Schedule of Accreditation

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Cambridge University Hospitals NHS Foundation Trust

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Blood Science Department
Box 232
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 0QQ

Contact: Rebecca Stevens
Tel: +44 (0)1223 808018
E-Mail: Rebecca.stevens7@nhs.net
Website: http://www.cuh.org.uk/

Testing performed at the above address only

Location details		Activity
Main Theatres 1,2 Box 206 Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ	**Local contact** Katherine Philpott	Blood Issue Fridge No testing occurs, blood storage only
ATC Box 283 Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ	**Local contact** Katherine Philpott	Blood Issue Fridge No testing occurs, blood storage only

Location details		Activity
Oncology Box 193 Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ	**Local contact** Katherine Philpott	Blood Issue Fridge No testing occurs, blood storage only
Neonatal unit Box 226 Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ	**Local contact** Katherine Philpott	Blood Issue Fridge No testing occurs, blood storage only
Delivery Unit Rosie Maternity Box 222 Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ	**Local contact** Katherine Philpott	Blood Issue Fridge No testing occurs, blood storage only
Haematology Day unit Box 259 Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ	**Local contact** Katherine Philpott	Blood Issue Fridge No testing occurs, blood storage only
A&E - Resuscitation Addenbrooke's Hospital Hills Road Cambridge CB2 0QQ	**Local contact** Katherine Philpott	Blood Issue Fridge No testing occurs, blood storage only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> <u>Haematology</u>	In house documented methods incorporating manufacturers' instructions where relevant
EDTA Whole Blood	Full blood count- automated differential: Total White Cell Count (WBC) Red Cell Count (RBC) Haemoglobin (Hb) Platelet Count MCV MCH MCHC RDW MPV PCT PDW NRBC Neutrophils Lymphocytes Monocytes Eosinophils Basophils	<u>Automated</u> Siemens Advia 2120i analyser SOP ADD.HAE 5345 SOP ADD.HAE 5348 SOP ADD.HAE 5346
EDTA Whole Blood	Reticulocyte count	<u>Automated</u> Advia 2120i ADD.HAE 16198 <u>Manual</u> Manual method using GCC diagnostics reticulocyte stain – Supra vital stain SOP ADD.HAE 16198

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities (cont'd)	In house documented methods
Whole Blood	Blood film examination: Detection of normal and abnormal morphologies and white blood cell differential	Manual Staining Giemsa staining using Haematek semi-automated stainer SOP ADD.HAE 8719 Blood film examination by light microscopy SOP ADD.HAE 16173 SOP ADD.HAE 32355
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Desega S2000-Sedivette® ESR System SOP ADD.HAE 16171
	Haemoglobinopathy	Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia Screening Programme(s) as defined in the laboratory QA evidence requirements.
Whole Blood	Quantification of: HbA HbA2 HbF HbS Identification/ Quantitation of other Variant Hb: HbC, HbD, HbE	Primary Screening Capillary electrophoresis using Sebia CAPILLARYS 3 OCTA Analyser SOP ADD.HAE 11699

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities (cont'd)	In house documented methods
Whole Blood	Quantification of: HbA HbA2 HbF HbS Identification/ Quantitation of other Variant Hb: HbC, HbD, HbE	Haemoglobin Variant Confirmation by Tosoh G11 HPLC Electrophoresis analyser (SOP ADD.HAE 10870)
Whole Blood	Blood Film examination for Malarial Parasites (Thick and Thin film examination) Detection of Malarial parasites of: P. *falciparum,* P. *malariae*, P. *ovale* & P. *vivax*	Film examination, staining of malarial parasites Giemsa stain and reversed field stain (pH7.2). Staining of malarial thick films. SOP ADD.HAE16173 SOP ADD.HAE 16347 SOP ADD.HAE 16346 SOP ADD.HAE 16345 SOP ADD.HAE 16341
Whole Blood	Detection of Malarial antigens of: P. *falciparum* Pan-detection for P. *malariae*, P. *ovale* & P. *vivax*	Carestart Malaria Rapydtest HRPII Card SOP ADD.HAE 6403
Whole Blood	Detection of Malarial Parasites	DNA amplification assay - Alethia Incubator/Reader® Alethia screen DNA Lamp technology (SOP ADD.HAE 11434)
Plasma/ Serum	Glandular Fever (Infectious Mononucleosis) - heterophile antibodies to Epstein Barr Virus	Biokit Monogen Infectious Mononucleosis Kit SOP ADD.HAE 16182
Blood	Glucose 6 Phosphate Dehydrogenase (G6PD)	Trinity Biotech Fluorescent Spot Test SOP ADD.HAE6395 SOP ADD.HAE 16336

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities</u> (cont'd)	In house documented methods
	<u>Coagulation</u>	
Plasma		<u>Automated</u> ACL-TOP 750 Analyser SOP ADD.HAE 32304
	Prothrombin Time (PT)	SOP ADD.HAE 32307
	Activated Partial Thromboplastin Time (APTT)	SOP ADD.HAE 32456
	Thrombin time (TT)	SOP ADD.HAE 32305
	INR determination	SOP ADD.HAE 32311
	D-dimer	SOP ADD.HAE 32309
	Fibrinogen assay	SOP ADD.HAE 32310
	Anti-Xa assay	SOP ADD.HAE 32312
	<u>Specialized haemostasis examination activities for clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
Plasma	<u>Clotting Factor Assays</u>	ACL-TOP 750 Analyser using CE marked/ Werfen Locked one stage clot-based assays unless otherwise indicated
	Factor VIII	One stage clot based SOP ADD.HAE 32332
		Chromogenic FVIII SOP ADD.HAE 32341
		Refacto Factor VIII SOP ADD.HAE 32352
	Factor IX	SOP ADD.HAE 32332
	Factor XI	SOP ADD.HAE 32332
	Factor XII	SOP ADD.HAE 32332
	Factor II	SOP ADD.HAE 32294

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
	Clotting Factor Assays (cont'd) Factor X	ACL-TOP 750 Analyser One stage clot based OP ADD.HAE 32294
		Chromogenic Factor X (Biophen) - SOP ADD.HAE 32342
		Factor X Antigen ELISA (Zymutest ELISA) SOP ADD. HAE.32293
	Factor V	SOP ADD.HAE 32294
	Factor VII	SOP ADD.HAE 32294
	Factor XIII	SOP ADD.HAE 32343
Plasma unless specified	Factor Inhibitor screens and quantification assays:	Semi-automated techniques performed with manual initial set up and automated clot-based measurements on the ACL-TOP 750 Analyser
	Immediate acting intrinsic factor inhibitor screen	SOP ADD.HAE 32337
	Time dependent intrinsic factor inhibitor screen	SOP ADD.HAE 32336
	Immediate acting extrinsic Factor inhibitor screen	SOP ADD.HAE 32296
	Time dependent extrinsic Factor inhibitor screen	SOP ADD.HAE 32295
	Intrinsic factor Bethesda Inhibitor assay	SOP ADD.HAE 32338
	Extrinsic factor Bethesda Inhibitor assay	SOP ADD.HAE32298
	Nijmegan modification Intrinsic factor Bethesda Inhibitor assay	SOP ADD.HAE 827
	Nijmegan modification Factor IX Bethesda Inhibitor Assay	SOP ADD.HAE 10898
	Nijmegan modification Extrinsic factor Bethesda Inhibitor assay	SOP ADD.HAE 32297

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
Plasma	Investigation of Willebrand's Disease	ACL-TOP750 analyser or Acustar automated analyser (Werfen - SOP ADD.HAE 5240) using CE marked/Werfen locked assays
	von Willebrand Factor Antigen	SOP ADD.HAE 32322 & ADD.HAE 11010
	von Willebrand Factor Activity	vWF:Ab – monoclonal antibody to VWF A1 domain epitope - ACL-TOP750 SOP ADD.HAE 32321
		Ristocetin-induced binding of VWF to a recombinant WT GPIb fragment using chemiluminescence SOP ADD.HAE 2572
		VWF Collagen Binding Activity using chemiluminescence (Acustar (Werfen) SOP ADD.HAE 5683
		VWF Collagen Binding Activity Zymutest Collagen Binding Assay ELISA SOP ADD.HAE 32135
		Platelet Ristocetin CoFactor Activity PAP8E SOP ADD.HAE 32221
Plasma	Thrombophilia	ACL-TOP 750 Analyser using CE marked/ Werfen Locked assays unless otherwise indicated
	Protein C	SOP ADD.HAE 32319
	Free Protein S	SOP ADD.HAE 32318
	Antithrombin (Human Factor X based Antithrombin Activity)	SOP ADD.HAE 4970
	Human Factor II Based Antithrombin Activity	Using STAGO STAchrom kit SOP ADD.HAE 32327
	DRVVT	SOP ADD.HAE 32243
	APTT Lupus Ratio	SOP ADD.HAE 2356

