


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>8217</p> <p>Accredited to ISO 15189:2012</p>	University Hospitals Birmingham NHS Foundation Trust	
	Issue No: 013	Issue date: 1 February 2021
	Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Contact: Michelle Waterworth Tel: +44 (0)121 424 2035 E-Mail: michellewaterworth@heartofengland.nhs.uk Website: www.heartofengland.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code	
Address Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Haematology Clinical Biochemistry Toxicology Cytopathology Immunology Molecular Biology Histopathology Transfusion Blood Issue Fridge MOHS Clinica	A
Address Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Haematology Clinical Biochemistry Transfusion Blood Issue Fridge Andrology	B
Address Solihull Hospital Lode Lane Solihull B91 2JL	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Haematology Clinical Biochemistry Transfusion Blood Issue Fridge MOHS Clinic	C
Address PHEPHLB Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Local contact Hannah Tanner Tel: +44 (0)121 424 3194	Processing Patient Samples	D



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Site activities performed away from the locations listed above:

Location details	Activity	
Address Ward 19, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Blood Issue Fridge
Address Main Theatres, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Blood Issue Fridge
Address Maternity Delivery Unit, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Blood Issue Fridge
Address Clinical Haematology Unit, Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Blood Issue Fridge
Address Main Theatres, Good Hope Hospital Rectory Rd, Sutton Coldfield, West Midlands B75 7RR	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Blood Issue Fridge
Address Maternity Delivery Unit, Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Blood Issue Fridge



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Location details	Activity
<p>Address Mortuary, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS</p> <p>Local contact Louise Fallon Tel: +44 (0)121 424 1235</p>	Body storage Post Mortem
<p>Address Body store Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR</p> <p>Local contact Louise Fallon Tel: +44 (0)121 424 1235</p>	Body storage
<p>Address Body store Solihull Hospital Lode Lane Solihull B91 2JL</p> <p>Local contact Louise Fallon Tel: +44 (0)121 424 1235</p>	Body storage
<p>Address Dermatology Department, Solihull Hospital Lode Lane Solihull B91 2JL</p> <p>Local contact Louise Fallon Tel: +44 (0)121 424 1235</p>	MOHs clinic



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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 / TISSUE	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> Quantitative determination of;	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000 and i2000SR with specific reference to CIT.S001 and CIT.S002 and:	
Serum/Plasma	Alanine Aminotransferase (ALT)	CIT.X009 CIT.I009	B,C
Serum/Plasma	Albumin	CIT.X200 CIT.I200	B,C
Fluid	Albumin	CIT.X200 CIT.I200	B
Serum/Plasma	Alkaline Phosphatase (ALP)	CIT.X005 CIT.I005	B,C
Plasma	Ammonia	CIT.X013 CIT.I013	B
Serum/Plasma	Amylase	CIT.X017 CIT.I017	B,C
Fluid	Amylase	CIT.X017 CIT.I017	B
Serum/Plasma	Beta HCG (not tumour marker)	CIT.X233 CIT.I233	B,C
Serum/Plasma	Bicarbonate	CIT.X021 CIT.I021	B,C
Serum	Bile Acids	CIT.X025 CIT.I025	B
Serum/Plasma	Caeruloplasmin	CIT.X280 CIT.I280	B



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000 and i2000SR with specific reference to CIT.S001 and CIT.S002 and: (cont'd)	
Serum/Plasma	Calcium	BS.X037 BS.I037	B,C
Faeces	Calprotectin	CIT.5980	B
Serum/Plasma/Urine	Chloride	CIT.X065 CIT.I065	B,C
Serum/plasma	Cholesterol	IT.X045 CIT.I04	B,C
Fluid	Cholesterol	CIT.X045 CIT.I045	B
Serum/Plasma	Conjugated Bilirubin (Synermed reagents)	CIT.X061 CIT.I061	B
Serum/Plasma	Cortisol	CIT.X197 CIT.I197	B
Serum/Plasma	C-reactive protein (CRP)	CIT.X053 CIT.I053	B,C
Serum/Plasma	Creatine Kinase (CK)	CIT.X043 CIT.I043	B,C
Serum/Plasma	Creatinine (Enzymatic)	CIT.S310 CIT.I049	B,C
Fluid	Creatinine (Enzymatic)	CIT.S310 CIT.I049	B
Serum/Plasma	Digoxin	CIT.X057 CIT.I057	B



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000 and i2000SR with specific reference to CIT.S001 and CIT.S002 and: (cont'd)	
Serum/Plasma	Ferritin	CIT.X213 CIT.I213	B,C
Serum/Plasma	Folate	CIT.X217 CIT.I217	B,C
Serum/Plasma	Follicle Stimulating Hormone (FSH)	CIT.X221 CIT.I221	B
Serum/Plasma	Free Thyroxine (FT4)	CIT.X229 CIT.I229	B,C
Serum/Plasma	Free Triiodothyronine (FT3)	CIT.X225 CIT.I225	B
Serum/Plasma	Gamma G.T. (GGT)	CIT.X254 CIT.I254	B,C
CSF	Glucose	CIT.X073 CIT.I073	B
Serum/Plasma	Glucose	CIT.X073 CIT.I073	B,C
Fluid	Glucose	CIT.X073 CIT.I073	B
Serum/Plasma	High Density Lipoprotein (HDL)	CIT.X077 CIT.I077	B,C
Serum/Plasma	hs-Troponin I	CIT.X199 CIT.I199	B,C
Serum/Plasma	Iron	CIT.X097 CIT.I097	B,C
Plasma/CSF	Lactate	CIT.X101 CIT.I101	B



