

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Heart of England NHS Foundation Trust Issue No: 003 Issue date: 14 July 2016	
	Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS United Kingdom	Contact: Mr Steve Waller Tel: +44 (0)121 424 2035 Fax: +44(0)121 7532470 E-Mail: steve.waller@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	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	C
Address PHEPHLB Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Local contact Andrea Audley 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
<p>Address Phlebotomy Services- Out Patient Dept 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>	Blood Collection
<p>Address Phlebotomy Services -Out Patient Dept Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR</p>	<p>Local contact Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Collection
<p>Address Phlebotomy Services -Out Patient Dept Solihull Hospital Lode Lane Solihull B91 2JL</p>	<p>Local contact Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Collection
<p>Address Ward 19, 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>	Blood Issue Fridge
<p>Address Main Theatres, 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>	Blood Issue Fridge
<p>Address Maternity Delivery Unit, 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>	Blood Issue Fridge



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Location details		Activity
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
Address Mortuary, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Body storage Post Mortem
Address Body store Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Body storage
Address Body store Solihull Hospital Lode Lane Solihull B91 2JL	Local contact Louise Fallon Tel: +44 (0)121 424 1235	Body storage
Address Dermatology Department, Solihull Hospital Lode Lane Solihull B91 2JL	Local contact Louise Fallon Tel: +44 (0)121 424 1235	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	Alpha-Feto Protein (AFP)	BS.X169 BS.I169	A
Serum/Plasma	Alanine Aminotransferase (ALT)	BS.X009 BS.I009	A,B,C
Serum/Plasma	Albumin	BS.X200 BS.I200	A,B,C
Fluid	Albumin	BS.X200 BS.I200	A,B
Serum/Plasma	Alkaline Phosphatase (ALP)	BS.X005 BS.I005	A,B,C
Plasma	Ammonia	BS.X013 BS.I013	A,B
Serum/Plasma	Amylase	BS.X017 BS.I017	A,B,C
Fluid	Amylase	BS.X017 BS.I017	A,B
Urine	Amylase	BS.X005 BS.I005	A
Serum	Angiotensin Converting Enzyme (ACE)	BS.X282 BS.I282	A
Serum/Plasma	Aspartate Transaminase (AST)	BS.X250 BS.I250	A



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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	Beta HCG (not tumour marker)	BS.X233 BS.I233	A,B,C
Serum/Plasma	Bicarbonate	BS.X021 BS.I021	A,B,C
Serum	Bile Acids	BS.X025 BS.I025	A,B
Serum/Plasma	CA 15-3	BS.X181 BS.I181	A
Serum/Plasma	CA-125	BS.X189 BS.I189	A
Serum/Plasma	Caeruloplasmin	BS.X280 BS.I280	A,B
Serum/Plasma	Calcium	BS.X037 BS.I037	A,B,C
Urine	Calcium	BS.X037 BS.I037	A
Serum/Plasma	Carbamazepine	BS.X041 BS.I041	A
Serum/Plasma/fluid	Carcinoembryonic Antigen (CEA)	BS.X193 BS.I193	A
Serum/Plasma	Chloride	BS.X065 BS.I065	A,B,C
Urine	Chloride	BS.X065 BS.I065	A
Serum/Plasma	Cholesterol	BS.X045 BS.I045	A,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)	
Fluid	Cholesterol	BS.X045 BS.I045	A,B
Serum/Plasma	Conjugated Bilirubin (Synermed reagents)	BS.X061 BS.I061	A,B
Serum/Plasma	Cortisol	BS.X197 BS.I197	A,B
Serum/Plasma	C-reactive protein (CRP)	BS.X053 BS.I053	A,B,C
Serum/Plasma	Creatine Kinase (CK)	BS.X043 BS.I043	A,B,C
Serum/Plasma	Creatinine	BS.X049 BS.I049	A,B,C
Fluid	Creatinine	BS.X049 BS.I049	A,B
Urine	Creatinine	BS.X049 BS.I049	A
Whole blood	Ciclosporin	BS.X205 BS.I205 BS.S017	A
Serum/Plasma	Digoxin	BS.X057 BS.I057	A,B
Serum/Plasma	Ethanol	BS.X069 BS.I069	A
Serum/Plasma	Ferritin	BS.X213 BS.I213	A,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	Folate	BS.X217 BS.I217	A,B,C
Serum/Plasma	Follicle Stimulating Hormone (FSH)	BS.X221 BS.I221	A,B
Serum/Plasma	Free Thyroxine (FT4)	BS.X229 BS.I229	A,B,C
Serum/Plasma	Free Triiodothyronine (FT3)	BS.X225 BS.I225	A,B
Serum/Plasma	Gamma G.T. (GGT)	BS.X254 BS.I254	A,B,C
CSF	Glucose	BS.X073 BS.I073	A,B
Serum/Plasma	Glucose	BS.X073 BS.I073	A,B,C
Fluid	Glucose	BS.X073 BS.I073	A,B
Serum/Plasma	Haptoglobin	BS.X255 BS.I255	A
Serum/Plasma	High Density Lipoprotein (HDL)	BS.X077 BS.I077	A,B,C
Serum/Plasma	HIV Ab/Ag	CIT.S400	A
Serum/Plasma	hs-Troponin I	BS.X199 BS.I199	A,B,C
Serum/Plasma	Iron	BS.X097 BS.I097	A,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)	
Plasma/CSF	Lactate	BS.X101 BS.I101	A,B
Serum/Plasma/Fluid	Lactate Dehydrogenase (LDH)	BS.X105 BS.I105	A
Serum/Plasma	Lipoprotein (a) (Lp(a))	BS.X283 BS.I283	A
Serum/Plasma	Lithium	BS.X111 BS.I111	A,B
Serum/Plasma	Luteinising Hormone (LH)	BS.X249 BS.I249	A,B
Serum/Plasma	Monomeric Prolactin (Investigation of Macroprolactin)	CIT.S200	A
Serum/Plasma	Magnesium	BS.X113 BS.I113	A,B,C
Urine	Magnesium	BS.X113 BS.I113	A
Urine	Microalbumin	BS.X117 BS.I117	A
Serum/Plasma	Oestradiol	BS.X209 BS.I209	A
Serum/Plasma	Paracetamol	CIT.S203 CIT.I203	A,B,C
Serum/Plasma	Parathyroid Hormone (PTH)	CIT.S999 CIT.I619	A,B,C
Serum/Plasma	Phenytoin	BS.X121 BS.I121	A