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
	Thrombophilia (cont'd)	ACL-TOP 750
	HemosIL DTI - Dilute Thrombin Time	SOP ADD.HAE 7674:
	Activated Protein C Sensitivity	SOP ADD.HAE 32320
	Heparin Induced Thrombocytopaenia (H.I.T.)	
Plasma	AcuStar HIT-IgG Screen	Acustar automated analyser (Werfen) SOP ADD.HAE 1821
	ACL-TOP HIT Ab (PF4-H) Screen	ACL-TOP 750 Analyser SOP ADD.HAE 398
Plasma	Thrombin Generation	Thrombinoscope Calibrated Automated Thrombography using in house reagent formulations SOP ADD.HAE. 32168
	Lag Time	Citrate Platelet Poor Plasma SOP ADD.HAE. 32168
		Corn Trypsin Inhibitor Platelet Poor Plasma SOP ADD.HAE. 32168
	Endogenous Thrombin Potential	Citrate Platelet Poor Plasma SOP ADD.HAE. 32168
		Corn Trypsin Inhibitor Platelet Poor Plasma SOP ADD.HAE. 32168
	Peak Thrombin	Citrate Platelet Poor Plasma SOP ADD.HAE. 32168
		Corn Trypsin Inhibitor Platelet Poor Plasma SOP ADD.HAE. 32168

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
	Thrombin Generation (cont'd)	Thrombinoscope
	Time to Peak	Citrate Platelet Poor Plasma SOP ADD.HAE. 32168
		Corn Trypsin Inhibitor Platelet Poor Plasma SOP ADD.HAE. 32168
	Velocity Index	Citrate Platelet Poor Plasma SOP ADD.HAE. 32168
		Corn Trypsin Inhibitor Platelet Poor Plasma SOP ADD.HAE. 32168
Plasma	ADAMTS13 activity and ADAMTS13 inhibitor	Commercial ELISA sourced from Pathways Diagnostics (Technozym)
	ADAMTS-13 Activity	Technozym ELISA SOP ADD.HAE 3215
	ADAMTS-13 Inhibitor quantification	Technozym ELISA SOP ADD.HAE 1543
	Platelet Function Analysis	
	Collagen/ ADP agglutination	PFA-100 analyser SOP ADD HAE 32217
	Collagen/ Epinephrine Agglutination	PFA-100 analyser SOP ADD HAE 32217
Platelet Rich Plasma	Light Transmission Platelet Aggregometry	PAP-8E semi-automated platelet aggregometer using Borne Aggregation
	ADP 2.5µM	SOP ADD.HAE. 32104
	ADP 5µM	SOP ADD.HAE. 32104
	ADP 10µM	SOP ADD.HAE. 32104
	ADP 20µM	SOP ADD.HAE. 32104
	Arachidonic Acid 1.5mM	SOP ADD.HAE. 32104
	Collagen 1.0µg/mL	SOP ADD.HAE. 32104
	Collagen 2.0µg/mL	SOP ADD.HAE. 32104
	Ristocetin 1.5mg/mL	Agglutination SOP ADD.HAE. 32104

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
	Platelet Function Analysis (cont'd)	PAP-8E
	Ristocetin 0.5mg/mL	Agglutination SOP ADD.HAE. 32104
	TRAP6 12.5µM	SOP ADD.HAE. 32104
	U46619 5µM	SOP ADD.HAE. 32104
Whole Blood	Impedance aggregometry for investigation of bleeding disorders	Multiplate analyser impedance aggregometry
	ADP 3.3µM	SOP ADD.HAE. 1169
	ADP 6.6µM	SOP ADD.HAE. 1169
	Arachidonic Acid 0.5mM	SOP ADD.HAE. 1169
	Collagen 0.65µg/mL	SOP ADD.HAE. 1169
	Ristocetin 0.77mg/mL	SOP ADD.HAE. 1169
	Ristocetin 0.20mg/mL	SOP ADD.HAE. 1169
	TRAP6 4µM	SOP ADD.HAE. 1169
	U46619 1.6µM	SOP ADD.HAE. 1169
	Spontaneous Aggregation	SOP ADD.HAE. 1169
Whole Blood	Impedance aggregometry for investigation of antiplatelet therapy	Multiplate analyser impedance aggregometry
	ADPTest	SOP ADD.HAE. 1375
	TRAPTest	SOP ADD.HAE. 1375
	ASPITest	SOP ADD.HAE. 1375
Platelet Rich Plasma	Platelet Nucleotide Analysis	Biorad Biologic Duoflow HPLC – in house method
	ADP Nucleotides	SOP ADD.HAE 32130
	ATP Nucleotides	SOP ADD.HAE 32130
	Total Nucleotides	SOP ADD.HAE 32130
	ATP/ADP Ratio	SOP ADD HAE 32130

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
Whole Blood	Rotational Thromboelastometry	Performed on the ROTEM – Delta (Werfen) with reagents sourced from Werfen
	Clot Time	Non-Activated Rotational Thromboelastometry (NATEM) SOP ADD.HAE. 32170 Extrinsic Thromboelastometry (EXTEM) SOP ADD.HAE. 7725 Functional Fibrinogen Rotational thromboelastometry (FIBTEM) SOP ADD.HAE. 8663
	Clot Formation Time	Non-Activated Rotational Thromboelastometry (NATEM) SOP ADD.HAE. 32170 Extrinsic Thromboelastometry (EXTEM) SOP ADD.HAE. 7725
	Angle	Non-Activated Rotational Thromboelastometry (NATEM) SOP ADD.HAE. 32170 Extrinsic Thromboelastometry (EXTEM) SOP ADD.HAE. 7725
	Area under curve	Non-Activated Rotational Thromboelastometry (NATEM) SOP ADD.HAE. 32170 Extrinsic Thromboelastometry (EXTEM) SOP ADD.HAE. 7725 Functional Fibrinogen Rotational Thromboelastometry (FIBTEM) SOP ADD.HAE. 8663

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
Whole Blood (cont'd)	Rotational Thromboelastometry (cont'd)	ROTEM – Delta (Werfen) (Cont'd)
	Maximum Clot Firmness	Non-Activated Rotational Thromboelastometry (NATEM) SOP ADD.HAE. 32170 Extrinsic Thromboelastometry (EXTEM) SOP ADD.HAE. 7725 Functional Fibrinogen Rotational Thromboelastometry (FIBTEM) SOP ADD.HAE. 8663
	Time to maximum velocity	Non-Activated Rotational Thromboelastometry (NATEM) SOP ADD.HAE. 32170 Extrinsic Thromboelastometry (EXTEM) SOP ADD.HAE. 7725 Functional Fibrinogen Rotational Thromboelastometry (FIBTEM) SOP ADD.HAE. 8663
	Maximum Lysis	Non-Activated Rotational Thromboelastometry (NATEM) SOP ADD.HAE. 32170 Extrinsic Thromboelastometry (EXTEM) SOP ADD.HAE. 7725
Plasma	A20	Functional Fibrinogen Rotational Thromboelastometry (FIBTEM) - SOP ADD.HAE. 8663 SOP ADD.HAE. 8663

