


# 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>	<b>University Hospitals Birmingham NHS Foundation Trust</b>	
	<b>Issue No: 006 Issue date: 08 August 2018</b>	
	<b>University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston B15 2WB</b>	<b>Contact: Ms Marie Nolan Tel: +44 (0)121 424 2035 Fax: +44(0)121 7532470 E-Mail: marie.nolan@heartofengland.nhs.uk Website: www.heartofengland.nhs.uk</b>
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code	
<b>Address</b> Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	<b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235	Haematology Clinical Biochemistry Toxicology Cytopathology Immunology Molecular Biology Histopathology Transfusion Blood Issue Fridge	A
<b>Address</b> Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR	<b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235	Haematology Clinical Biochemistry Transfusion Blood Issue Fridge Andrology	B
<b>Address</b> Solihull Hospital Lode Lane Solihull B91 2JL	<b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235	Haematology Clinical Biochemistry Transfusion Blood Issue Fridge	C
<b>Address</b> PHEPHLB Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	<b>Local contact</b> Andrea Blowers 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><b>Address</b> Phlebotomy Services- Out Patient Dept Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Collection
<p><b>Address</b> Phlebotomy Services -Out Patient Dept Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Collection
<p><b>Address</b> Phlebotomy Services -Out Patient Dept Solihull Hospital Lode Lane Solihull B91 2JL</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Collection
<p><b>Address</b> Ward 19, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Issue Fridge
<p><b>Address</b> Main Theatres, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Issue Fridge
<p><b>Address</b> Maternity Delivery Unit, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Issue Fridge