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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	Phosphate	BS.X125 BS.I125	A,B,C
Urine	Phosphate	BS.X125 BS.I125	A
Serum/Plasma	Potassium	BS.X065 BS.I065	A,B,C
Urine	Potassium	BS.X065 BS.I065	A,B
Serum/Plasma	Progesterone	BS.X253 BS.I253	A,B,C
Serum/Plasma	Prolactin	BS.X257 BS.I257	A,B
Serum/Plasma	Prostate Specific Antigen (PSA)	BS.X273 BS.I273	A,B,C
Serum/Plasma	Salicylate	BS.X133 BS.I133	A,B,C
Serum/Plasma	Sex Hormone Binding Globulin (SHBG).	BS.X261 BS.I261	A
Serum/Plasma	Sodium	BS.X065 BS.I065	A,B,C
Urine	Sodium	BS.X065 BS.I065	A,B
Serum/Plasma	Testosterone (Male)	BS.X269 BS.I269	A
Serum/Plasma	Theophylline	BS.X137 BS.I137	A,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	Thyroid Stimulating Hormone (TSH)	BS.X281 BS.I281	A,B,C
Serum/Plasma	Total Bilirubin	BS.X141 BS.I141	A,B,C
Serum/Plasma	Total Protein	BS.X258 BS.I258	A,B,C
Fluid/CSF	Total Protein	BS.X258 BS.I258	A,B
Urine	Total Protein	BS.X258 BS.I258	A
Serum/Plasma	Triglycerides	BS.X258 BS.I258	A,B,C
Fluid	Triglycerides	BS.X258 BS.I258	A,B
Serum/Plasma	Unsaturated Iron Binding Capacity (UIBC)	BS.X149 BS.I149	A,B,C
Serum/Plasma	Urate	BS.X157 BS.I157	A,B,C
Urine	Urate	BS.X157 BS.I157	A
Serum/Plasma	Urea	BS.X153 BS.I153	A,B,C
Fluid	Urea	BS.X153 BS.I153	A,B
Urine	Urea	BS.X153 BS.I153	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	Valproate	BS.X165 BS.I165	A
Serum/Plasma	Vitamin B12	BS.X177 BS.I177	A,B,C
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
Urine	Albumin: Creatinine Ratio	BS.X117 BS.I117 BS.X049 BS.I049 CIT.S049	A,B,C
Serum/Plasma	Corrected Calcium	BS.X037 BS.I037 CIT.S049	A,B,C
Serum/Plasma	Globulins	BS.X258 BS.I258 BS.X200 BS.I200 CIT.S049	A,B,C
Serum/Plasma	Glomerular Filtration Rate (GFR)	BS.X049 BS.I049 CIT.S049	A,B,C
Serum/Plasma	Glucose Tolerance Tests	BS.S048	A,B,C
Serum/Plasma	LDL-Cholesterol	BS.X045 BS.I045 BS.X145 BS.I145 BS.X077 BS.I077 CIT.S049	A,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>		
Urine	Protein : Creatinine Ratio	BS.X161 BS.I161 BS.X049 BS.I049 CIT.S049	A
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,C
Serum/Plasma	Parathyroid Hormone (PTH)	Documented In-house Methods and Manufacturer's instructions for Roche Cobas e411 with specific reference to CIT.S999	A
Serum/Plasma	NT-Pro BNP	Documented In-house Methods and Manufacturer's instructions for Roche Cobas e411 with specific reference to CIT.S301	A
Serum/Plasma	CA 19-9	Documented In-house Methods and Manufacturer's instructions for Roche Cobas e411 with specific reference to CIT.S300	A
Urine	Urinary metanephrines Metanephrine, 3MT - 3-methoxytyramine	Documented In-house Methods and Manufacturer's instructions for API 5000 Tandem Mass Spectrometer: ST.S455	A
Plasma	Homocysteine	ST.S585	A
Serum/ Plasma	Female testosterone	ST.S066	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	Prednisolone Prednisolone, Prednisone, Cortisol and Cortisone	ST.S171	A
Serum/ Plasma	Urinary cortisol	ST.S1044	A
CSF	Xanthochromia	Documented In-house Methods and Manufacturer's instructions for Northstar Scientific Spectrophotometer ST.S077	A
Urine	Urinary Catecholamines Noradrenaline, Adrenaline and Dopamine	Documented In-house Methods and Manufacturer's instructions for Gilson ASTED XL HPLC with specific reference to ST.S076	A
Serum	ACRA -Acetylcholine Receptor Antibody	Documented In-house Methods and Manufacturer's instructions for the Wizard Gamma Counter ST.S211	A
Plasma	Renin Mass	Documented In-house Methods and Manufacturer's instructions for the GAMMA Counter CIT.S1952 Documented In-house Methods and Manufacturer's instructions for the API 6500 Tandem Mass Spectrometer:	A
Serum, Plasma	Aldosterone	CIT.S1000	A
Urine	Urinary Free Catecholamines: Adrenaline Noradrenaline Dopamine	CIT.S1004	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	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 ST.S465 ST.S172	A
Urine	Urinary 5HIAA	Documented In-house Methods and Manufacturer's instructions for KNAEUER and GILSON HPLC with specific reference to ST.S074	A
Serum/Plasma	TPMT – phenotype	Documented In-house Methods and Manufacturer's instructions for Waters HPLC: ST.S453 ST.S481 ST.S464	A
Serum	Vitamin A and E	ST.S450	
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	Sweat Conductivity Analysis	Documented In-house Methods and Manufacturer's instructions for Sweat Check Conductivity Analyser. Wescor Macroduct sweat collection system CIT.S1001	A
Sweat	Sweat Chloride	Documented In-house Methods and Manufacturer's instructions for Coulometric Titration using 925 Corning Analyser: CIT.S1006	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: Acute Kidney Injury (derived from creatinine)	CIT.S049	A, B, C
Serum/Plasma	Albumin:Globulin Ratio (derived from albumin and total protein)	CIT.S049	A, B, C
Serum/Plasma	Aldosterone:Renin Ratio	CIT.S049	A, B, C
Serum/Plasma	Creatinine Clearance	CIT.S049	A, B, C
Serum/Plasma	Non-HDL Cholesterol (derived from lipid profile (HDL, LDL-cholesterol)	CIT.S049	A, B, C
Serum/Plasma	Free Testosterone	CIT.S049	A, B, C
Serum/Plasma	Derived Tests in Immunology: Kappa:Lambda Ratio (derived from free light chains)	CIT.S049	A
	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Blood, Plasma, Serum, Urine	Bendroflumethiazide, Chlorthalidone (chlortalidone), Chlorothiazide, Frusemide (Furosemide), Hydrochlorothiazide, Indapamide, Metolazone, Polythiazide.	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2005	A
Serum, Plasma, Blood, Urine	Trace Elements: Aluminium, Arsenic, Cadmium, Chloride Chromium, Cobalt, Copper, Lead, Manganese, Selenium, Sodium, Zinc	Documented In-house Methods and Manufacturer's instructions for ICP-MS: CIT.S2008	A