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Specialized haemostasis examination activities</u> (cont'd)	In house documented methods
	<u>Direct Oral Anticoagulants</u>	ACL-TOP 750 Analyser using CE marked/Werfen Locked assays with backup assays using biophen reagent
Plasma unless specified	Dabigatran Quantification	ACL-TOP750 (Werfen Assay) SOP ADD HAE 6026 ACL-TOP 750 (Biophen Assay) SOP ADD.HAE 988
	Rivaroxaban Quantification	ACL-TOP750 ((Werfen Biophen Assay) SOP ADD.HAE. 843 ACL-TOP 750 (Biophen Werfen Assay) SOP ADD.HAE 6249
	Apixaban Quantification	ACL-TOP750 (Werfen Biophen Assay) SOP ADD.HAE. 2956 ACL-TOP 750 (Biophen Werfen Assay) SOP ADD.HAE. 5967
	Edoxaban Quantification	ACL-TOP750 (Werfen Assay) SOP ADD. HAE. 8379
	<u>Investigation of Fibrinolysis</u>	ACL-TOP 750 Analyser using CE marked/Werfen Locked assays.
Plasma unless specified	Plasmin Inhibitor	SOP ADD.HAE. 5227
	Plasminogen	SOP ADD.HAE. 5226
ADD	Thrombin Induced Lysis Time	SOP ADD.HAE 8411
	PAI-I antigen	SOP ADD.HAE 32150 (ELISA)
	TAFI:Ag	SOP ADD.HAE 32151 (ELISA)
	Thrombin-Antithrombin Complex	SOP ADD.HAE. 32152 (ELISA)
	Prothrombin Fragment F1+2	SOP ADD.HAE 8428 (ELISA)
	tPA – Tissue Plasminogen Activator	SOP ADD.HAE 32154 (ELISA)
	<u>Miscellaneous ELISA</u>	
Plasma	Tissue Factor Pathway Inhibitor (TFPI)	SOP ADD.HAE 32153

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Specialized haemostasis examination activities</u> (cont'd)	In house documented methods
	<u>Routine Assays of Haemostasis</u>	ACL-TOP 750 Analyser SOP ADD.HAE 32305
Plasma unless specified	Prothrombin Time	PT based INR for Warfarin Control SOP ADD.HAE 32307
	INR	PT based INR for Warfarin Control SOP ADD.HAE 32307
	APTT	SOP ADD.HAE 32456
	Thrombin Time	SOP ADD.HAE 32305
	Liquid Heparin Anti Xa	SOP ADD.HAE 32312
	D-dimer	SOP ADD.HAE 32309
	Fibrinogen	Quantified Fibrinogen Assay (QFA) SOP ADD.HAE 32310
	Fibrinogen Antigen	ACLTOP Liaphen Fibrinogen Assay SOP ADD.HAE 1164
		Semi-automated assays - KC10
	Prothrombin Time	SOP ADD.HAE 32119
	APTT	SOP ADD.HAE 32120
	Reptilase Time	SOP ADD.HAE 32251
Citrated whole blood	Post-infusion monitoring of Refixia, Benefix or Alprolix Rossix	ACL-TOP chromogenic method. SOP:Rossix Chromogenic Factor IX Add.Hae 11385
	Quantitative analysis of dense granule release via direct measurement of ATP secretion in response to different agonists	Chrono-log Platelet Nucleotide Release screen Chrono-Lume kit SOP ADD.HAE 11369:
	Argatroban	HemosIL DTI Assay for Argatroban measured on ACL-TOP SOP : HemosIL DTI Assay for Argatroban Add.Hae 11081
	Emicizumab	Emicizumab Assay kit from r^2 Diagnostics ACL TOP analyser using a modified OSCA assay using IL- SynthASil APTT, IL-SynthASil $CaCl_2$ and FVIII deficient plasma SOP Add.Hae 9183

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Specialized haemostasis examination activities (cont'd)	In house documented methods
	FVIII concentrate levels for patients on Emicizumab	Bovine Chromogenic Factor VIII Add.Hae 11086 Bovine Chromogenic FVIII Bethesda Add.Hae 11367
	Factor VIII level in acquired Haemophilia A patients and congenital haemophilia A patients with inhibitors that have been treated with Obizur	Porcine Factor VIII Add.Hae 11380 Porcine Factor VIII Bethesda Add.Hae 11382
	Blood Transfusion examination activities for the purpose of clinical diagnosis:	Documented procedures based on manufacturer's instructions
Whole blood (EDTA)	Blood grouping by antigen detection: • ABO blood groupRhD type	Automated - Ortho Swift analyser cell screen using glass bead column agglutination technology SOP ADD.HAE 5551 Manual – Ortho cards cell screen using card column agglutination technology SOP ADD.HAE 16250 Manual - BioRad BioRad card column agglutination technology SOP ADD.HAE 16250 SOP ADD.HAE 16206 Manual – Tube SOP ADD.HAE 16250 SOP ADD.HAE 16206

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis: (cont'd)	Documented procedures based on manufacturer's instructions
Whole blood (EDTA)	Antibody screening for the identification of the following antibodies: D,C,E,c,e,Cw,K,k,Kpa, ,Fya,Fyb,Jka,Jkb,Lea,Leb,P, P1,M,N,S,s,Lua,	Manual – Ortho Swift cell screen using card column agglutination technology SOP ADD.HAE 16250 Manual - BioRad 3 cell screen using BioRad card column agglutination technology SOP ADD.HAE 16250 SOP ADD.HAE 16206 Manual – Tube 3 cell screen SOP ADD.HAE 16250 SOP ADD.HAE 16206
Whole blood (EDTA)	Direct Antiglobulin Test (DAT) for identification of IgG and C3d red cell coating	Automated Quidel Ortho Vision analyser SOP ADD.HAE 16226 Manual – Ortho Vision Card column agglutination technology SOP ADD.HAE 2606 Manual - BioRad BioRad card column agglutination technology SOP ADD.HAE 16226 Manual – Tube SOP ADD.HAE 16226

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis: (cont'd)	Documented procedures based on manufacturer's instructions
Whole blood (EDTA)	Red cell phenotyping: Rh & K blood group antigens: C, c, E, e, K	Automated Ortho Swift analyser cell screen using glass bead column agglutination technology SOP ADD.HAE 16226 Manual – Ortho Vision card column agglutination technology SOP ADD.HAE 32257 Manual - BioRad BioRad card column agglutination technology SOP ADD.HAE 32257
Whole blood (EDTA)	Red cell phenotyping: Jka, Jkb, Fya, Fyb, M, N, S, s	Manual – Ortho Vision card column agglutination technology SOP ADD.HAE 16250
Whole blood (EDTA)	Antibody investigation for the identification of the following antibodies: D,C,E,c,e,Cw,K,k,Kpa,Fya,Fyb,Jka, Jkb,Lea,Leb,P1,M,N,S,s,Lua,	Manual – Ortho Vision Card column agglutination technology SOP ADD.HAE 16250 Manual - BioRad 10 cell panel using BioRad card column agglutination technology SOP ADD.HAE 16209 SOP ADD.HAE 3384 SOP ADD.HAE 16239 SOP ADD.HAE 1313 SOP ADD.HAE 789 SOP ADD.HAE 16231 Manual – Tube 10 cell panel SOP ADD.HAE 16209 SOP ADD.HAE 3384

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis: (cont'd)	Documented procedures based on manufacturer's instructions
Whole blood (EDTA)	Antibody titration: Titration of anti-A and Anti-B against A1, A2 and B cells	Manual - BioRad BioRad card column agglutination technology SOP ADD.HAE 32029
Whole blood (EDTA)	Titration of the following antibodies against a heterozygous expression of the corresponding antigen for determination of the risk of Haemolytic Disease of the Newborn and Fetus: C,E,e,Cw,K,Kpa ,Fya,Fyb,Jka,Jkb M,S,s	Manual - BioRad BioRad card column agglutination technology SOP ADD.HAE 32452
Whole blood (EDTA)	Compatibility testing: Serological crossmatch – serological compatibility testing between donor red cell antigens and patient plasma	Automated Ortho Swift analyser cell screen using glass bead column agglutination technology SOP ADD.HAE 16212 SOP ADD.HAE 2425 Manual – Ortho Vision Card bead column agglutination technology SOP ADD.HAE 16212 Manual - BioRad BioRad card column agglutination technology SOP ADD.HAE 16212 Manual – Tube SOP ADD.HAE 16212
Whole blood (EDTA)	Detection and estimation of Feto-Maternal Haemorrhage	Flow cytometry FACS Canto SOP ADD.HAE 32031
Whole Blood (EDTA)	Fetomaternal Haemorrhage Assessment	Kleihauer Acid Elution Technique Guest Medical kit SOPADD.HAE.32060