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Location details	Activity
<p><b>Address</b> Clinical Haematology Unit, Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Issue Fridge
<p><b>Address</b> Main Theatres, Good Hope Hospital Rectory Rd, Sutton Coldfield, West Midlands B75 7RR</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Issue Fridge
<p><b>Address</b> Maternity Delivery Unit, Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Blood Issue Fridge
<p><b>Address</b> Mortuary, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Body storage Post Mortem
<p><b>Address</b> Body store Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Body storage
<p><b>Address</b> Body store Solihull Hospital Lode Lane Solihull B91 2JL</p> <p><b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235</p>	Body storage
<p><b>Address</b> Dermatology Department, Solihull Hospital Lode Lane Solihull B91 2JL</p> <p><b>Local contact</b> 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	Alpha-Feto Protein (AFP)	CIT.X169 CIT.I169	A
Serum/Plasma	Alanine Aminotransferase (ALT)	CIT.X009 CIT.I009	A,B,C
Serum/Plasma	Albumin	CIT.X200 CIT.I200	A,B,C
Fluid	Albumin	CIT.X200 CIT.I200	A,B
Serum/Plasma	Alkaline Phosphatase (ALP)	CIT.X005 CIT.I005	A,B,C
Plasma	Ammonia	CIT.X013 CIT.I013	A,B
Serum/Plasma	Amylase	CIT.X017 CIT.I017	A,B,C
Fluid	Amylase	CIT.X017 CIT.I017	A,B
Urine	Amylase	CIT.X005 CIT.I005	A
Serum	Angiotensin Converting Enzyme (ACE)	CIT.X282 CIT.I282	A
Serum/Plasma	Aspartate Transaminase (AST)	CIT.X250 CIT.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)	CIT.X233 CIT.I233	A,B,C
Serum/Plasma	Bicarbonate	CIT.X021 CIT.I021	A,B,C
Serum	Bile Acids	CIT.X025 CIT.I025	A,B
Serum/Plasma	CA 15-3	CIT.X181 CIT.I181	A
Serum/Plasma	CA-125	CIT.X189 CIT.I189	A
Serum/Plasma	Caeruloplasmin	CIT.X280 CIT.I280	A,B
Serum/Plasma	Calcium	BS.X037 BS.I037	A,B,C
Urine	Calcium	CIT.X037 CIT.I037	A
Serum/Plasma	Carbamazepine	CIT.X041 CIT.I041	A
Serum/Plasma/fluid	Carcinoembryonic Antigen (CEA)	CIT.X193 CIT.I193	A
Serum/Plasma/Urine	Chloride	CIT.X065 CIT.I065	A,B,C
Serum/plasma	Cholesterol	IT.X045 CIT.I04	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	CIT.X045 CIT.I045	A,B
Serum/Plasma	Conjugated Bilirubin (Synermed reagents)	CIT.X061 CIT.I061	A,B
Serum/Plasma	Cortisol	CIT.X197 CIT.I197	A,B
Serum/Plasma	C-reactive protein (CRP)	CIT.X053 CIT.I053	A,B,C
Serum/Plasma	Creatine Kinase (CK)	CIT.X043 CIT.I043	A,B,C
Serum/Plasma	Creatinine	CIT.X049 CIT.I049	A,B,C
Fluid	Creatinine	CIT.X049 CIT.I049	A,B
Urine	Creatinine	CIT.X049 CIT.I049	A
Whole blood	Ciclosporin	CIT.X205 CIT.I205 CIT.S017	A
Serum/Plasma	Digoxin	CIT.X057 CIT.I057	A,B
Serum/Plasma	Ethanol	CIT.X069 CIT.I069	A
Serum/Plasma	Ethylene Glycol	CIT.S222	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	Ferritin	CIT.X213 CIT.I213	A,B,C
Serum/Plasma	Folate	CIT.X217 CIT.I217	A,B,C
Serum/Plasma	Follicle Stimulating Hormone (FSH)	CIT.X221 CIT.I221	A,B
Serum/Plasma	Free Thyroxine (FT4)	CIT.X229 CIT.I229	A,B,C
Serum/Plasma	Free Triiodothyronine (FT3)	CIT.X225 CIT.I225	A,B
Serum/Plasma	Gamma G.T. (GGT)	CIT.X254 CIT.I254	A,B,C
CSF	Glucose	CIT.X073 CIT.I073	A,B
Serum/Plasma	Glucose	CIT.X073 CIT.I073	A,B,C
Fluid	Glucose	CIT.X073 CIT.I073	A,B
Serum/Plasma	Haptoglobin	CIT.X255 CIT.I255	A
Serum/Plasma	High Density Lipoprotein (HDL)	CIT.X077 CIT.I077	A,B,C
Serum/Plasma	HIV Ab/Ag	CIT.S400	A
Serum/Plasma	hs-Troponin I	CIT.X199 CIT.I199	A,B,C
Serum/Plasma	Iron	CIT.X097 CIT.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	CIT.X101 CIT.I101	A,B
Serum/Plasma/Fluid	Lactate Dehydrogenase (LDH)	CIT.X105 CIT.I105	A
Serum/Plasma	Lipoprotein (a) (Lp(a))	CIT.X283 CIT.I283	A
Serum/Plasma	Lithium	CIT.X111 CIT.I111	A,B
Serum/Plasma	Luteinising Hormone (LH)	CIT.X249 CIT.I249	A,B
Serum/Plasma	Monomeric Prolactin (Investigation of Macroprolactin)	CIT.S200	A
Serum/Plasma	Magnesium	CIT.X113 CIT.I113	A,B,C
Urine	Magnesium	CIT.X113 CIT.I113	A
Blood, serum, urine	Methotrexate (MTX)	CIT.S2025	A
Urine	Microalbumin	CIT.X117 CIT.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	CIT.X121 CIT.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	CIT.X125 CIT.I125	A,B,C
Urine	Phosphate	CIT.X125 CIT.I125	A
Serum/Plasma	Potassium	CIT.X065 CIT.I065	A,B,C
Urine	Potassium	CIT.X065 CIT.I065	A,B
Serum/Plasma	Progesterone	CIT.X253 CIT.I253	A,B,C
Serum/Plasma	Prolactin	CIT.X257 CIT.I257	A,B
Serum/Plasma	Prostate Specific Antigen (PSA)	CIT.X273 CIT.I273	A,B,C
Serum/Plasma	Salicylate	CIT.X133 CIT.I133	A,B,C
Serum/Plasma	Sex Hormone Binding Globulin (SHBG).	CIT.X261 CIT.I261	A
Serum/Plasma	Sodium	CIT.X065 CIT.I065	A,B,C
Urine	Sodium	CIT.X065 CIT.I065	A,B
Serum/Plasma	Testosterone (Male)	CIT.X269 CIT.I269	A
Serum/Plasma	Theophylline	CIT.X137 CIT.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)	CIT.X281 CIT.I281	A,B,C
Serum/Plasma	<u>Tobramycin</u>	CIT.S2021	A
Serum/Plasma	Total Bilirubin	CIT.X141 CIT.I141	A,B,C
Serum/Plasma	Total Protein	CIT.X258 CIT.I258	A,B,C
Fluid/CSF	Total Protein	CIT.X258 CIT.I258	A,B
Urine	Total Protein	CIT.X258 CIT.I258	A
Serum/Plasma	Triglycerides	CIT.X258 CIT.I258	A,B,C
Fluid	Triglycerides	CIT.X258 CIT.I258	A,B
Serum/Plasma	Unsaturated Iron Binding Capacity (UIBC)	CIT.X149 CIT.I149	A,B,C
Serum/Plasma	Urate	CIT.X157 CIT.I157	A,B,C
Urine	Urate	CIT.X157 CIT.I157	A
Serum/Plasma	Urea	CIT.X153 CIT.I153	A,B,C
Fluid	Urea	CIT.X153 CIT.I153	A,B
Urine	Urea	CIT.X153 CIT.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>	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	Vancomycin CIT.S2021	CIT.S2021	A
Serum/Plasma	Valproate	CIT.X165 CIT.I165	A
Serum/Plasma	Vitamin B12	CIT.X177 CIT.I177	A,B,C
Serum/plasma	25 – hydroxyvitamin D	CIT.S505	A
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,C
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