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<p>HUMAN BODY FLUIDS / TISSUE (cont'd)</p> <p>Urine</p>	<p><u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis: (cont'd)</u></p> <p>Opiates - Morphine, Codeine, Dihydrocodeine & 6-monoacetyl morphine (6MAM)</p> <p>Opioids - Methadone and metabolite (EDDP), Buprenorphine and metabolite (norbuprenorphine)</p> <p>Amphetamines – Amphetamine (Amphetamine), Methamphetamine (Metamphetamine), MDA, MDMA & MDEA</p> <p>Benzodiazepines – Diazepam and metabolite (nordiazepam), oxazepam, temazepam, lorazepam, nitrazepam & midazolam</p> <p>Designer drugs - Benzylpiperazine (BZP), MDPV (bath salts), 4-Methylethcathinone (4-MEC, NRG), 4-Methylmethcathinone (Mephedrone, Meow Meow)</p> <p>Other drugs - Cocaine and metabolite (benzoylecgonine), Ketamine, Cannabis metabolite (11-nor-9-carboxy-tetrahydrocannabinol)</p>	<p>Documented In-house Methods and Manufacturer's instructions for API 4000 ((Tandem Mass Spectrometer) ST.S1050</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS / TISSUE (cont'd)</p> <p>Blood, Plasma, Serum, Tissues</p>	<p><u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis: (cont'd)</u></p> <p>Quantitative Method for: 4-methylethcathinone (4-MEC), Amphetamine (Amphetamine) Amitriptyline & Nortriptyline, Bisoprolol, Cocaine & Benzoyllecgonine, Codeine, Citalopram and Desmethylcitalopram, Clomipramine Diazepam Desipramine, Dihydrocodeine Diphenhydramine, Dothiepin (Dosulepin), EDDP, Fentanyl, Fluoxetine, Gliclazide, Ibuprofen, Imipramine, Ketamine, Lamotrigine, Levetiracetam, Lorazepam, MDA Mephedrone (Methymethcathinone), Midazolam, Methadone Methylenedioxyethylamphetamine (MDEA), Methylenedioxymethylamphetamine (MDMA), Methylmethcathinone (MMC), Midazolam, Mirtazapine, Naproxen, Nitrazepam, Norclozapine, Norcodeine, Nordiazepam, Nordothiepin (northiaden), Nortriptyline, ODV, Olanzapine, Oxazepam Oxycodone,</p>	<p>Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2001</p>	<p>A</p>