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis</u>	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified	Antinuclear antibody specificities (ANA)	ADD.BIO 5855 ANA CTD
	ANCA MPO	ADD.BIO 5848 ANCA MPO
	Ds DNA antibody	ADD.BIO 5853 dsDNA
	CCP antibodies	ADD.BIO 5854 CCP
	ENA antibodies	ADD.BIO 5850 ENA Profile & 5852 ENA Screen
	ANCA PR3	ADD.BIO 5847 ANCA PR3
	GBM antibodies	ADD.BIO 5849 GBM
	Tissue Transglutaminase IgG antibody	ADD.BIO 5845 TTG (IgG)
	Tissue Transglutaminase IgA antibody	ADD.BIO 5826
	Total IgE	ADD.BIO 5844 IgE
	Specific IgE(include all allergens)	ADD.BIO 5846 Specific IgE
	Specific IgE nut mix (fx1)	
	Specific IgE nut mix (fx22)	
	Specific IgE rPru p 4 Profilin Peach (f421)	
	Specific IgE walnut (f256)	
	Specific IgE alder tree (t2)	
	Specific IgE almond nut (f20)	
	Specific IgE alternaria alternata (m6)	
	Specific IgE amoxicilloyl (c6)	
	Specific IgE ampicilloyl (c5)	
	Specific IgE anisakis p4	
	Specific IgE anchovy (f313)	
	Specific IgE animal dander mix (ex1)	
	Specific IgE apple (f49)	
	Specific IgE apricot (f237)	
	Specific IgE ascaris p1	
	Specific IgE aspergillus flavus (m228)	
	Specific IgE aspergillus fumigatus (m3)	
	Specific IgE aspergillus niger (m207)	
	Specific IgE(include all allergens)	
	Specific IgE aubergine (f262)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE avocado (f96) Specific IgE banana (f92) Specific IgE barley (f6) Specific IgE beech tree (t5) Specific IgE beef meat (f27) Specific IgE blue mussel (f37) Specific IgE Blueberry (f288) Specific IgE Box Elder Specific IgE brazil nut (f18) Specific IgE broccoli (f260) Specific IgE Bromelain MUXF3 CCD (o214) Specific IgE Buckwheat (f11) Specific IgE budgerigar feathers (e78) Specific IgE Budgerigar, Canary,Parakeet, Parrot,finch feathers (ex72) Specific IgE bumble bee venom (i205) Specific IgE canary feathers (e201) Specific IgE candida albicans(m5) Specific IgE Carrot (f31) Specific IgE cashew nut (f202) Specific IgE Cat dander (e1) Specific IgE cefaclor (c7) Specific IgE celery (f85) Specific IgE Cheese (Mould Type) (f82) Specific IgE cheese(cheddar type) (f81) Specific IgE cherry (f242) Specific IgE chicken feather (e85) Specific IgE chicken meat (f83) Specific IgE chilli pepper (f279) Specific IgE chlorhexidine (c8) Specific IgE chocolate (f93) Specific IgE cladosporium herbarum (m2) Specific IgE cocksfoot (g3) Specific IgE coconut (f36)	ADD.BIO 5846 Specific IgE

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE(include all allergens) Specific IgE Cockroach (i6) Specific IgE cod (f3) Specific IgE coffee (f221) Specific IgE Common Wasp Venom (i3) Specific IgE coriander (f317) Specific IgE cow dander (e4) Specific IgE cow milk (f2) Specific IgE cow whey (f236) Specific IgE crab(f23) Specific IgE cucumber (f244) Specific IgE cultivated wheat pollen (g15) Specific IgE date (f289) Specific IgE dog dander (e5) Specific IgE Duck feathers (e86) Specific IgE egg white (f1) Specific IgE egg yolk (f75) Specific IgE ethylene oxide (k78) Specific IgE european hornet venom (i75) Specific IgE ferret epithelium (e217) Specific IgE fig (f328) Specific IgE fish Mix (fX2) Specific IgE food mix (fx5) Specific IgE fowl mix, Goose,Chicken,Duck,Turkey feathers (ex71) Specific IgE Gal-Alpha-1, 3-Gal Thyroglobulin, Bovine (o215) Specific IgE garlic (f47) Specific IgE gelatin (C74) Specific IgE gerbil epithelium (e209) Specific IgE ginger (f270) Specific IgE gluten (f79) Specific IgE goat epithelium (e80) Specific IgE goat milk (f300) Specific IgE golden rod (w12) Specific IgE goose feather (e70) Specific IgE goosefoot (w10)	ADD.BIO 5846 Specific IgE

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE(include all allergens) Specific IgE grape (f259) Specific IgE grapefruit (f209) Specific IgE grass mix (gx1) Specific IgE green bean (f315) Specific IgE guinea pig epithelium (e6) Specific IgE haddock (f42) Specific IgE hamster epithelium (e84) Specific IgE hazel nut (f17) Specific IgE hazel tree (t4) Specific IgE herring (f205) Specific IgE Honey Bee Venom (i1) Specific IgE horse dander (e3) Specific IgE horse fly (i204) Specific IgE house dust mite dermatophagoides pteronyssinus (d1) Specific IgE house dust mite. d.farinae (d2) Specific IgE insulin human (c73) Specific IgE isocyanate MDI (k76) Specific IgE isocynate HDI (k77) Specific IgE isocynate TDI (K75) Specific IgE kidney bean (f287) Specific IgE kiwi fruit (f84) Specific IgE lamb meat (f88) Specific IgE latex (k82) Specific IgE lemon (f208) Specific IgE lentil (f235) Specific IgE lettuce (f215) Specific IgE linseed (f333) Specific IgE lobster (f80) Specific IgE London Plane (T11) Specific IgE lupin seed (f335) Specific IgE macadamia nut (f345) Specific IgE mackerel (f206) Specific IgE maize (f8) Specific IgE mango (f91) Specific IgE meadow fescue (g4)	ADD.BIO 5846 Specific IgE

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE(include all allergens) Specific IgE mealworm (o211) Specific IgE melon (f87) Specific IgE maize corn (g202) Specific IgE mint (f332) Specific IgE morphine (c260) Specific IgE mosquito (i71) Specific IgE mould mx1-penicillium etc (m1) Specific IgE mouse epithelium (e71) Specific IgE mouse urine (e72) Specific IgE mugwort (w6) Specific IgE mushroom (f212) Specific IgE mustard (f89) Specific IgE nBos d 4 alpha-lactalbumin (f76) Specific IgE nBos d 5 beta-lactoglobulin (f77) Specific IgE nettle (w20) Specific IgE nGal d 3 Conalbumin (f323) Specific IgE nGal d 4 Lysozyme (k208) Specific IgE oak tree (t7) Specific IgE oat (f7) Specific IgE olive tree (t9) Specific IgE omega 5 gliadin (f416) Specific IgE onion (f48) Specific IgE orange (f33) Specific IgE Ovoalbumin nGal d2 (f232) Specific IgE Ovomucoid nGal d1 (f233) Specific IgE oyster (f290) Specific IgE paperwasp venom (i77) Specific IgE paprika (f218) Specific IgE papaya (f293) Specific IgE parrot feathers (e213) Specific IgE passion fruit (f294) Specific IgE pea (f12) Specific IgE peach (f95)	ADD.BIO 5846 Specific IgE

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE(include all allergens) Specific IgE peanut (f13) Specific IgE pear (f94) Specific IgE pecan nut (f201) Specific IgE penicilloyl G (c1) Specific IgE penicilloyl V (c2) Specific IgE pepper green (f263) Specific IgE pholocodine (c261) Specific IgE pigeon feathers (e215) Specific IgE pine tree (t213) Specific IgE pineapple (f210) Specific IgE pinenut (f253) Specific IgE pistachio nut (f203) Specific IgE plaice (f254) Specific IgE plantain (w9) Specific IgE plum (f255) Specific IgE Pollock f413 Specific IgE poppy seed (f224) Specific IgE pork meat (f26) Specific IgE potato (f35) Specific IgE pumpkin seed (f226) Specific IgE Quinoa Specific IgE rabbit epithelium (e82) Specific IgE ragweed (w3) Specific IgE rAna O 3 Cashew Nut (f443) Specific IgE rAra h6 peanut (f447) Specific IgE rape pollen (w203) Specific IgE rape seed (f316) Specific IgE rApi m 10 Honey Bee (i217) Specific IgE rApi m 2 Honey Bee (i214) Specific IgE rApi m 3 Honey Bee (i215) Specific IgE rApi m 5 Honey Bee (i216) Specific IgE rApi M1 phospholipase A2, honey bee (i208) Specific IgE rAra h1 peanut (f422) Specific IgE rAra h2 peanut (f423)	ADD.BIO 5846 Specific IgE