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000 and i2000SR with specific reference to CIT.S001 and CIT.S002 and: (cont'd)	
Serum/Plasma	Lithium	CIT.X111 CIT.I111	B
Serum/Plasma	Luteinising Hormone (LH)	CIT.X249 CIT.I249	B
Serum/Plasma	Magnesium	CIT.X113 CIT.I113	B,C
Serum/Plasma	Paracetamol	CIT.S203 CIT.I203	B,C
Serum/Plasma	Parathyroid Hormone (PTH)	CIT.S999 CIT.I619	B,C
Serum/Plasma	Phosphate	CIT.X125 CIT.I125	B,C
Serum/Plasma	Potassium	CIT.X065 CIT.I065	B,C
Urine	Potassium	CIT.X065 CIT.I065	B
Serum/Plasma	Progesterone	CIT.X253 CIT.I253	B,C
Serum/Plasma	Prolactin	CIT.X257 CIT.I257	B
Serum/Plasma	Prostate Specific Antigen (PSA)	CIT.X273 CIT.I273	B,C
Serum/Plasma	Salicylate	CIT.X133 CIT.I133	B,C
Serum/Plasma	Sodium	CIT.X065 CIT.I065	B,C



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000 and i2000SR with specific reference to CIT.S001 and CIT.S002 and: (cont'd)	
Urine	Sodium	CIT.X065 CIT.I065	B
Serum/Plasma	Theophylline	CIT.X137 CIT.I137	B
Serum/Plasma	Thyroid Stimulating Hormone (TSH)	CIT.X281 CIT.I281	B,C
Serum/Plasma	Total Bilirubin	CIT.X141 CIT.I141	B,C
Serum/Plasma	Total Protein	CIT.X258 CIT.I258	B,C
Serum/Plasma	Triglycerides	CIT.X258 CIT.I258	B,C
Serum/Plasma	Unsaturated Iron Binding Capacity (UIBC)	CIT.X149 CIT.I149	B
Serum/Plasma	Urate	CIT.X157 CIT.I157	B,C
Serum/Plasma	Urea	CIT.X153 CIT.I153	B,C
Serum/Plasma	Vitamin B12	CIT.X177 CIT.I177	B,C



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000 and i2000SR with specific reference to CIT.S001 and CIT.S002 and: (cont'd)	
Serum/Plasma/urine	Osmolality — Solute concentration of the sample	Documented In-house Methods and Manufacturer's instructions for Advanced Instruments with specific reference to CIT.S221	A,B
Serum/Plasma	Sodium (Direct ISE)	Documented In-house Methods and Manufacturer's instructions for IL Lab – Ilyte with specific reference to CIT.S220	A,B,
Urine	Urinary metanephrines Metanephrine, 3MT - 3-methoxytyramine	Documented In-house Methods and Manufacturer's instructions for API 5000 Tandem Mass Spectrometer: CIT.S455	A
Plasma	Homocysteine	CIT.S585	A
Serum/ Plasma	Female testosterone	CIT.S171	A
Serum/ Plasma	Prednisolone Prednisolone, Prednisone, Cortisol and Cortisone	CIT.S1066	A
Serum/ Plasma	Urinary cortisol	CIT.S1044	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Plasma	Metanephrines	Documented In-house Methods and Manufacturer's instructions for Sciex 6500Q Tandem Mass Spectrometer: CIT.S1020	A
Urine	Urinary Free Catecholamines Noradrenaline, Adrenaline and Dopamine	Documented In-house Methods and Manufacturer's instructions API65000 LC-MS/MS with specific reference to CIT.S1004	A
Blood	Thiopurine metabolites	Documented In-house Methods and Manufacturer's instructions API65000 LC-MS/MS with specific reference to CIT.X250	A
Serum/ Plasma	Vitamin D Vitamin D2, Vitamin D3 Total Vitamin D	Documented In-house Methods and Manufacturer's instructions for the API 4500 and API 5000 Tandem Mass Spectrometer CIT.S1011	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Urine	Urinary 5HIAA	Documented In-house Methods and Manufacturer's instructions for KNAEUER and GILSON HPLC with specific reference to CIT.S1060	A
Serum/Plasma	TPMT – phenotype	Documented In-house Methods and Manufacturer's instructions for Waters HPLC: CIT.S1008, CIT.S1014, ST.S464	A
Serum	Vitamin A and E	Documented In-house Methods and Manufacturer's instructions for Waters HPLC: CIT.S1450	A
Serum	Vitamin E:Cholesterol ratio Derived test based on ratio of Vitamin E to Cholesterol	Vitamin E-HPLC with florescence detection: CIT.S049	A
Sweat	Sodium	Documented In-house Methods and Manufacturer's instructions ICP/MS: CIT.S1001, CIT.S2008	A
Sweat	Chloride	Documented In-house Methods and Manufacturer's instructions ICP/MS: CIT.S1001, CIT.S2008	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Serum/Plasma	Derived Tests in Clinical Chemistry: Non-HDL Cholesterol	CIT.S049	A, B, C
Serum/Plasma	Free Testosterone	CIT.S049	A, B, C
Urine	Albumin: Creatinine Ratio	CIT.X117 CIT.I117 CIT.X049 CIT.I049 CIT.S049	A,B,C
Serum/Plasma	Corrected Calcium	CIT.X037 CIT.I037 CIT.S049	A,B,C
Serum/Plasma	Globulins	CIT.X258 CIT.I258 CIT.X200 CIT.I200 CIT.S049	A,B,C
Serum/Plasma	Glomerular Filtration Rate (GFR)	CIT.X049 CIT.I049 CIT.S049	A,B,C
Serum/Plasma	LDL-Cholesterol	CIT.X045 CIT.I045 CIT.X145 CIT.I145 CIT.X077 CIT.I077 CIT.S049	A,B,C
Urine	Protein: Creatinine ratio	CIT.X161 CIT.I161 CIT.X049 CIT.I049 CIT.S049	A
Serum/Plasma	Acute Kidney Injury	CIT.S049	A, B, C
Serum/Plasma	Albumin: Globulin Ratio	CIT.S049	A, B, C
Serum/Plasma	Creatinine Clearance	CIT.S049	A, B, C