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD CIT.S2001 (cont'd):	
Blood, Plasma, Serum, Tissues (cont'd)	Paracetamol, Paramethoxyamphetamine (PMA), Paramethoxymethamphetamine (PMMA), Paroxetine, Pethidine, Phencyclidine (PCP), Phenobarbital, Phenytoin, Pimozide, Promethazine & Promethazine Sulphoxide, Propranolol, Quetiapine, Quinine, Salicylate, Sertraline, Sildenafil Temazepam, Trifluoromethylphenylpiperazine (TFMPP), Theophylline, Teriflunomide Tolbutamide, Tramadol & Desmethyltramadol, Tramadol Trazodone Venlafaxine, Verapamil Zopiclone		A
Blood, Plasma, Serum, Urine	Chlorpropamide, Glibenclamide, Gliclazide, Glimepiride, Glipizide, Tolbutamide	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2004	A



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HUMAN BODY FLUIDS / TISSUE (cont'd) Blood, Plasma, Serum, Urine, Tissues	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis (cont'd):</u> Qualitative Screening for: 4-Methylethcathinione (4MEC), 6-Monacetylmorphine (6MAM), 7-Aminoflunitrazepam, Amitriptyline, Amphetamine (Amfetamine), Bendroflumethiazide, Benzylpiperazine (BZP), Caffeine, Carbamazepine, Cathinone, Chlorpropamide, Chlorpheniramine, Citalopram, Clobazam, Clomipramine, Clozapine, Cocaine, Codeine, Cyclizine, Demoxepam, Desipramine, Desmethylcitalopram, Desmethyltramadol, Desmethylvenlafaxine, Diazepam, Dihydrocodeine, Diltiazem, Diphenhydramine, Dothiepin (Dosulepin), Doxazosin, EDDP (methadone metabolite), Escitalopram, Flunitrazepam, Furosemide, Glibenclamide, Gliclazide, Glimepiride, Glipizide, Hydrocodone, Ibuprofen, Imipramine, Indapamide	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD CIT.S2002	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Blood, Plasma, Serum, Urine, Tissues (cont'd)	Qualitative Screening for: Ketamine, Lamotrigine, Lorazepam, Methylenedioxypropyvalerone (MDPV), Mefenamic Acid, Methadone, Methamphetamine (Metamphetamine), Methylenedioxyamphetamine (MDA),	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD CIT.S2002 (cont'd)	
Blood, Plasma, Serum, Tissues	Cocaine Benzoylecgonine	Documented In-house Methods and Manufacturer's instructions for API 4000 ((Tandem Mass Spectrometer) CIT.S2018	A
Blood, Plasma, Serum, Tissues	Fentanyl Buprenorphine & Norbuprenorphine	Documented In-house Methods and Manufacturer's instructions for API 4000 ((Tandem Mass Spectrometer) CIT.S2013	A
Blood, Plasma, Serum, Tissues	Morphine glucuronide metabolites	Documented In-house Methods and Manufacturer's instructions for API 4000 ((Tandem Mass Spectrometer) ST.S1051	A
Blood, Plasma, Serum, Tissues	Paracetamol	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD ST.S591	A
Blood, Plasma, Serum, Tissues	Valproate	Documented In-house Methods and Manufacturer's instructions for API 4000 ((Tandem Mass Spectrometer) ST.S1052	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis (cont'd):</u>		
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: CIT.S2010	A
Blood, Plasma, Serum	Gabapentin and Pregabalin	Documented In-house Methods and Manufacturer's instructions for HPLC-DAD: CIT.S2003	A
Blood, Plasma, Serum	Clozapine, Olanzapine, Quetiapine, Risperidone, 9hydroxy risperidone	Documented In-house Methods and Manufacturer's instructions for LC-MS/MS: CIT.S2007	A
Oral Fluid	Drugs of Abuse: Opiates - Morphine, Codeine, Dihydrocodeine & 6-monoacetyl morphine (6MAM) Opioids - Methadone and metabolite (EDDP), Buprenorphine and metabolite (norbuprenorphine) Amphetamines – Amphetamine (Amphetamine), Methamphetamine (Metamphetamine), MDA, MDMA & MDEA Benzodiazepines – Diazepam and metabolite (Nordiazepam), Oxazepam, Temazepam, Lorazepam, Nitrazepam, Midazolam & Flunitrazepam	Documented In-house Methods and Manufacturer's instructions for LC-MS: CIT.S2011	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for LC-MS: CIT.S2011 (cont'd):	
Oral Fluid	Designer drugs - Benzylpiperazine (BZP), MDPV (bath salts), 4-Methylethcathinone (4-MEC, NRG), 4-Methylmethcathinone (Mephedrone, Meow Meow) Other drugs - Cocaine and metabolites (AEME and Benzoylecgonine), Ketamine, Cannabis (THC), Gabapentin, Pregabalin, Quetiapine		A
Urine	Antihypertensive Drugs Calcium Channel Blockers (CBB's): - Amlodipine, Diltiazem, Felodipine, Nifedipine, Verapamil Angiotensin-Converting Enzyme (ACE) Inhibitors: - Enalapril, Lisinopril, Perindopril, Ramipril Angiotensin Receptor Blockers (ARB's): - Candesartan , Irbesartan, Losartan Diuretics: - Bendroflumethiazide, Hydrochlorothiazide, Indapamide, Furosemide Sympathetic Blockers (α and β blockers: - Atenolol, Bisoprolol, Doxazosin, Labetalol, Metoprolol Others: - Carenone (Spironolactone metabolite) and Moxonidine (Imidazoline receptor subtype 1 agonist)	Documented In-house Methods and Manufacturer's instructions for LC-MS/MS: CIT.S2012	A