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE(include all allergens) Specific IgE rAra h3 PEANUT (f424) Specific IgE rAra h8 pr-10 peanut (f352) Specific IgE rAra h9 ltp peanut (f427) Specific IgE raspberry (f343) Specific IgE rat epithelium (e73) Specific IgE rat urine (e74) Specific IgE rBer e1 (f354) Specific IgE rBet v 2 Profilin Birch (t216) Specific IgE rBet v 4 Birch (t220) Specific IgE rBet v 6 Birch (t225) Specific IgE(include all allergens) Specific IgE rbetv1 pr-10 birch (t215) Specific IgE rCor a 1 PR-10 Hazel nut (f428) Specific IgE rCor a 14 Hazel nut (f439) Specific IgE rCor a 8 LTP Hazel nut (f425) Specific IgE rGly m 4 PR10 Soy (F353) Specific IgE rGly m 5 beta-conglycinin Soy (F431) Specific IgE rGly m 6 Glycinin soy (f432) Specific IgE rCor a 9 Hazel nut (f440) Specific IgE rHev b 5 Latex (k218) Specific IgE rHev b 6.02 Latex (k220) Specific IgE rice (f9) Specific igE rJug 1 Walnut (f441) Specific IgE rJug r 3 LTP Walnut (f442) Specific IgE rMal d 1 pr-10 apple (f434) Specific IgE rMal d 3 ltp apple (f435)	ADD.BIO 5846 Specific IgE

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE(include all allergens) Specific IgE rpol d5 paperwasp (i210) Specific IgE rPru p 1 PR-10 peach (f419) Specific IgE rPru P3 ltp peach (f420) Specific IgE rPru p 7 peach Specific IgE rTri a14 ltp wheat (f433) Specific IgE rves v1 (i211) Specific IgE rves v5 (i209) Specific IgE rye (f5) Specific IgE Salmon (f41) Specific IgE sardine (f308) Specific IgE scallop (f338) Specific IgE seminal fluid (o70) Specific IgE sesame seed (f10) Specific IgE sheep epithelium (e81) Specific IgE shrimp (f24) Specific IgE silver birch (t3) Specific IgE soya bean (f14) Specific IgE spinach (f214) Specific IgE squid (f258) Specific IgE storage mite acarus siro (d70) Specific IgE storage mite destructor (d71) Specific IgE strawberry (f44) Specific IgE sunflower seed (k84) Specific IgE suxamethonium (c202) Specific IgE Sweet Chestnut (f299) Specific IgE swine epithelium (e83) Specific IgE swordfish (f312) Specific IgE tea (f222) Specific IgE tilapia Specific IgE timothy grass (g6) Specific IgE tomato (f25) Specific IgE tree mix (tx8) Specific igE Tropmysin Shrimp (f351) Specific IgE tuna (f40) Specific IgE turkey feathers (E89)	ADD.BIO 5846 Specific IgE

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Thermoscientific Phadia 2500 and 250 analyser (Fluorescence Enzyme Immunoassay) (FEIA) with specific reference to:
Serum unless otherwise specified (cont'd)	Specific IgE(include all allergens) Specific IgE turkey meat (f284) Specific IgE vanilla (f234) Specific igE Weed Mix (wx3) Specific IgE wheat (f4) Specific IgE white bean (f15) Specific IgE whole egg (f245) Specific IgE willow tree (t12) Specific IgE yeast (f45)	ADD.BIO 5846 Specific IgE
	Cardiolipin IgG antibodies	ADD.BIO.5371 Cardiolipin IgG
	Cardiolipin IgM antibodies	ADD.BIO.5372 Cardiolipin IgM
	Beta 2 glycoprotein 1 IgG antibodies	ADD.BIO 5373 IgG Beta 2 glycoprotein 1 antibody
	Beta 2 glycoprotein 1 IgM antibodies	ADD.BIO 5374 IgM Beta 2 glycoprotein 1 antibody
	Specific IgG Aspergillus Fumigatus Specific IgG Pigeon Specific IgG Budgerigar	ADD.BIO 33993 Specific IgG
	Specific IgG Parrot Specific IgG micropolyspora faeni	ADD.BIO 33993 Specific IgG
	Specific IgG Insulin Antibody Mast cell tryptase	ADD.BIO 5839 Mast Cell Tryptase
	Anti-Nuclear Antibody (Hep 2)	ADD.BIO 33845 HEP2 ANA
	Liver Autoantibodies Gastric Parietal Cell Antibody	ADD.BIO 33847 Composite Block antibodies ADD.BIO.11542 LKS conjugate change
	DNA (DS) Antibody, Crithidia luciliae, IFA	ADD.BIO 33844 dsDNA Autoantibodies (Crithidia)
	ANCA	ADD.BIO 33838

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's instructions for Werfen IL Quantalyser 3000 with specific reference to:
Serum unless otherwise specified (cont'd)	Adrenal Cortex Antibody	INOVA Manual assay Autoantibodies by indirect immunofluorescence(IIF) ADD.BIO 33837 Adrenal Autoantibodies
	Islet cell antibody	INOVA Manual assay, Autoantibodies by indirect immunofluorescence(IIF) ADD.BIO 33839 Islet Cell Autoantibodies
	Pemphigoid and Pemphigus Antibody	INOVA – Assay indirect immunofluorescence Autoantibodies ADD.BIO 33842 Skin Autoantibodies
	Ovarian Antibody	INOVA – Assay indirect immunofluorescence Autoantibodies ADD.BIO 33840 Ovarian Autoantibodies
	Paraneoplastic Antibody Profile	INOVA- Assay indirect immunofluorescence (IIF) ADD.BIO 33924 Paraneoplastic Autoantibodies
	Endomysial Antibody IgA and IgG	INOVA – Assay indirect immunofluorescence (IIF) ADD.BIO 1740 Endomysial Autoantibodies ADD.BIO.11542 LKS conjugate change

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Autoantibodies by Immunoblotting and Manufacturer's assay using Euroimmun Blotmaster or Euroblot One with specific reference to:
Serum unless otherwise specified (cont'd)	Neuronal Antibody	ADD.BIO 33950 Paraneoplastic Antibody Immunoblot
	Liver Antibody	ADD.BIO 33923 Liver Autoantibodies Line Blot
	Myositis Antibodies	ADD.BIO 34223 Anti-Nuclear Antibody (ANA) Myositis Line Blot
	Scleroderma Antibody Profile	ADD.BIO 33846 Anti-Nuclear Antibody (ANA) Scleroderma Line Blot
	Histone Antibody	ADD.BIO 134 Anti ANA, Nucleosome and Histone Antibody Dot Blot
		Manufacturer's assay using Dynex DS2 Autoantibodies by ELISA with specific reference to:
	Intrinsic Factor Antibody	ADD.BIO 33811 Inova Intrinsic Factor
	Glutamic Acid Decarboxylase (GAD) Antibody	Manufacturers Euroimmun Limited Assay using manual ELISA ADD.BIO 33812 GAD 65 EuroImmun
	Acetyl Choline Receptor Antibody	Manufacturers RSR Assay using manual ELISAADD.BIO 34047 AChR
	IA2 Antibody	ADD.BIO 4334 Islet IA-2
	C1 Inhibitor (Functional)	Manufacturers Technoclone Functional complement assay and manual ELISA using SOP ADD.BIO 33855 C1 Functional

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Autoantibodies by Immunoblotting and Manufacturer's assay using Euroimmun Blotmaster or Euroblot One with specific reference to:
Serum unless otherwise specified (cont'd)	Cryoglobulin screen	Protein quantitation using in house method and SOP ADD.BIO 33931 Cryoglobulin Manufacturer's assay using Siemens BNII and Plasma protein quantitation with specific reference to:
	Complement C3/C4	ADD.BIO 5364 Complement C3 and C4 Quantitation on BNII
	IgA	ADD.BIO 5367 IgA Quantitation on BNII
	Complement 1 Inhibitor Immunochemical	ADD.BIO 5365 C1 Esterase inhibitor (chemical-C1 INH) Quantitation on BNII
	Classical and alternative Pathway Complement assay	CH100/AP100 Functional Complement Assay by Manual ELISA using Weislab Complement System ELISA ADD.BIO.11314
	IgG and IgG subclasses	ADD.BIO 5368 IgG and IgG subclasses quantitation on BNII Manufacturer's assay using Siemens BN2 and Plasma protein quantitation with specific reference to:
	CRP High sensitivity	ADD.BIO 5392 High Sensitivity CRP (hsCRP) Quantitation on BNII Analyser
	Caeruloplasmin	ADD.BIO 5366 Caeruplasmin quantitation on BNII