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Serum, Plasma, Blood, Urine	Quantitative measurement of the following elements: Aluminium, Arsenic, Cadmium, Chromium, Cobalt, Copper, Lead, Manganese,	Documented In-house Methods and Manufacturer's instructions for ICP-MS: CIT.S2008	A
Serum, Plasma, Blood, Urine	Selenium, Zinc	Documented In-house Methods and Manufacturer's instructions for ICP-MS: CIT.S2008	A
Sweat	Quantitative measurement of Sodium and Chloride		A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Urine	Opiates - Morphine, Codeine, Dihydrocodeine & 6-monoacetyl morphine (6MAM)	Documented In-house Methods and Manufacturer's instructions for API 4000 (Tandem Mass Spectrophotometer) CIT.S2017	A
Urine	Targeted drugs of abuse screen in urine. The method will detect the following compounds:	Documented In-house Methods and Manufacturer's instructions for API 4000 (Tandem Mass Spectrophotometer) CIT.S2017	A
	Opioids - Methadone and metabolite EDDP), Buprenorphine and metabolite (norbuprenorphine)		A
	Amphetamines – Amphetamine (Amphetamine)		A
	Methamphetamine (Metamphetamine),		A
	MDA, MDMA & MDEA		A
	Benzodiazepines – Diazepam and metabolite (nordiazepam), oxazepam, temazepam, lorazepam, nitrazepam & midazolam		A
Urine	Designer drugs - Benzylpiperazine (BZP), MDPV (bath salts), 4-Methylethcathinone (4-MEC, NRG), 4-Methylmethcathinone (Mephedrone, Meow Meow)		A
	Other drugs - Cocaine and metabolite (benzoylecgonine), Ketamine, Cannabis metabolite (11-nor-9-carboxy-tetrahydrocannabinol)		A



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<p>HUMAN BODY FLUIDS / TISSUE (cont'd)</p> <p>Blood, Plasma, Serum, Urine</p>	<p><u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u></p> <p><u>Presumptive screening and confirmation for the presence of drugs from the following drug classes:</u></p> <p>ACE inhibitors Amfetamines (including MDMA and related drugs) Angiotensin II Receptor Antagonists (ARBs) Alpha receptor agonists Antibiotics Antidepressants (tricyclics, tetracyclics, SARIs, SSRIs, SSNRIs) Antiepileptics Antifungals Antihistamines Antipsychotics (typical and atypical) Anti-retrovirals Alpha Blockers Barbiturates Beta Blockers Benzodiazepines Bronchodilators Calcium Channel blockers Cocaine Diuretics Dissociatives Fentanyl and fentanyl analogues Gabapentinoids Glucocorticoids Hypnotics Ketamine Metformin Non-steroidal anti-inflammatory drugs Novel psychoactive substances Opiates Opioids Paracetamol Psychedelics Renin Inhibitors</p>	<p>Flexible scope for LC-QToF MS limited to the application of additional drugs bounded within the named classes in accordance with documented in-house procedure GEN.S003</p> <p>Documented methods and manufactures instructions for Liquid Chromatography Quadrupole Time of Flight Mass Spectrometry (LC-QToF MS) using Waters Acquity UPLC with Waters Xevo G2-XS QToF (CIT.S2023)</p> <p>The verified scope of the screens is identified within laboratory controlled Waters Toxicology Library</p>	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Salicylates Statins Stimulants Sulphonylureas Synthetic Cannabinoids THC and related compounds Z-drugs		
Urine only	Presumptive screening and confirmation of cardiovascular disease modifying drugs from the following drug classes: ACE inhibitors Angiotensin II Receptor Antagonists (ARBs) Alpha receptor agonists Alpha Blockers Beta Blockers Calcium Channel blockers Diuretics Metformin Renin Inhibitors Statins Sulphonylureas	Flexible scope for LC-QToF MS limited to the application of additional drugs bounded within the named classes in accordance with documented in-house procedure GEN.S003 Documented methods and manufactures instructions for Liquid Chromatography Quadrupole Time of Flight Mass Spectrometry (LC-QToF MS) using Waters Acquity UPLC with Waters Xevo G2-XS QToF (CIT.S2023) The verified scope of the screens is identified within laboratory controlled Waters Toxicology Library	A



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HUMAN BODY FLUIDS / TISSUE (cont'd) Blood, serum, urine	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u> Quantitative measurement of: Amphetamine Benzodiazepine Quantitation (Diazepam, Nordiazepam, Oxazepam and Temazepam) Citalopram & Desmethylcitalopram Clozapine Codeine Cocaine & Benzoylecgonine Cotinine Dihydrocodeine Duloxetine Fluoxetine Gabapentin MDMA / MDA Methadone Midazolam Mirtazapine Oxycodone Olanzapine Paroxetine	Documented In-house Methods and Manufacturer's instructions for API 4000 ((LC-MS/MS Tandem Mass Spectrometer): CIT.S2025	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Blood, serum, urine	Quantitative measurement of: Pregabalin Quetiapine Risperidone & 9hydroxy risperidone Sertraline, Valproate Venlafaxine / ODV	Documented In-house Methods and Manufacturer's instructions for API 4000 ((LC-MS/MS Tandem Mass Spectrometer) CIT.S2025	A
Blood, Plasma, Serum, Tissues	Fentanyl Buprenorphine & Norbuprenorphine	CIT.S2013	
Blood, Plasma, Serum, Tissues	Morphine and glucuronide metabolites	CIT.S2019	
Blood, urine	Ethanol, Methanol, Acetone	Documented In-house Methods and Manufacturer's instructions for GC-HS: CIT.S2009	A
Blood, Plasma, Serum	Ethylene and Diethylene Glycol	Documented In-house Methods and Manufacturer's instructions for GC-MS: CIT.S2006	A
Blood, Urine	BHB and GHB	Documented In-house Methods and Manufacturer's instructions for GC-MS: CIT.S2006	A
Blood, Plasma, Serum	Levetiracetam	Documented In-house Methods and Manufacturer's instructions for GC-MS:	A