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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 API 5000 Tandem Mass Spectrometer (cont):	
Serum/ Plasma	Urinary cortisol	CIT.S1044	A
CSF	Xanthochromia	Documented In-house Methods and Manufacturer's instructions for Northstar Scientific Spectrophotometer CIT.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 CIT.S1004	A
Serum	ACRA -Acetylcholine Receptor Antibody	Documented In-house Methods and Manufacturer's instructions for the Wizard Gamma Counter CIT.S1971	A
Urine	Urinary Free Catecholamines: Adrenaline Noradrenaline Dopamine	Documented In-house Methods and Manufacturer's instructions for the API 6500 Tandem Mass Spectrometer:  CIT.S1004	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
Urine	Urinary 5HIAA	Documented In-house Methods and Manufacturer's instructions for KNAEUER and GILSON HPLC with specific reference to CIT.S1060	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	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	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
Whole Blood	HbA1c	Documented In-house Methods and Manufacturer's instructions for TOSOH G8 HPLC analyser with specific reference to CIT.S1015	A
	Derived Tests in Clinical Chemistry:		
Serum/Plasma	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



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>		
	Derived Tests in Clinical Chemistry (cont'd):		
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>		
Blood, Plasma, Serum, Urine	Qualitative screen for diuretic drugs. This method will detect the following:  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	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



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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	Selenium,  Zinc	Documented In-house Methods and Manufacturer's instructions for ICP-MS: CIT.S2008	A
Sweat	Quantitative measurement of Sodium and Chloride		A
Urine	Targeted drugs of abuse screen in urine. The method will detect the following compounds:  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:  Opioids - Methadone and metabolite	Documented In-house Methods and Manufacturer's instructions for API 4000 (Tandem Mass Spectrophotometer) CIT.S2017	A
	Opiates - Morphine, Codeine, Dihydrocodeine & 6-monoacetyl morphine (6MAM)		A
	EDDP), Buprenorphine and metabolite (norbuprenorphine)		A
	Amphetamines – Amphetamine (Amphetamine)		A
	Methamphetamine (Methamphetamine),		A