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's assay using Siemens BN2 and Plasma protein quantitation with specific reference to:
Serum and Fluid	Beta trace protein	ADD.BIO 5369 Beta Trace Protein Quantitation on BNII
Serum	Free Light Chains	ADD.BIO 5393 Serum Free Light Chain Quantitation on BNII Using binding-site assay
Serum unless otherwise specified	Protein Electrophoresis Immunofixation and monoclonal band quantification	Manufacturer's assay using Helena V8 Capillary zone protein electrophoresis and using SOP ADD.BIO 5394 Serum Protein Capillary Electrophoresis (Immunodisplacement and Monoclonal Band Quantitation Protein immunofixation Manufacturer's assay using Helena SAS 3 and 4 using Gel electrophoresis with specific reference to:
Urine	Bence Jones Protein Screen and quantification	ADD.BIO 3624 Urine Bence Jones Protein Screen and Quantitation
Urine and serum	Protein Immunofixation	ADD.BIO 3594 Urine and serum gel immunofixation
	Alpha-1 Antitrypsin Phenotype	Manufacturer's assay using Sebia Hydrasys and isoelectric focussing using SOP ADD.BIO 33925 Alpha 1 Antitrypsin (AAT) Phenotype
CSF, Serum	Oligoclonal banding	Manufacturer's assay using Sebia Hydrasys and isoelectric focusing for CSF Oligoclonal Banding ADD.BIO 33957 CSF Oligoclonal Banding

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	
Blood unless otherwise specified (cont'd)		Manufacturer's assay using BD Facs Lyric Flow cytometry with specific reference to:
Blood	Lymphocyte Phenotype CD3, 4, 8, 19, 56	ADD.BIO 11368 Lymphocyte Phenotyping on Becton Dickinson Facs Lyric
		Manufacturer's assay using BD Facs LyricFlow cytometry with specific reference to:
Blood unless otherwise specified	T Lymph Subset CD3, 4, 8	
	Lymphocyte Phenotyping Extended Panel	ADD.BIO 11368 Extended Lymphocyte Immunophenotype
	Alps Screen	ADD.BIO 11411ALPS Screen
	Freiberg B Cell Panel	Flow cytometric in-house methods using BD Facs Lyric with specific reference toADD.BIO 11559 Freiburg B Cell Panel
	Neutrophil Oxidative Burst	ADD.BIO 11585 DHR Neutrophil Oxidative Burst Assay
	CD62 Ligand Shedding	ADD.BIO 11607 CD62 ligand Shedding Assay
		Luminex 200 in house methods using Specific microbial antibodies with specific reference to:
	Serotype Specific APA	ADD.BIO 33991 Serotype Pneumococcal Antibody Multiplex Assay
	Tetanus IgG Antibody	ADD.BIO 608 H.influenzae type b(hib) and Tetanus Multiplexed Antibodies
	Haemophilus influenzae B (HIB) Antibody	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Luminex in house methods using Specific microbial antibodies with specific reference to:
Serum unless otherwise specified (cont'd)	SARS-CoV-2 (COVID-19) IgG Antibodies to indicate past infection	SOP ADD.BIO.11019 Multiplex assay for the detection of antibodies (IgG) to SARS-CoV-2.
Blood	TH1 Cytokine Panel	Luminex and ELISA in house Cellular activation assays using SOP ADD.BIO 33874 whole blood activation ADD.BIO 33865 Interferon gamma ELISA ADD.BIO 2771 Cytokine antibodies
Serum	Gangliosides	Ganglioside Line Blots IgG and IGM SOP ADD.BIO 33949
Serum	Neuronal Mosaics	ADD.BIO 10916 Anti NMDA, CASPR2 and LGI1 by indirect Immunofluorescence
Whole Blood	Quantiferon Gold TB	Indirect test for M.Tuberculosis QFT-Plus assay using Nil, TB1, TB2 and Mitogen collection tubes on Diasorin-Liaison analyser ADD.BIO.421

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis:	Documented in house methods and manufacturer's instructions for
Serum unless otherwise specified	Quantification of:	Siemens Atellica platform and Siemens Atellica Performance Database for:
	Alanine Aminotransferase (ALT)	Siemens Atellica Alanine Aminotransferase (ALT) SOP ADD.BIO.11005
	Aspartate Aminotransferase (AST)	Siemens Atellica Aspartate Aminotransferase (AST) SOP ADD.BIO 11055
Serum, fluid	Albumin	Bromocresol Purple (BCP) dye binding Siemens Atellica Albumin BCP (AlbP) SOP ADD.BIO11006
	Alkaline Phosphatase (ALP)	Siemens Atellica Alkaline Phosphatase (ALP) SOP ADD.BIO 11010
Serum, urine, fluid	Amylase	Siemens Atellica Amylase 2 (AMY_2) SOP ADD.BIO 11056
	Bicarbonate	Siemens Atellica Bicarbonate (CO2) SOP ADD.BIO 11201
	Bile acid	Sentinel Assay on Siemens Atellica Total Bile Acids SOP ADD.BIO 11219
Serum, urine, fluid	Calcium	Siemens Atellica Calcium (Ca) SOP ADD.BIO 11097
Serum, urine	Chloride	Siemens Atellica Sodium Potassium, Chloride by A-Lyte Integrated Multisensor SOP ADD.BIO 11143
Serum, Plasma, urine, fluid	Potassium	Siemens Atellica Sodium Potassium, Chloride by A-Lyte Integrated Multisensor SOP ADD.BIO 11143

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturer's instructions for
Serum unless otherwise specified (cont'd)	Quantification of: (cont'd)	Siemens Atellica platform and Siemens Atellica Performance Database for:
Serum, urine, fluid	Sodium	Siemens Atellica Sodium Potassium, Chloride by A-Lyte Integrated Multisensor SOP ADD.BIO 11143
Serum, plasma, urine	Creatinine	Siemens Atellica Enzymatic Creatinine 2 (ECre_2) SOP ADD.BIO 11049
	Bilirubin -direct	Siemens Atellica Direct Bilirubin 2 (DBil_2) SOP ADD.BIO 11103
Serum, fluid	Bilirubin -total	Siemens Atellica Total Bilirubin 2 (TBil_2) SOP ADD.BIO 11035
Serum	Iron 3	Siemens Atellica Iron 3 ADD.BIO. 11539
	GGT	Siemens Atellica Gamma-Glutamyl Transferase (GGT) SOP ADD.BIO 11047
Serum, Plasma, Urine, fluid	Glucose	Siemens Atellica Glucose Hexokinase 3 (GluH_3) SOP ADD.BIO 11105
	Lipase	Siemens Atellica Lipase (Lip) SOP ADD.BIO 11040
Serum	Lactate 3	Siemens Atellica Lactate 3 ADD.BIO.11594
Serum, fluid	Lactate dehydrogenase (LDH)	Siemens Atellica Lactate Dehydrogenase L-P (LDLP) SOP ADD.BIO 11043
Serum, Urine	Magnesium	Siemens Atellica Magnesium (Mg) SOP ADD.BIO 11039

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for
Serum unless otherwise specified (cont'd)	Quantification of: (cont'd)	Siemens Atellica platform and Siemens Atellica Performance Database for:
Serum, Plasma, Urine, fluid	Phosphate	Siemens Atellica Inorganic Phosphorus (IP) SOP ADD.BIO 11109
Serum, Urine, fluid	Total Protein	Siemens Atellica Total Protein II (TP) SOP ADD.BIO 11115
Serum, Urine, fluid	Urea	Siemens Atellica Urea Nitrogen (UN_c) SOP ADD.BIO 11017
Serum, Urine, fluid	Uric acid	Siemens Atellica Uric Acid (UA) SOP ADD.BIO 11018
	CK	Siemens Atellica Creatine Kinase (CK L) SOP ADD.BIO 11052
Serum, Fluid	Cholesterol	Siemens Atellica Cholesterol 2 (Chol 2) SOP ADD.BIO 11053
	HDL Cholesterol	Siemens Atellica HDL Cholesterol (HDLC) SOP ADD.BIO 11051
Serum, Fluid	Triglycerides	Siemens Atellica Triglycerides (Concentrated) (trig) SOP ADD.BIO 11021
	Alpha-1-Antitrypsin	Siemens Atellica Alpha-1-antitrypsin (AAT) SOP ADD.BIO 11058
	CRP	Siemens Atellica C Reactive Protein 2 (CRP 2) SOP ADD.BIO 11226
	Rheumatoid Factor	Siemens Atellica Rheumatoid Factor (RF) SOP ADD.BIO 11037
	B2-Microglobulin	Siemens Atellica β2-Microglobulin(B2M) SOP ADD.BIO 11101