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		CIT.S2010	
HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u>	Documented In-house Methods and Manufacturer's instructions for Instrumentation Laboratory ACL TOP550 (site A)/ TOP350 (site B,C):	
Citrated Plasma	Anti Xa assay	HA.S661	A
Citrated Plasma	Antithrombin III level	HA.S657	A
Citrated Plasma	Apixaban	HA.S402	A
Citrated Plasma	Activated Partial Thromboplastin Time (APTT)	HA.S653	A,B,C
Citrated Plasma	D-Dimer Test	HA.S654	A,B,C
Citrated Plasma	Edoxaban	Drug monitoring – Anticoagulation using Werfen TOP chromogenic assay HA.S404	A
Citrated Plasma	Factor II, V, VII, VIII, IX, X, XI, XII assay	HA.S662	A
Citrated Plasma	Fibrinogen level	HA.S665	A,B
Citrated Plasma	Lupus Screen, Lupus Confirm	HA.S660	A
Citrated Plasma	Plasma total protein S level	HA.S659	A
Citrated Plasma	Protein C level	HA.S658	A
Citrated Plasma	Prothrombin Time (INR)	HA.S652	A,B,C
Citrated Plasma	Prothrombin Time MIX (50/50)	HA.S667	A,B,C
Citrated Plasma	Partial Thromboplastin Time (PTT) Mix (50/50)	HA.S667	A,B,C
Citrated Plasma	Ristocetin Cofactor	HA.S664	A
Citrated Plasma	Rivaroxaban	HA.S401	A
Citrated Plasma	von Willebrand factor level	HA.S663	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Whole Blood:EDTA	Blood Films - morphology of the red cells, platelets and white cells. Manual differential of white cells	Documented in-house visual examination method using microscopy: Manual HA.S610 and automated HA.S604 staining, followed by microscopy.	A, B
Whole Blood:EDTA	Full Blood Count: Includes the following parameters:- WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, PDW, IPF, NEUT, LYMPH, MONO, EOS, BASO, NRBC Reticulocytes (site A and B only): RETIC, RETIC HGB, IRF, %HYPO	Documented In-house Methods and Manufacturer's instructions for Sysmex XN9000,XN2000 XN10: HA.S602 HA.S601	A,B,C
Whole Blood:EDTA	Malarial Parasite Antigen for pLDH (plasmodium Lactate Dehydrogenase). Detects Plasmodium +/- Falciparum	Documented In-house Methods and Manufacturer's instructions for Antigen testing using Carestart Antigen kit: HA.S159	A,B,C
Whole Blood:EDTA	Detection of Malarial Parasites by microscopy	Documented in-house visual examination method using microscopy: HA.S605	A,B,C
Whole Blood:EDTA	Erythrocyte sedimentation rate	Documented In-house Methods and Manufacturer's instructions for Alifax Test 1 HA.S608	A
Plasma :EDTA	Glandular Fever Screen for heterophile antibodies	Documented In-house methods and manufacturer's instructions for DiaQUICK Mononucleosis Cassette HA.S540	A, B, C



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Plasma: EDTA	Plasma viscosity	Documented in-house method for Capillary resistance, Benson BV1 analyser: CIT.S197 Documented -in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements	A
Whole Blood	Haemoglobinopathy screen to confirm or exclude presence of haemoglobin variant and / or thalassaemia	Documented In-house Methods and Manufacturer's instructions for TOSOH G8 HPLC analyser with specific reference to HA.S600 Documented -in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements	A
Whole Blood	Hb variant confirmation	Documented In-house Methods and Manufacturer's instructions for Sebia Capillary Electrophoresis: HA.S901	A
Bone Marrow Aspirates	Bone marrow slide staining for microscopic examination for evidence of haematological disease	Documented in-house method based on May Grunwald and Giemsa stain HA.S008	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>		
Whole Blood	G6PD (Quantitative) assay	Abbott Architect using Pointe Scientific kit to HA.S931 Documented -in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements	A
Whole Blood	Sickle solubility test for presence of sickle haemoglobin (HbS)	Streck Sickledex Kit: HA.S900 Documented In-house Methods and Manufacturer's instructions for Navios Flow Cytometer:	A, B A
Bone marrow peripheral blood	Acute Leukaemias	HA.S021	
Bone marrow peripheral blood	B lymphoproliferative T lymphoproliferative	HA.S024 HA.S010	
Whole Blood	CD34	HA.S009	
Whole Blood	Feto Maternal Haemorrhage	ST.S013	
Bone marrow/ Peripheral blood	Lymphocyte screen. Short panel to identify presence of T or B cell clonality.	HA.S507	



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented In-house Methods and Manufacturer's instructions for Navios Flow Cytometer:	A
Bone marrow/ Peripheral blood	MDS/Leukaemia screen. Short panel to identify presence of blast cells.	HA.S509	
Bone marrow/ Peripheral blood	Minimal Residual Disease (MRD)	HA.S358	
Bone marrow/Peripheral blood	Myeloma /MGUS	HA.S506	
Whole Blood	Paroxysmal Nocturnal Haemoglobinuria	HA.S063	
	<u>Transfusion examination activities for the purposes of clinical diagnosis:</u>		
Plasma	Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma antibody	Compatibility testing using LISS/Coombs gel column agglutination and centrifugation BB.S119. Automated and Manual techniques	A, B, C
Plasma	Antibody Screening: Screening of anti-D, C, E, c, e, Cw, K, k, Kp(a),Kp(b), Fy(a), Fy(b), Jk(a), Jk(b), Le(a), Le(b), P1, M, N, S, s, Lu(a) and Lu(b).	Automated Antibody screening using LISS/Coombs gel column agglutination and centrifugation BB.S205 Antenatal BB.S201	A, B, C
Whole blood	Red Cell Phenotyping	LISS/Coombs gel column agglutination and Centrifugation. BB.S109	A, B, C