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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Urine	Targeted drugs of abuse screen in urine. The method will detect the following compounds:  MDA, MDMA & MDEA  Benzodiazepines – Diazepam and metabolite (nordiazepam), oxazepam, temazepam, lorazepam, nitrazepam & midazolam	Documented In-house Methods and Manufacturer's instructions for API 4000 (Tandem Mass Spectrophotometer) CIT.S2017	A  A
Urine	Designer drugs - Benzylpiperazine (BZP), MDPV (bath salts), 4-Methylethcathinone (4-MEC, NRG), 4-Methylmethcathinone (Mephedrone, Meow Meow)  Other drugs - Cocaine and metabolite (benzoylecgonine), Ketamine, Cannabis metabolite (11-nor-9-carboxy-tetrahydrocannabinol)		A
Blood, Plasma, Serum, Tissues	Quantitative Methods for the following drugs:  4-methylethcathinone (4-MEC),  Amitriptyline & Nortriptyline,  Bisoprolol, Cocaine & Benzoylecgonine, Codeine, Citalopram and Desmethylcitalopram,  Clomipramine  Desipramine,  Dihydrocodeine	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2001	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Blood, Plasma, Serum, Tissues	Quantitative Methods for the following drugs:  Diphenhydramine, Dothiepin (Dosulepin), EDDP, Fentanyl, Fluoxetine, Gliclazide, Ibuprofen, Imipramine, Ketamine, Lamotrigine, Levetiracetam, Lorazepam, Mephedrone (Methymethcathinone), Midazolam, Methylenedioxyethylamphetamine (MDEA), Methylmethcathinone (MMC), Mirtazapine, Naproxen, Nitrazepam,	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2001	A