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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 TOP500 (site A)/ TOP300 (site B,C):	
Citrated Plasma	Anti Xa assay	HA.S661	A
Citrated Plasma	Antithrombin III level	HA.S657	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	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	von Willebrand factor level	HA.S663	A
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: HA.S604	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>		
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 OptiMAL IT kit: BS.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 MONO-LEX IM TEST KIT BS.S058	A,B,C
Plasma: EDTA	Plasma viscosity	Documented in-house method for Capillary resistance, Benson BV1 analyser: BS.S197	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	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	HbA1c	Documented In-house Methods and Manufacturer's instructions for TOSOH G8 HPLC analyser with specific reference to ST.090	A
Whole Blood	Hb variant confirmation	Documented In-house Methods and Manufacturer's instructions for Sebia Capillary Electrophoresis: ST.S399	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 ST.S008	A
Whole Blood	G6PD (Qualitative) screen	Trinity Biotech 203-A screening kit - fluorescence under UV light: HA.S082	A
Whole Blood	G6PD (Quantitative) assay	Trinity Biotech Kit 345 assay – measured using UVIKON Xs Spectrophotometer: HA.S082	A
Whole Blood	Sickle solubility test for presence of sickle haemoglobin (HbS)	Streck Sickledex Kit: ST.S400	A, B
CSF	Production of Cytospin and Staining Preparations	Shandon Cytospin Centrifuge. ST.S176	A



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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:	
Bone marrow peripheral blood	Acute Leukaemias	ST.S021	
Bone marrow peripheral blood	B lymphoproliferative T lymphoproliferative	ST.S024 ST.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	
Bone marrow/ Peripheral blood	MDS/Leukaemia screen. Short panel to identify presence of blast cells.	ST.S026	
Bone marrow/ Peripheral blood	Minimal Residual Disease (MRD)	ST.S033	
Bone marrow/Peripheral blood	Myeloma /MGUS	HA.S506	
Whole Blood	Paroxysmal Nocturnal Haemoglobinuria	ST.S017	
	<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. – (excluding neonatal patients)	Compatibility testing using LISS/Coombs gel column agglutination and centrifugation BB.S119. Manual techniques	A, B, C
Plasma	Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma antibody. - Neonatal patients ≤ 4 months of age	Compatibility testing using LISS/Coombs gel column agglutination and centrifugation BB.S107. Manual techniques	A, B