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Transfusion examination activities for the purposes of clinical diagnosis:</u>		
Whole blood	Direct Antiglobulin Test	LISS/Coombs gel column agglutination and Centrifugation. BB.S111	A, B, C
Plasma	ABH Isoagglutinin Titres	LISS/Coombs gel column agglutination and Centrifugation. Doubling dilution patient's Plasma to achieve end point agglutination BB.S197	A
Whole blood	Detection and Estimation of Foetal Maternal Haemorrhage	Visual method to BB.S112	A, B
Whole blood	Blood Group	Automated Grifols analysers, Eyrtra and Erytra Eflexis. ABO/D Forward + Reverse Grouping by Gel column agglutination and centrifugation BB.S205	A, B, C
Whole Blood	Blood Group	Manual Cards and tubes: BB.S105	A, B, C
Plasma	Identification of Red Cell anti-D, C, E, c, e, Cw, K, k, Kp(a), Kp(b), Fy(a), Fy(b), Jk(a), Jk(b), Le(a), Le(b), P1, M, N, S, s, Lu(a) and Lu(b).	BB.S108	A, B, C
	<u>Immunology examination activities for the purposes of clinical diagnosis:</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000	
Serum/plasma	Alpha-1-antitrypsin	CIT.X251 CIT.I251	A
Serum/Plasma	Anti-thyroid TPO aCIT.	CIT.X173 CIT.I173	A
Serum/Plasma	B2-microglobulin	CIT.X252 CIT.I252	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry c16000/8000	
Serum/Plasma	Complement C3	CIT.X029 CIT.I029	A
Serum/Plasma	Complement C4	CIT.X033 CIT.I033	A
Serum/Plasma	IgA	CIT.X085 CIT.I085	A, B
Serum/Plasma	IgM	CIT.X093 CIT.I093	A, B
Serum/Plasma	IgG	CIT.X089 CIT.I089	A, B
Serum/Plasma	Rheumatoid Factor	CIT.X129 CIT.I129	A, B
Serum	Free Light Chains (Kappa & Lambda)	Documented In-house Methods and Manufacturer's instructions for Binding Site Optilite Turbidimeter: CIT.X1112, CIT.S112	A
Serum	IgG Subclasses (IgG, IgG1, IgG2, IgG3, IgG4)	CIT.S207	A
Serum/plasma	C1 Esterase Inhibitor (CIN)	CIT.S205	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Whole blood	Lymphocyte proliferation studies using the following stimuli to measure cell proliferation by incorporation of ³ H thymidine. To evaluate T-lymphocyte function. Candida albicans (CAND) Anti-CD3 (OKT3) Phytohaemagglutinin (PHA) Purified protein derivation of M Tuberculin (PPD) Pokeweed mitogen (PWM) Tetanus toxoid (TET) Varicella zoster virus (VZV)	Documented In-house Methods and Manufacturer's instructions for Beta Counter: CIT.S1695:	A
Serum	ACRA -Acetylcholine Receptor Antibody	Documented In-house Methods and Manufacturer's instructions for the Wizard Gamma Counter CIT.S1971	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Serum/plasma	Intrinsic factor antibodies (IFAB)	Documented In-house Methods and Manufacturer's instructions for DS2 Automated ELISA workstation ST.S163 and: ST.S340	A
	Diphtheria antibodies (DIPH)	CIT.S146	
	Haemophilus influenza type B antibodies (HIBAB)	CIT.S147	
	Pneumococcal antibodies (PNEUAB)	CIT.S148	
Plasma	Quantiferon TB Plus (QFTPL)	CIT.S1696	
Serum/plasma	Salmonella typhii antibody quantification	CIT.S1148	
	Tetanus antibodies (TETAB)	CIT.S149	
Plasma	GAD antibodies	Documented In-house Methods and Manufacturer's instructions for manual ELISA CIT.X1116, CIT.S1514	A
Whole blood	TB TSpot. Elispot to measure Interferon gamma production by TB antigens in investigation of latent TB.	Elispot to measure Interferon gamma production by TB antigens CIT.S109	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Whole blood	Cell marker analysis for diagnosis and monitoring of Immunodeficiency: EUROclass B cell panel TBNK, TCR EUROclass extended T cell panel NK cell markers, MHC ABC and DR, CD45 Ra and Ro Leucocyte adhesion deficiency markers Neutrophil respiratory burst	Documented In-house Methods and Manufacturer's instructions for Navios Flow Cytometer using Duraclone tubes: CIT.S1698 CIT.S1681 CIT. S1683 CIT.S1627 CIT.S1624	A
Whole blood	Cell marker analysis for diagnosis and monitoring of Immunodeficiency: T cell markers B cell markers NK cell markers	Documented In-house Methods and Manufacturer's instructions Beckman Aquios flow cytometer with specific reference to:CIT.S1640	A
Whole Blood	CD62 Ligand shedding for assessment of Toll-like receptor signalling pathways	Documented In-house Methods and Manufacturer's instructions for Navios Flow Cytometer – Beckman Coulter: CIT.S1697	A



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<p>HUMAN BODY FLUIDS / TISSUE (cont'd)</p> <p>Serum</p>	<p><u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Anti-Cardiolipin antibodies (IgG+IgM)</p> <p>Anti-Beta2glycoprotein antibodies (IgG+IgM)</p> <p>Specific IgG to Aspergillus (ASPG)</p> <p>Specific IgG to Avian (budgerigar and pigeon) (AVG)</p> <p>Anti-Cyclic citrullinated peptide antibodies (CCP)</p> <p>Anti-Double stranded DNA antibodies (DNA)</p> <p>Anti-Extractable nuclear antigen antibody screen (ENAS)</p> <p>Anti-Extractable nuclear antigen antibody typing (Ro, La, SmDP, RNP, Jo-1 and Scl-70) (ENAT)</p> <p>Anti-Glomerular basement membrane antibody (GBM)</p>	<p>Documented In-house Methods and Manufacturer's instructions for Phadia Immunocap 250: CIT.S1512</p>	<p>A</p>



