u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Full Blood Count including the following parameters:</p> <p>Automated cell count – Haematopoietic Progenitor Cell Count (HPC)</p> <p><u>Peripheral Blood Cell Morphology</u></p> <p>Blood film for Morphology</p> <p>Manual differential</p> <p>Digital morphology</p> <p><u>Bone Marrow Morphology</u></p> <p>Bone marrow morphology</p> <p>Bone Marrow differential</p> <p>Iron stain</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Sysmex XN9100</p> <p>Electrical impedance, laser light scatter & dye bonding</p> <p>Sysmex based flow cytometric assay HASOPHPC</p> <p>Blood smears stained with May-Grunwald and Giemsa stains HASOPSP-50 HASOP RAL Stainer</p> <p>Automated stainer SP-50 HASOPSP-50</p> <p>DI-60 Digital Morphology combined with Cellavision Interpretative software HASOPDI-60</p> <p>Manual MCDh panoptic staining HASOP RAL Stainer</p> <p>Stained using RAL stainer HASOP RAL stainer</p> <p>Manual staining using Prussian Blue HASOPS-0008</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	<u>Manual Haematology</u>	
Urine	Urinary Haemosiderin	Manual staining using Prussian Blue HASOPS-0014
CSF	Morphology	Shandon Cytospin Manual MCDh panoptic staining Microscopy HASOPM-0001
EDTA whole blood	Erythrocyte Sedimentation Rate (ESR)	Manual method using Sarstedt Tubes HASOPM-0004
EDTA Plasma and serum	Glandular Fever screen	Monogen test using latex agglutination HASOPM-0007
	<u>Haemoglobinopathy</u>	
EDTA whole blood	Haemoglobinopathy screening including the NHS Sickle Cell and Thalassaemia Screening Programme quantification of:	Documented in-house methods to meet the requirements of the NHS Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements (tests marked *)
	HbA2*	HASOPTAL using Sebia Capillarys 3 Tera
	HbF*	
	HbS*	
	Sickle Cell Solubility	Sickledex test kit using a turbidimetric assay HASOPM-0020
	Detection of HRP2 and pLDH antigens for the identification of Malaria parasites	CareUS test using an immunoassay by laminar flow HASOPM-0032



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
EDTA whole blood (cont'd)	Malaria Blood films	Blood Film review using Giemsa (thin film) and Field's (thick film) stains HASOPS-0009
	Molecular malaria assay Detection of <i>Plasmodium</i> mitochondrial DNA	Loop-mediated amplification using the ILLumiGene assay HASOPO-0012
	HbA1c testing	
EDTA whole blood from venous or capillary collection	HbA1c (Glycated Haemoglobin)	Sebia Capillarys Tera Capillary electrophoresis HASOPGHB
	<u>Routine Coagulation</u>	IL Werfen ACL TOP 550 analyser using Coagulometric (turbidimetric) and Immuno-turbidimetric
Citrated whole blood	Coagulation screen	HASOPC-0024
	Prothrombin time	HASOPC-0024
	INR	HASOPC-0024
	APTR	HASOPC-0024
	D-dimer	HASOPC-0024
	Clauss Fibrinogen	HASOPC-0024
	Thrombin Time	HASOP-0018HASOPC-0018
	<u>Special Coagulation</u>	IL Werfen ACL TOP analyser 550
Citrated whole blood	Liquid Heparin	One stage chromogenic assay HASOPC-0040
	Coagulation Factors 2, 5, 7,8, 9, 10,11 and 12	One stage factor assay HASOPC-0035



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	<u>Special Coagulation</u> (cont'd)	
Citrated whole blood (cont'd)	Coagulation Factor Inhibitor Assay	Bethesda Assay HASOPC-0017
	Von Willebrand Factor Antigen	Immunoturbidometric assay for vWF Antigen HASOPC-0026
	Von Willebrand Factor Activity	Immunoturbidometric assay for vWF Activity HASOPC-0027
	Thrombophilia screen	IL Werfen ACL TOP 550 analyser analyser
	Lupus Anticoagulant	Direct Russells Viper Venom time HASOPC-0014
	Antithrombin	Chromogenic assay HASOPC-0011
	Free Protein S	Latex Agglutination HASOPC-0013
	Protein C	Chromogenic assay HASOPC-0025
	Direct oral anticoagulants: <ul style="list-style-type: none"> • Apixaban • Rivaroxaban 	DOAC assay HASOPC-0048