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for
Serum unless otherwise specified (cont'd)	Quantification of: (cont'd)	Siemens Atellica platform and Siemens Atellica Performance Database for:
	Haptoglobin	Siemens Atellica Haptoglobin (Hapt) SOP ADD.BIO 11218
	IgA	Siemens Atellica Immunoglobulin A 2 (IgA 2) SOP ADD.BIO 11046
	IgG	Siemens Atellica Immunoglobulin G_2 (IgG_2) SOP ADD.BIO 11045
	IgM	Siemens Atellica Immunoglobulin M_2 (IgM_2) SOP ADD.BIO 11044
	Transferrin	Siemens Atellica Transferrin (Trf) SOP ADD.BIO 11025
Urine	Microalbumin	Siemens Atellica Microalbumin_2 (µALB_2) SOP ADD.BIO 11007
Plasma	Ammonia	Siemens Atellica Ammonia (Amm) SOP ADD.BIO 11044
	Angiotension Converting Enzyme (ACE)	Sentinel Kit on Siemens Atellica Angiotensin Converting Enzyme (ACE) SOP ADD.BIO 11198
Serum, Urine	Osmolality	Osmolality Determination Using the Advanced Instruments OsmoPRO Advantage Multi-Sample Micro-osmometer using freezing point ADD.BIO 6741
CSF	Xanthochromia	Cary 60 Bio double beam Spectrophotometry using SOP ADD.BIO 34177 CSF Bilirubin and Oxyhaemoglobin Analysis for the Detection of Xanthochromia

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for
Serum unless otherwise specified (cont'd)	Quantification of: (cont'd)	Siemens Atellica platform and Siemens Atellica Performance Database for:
	LDL-Cholesterol	Calculation using SOP ADD.BIO 7090 Full Lipid Profile Calculations (LDL, Non-HDL, Cholesterol/HDL Ratio)
CSF, Urine	Protein	Siemens Atellica Urinary/Cerebrospinal Fluid Protein (UCFP) SOP ADD.BIO 11228
Sweat	Chloride	Sherwood Scientific Limited Chloride analyser model 926S Sweat chloride meter using SOP ADD BIO 33935
Urine	VMA & HVA (Urine Vanillymandelic acid & homovanillic acid)	Agilent GC-MS and using SOP ADD BIO 33980
Serum unless otherwise specified	Therapeutic drug monitoring and Toxicology	Siemens Atellica platform and Siemens Atellica Performance Database for:
	Salicylate	Siemens Atellica Salicylate SOP ADD.BIO 11036
	Paracetamol (Acetaminophen)	Siemens Atellica Acetaminophen (Acet) SOP ADD.BIO 11099
Plasma	Ethanol / Alcohol	Siemens Atellica Ethanol / Alcohol (ETOH) SOP ADD.BIO 11189
	Carbamazepine	Siemens Atellica Carbamazepine (Carb) SOP ADD.BIO 11054
	Phenytoin	Siemens Atellica Phenytoin (Phny) SOP ADD.BIO 11038
	Theophylline	Siemens Atellica Theophylline (Theo) SOP ADD.BIO 11034

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for
Serum unless otherwise specified (cont'd)	Therapeutic drug monitoring and Toxicology (cont'd)	Siemens Atellica platform and Siemens Atellica Performance Database for:
	Digoxin	Siemens Atellica Digoxin (Dgn) SOP ADD.BIO 11050
	Lithium	Siemens Atellica Lithium (Li) SOP ADD.BIO 11041
	Methotrexate	ARK assay on Siemens Atellica Methotrexate SOP ADD.BIO 11209
	Antibiotics	
	Amikacin	Siemens Atellica Amikacin Assay SOP ADD.BIO 11200
	Gentamicin	Siemens Atellica Gentamicin (Gent) SOP ADD.BIO 11048
	Tobramycin	Siemens Atellica Tobramycin (Tob) SOP ADD.BIO 11026
	Vancomycin	Siemens Atellica Vancomycin (Vanc) SOP ADD.BIO 11014
	SARS-CoV-2 (Quantitative)	Siemens Atellica SARS-CoV-2 IgG (SCOVG) SOP ADD.BIO 11191
	Thyroid Hormones	
	TSH	Siemens Atellica Thyroid Stimulating Hormone Ultra (TSH3-UL) SOP ADD.BIO 11096
	Total T4	Siemens Atellica Total Thyroxine (T4) SOP ADD.BIO 11215
	FT4	Siemens Atellica Free Thyroxine (FT4) SOP ADD.BIO 11084

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Thyroid Hormones (cont'd)	Siemens Atellica platform and Siemens Atellica Performance Database for:
	FT3	Siemens Atellica Free Triiodothyronine SOP ADD.BIO 11080
	Steroid Hormones	
	Cortisol	Siemens Atellica Cortisol (Cor) SOP ADD.BIO 11073
	Progesterone	Siemens Atellica Progesterone SOP ADD.BIO
	Testosterone (male)	Siemens Atellica Testosterone II (TSTII) SOP ADD.BIO 11091
	Oestradiol (E2)	Siemens Atellica Enhanced Estradiol (eE2) SOP ADD.BIO 11074
	Peptide Hormones	
	FSH	Siemens Atellica Follicle Stimulating Hormone (FSH) SOP ADD.BIO 11078
	Prolactin	Siemens Atellica Prolactin (PRL) SOP ADD.BIO
	LH	Siemens Atellica Lutenizing Hormone (LH) SOP ADD.BIO 11085
	Ferritin	Siemens Atellica Ferratin (Fer) SOP ADD.BIO 11076
	Folate	Siemens Atellica Folate (Fol) SOP ADD.BIO 11077

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Peptide Hormones (cont'd)	Siemens Atellica platform and Siemens Atellica Performance Database for:
	Vitamin B12	Siemens Atellica Vitamin B12 SOP ADD.BIO 11095
	Tumour markers	
	CA125	Siemens Atellica CA 125II (CA 125II) SOP ADD.BIO 11068
	CA-199	Siemens Atellica CA 199 (CA 199) SOP ADD.BIO 11070
	CA-153	Siemens Atellica CA-153 SOP ADD.BIO 11069
	PSA Total	Siemens Atellica Prostate-Specific Antigen (PSA) SOP ADD.BIO 11088
	PSA Free	Siemens Atellica Free Prostate-Specific Antigen (fPSA)SOP ADD.BIO 11139
	HCG	Siemens Atellica Total hCG OUS (ThCG) SOP ADD.BIO 11233
	AFP	Siemens Atellica Alpha Fetoprotein (AFP) SOP ADD.BIO 11059
	CEA	Siemens Atellica Carcinoembyonic Antigen (CEA) SOP ADD.BIO 11072
	Anti-Thyroid Peroxidase Auto antibody (aTPO)	Siemens Atellica Anti-Thyroid Peroxidase SOP ADD.BIO 11067

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Cardiac Markers	Siemens Atellica platform and Siemens Atellica Performance Database for:
	NT-ProBNP	Siemens Atellica NT-proBNP (PBNP) Assay SOP ADD.BIO 11126
	Troponin I	Siemens Atellica Troponin I high sensitivity (TnIH) SOP ADD.BIO 11090
	Immunoassay	
	Procalcitonin	Siemens Atellica Procalcitonin (PCT) SOP ADD.BIO 11237
Plasma	PTH	Siemens Atellica Intact Parathyroid Hormone (PTH) SOP ADD.BIO 11217
	Anti-Thyroglobulin Auto antibody (aTG)	Siemens Atellica Anti-Thyroglobulin II (aTgII) SOP ADD.BIO 11060
	250OH-Vitamin D	Siemens Atellica Vitamin D Total (VitD) SOP ADD.BIO 11141
Serum	P3NP HA TIMP-1	Siemens Atellica ELF ADD.BIO.11459
	Calculated Tests	
	eGFR	ADD.BIO 7485
	AKI alert	ADD.BIO 7494
	FIB-4	ADD.BIO 7501
	Transferrin Saturation	ADD.BIO 3631
	Adjusted Calcium	ADD.BIO 34071, ADD.BIO 6643
	Non-HDL Cholesterol	ADD.BIO 7090
Serum	Enhanced Liver Fibrosis (ELF)	ADD.BIO 11459