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HUMAN BODY FLUIDS / TISSUE (cont'd) Serum	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u> Specific IgG to M.faeni (MFG) Anti-Myeloperoxidase antibodies (MPOS) Anti-Proteinase 3 antibodies (PR3S) Specific IgE - Various Total IgE Mast cell Tryptase Anti-Tissue transglutaminase IgA antibodies (TTGA) Anti-Tissue transglutaminase IgG antibodies (TTGG)	Documented In-house Methods and Manufacturer's instructions for Phadia Immunocap 250: CIT.S1512	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Serum/plasma	Anti-nuclear antibodies (ANA) Anti-neutrophil cytoplasmic antibodies (ANCA) Anti-gastric parietal cell antibodies (GPC) Anti-smooth muscle cell antibodies (SM) Anti-mitochondrial antibodies (MT) Anti-liver,kidney,microsomal antibodies (LKM) Anti-endomysial antibodies (ENDO) Anti-dsDNA antibodies utilising crithidia lucilliae (CRITH)	Documented In-house Methods and Manufacturer's instructions for immunofluorescence using QL 3000 Quantalyser slide staining workstation UV microscope and QUANTALink reporting software: CIT.S164, CIT.S100, CIT.S104	A
Serum/plasma	Anti-adrenal antibodies (ADR) Anti-epidermal antibodies (EPI) Anti-neuronal antibodies screen (NEURO) Anti-pancreatic islet cell antibodies (PIC)	Documented In-house Methods and Manufacturer's instructions for Manual Indirect Immunofluorescence and use of UV microscope: CIT.S1581	A
Blood	Detection of myositis IgG antibodies Detection IgG antibodies for autoimmune liver disease.	Immunoblot using EUROLINE Myositis Antigens Profile and EUROLINE Autoimmune Liver disease profile. CIT.S165, CIT.X1113	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for Sebia Capillarys 3 and Hydrasys instruments:	A
Urine	Bence-Jones protein (BJP)	CIT.S1505	
Serum	Paraprotein densitometry (DEN)	CIT.S1114	
Serum	Protein electrophoresis (EL)	CIT.S101	
Serum/ urine	Immunofixation (IFIX and IFIXU)	CIT.S109 CIT.S108	A
Serum	Alpha-1-antitrypsin phenotyping (PI)	CIT.S1961	A
CSF	CSF Oligoclonal bands (OLIGO)	Documented In-house Methods and Manufacturer's instructions for Helena kit and high resolution electrophoresis equipment: CIT.S132	A
Serum/Plasma	Derived Tests in Immunology: Kappa:Lambda Ratio (derived from free light chains)	CIT.S049	A
Whole blood	<u>Molecular (Haematology) examination activities for the purposes of clinical diagnosis:</u> Factor V Leiden (FVL) HFE Genotyping (C282Y/H63D) methylenetetrahydrofolate reductase (MTHFR) Prothrombin gene (G20210A)	Documented In-house Methods and Manufacturer's instructions for Taqman (PCR – Allelic discrimination methods): HA.S502	A, D



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<p>HUMAN BODY FLUIDS / TISSUE (cont'd)</p> <p>Whole blood</p>	<p><u>Molecular (Chemistry) examination activities for the purposes of clinical diagnosis:</u></p> <p>TPMT- genotype</p>	<p>Documented In-house Methods and Manufacturer's instructions for Step-One RT-PCR (PCR – Allelic discrimination methods): CIT.S1014</p>	<p>A, D</p>



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<p>HUMAN BODY TISSUE</p> <p>Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue Frozen Tissue MOHs collected tissue</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p> <p>Routine diagnostic examination of Histological specimens using the following:</p>	<p>Using in house methods: HI.S054 Trimming Room Protocols HI.S067 BHH Dissection of Category A-E Specimens. HI.S071 BHH Excelsior ES Processor Operation. HI.S051 BHH Tissue Embedding, Reprocessing and Re-infiltration in Histopathology. HI.S044 BHH Microtomy – rotary and sledge HI.S083 BHH Tissue Tek Prisma Staining Machine/Coverslipper. HI.S031 Frozen Section HI.S006 MOHS Surgery</p>	<p>A, C</p>
<p>Body Fluids: Urines, sputum, bronchial washings, bronchial washings, serous fluids, CSF</p>	<p>Routine diagnostic examination of non-cervical cytological specimens</p>	<p>Hologic T5000 Benchtop Processor CY.S343 Hologic T2000 Processor CY.S306 Prisma automated stainer and coverslipper Non – gynae Sample Preparation Manual CY.S301</p>	<p>A</p>
<p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p>Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues.</p>	<p>Documented In-house Methods and Manufacturer's instructions for Haematoxylin & Eosin stain: HI.S083 Tissue Tek Prisma Staining Machine / Coverslipper.</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd) 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis</u> (cont'd) Special staining of Histopathology examinations to assist in detection of clinical abnormalities. Acid mucins Glycogen and neutral mucins Acid and neutral mucins Glycogen and mucins Gram positive and negative bacteria Amyloid H.pylori Elastic fibres Malarial parasites Fungi Connective tissue and fibrin Melanin Basophil/Eosinophil/Neutrophil granules	Documented In-house Methods for special stains HI.S216 Alcian Blue pH 1.0, pH2.5 (AB) Periodic Acid Schiff (PAS) (Diastase PAS) Alcian Blue pH 2.5 PAS Alcian Blue pH 2.5 Hyaluronadase Brown Brenn Gram Gram stain Congo Red Cresyl Fast violet (CFV) Elastic Van Gieson Haematoxylin Van Gieson Geimsa Grocotts Silver Stain (Manual) Grocotts Silver Stain (Benchmark Special Stainer BSS) Martius Scarlet Blue Masson Fontana Masson's Trichrome Stain	A