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>EDTA whole Blood</p>	<p><u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u></p> <p>Blood grouping (ABO and RhD) and antibody screening</p> <p>Antibody identification: Detection of antibodies to the following antigen: D, C, c, E, e, Cw, V, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua, Lub, Xga</p> <p>Manual ABO/D for Newborns</p> <p>Direct Antiglobulin Test: detection of IgG, IgA, IgM, C3d, C3c on the surface of red cells</p> <p>Red cell antigen phenotyping: detection of antigen types: C, c, E, e, K</p> <p>Detection of A subgroup</p> <p>Feto-maternal haemorrhage</p> <p>Weak/Partial D testing</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>BioRad IH500 analyser using column agglutination technology TRLP0103</p> <p>Manual technique using BioRad column agglutination technique TRLP0020</p> <p>BioRad IH500 analyser using column agglutination technology TRLP0056</p> <p>Manual techniques using BioRad column agglutination technology TRLP0010</p> <p>Manual technique using BioRad column agglutination technology</p> <p>Automated method using BioRad IH500 column agglutination TRLP0017</p> <p>Automated method using BioRad IH500 column agglutination TRLP0084</p> <p>A1 test: manual using tube technology TRLP0080</p> <p>Manual test using Guest Medical acid elution technique TRLP0019</p> <p>Manual technique using BioRad column agglutination technology TRLP0031</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
EDTA whole Blood Plasma	Crossmatch- Compatibility testing of patient plasma with donor cells	Manual serological crossmatch using BioRad column agglutinin IAT TRLP0029 Electronic Crossmatch TRLP0098 Manual Neonatal serological Crossmatching using BioRad column agglutination TRLP0041
Blood	<u>Immunology examination activities for the purpose of clinical diagnosis</u> Cryoglobulins	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Manual methodology HASOPP-0005
Serum	Protein analysis and monoclonal band quantification: gamma globulins, beta-2 globulins, beta-1 globulins, alpha-2 globulins, alpha-1 globulins albumin	Sebia Capillarys 3 using capillary zone electrophoresis HASOPP-0008
Urine	Bence-Jones protein	Sebia Hydrasys 2 using agarose gel electrophoresis HASOPP-0007 HASOPP-0009
Blood, urine	Paraprotein typing: IgG, IgM, IgA, IgD, IgE, kappa, lambda	Sebia Hydrasys 2 using agarose gel electrophoresis immunofixation HASOPP-0007



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Anti-nuclear antibodies screen</p> <p>Smooth muscle antibodies Mitochondrial antibodies Liver and kidney microsomal antibodies</p> <p>IgG antibodies against the GBM (glomerular basement membrane) antigen</p> <p>IgG antibodies against MPO (myeloperoxidase) antigen</p> <p>IgG class autoantibodies directed against PR3 (proteinase 3) antigen</p> <p>Autoimmune test – Beta 2 glycoprotein 1 (B2GP-1); components for IgM and IgG</p> <p>ENA screen and ENA profile</p> <p>Tissue Transglutaminase</p> <p>Cardiolipins; components for IgG and IgM</p> <p>IgG antibodies directed Double stranded DNA (dsDNA)</p> <p>TSH Receptor Antibodies</p> <p>Intrinsic Factor Antibodies</p> <p>IgG antibodies directed to M2</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>IL Quantalyser 2 using immunofluorescence</p> <p>Hep2 method IMSOP121, IMSOP127, IMSOP168, IMSOP169</p> <p>LKS method</p> <p>Phadia 250 ELISA IMSOP179, IMSOP170</p> <p>IMSOP179, IMSOP170</p> <p>IMSOP179, IMSOP170</p> <p>IMSOP179, IMSOP170</p> <p>IMSOP179, IMSOP170</p> <p>IMSOP179</p> <p>IMSOP142</p> <p>IMSOP179, IMSOP170</p> <p>IMSOP179, IMSOP170</p> <p>IMSOP176</p> <p>IMSOP179</p> <p>IMSOP170, IMSOP179</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Specific IgE to:</p> <p>Almond Aspergillus fumigatus Banana Blue Mussel Brazil nut Cashew nut Cat epithelium and dander Cheddar cheese Coconut Common wasp Dog dander Egg white Egg yolk</p> <p>Feather mix:</p> <ul style="list-style-type: none"> • Goose • Chicken • Duck • Turkey <p>Fish Gluten</p> <p>Grass pollen mix:</p> <ul style="list-style-type: none"> • Cocksfoot • Meadow fescue • Rye • Timothy • Meadow <p>Hazel nut Honey bee Horse dander House dust mite Kiwi Latex Macadamia nut Milk</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Phadia 250 ELISA</p> <p>IMSOP166, IMSOP170</p>



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Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Specific IgE to: (cont'd)</p> <p>Mould mix:</p> <ul style="list-style-type: none"> • Penicillium chrysogenum • Cladosporium herbarium • Aspergillus fumigatus • Alternaria alternata <p>Peanut Pecan nut Pine nut pignols Pistachio nut Rabbit epithelium Sesame seed Shrimp Soya bean Strawberry</p> <p>Tomato</p> <p>Tree pollen mix:</p> <ul style="list-style-type: none"> • Box elder • Silver birch • Oak • Elm • Walnut <p>Walnut</p> <p>Weed pollen mix:</p> <ul style="list-style-type: none"> • Ambrosia artemisiifolia • Artemisia vulgaris • Plantago lanceolata • Chenopodium album <p>Wheat</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Phadia 250 ELISA</p> <p>IMSOP166, IMSOP170</p>

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