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Plasma	Antibody Screening – Automated Technique 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).	Antibody screening using LISS/Coombs gel column agglutination and centrifugation SOP BB.S103 BB.S205 Antenatal BB.S201	A, B, C
Whole blood	Red Cell Phenotyping	LISS/Coombs gel column agglutination and Centrifugation. Titres by macroscopic agglutination in tubes BB.S109	A, B, C
Whole blood	Direct Antiglobulin Test	LISS/Coombs gel column agglutination and Centrifugation. Titres by macroscopic agglutination in tubes 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	Biorad analysers, Gelstation and IH1000. ABO/D Forward + Reverse Grouping by Gel column agglutination and centrifugation BB.S103 BB.S205	A, B, C
WHOLE BLOOD	Blood Group - Manual	Cards: BB.S104	A, B, C
WHOLE BLOOD	Blood Group: Manual	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



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<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	BS.X251 BS.I251	A
Serum/Plasma	Anti-thyroid TPO abs.	BS.X173 BS.I173	A
Serum/Plasma	B2-microglobulin	BS.X252 BS.I252	A
Serum/Plasma	Complement C3	BS.X029 BS.I029	A
Serum/Plasma	Complement C4	BS.X033 BS.I033	A
Serum/Plasma	IgA	BS.X085 BS.I085	A, B
Serum/Plasma	IgM	BS.X093 BS.I093	A, B
Serum/Plasma	IgG	BS.X089 BS.I089	A, B
Serum/Plasma	Rheumatoid Factor	BS.X129 BS.I129	A, B
Serum	Free Light Chains (Kappa & Lambda)	Documented In-house Methods and Manufacturer's instructions for Binding Site SPA ^{PLUS} Turbidimeter: BS.X650 BS.I650 BS.X263 BS.I651	A
Serum	IgG Subclasses (IgG, IgG1, IgG2, IgG3, IgG4)	BS.X256 BS.I625	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>	Documented In-house Methods and Manufacturer's instructions for Beta Counter: CIT.S1695 (cont'd):	
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/plasma	Intrinsic factor antibodies (IFAB)	Documented In-house Methods and Manufacturer's instructions for DS2 Automated ELISA workstation ST.S163 and: ST.S340	A
Serum/plasma	Diphtheria antibodies (DIPH)	ST.S146	
Serum/plasma	Haemophilus influenza type B antibodies (HIBAB)	ST.S147	
Serum/plasma	Pneumococcal antibodies (PNEUAB)	ST.S148	
Serum/plasma	Tetanus antibodies (TETAB)	ST.S149	
Plasma	Detection of latent TB	Documented In-house Methods and Manufacturer's instructions for manual ELISA using the Multiskan plate reader: Quantiferon TB Gold (QFT)ST.S046	A
Plasma		Quantiferon TB Plus (QFTPL)CIT.S1696	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>		A
Plasma	Detection of CMV antibodies	Documented In-house Methods and Manufacturer's instructions for manual ELISA using the Multiskan plate reader: (cont'd) Quantiferon CMV (QFCMV)CIT.S1699	
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
Whole blood	Cell marker analysis for diagnosis and monitoring of Immunodeficiency: T cell markers B cell markers NK cell markers MHC ABC and DR CD45 Ra and Ro TCR alpha/beta and gamma/delta Leucocyte adhesion deficiency markers Neutrophil respiratory burst	Documented In-house Methods and Manufacturer's instructions for Navios Flow Cytometer: CIT.S1619 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 for FP1000 and Navios flow cytometer with specific reference to:CIT.S1625	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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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Serum	Anti-Cardiolipin antibodies (IgG+IgM) Anti-Beta2glycoprotein antibodies (IgG+IgM) Specific IgG to Aspergillus (ASPG) Specific IgG to Avian (budgerigar and pigeon) (AVG) Anti-Cyclic citrullinated peptide antibodies (CCP) Anti-Double stranded DNA antibodies (DNA) Anti-Extractable nuclear antigen antibody screen (ENAS) Anti-Extractable nuclear antigen antibody typing (Ro, La, SmDP, RNP, Jo-1 and Scl-70) (ENAT) Anti-Glomerular basement membrane antibody (GBM) 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
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 Quantalyser slide staining workstation UV microscope and QUANTALink reporting software: ST.S301, ST.S100, ST.S104	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-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 Documented In-house Methods and Manufacturer's instructions for Sebia Capillarys and Hydrasys instruments:	A
Urine	Bence-Jones protein (BJP)	ST.S113	A
Serum	Paraprotein densitometry (DEN)	ST.S114	A
Serum	Protein electrophoresis (EL)	ST.S101	A
Serum/ urine	Immunofixation (IFIX and IFIXU)	ST.S109 ST.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: ST.S132	A
	<u>Molecular (Haematology) examination activities for the purposes of clinical diagnosis:</u>		
Whole blood	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



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Molecular (Chemistry) examination activities for the purposes of clinical diagnosis:</u>		
Whole blood	TPMT- genotype	Documented In-house Methods and Manufacturer's instructions for Step-One RT-PCR (PCR – Allelic discrimination methods): ST.S481	A
HUMAN BODY TISSUE	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u>		
Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue Frozen Tissue MOHs collected tissue	Routine diagnostic examination of Histological specimens using the following:	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 Hologic T5000 Benchtop Processor CY.S343 Hologic T2000 Processor CY.S306 Prisma automated stainer and coverslipper Non – gynae Sample Preparation Manual CY.S301	A