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd):</p> <p>Neutral mucins</p> <p>Hepatitis B Antigen</p> <p>Basement Membranes</p> <p>Ferric iron</p> <p>Fibrin, neuroglia, muscle striations</p> <p>Reticulin fibres</p> <p>Copper</p> <p>Calcium</p> <p>Spirocheates</p>	<p>Documented In-house Methods for special stains HI.S216 (cont'd):</p> <p>Mucicarmine (Manual) Mucicarmine (Benchmark Special Stainer BSS)</p> <p>Orcein</p> <p>Periodic Acid Silver Method for Basement Membranes (Manual) Periodic Acid Silver Method for Basement Membranes (Benchmark Special Stainer BSS)</p> <p>Perl's Prussian Blue (Manual) Perl's Prussian Blue (Benchmark Special Stainer BSS)</p> <p>Phosphotungstic acid Haematoxylin PTAH</p> <p>Reticulin Method (Manual) Reticulin Method (Benchmark Special Stainer BSS)</p> <p>Rubeanic Acid</p> <p>Von Kossa Method</p> <p>Warthin-Starry (Manual) Method (Benchmark Special Stainer BSS)</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p>		
	Acid and Alcohol Fast Bacilli Leprosy	Ziehl Neelsen Modified Ziehl Neelsen (Wade Fite)	A
	Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.	Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry- Routine Ventana Benchmark XT and Ultras to HI.S078:	A
	Germ Cell Tumours	Alpha Feta Protein/OCT3-4 Placental Alkaline Phosphatase	
	Anaplastic Large Cell Lymphoma	Anaplastic Lymphoma Kinase (ALK)	
	Expression for companion treatments in lung tumours	ALK Lung	
	Primary breast cancer marker	GATA 3 Antibody	
	Pulmonary squamous cell carcinoma marker	P40 Antibody	
	Pulmonary adenocarcinoma marker	Napsin A Antibody	
	Primary erythroid marker	CD71 Antibody	
	Neoplastic mast cell marker	CD 25 Antibody	
	T Follicular helper cells	PD1 Antibody	
	B-cell lymphoma	BOB1 Antibody	
Chronic Lymphocytic Leukaemia	LEF1 Antibody		



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>High grade prostatic intraepithelial neoplasm (HGPIN) & prostate adenocarcinoma</p> <p>Most cells / Loss of in subset of Mesotheliomas</p> <p>Subtypes of endometrioid & mesenchymal tumours</p> <p>Lymphoid tumours, particularly follicular lymphoma</p> <p>Follicle centre B-cells – lymphoid tumours</p> <p>Epithelial Cell types</p> <p>Gastrintestinal stromal tumours (GISTs), mast cells and their relevant disorders.</p> <p>Characterization of various neoplasms including lung, endometrial and ovarian</p> <p>Most epithelial CXells / Pagets disease</p> <p>Clear cell carcinoma of the kidney</p> <p>C cell abnormalities of the thyroid</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT & Ultras to HI.S078 (cont'd):</p> <p>Racemase - AMACR</p> <p>BAP1</p> <p>Beta Catenin</p> <p>BCL2</p> <p>BCL6</p> <p>BerEP4/MOC31</p> <p>CKIT/CD117</p> <p>CA125</p> <p>CAM5.2</p> <p>Carbonic Anhydrase IX</p> <p>Calcitonin</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Pulmonary subtypes - mesothelioma</p> <p>Categorisation of lymphoid, renal, liver, connective tissue, and endometrial tumours</p> <p>Monocytic leukaemia</p> <p>Characterization of lymphoid tumours – Hodgkins disease</p> <p>Langerhan Cells</p> <p>Plasmacytoid Dendritic Cells / Associated Diseases</p> <p>Plasma Cells – Multiple Myeloma</p> <p>Colonic epithelium – normal/neoplastic</p> <p>B cells – normal/neoplastic</p> <p>Follicular dendritic cells– lymphoid tumour</p> <p>Systemic Mastocytosis</p> <p>T Cells – normal/neoplastic</p> <p>Endothelial Cells/tumours`</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT & Ultras to HI.S078 (cont'd):</p> <p>Calretinin/Thrombomodulin</p> <p>CD10</p> <p>CD14</p> <p>CD15</p> <p>CD1a/Langerin</p> <p>CD123</p> <p>CD138</p> <p>CDX2</p> <p>CD20/CD79a/PAX5/MUM1</p> <p>CD21/CD23</p> <p>CD25</p> <p>CD3/CD5/CD7/CD43/ Granzyme B/UCHL-1</p> <p>CD31/Factor 8</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Endothelial cells, GISTs, leukaemia's, and Connective tissue tumours</p> <p>T cell disease entities</p> <p>Bladder epithelium</p> <p>Small cell carcinoma of the lung & Carcinoids/neuroendocrine tumours</p> <p>Natural Killer cells</p> <p>Megakaryocytes</p> <p>Macrophages</p> <p>Erythroid precursor cells</p> <p>Ewings Sarcoma</p> <p>Distinguish between adenocarcinoma (+ve) and malignant mesothelioma (-ve).</p> <p>Neuroendocrine tumours</p> <p>Epithelial Cells</p> <p>Identifying primary site of a carcinoma – used in a panel</p> <p>Cytomegalovirus</p> <p>Mantle Cell Lymphoma</p> <p>Lymphatic endothelium</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT & Ultras to HI.S078 (cont'd):</p> <p>CD34</p> <p>CD4/8</p> <p>CD44</p> <p>CD56</p> <p>CD57</p> <p>CD61</p> <p>CD68/CD68PG</p> <p>CD71</p> <p>CD99</p> <p>CarcinoEmbryonic Antigen</p> <p>Chromogranin/Synaptophysin</p> <p>Cytokeratin pan (CK)</p> <p>CK5/CK7/CK8/CK14/CK17/CK18/CK19/CK20</p> <p>Cytomegalovirus</p> <p>CyclinD1/SOX11</p> <p>D2-40</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd) 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u> Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions. Smooth Muscle Cells – Normal/Neoplastic Gastrintestinal stromal tumours (GISTs) Epstein Bar Virus Breast Carcinoma Subtype - Ductal Tumour subtyping – Skin, Lymphoid Dermatofibromas Reed-Sternberg cells/dendritic cells Thyroid tumour subtyping Erythrocytes - Normal/Neoplastic Metastatic Breast Cancer Subtyping Germ cell tumours and Molar Pregnancies Hepatocytes – Normal/Neoplastic Kaposi Sarcoma Basal cells in Prostate/Thyroid tumour Subtyping	Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT & Ultras to HI.S078 (cont'd): Desmin/ H-Caldesmon/ Smooth Muscle Actin/ Smooth Muscle Myosin DOG 1 EBER/Epstein Bar Virus (LMP) ECaderin Epithelial Membrane Antigen Factor 13a FACSIN HBME (mesothelial cell) Glycophorin A Gross Cystic Disease Fluid Protein-15 Human Chorionic Gonadotrapin Hepatocyte Human Herpes Virus 8 High Molecular Weight Cytokeratin	A