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Metabolic Testing	
CSF, Plasma, urine	Amino Acids	Biochrom amino acid analyser ADD.BIO 33965 Quantitative amino acid analysis by ion exchange chromatography
Urine, Plasma	Creatine & Guanidinoacetate	Tandem mass spectrometer and using SOP ADD.BIO 33973
Plasma	Total Homocysteine & methionine	ADD BIO 33988
Urine	Sulphocysteine	ADD.BIO 34178
Blood spot	Acylcarnitines	Panthera Puncher equipment and Tandem mass spectrometer using ADD.BIO 33971
	Phenylanine and Tyrosine for PKU monitoring	ADD.BIO 34055 Expanded newborn screening for IEM by TMS
	Galactose-1-Phosphate Uridyl Transferase	Fluoroscan and using SOP ADD.BIO 33936
Plasma	Chitotriosidase	ADD.BIO 33938
Urine	Glycosaminoglycan Typing	Electrophoretic tank using SOP ADD.BIO 33941 two-dimensional glycosaminoglycan electrophoresis
Plasma	Biotinidase	Spectrophotometer using Cary 60 SOP ADD.BIO 33937
Urine	Glycosaminoglycans	Spectrophotometer using Cary 60 ADD.BIO 33939
	PBG Quantitation	Spectrophotometer using Cary 60 ADD.BIO 34178
Plasma	Very Long Chain Fatty Acids	Agilent GC-MS using SOP ADD BIO 33970

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Metabolic testing (cont'd)	
Urine	Organic Acids- Qualitative Orotate-Quantitative Methylmalonic Acid-Quantitative	ADD.BIO 33940
Serum, Plasma	Methylmalonate (MMA)	Recipe ClinMass® Complete Kit for MMA on 4500 Tandem Mass Spectrometer System SOP ADD.BIO 11592
Whole Blood	Ciclosporin	Immunosuppressant drug analysis using ADD.BIO 33992
Whole Blood	Sirolimus	Immunosuppressant drug analysis using Shimadzu Liquid Chromatography and Sciex 4500MD Tandem Mass Spectrometer ADD.BIO 33992
Whole Blood	Tacrolimus (FK506)	Immunosuppressant drug analysis using Shimadzu Liquid Chromatography and Sciex 4500MD Tandem Mass Spectrometer ADD.BIO 33992
	Endocrinology	
Urine	5HIAA	Tandem mass spectrometer using SOP ADD.BIO 6754 by LCMSMS
	Metanephrines	SOP ADD.BIO 470 by LC MSMS using Gilson 215 SPE station
	17 Hydroxy Progesterone	SOP ADD BIO 1988 and ADD.BIO 368 SOP: 5500 Mass Spec maintenance
	25 Hydroxy Vitamin D	25-Hydroxy Vitamin D3 / D2 analysis by LC-MS/MS ADD.BIO 34143

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Endocrinology (cont'd)	
Serum	Total T3	Total T3 analysis using AB Sciex API5500 Tandem Mass Spectrometer and Shimadzu liquid chromatography and autosampler by LC-MS/MS ADD.BIO.11467
Saliva	Cortisol Cortisone	Analysis by LC MS/MS using AB Sciex API5500 Tandem Mass Spectrometer and Shimadzu liquid chromatography and autosampler ADD. BIO. 11780
Plasma	Aldosterone	ADD.BIO 3266 SOP: Aldosterone by LC-MS
	Androstenedione	ADD.BIO 2387 SOP: Androstenedione by LC-MS
	Cortisol	ADD.BIO 446 SOP: Mass Spec Serum Cortisol
	Testosterone	ADD.BIO 146 SOP: Testosterone by Tandem Mass Spec
Urine	Free Cortisol	ADD.BIO 181 SOP: Urine Cortisol by Mass Spec ADD.BIO 34215
Plasma	ACTH	Siemens Immulite 2000 and using SOP ADD.BIO 33894 SOP: ACTH by IMMULITE 2000 ADD.BIO 33922

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Endocrinology (cont'd)	
Serum	DHEA Sulphate (Dehroepiandrosterone sulphate)	DHEAS on Immulite 2000 ADD.BIO 33896
	Growth Hormone	ADD.BIO 33897 on Immulite 2000
	Sex Hormone Binding Globulin	Siemens Atellica Sex Hormone Binding Globulin (SHBG) ADD.BIO 11089
	Thyroxine Binding Globulin	TBG on Immulite 2000 ADD.BIO 34221
	Erythropoietin	Erythropoietin on Immulite 2000 ADD.BIO 6336
	Thyroid Stimulating Immunoglobulins	TBG on Immulite 2000 ADD.BIO 6801
	Total hCG (Tumour marker)	Siemens Atellica Total hCG OUS (ThCG) ADD.BIO 11233
Plasma	Placental Growth Factor	Manufacturer's assay using Quidel TriageR MeterPro ADD.BIO.8033
Faeces	Calprotectin	Siemens Atellica Faecal Calprotectin Buhlmann assay on Siemens Atellica ADD.BIO 11216
	Faecal Elastase	Siemens Atellica Faecal Buhlmann assay on Siemens Atellica ADD.BIO.11521
	Elastase	V-MAX plate reader using SOP ADD.BIO 16013
Plasma	Metanephrines	ADD.BIO 34064

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers' instructions for
Serum unless otherwise specified (cont'd)	Endocrinology (cont'd)	
Whole blood	HbA1c	Tosoh G11 and using SOP ADD.BIO 2223 HbA1c analysis on the TOSOH G11
	HbA1c	Enzymatic HbA1c analysis on Siemens Atellica platform ADD.BIO 2222
Serum	IGF 1	IGF1 on Immulite 2000 ADD.BIO 33898
Lithium Heparin Plasma (serum)	Insulin	Disorin Liasion SOP ADD.BIO 2260 CBAL Diasorin Liaison XL Routine Use
	C-Peptide	SOP ADD.BIO.16020 on Disorin Liasion XL
Serum	Renin (Immunoassay Mass)	ADD.BIO 16062 on Diasorin Liasion XL
	Thyroglobulin	Thyroglobulin analysis on the Beckman Access using chemiluminescent immunoassay ADD.BIO 11340
Serum	Macro Prolactin studies	Siemens Atellica and using SOP ADD.BIO 7472 SOP: Macro prolactin investigations

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for
Serum unless otherwise specified (cont'd)	Antenatal & Newborn Screening	Documented in-house methods to meet the requirements of the Fetal anomaly Screening Programme(s) as defined in the laboratory QA evidence requirements'
		Perkin Elmer AutoDELFIA using SOP ADD.BIO 16036 AutoDELFIA maintenance and SOP ADD.BIO 16026 AutoDELFIA Operation
	Free B HCG (DOWNS 1ST Trimester)	ADD.BIO 33901 SOP: freeBhCG DOWNS
	PAPP-A (DOWNS 1ST Trimester)	ADD.BIO 33900
	Intact HCG (DOWNS 2nd Trimester)	Intact hCG analysis by AutoDELFIA immunoassay for second trimester screening ADD.BIO.16047
	AFP (DOWNS 2nd Trimester)	AFP analysis by AutoDELFIA immunoassay for second trimester screening and CSF tumour marker analysis ADD.BIO.33905
Serum	Unconjugated Estriol (Down's 2nd Trimester)	Unconjugated estriol analysis by AutoDELFIA immunoassay for second trimester screening ADD.BIO 6831
	Inhibin (DOWNS 2nd Trimester)	Inhibin A Analysis by AutoDELFIA immunoassay for second Trimester Screening ADD.BIO 9126

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	
	Newborn blood spot screening	Documented in-house methods to meet the requirements of the Newborn Blood spot Screening Programme(s) as defined in the laboratory QA evidence requirements
New-born Blood spot	Screening for CF using immune-reactive trypsinogen	Panthera Puncher and GSP and using SOP ADD.BIO 3613 Measurement of bloodspot IRT by GSP
	Screening for Congenital Hypothyroidism using Thyroid Stimulating Hormone	SOP ADD.BIO 3614
	Screening for IMDs Phenylalanine Tyrosine Leucines Methionine Octanoylcarnitine Decanoylcarnitine Isovalerylcarnitine Glutarylcarnitine Saccinyllacetone	Revvity Neobase2 Non-derivatised MSMS Kit (including succinylacetone) and ABSciex 4500MD and 5500MD mass spectrometers ADD.BIO.4791
	Screening for Sickle Cell Disorders	Blood spot haemoglobinopathies using tandem mass spectrometry ADD.BIO 33989
END		