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HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues.	Documented In-house Methods and Manufacturer's instructions for Haematoxylin & Eosin stain: HI.S083 Tissue Tek Prisma Staining Machine / Coverslipper.	A
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	Special staining of Histopathology examinations to assist in detection of clinical abnormalities.	Documented In-house Methods for special stains HI.S216	A
	Acid mucins	Alcian Blue pH 1.0, pH2.5 (AB)	
	Glycogen and neutral mucins	Periodic Acid Schiff (PAS) (Diastase PAS)	
	Acid and neutral mucins	Alcian Blue pH 2.5 PAS	
	Glycogen and mucins	Alcian Blue pH 2.5 Hyaluronadase	
	Gram positive and negative bacteria	Brown Brenn Gram Gram stain	
	Amyloid	Congo Red	
	H.pylori	Cresyl Fast violet (CFV)	
	Elastic fibres	Elastic Van Gieson Haematoxylin Van Gieson	
	Malarial parasites	Geimsa	
	Fungi	Grocotts Silver Stain (Manual) Grocotts Silver Stain (Benchmark Special Stainer BSS)	
	Connective tissue and fibrin	Martius Scarlet Blue	



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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> Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd):. Melanin Basophil/Eosinophil/Neutrophil granules Neutral mucins Neutral lipids Hepatitis B Antigen Basement Membranes Ferric iron Fibrin, neuroglia, muscle striations Reticulin fibres Copper Calcium Spirocheates	Documented In-house Methods for special stains HI.S216 (cont'd): Masson Fontana Masson's Trichrome Stain Mucicarmine (Manual) Mucicarmine (Benchmark Special Stainer BSS) Oil Red O Orcein Periodic Acid Silver Method for Basement Membranes (Manual) Periodic Acid Silver Method for Basement Membranes (Benchmark Special Stainer BSS) Perl's Prussian Blue (Manual) Perl's Prussian Blue (Benchmark Special Stainer BSS) Phosphotungstic acid Haematoxylin PTAH Reticulin Method (Manual) Reticulin Method (Benchmark Special Stainer BSS) Rubeanic Acid Von Kossa Method Warthin-Starry (Manual) Method (Benchmark Special Stainer BSS)	A



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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> 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 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	
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	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 to HI.S078 (cont'd):	A
	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	



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HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	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 to HI.S078 (cont'd):	A
	High grade prostatic intraepithelial neoplasm (HGPIN) & prostate adenocarcinoma	Racemase - AMACR	
	Subtypes of endometrioid & mesenchymal tumours	Beta Catenin	
	Lymphoid tumours, particularly follicular lymphoma	BCL2	
	Follicle centre B-cells – lymphoid tumours	BCL6	
	Epithelial Cell types	BerEP4/MOC31	
	Gastrintestinal stromal tumours (GISTs), mast cells and their relevant disorders.	BerEP4/MOC31	
	Characterization of various neoplasms including lung, endometrial and ovarian	CKIT/CD117	
	Clear cell carcinoma of the kidney	CA125	
	C cell abnormalities of the thyroid	Carbonic Anhydrase IX	
	C cell abnormalities of the thyroid	Calcitonin	
	Pulmonary subtypes - mesothelioma	Calretinin/Thrombomodulin	
	Categorisation of lymphoid, renal, liver, connective tissue, and endometrial tumours	CD10	
	Monocytic leukaemia	CD14	
	Characterization of lymphoid tumours – Hodgkins disease	CD15	



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HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	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 to HI.S078 (cont'd):	A
	Langerhan Cells	CD1a/Langerin	
	Plasma Cells – Multiple Myeloma	CD138	
	Colonic epithelium – normal/neoplastic	CDX2	
	B cells – normal/neoplastic	CD20/CD79a/PAX5/MUM1	
	Follicular dendritic cells– lymphoid tumour	CD21/CD23	
	Systemic Mastocytosis	CD25	
	T Cells – normal/neoplastic	CD3/CD5/CD7/CD43/ Granzyme B/UCHL-1	
	Endothelial Cells/tumours	CD31/Factor 8	
	Endothelial cells, GISTs, leukaemia's, and Connective tissue tumours	CD34	
	Thyroid tumour subtyping	CD4/8	
	Astrocytes – Normal/Neoplastic	CD44	
	Erythrocytes - Normal/Neoplastic	CD56	
	Metastatic Breast Cancer	CD57	
	Subtyping Germ cell tumours and Molar Pregnancies	CD61	
	Hepatocytes – Normal/Neoplastic	CD68/CD68PG	
	Kaposi Sarcoma	CD71	