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Melanomas</p> <p>Immune-complex disorders/Lymphoid tumour subtyping</p> <p>IgG-4 related systemic disease</p> <p>Characterisation of various genitourinary tract tumours</p> <p>Distinction between monoclonal (i.e. neoplastic), versus polyclonal (i.e. reactive) proliferation of B lymphoid cells</p> <p>Proliferation marker</p> <p>Lymphoid Cells</p> <p>Myeloid cells- Acute Myeloid Leukaemia</p> <p>Mast cells</p> <p>Mismatch repair proteins – Lynch Syndrome</p> <p>Skeletal muscle differentiation</p> <p>Striated muscle differentiation Expression levels for directed therapies</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry- Routine Ventana Benchmark XT & Ultras to HI.S078 (cont'd):</p> <p>HMB45/ MELA – Melanosome</p> <p>IgA/IgD/IgG/IgM</p> <p>IGG4</p> <p>Inhibin</p> <p>Kappa/Lambda</p> <p>KI67</p> <p>Leucocyte Common Antigen</p> <p>Lysozyme/ Myeloperoxidase</p> <p>MAST cell tryptase</p> <p>MLH1 MSH2 MSH6 PMS2</p> <p>Myogenin/Sarcometric</p> <p>Myoglobin Oestrogen/Progesterone Receptor</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Sub typing tumours of Mullerian origin</p> <p>Identification HPV associated neoplastic lesions – Cervix/Oral cavity</p> <p>Type II Pneumocytes / Basal Cells in Lung</p> <p>Subtyping Genitourinary tract tumours/ Prognostic indicator</p> <p>Complete Molar pregnancies</p> <p>Malignant prostatic/breast glands, and Squamous cell carcinoma</p> <p>Malignant Prostatic glands</p> <p>Epithelial cells / Lobular Carcinoma + ve</p> <p>Angioimmunoblastic lymphoma</p> <p>Prostate glands – Normal/Neoplastic</p> <p>Melanomas/nerve tumours</p> <p>Smooth Muscle and Myoepithelial cells</p> <p>Smooth Muscle and Myoepithelial cells Melanocytes / Melanoma</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT & Ultras to HI.S078 (cont'd): PAX8</p> <p>P16</p> <p>P40NAP</p> <p>P53</p> <p>P57</p> <p>P63</p> <p>P63/AM (double stain)</p> <p>P120</p> <p>PD1</p> <p>Prostatic Specific Antigen/</p> <p>Prostatic Acid Phosphatase</p> <p>S100</p> <p>Smooth muscle actin/ Smooth muscle myosin SOX 10</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Acute lymphoblastic lymphoma</p> <p>Thyroid epithelium – normal/neoplastic</p> <p>Primary adenocarcinoma of the Lung/Thyroid epithelium – normal/neoplastic</p> <p>Type II Pneumocytes / Basal Cells in Lung</p> <p>Metastatic Colorectal tumours</p> <p>All mesenchymal cells/co expression with CK in wide variety of tumours</p> <p>Ovarian tumours/mesothelioma/sarcomas</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT & Ultras to HI.S078 (cont'd):</p> <p>Terminal Deoxynucleotidyl Transferase</p> <p>Thyroglobulin</p> <p>Thyroid Transcription Factor 1</p> <p>TTFCK5</p> <p>Villin</p> <p>Vimentin</p> <p>Wilms Tumour</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE).</p> <p>Fresh tissue received in saline (predominantly renal and skin tissue)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue. DNA from whole blood</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of DNA or RNA sequences by means of hybridization of complimentary DNA/RNA:</p> <p>HER2 Breast HER2 Gastric</p> <p>Identification of antigens at a subcellular level by means of fluorescent antibodies.</p> <p>Identification of TCR and IGH in lymphoma cases by means of Polymerase Chain Reaction (PCR) technique.</p>	<p>Documented In-house Methods and Manufacturer's instructions for FISH (Fluorescence <i>in-situ</i> Hybridisation):</p> <p>Use of the probe types: Dual colour dual fusion Dual colour breakapart Locus specific Centromeric</p> <p>To detect the following chromosome anomalies: Chromosome rearrangements /translocations Gene amplifications/deletions</p> <p>HI.S059 BHH FISH protocol for HER2, Lymphoma and Lung. HER2 FISH scoring using the Abbott Bioview FISH digital Pathology Image Capture System SOP HI.S726</p> <p>Documented In-house Methods and Manufacturer's instructions for Histology Direct Immunofluorescence (DIF): HI.S333</p> <p>Documented In-house Methods and Manufacturer's instructions for PCR: HI.S203 Molecular SOP</p>	<p>A</p> <p>A</p> <p>A, D</p>



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HUMAN BODY FLUIDS	<u>Andrology examination activities for the purposes of clinical diagnosis</u>	Documented In-house Methods based on WHO 5 th Ed Guidelines:	
Semen	<u>Fertility Investigation semen analysis:</u> <ul style="list-style-type: none"> - <u>pH</u> - <u>Volume</u> - <u>Concentration</u> - <u>Total Sperm Count</u> - <u>Motility</u> - <u>Morphology</u> - <u>Sperm vitality</u> 	Semen analysis for Diagnostic Semen Analysis SOP: AY.S002	B
Semen	<u>Post vasectomy semen analysis:</u> -Absence/ presence of sperm (concentration) - Motility - Volume	Post vasectomy semen analysis SOP: AY.S003	B
Urine	<u>Identification of Retrograde Ejaculation:</u> Detection of semen	GHH Retrograde Examination Procedure SOP AY.S033	B
END			