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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>Basal cells in Prostate/Thyroid tumour Subtyping</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 Leukeamia</p> <p>Mast cells</p> <p>Mismatch repair proteins – Lynch Syndrome</p> <p>Skeletal muscle differentiation Striated muscle differentiation</p> <p>Tumours showing neural differentiation</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark to HI.S078 (cont'd):</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>Desmin/ H-Caldesmon/ Smooth Muscle Actin/ Smooth Muscle Myosin</p> <p>DOG 1</p> <p>EBER/Epstein Bar Virus (LMP)</p> <p>Desmin/ H-Caldesmon/ Smooth Muscle Actin/ Smooth Muscle Myosin</p> <p>DOG 1</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	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 to HI.S078 (cont'd):	A
	Prognostic indicator for Acute Myeloid Leukeamia	EBER/Epstein Bar Virus (LMP)	
	Expression levels for directed therapies	ECaderin	
	Sub typing tumours of Mullerian origin	Epithelial Membrane Antigen	
	Identification HPV associated neoplastic lesions – Cervix/Oral cavity	Factor 13a	
	Subtyping Genitourinary tract tumours/ Prognostic indicator	FASCIN	
	Complete Molar pregnancies	Galactin 3/ HBME (mesothelial cell)	
	Malignant prostatic/breast glands, and Squamous cell carcinoma	Glial Fibrillary Protein	
	Malignant Prostatic glands	Glycophorin A	
	Angioimmunoblastic lymphoma	Gross Cystic Disease Fluid Protein-15	
	Pneumocystis Carinii	Human Chorionic Gonadothrapin	
	Prostate glands – Normal/Neoplastic	Hepatocyte	
	Melanomas/nerve tumours	Human Herpes Virus 8	
	Smooth Muscle and Myoepithelial cells	High Molecular Weight Cytokeratin	
	Acute lymphoblastic lymphoma	HMB45/ MELA – Melanosome	



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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>Thyroid epithelium – normal/neoplastic</p> <p>Primary adenocarcinoma of the Lung/ Thyroid epithelium – normal/neoplastic</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 to HI.S078 (cont'd):</p> <p>IgA/IgD/IgG/IgM</p> <p>IGG4</p> <p>Inhibin</p> <p>Kappa/Lambda</p> <p>KI67 Leucocyte Common Antigen Lysozyme/ Myeloperoxidase MAST cell tryptase MLH1 MSH2 MSH6 PMS2 Myogenin/Sarcometric Myoglobin Neuro filament protein Oestrogen/Progesterone Receptor PAX8 P16 P53 P57 P63 & P63/AM (double stain) PD1 Pneumocystis Prostatic Specific Antigen/ Prostatic Acid Phosphotase S100 Smooth muscle actin/ Smooth muscle myosin Terminal Deoxynucleotidyl Transferase Thyroglobulin</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	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 to HI.S078 (cont'd):	A
	Ovarian tumours/mesothelioma/sarcomas (cont'd)	Thyroid Transcription Factor 1 Villin Vimentin Wilms Tumour	
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE).	Identification of DNA or RNA sequences by means of hybridization of a complimentary DNA/RNA (probes). HER2 Breast HER2 Gastric ALK1 Lung Lymphoma	Documented In-house Methods and Manufacturer's instructions for FISH (Fluorescence <i>in-situ</i> Hybridisation): HI.S059 BHH FISH protocol for HER2, Lymphoma and Lung	A
Fresh tissue received in saline (predominantly renal and skin tissue)	Identification of antigens at a subcellular level by means of fluorescent antibodies.	Documented In-house Methods and Manufacturer's instructions for Histology Direct Immunofluorescence (DIF): HI.S333	A
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue. DNA from whole blood	Identification of TCR and IGH in lymphoma cases by means of Polymerase Chain Reaction (PCR) technique.	Documented In-house Methods and Manufacturer's instructions for PCR: HI.S203 Molecular SOP	A, D



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HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Liquid based cytology samples taken as part of the cervical screening programme	Morphology assessment of gynaecological Cervical ThinPrep Liquid Based Specimens	Documented In-house Methods and Manufacturer's instructions for: Hologic T5000 Autoloader: CY.S238 Papanicolaou Stain CY.S347	A
Liquid based cytology samples taken as part of the cervical screening programme	Identification of Human Papilloma Virus	Documented In-house Methods and Manufacturer's instructions for Abbott m2000sp using magnetic particle technology to capture nucleic acids. MI.S2078 MI.S2106 CY.S440	A, D
Semen	<u>Andrology examination activities for the purposes of clinical diagnosis</u> <u>Fertility Investigation semen analysis:</u> - pH - Volume - Concentration - Count - Motility - Morphology - Sperm vitality	Documented In-house Methods based on WHO 5 th Ed Guidelines: Semen analysis for fertility SOP: AY.S002	B
Semen	<u>Post vasectomy semen analysis:</u> -Absence/ presence of sperm - Motility	Post vasectomy SOP: AY.S003	B
END			