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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:</u></p> <p>Quantitative Methods for the following drugs:</p> <p>Norclozapine,</p> <p>Norcodeine,</p> <p>Nordothiepin (northiaden),</p> <p>Nortriptyline,</p> <p>ODV,</p> <p>Olanzapine,</p> <p>Oxycodone,</p> <p>Paracetamol,</p> <p>Paramethoxyamphetamine (PMA),</p> <p>Paramethoxymethamphetamine (PMMA), Paroxetine,</p> <p>Pethidine,</p> <p>Phencyclidine (PCP),</p> <p>Phenobarbital,</p> <p>Phenytoin,</p> <p>Pimozide,</p> <p>Promethazine &amp; Promethazine Sulphoxide,</p> <p>Propranolol,</p> <p>Quetiapine,</p> <p>Quinine,</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:</u>		
Blood, Plasma, Serum, Tissues	Quantitative Methods for the following drugs:  Salicylate,  Sertraline,  Sildenafil  Trifluoromethylphenylpiperazine (TFMPP)  Theophylline  Teriflunomide  Tolbutamide,  Tramadol & Desmethyltramadol,  Tramadol  Trazodone  Venlafaxine,  Verapamil  Zopiclone	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2001	A
Blood, Plasma, Serum, Urine	Qualitative screen for sulphonylurea drugs. This method will detect the following:  Chlorpropamide,  Glibenclamide,  Gliclazide,  Glimepiride,	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2004	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Blood, Plasma, Serum, Urine	Qualitative screen for sulphonylurea drugs. This method will detect the following:  Glipizide,  Tolbutamide	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD: CIT.S2004	A
Blood, Plasma, Serum, Urine, Tissues	Qualitative Screening for the following drugs:  4-Methylethcathinone (4MEC), 6-Monacetylmorphine (6MAM), 7-Aminoflunitrazepam, Amitriptyline, Amphetamine (Amfetamine), Bendroflumethiazide, Benzylpiperazine (BZP), Caffeine, Carbamazepine, Cathinone, Chlorpropamide, Chlorpheniramine, Citalopram, Clobazam, Clomipramine, Clozapine,	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD CIT.S2002	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:</u>  Qualitative Screening for the following drugs:  Cocaine,  Codeine,  Cyclizine,  Demoxepam,  Desipramine,  Desmethylcitalopram,  Desmethyltramadol, Desmethylvenlafaxine,  Diazepam,  Dihydrocodeine,  Diltiazem,  Diphenhydramine,  Dothiepin (Dosulepin),  Doxazosin,  EDDP (methadone metabolite), Escitalopram,  Flunitrazepam,  Furosemide,  Glibenclamide,  Qualitative Screening for:  Gliclazide,	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD CIT.S2002	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:</u>  Qualitative Screening for the following drugs:  Glimepiride,  Glipizide,  Hydrocodone,  Ibuprofen,  Imipramine,  Indapamide  Ketamine,  Lamotrigine,  Lorazepam,  Methylenedioxypropylamphetamine (MDPV),  Mefenamic Acid  Methadone,  Methamphetamine (Metamphetamine),  Methylenedioxyamphetamine (MDA),  Methylenedioxyethylamphetamine (MDEA),  Methylenedioxymethylamphetamine (MDMA),  Methylmethcathinone (MMC),	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD CIT.S2002	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:</u>  Qualitative Screening for the following drugs:  Midazolam,  Mirtazipine,  Naproxen,  Nitrazepam,  Norclozapine,  Norcodeine,  Nordiazepam,  Nordothiepin (northiaden),  Nortriptyline,  Olanzapine,  Oxazepam,  Oxycodone,  Paracetamol,  Paramethoxyamphetamine (PMA),  Paramethoxymethamphetamine (PMMA)  Paroxetine,  Phencyclidine (PCP),  Phenytoin,	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD CIT.S2002	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:</u>  Qualitative Screening for the following drugs:  Pimozide,  Propranolol,  Quetiapine,  Quinine,  Salicylate,  Sertraline,  Temazepam, Trifluoromethylphenylpiperazine (TFMPP), Theophylline,  Tolbutamide,  Tramadol,  Trazadone,  Venlafaxine,  Verapamil,  Zopiclone	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:</u>  Quantitative measurement of:	Documented In-house Methods and Manufacturer's instructions for API 4000 ((LC-MS/MS Tandem Mass Spectrometer):	
Blood, serum, urine	Benzodiazepine Quantitation (Diazepam, Nordiazepam, Oxazepam and Temazepam) Midazolam Amphetamine Gabapentin Pregabalin Methadone MDMA / MDA Urine Cotinine	CIT.S2025	A
Blood, Plasma, Serum	Clozapine, Olanzapine, Quetiapine, Risperidone, 9hydroxy risperidone	CIT.S2007	A
Blood, Plasma, Serum, Tissues	Cocaine Benzoyllecgonine	CIT.S2018	A
Blood, Plasma, Serum, Tissues	Fentanyl Buprenorphine & Norbuprenorphine	CIT.S2013	A
Blood, Plasma, Serum, Tissues	Morphine and glucuronide metabolites	CIT.S2019	A
Blood, Plasma, Serum, Tissues	Valproate	ST.S1052	A
Blood, Plasma, Serum, Tissues	Paracetamol	Documented In-house Methods and Manufacturer's instructions for HPLC_DAD ST.S591	A
Blood, urine	Ethanol, Methanol, Acetone	Documented In-house Methods and Manufacturer's instructions for GC-HS: CIT.S2009	A



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HUMAN BODY FLUIDS / TISSUE (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
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
Oral Fluid	Targeted drugs of abuse screen in oral fluid. The method will detect the following compounds:  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  Designer drugs - Benzylpiperazine (BZP), MDPV (bath salts),  4-Methylethcathinone (4-MEC, NRG), 4-Methylmethcathinone (Mephedrone, Meow Meow)	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:</u>		
Oral Fluid	Targeted drugs of abuse screen in oral fluid. The method will detect the following compounds:  Other drugs - Cocaine and metabolites (AEME and Benzoylecgonine), Ketamine, Cannabis (THC), Gabapentin, Pregabalin, Quetiapine	Documented In-house Methods and Manufacturer's instructions for LC-MS: CIT.S2011	A
Urine	Targeted screen for antihypertensive drugs in urine. The method will detect the following compounds:  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 ( $\alpha$ and $\beta$ 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	



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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	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	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
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 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	Plasma viscosity	Documented in-house method for Capillary resistance, Benson BV1 analyser: CIT.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	Hb variant confirmation	Documented In-house Methods and Manufacturer's instructions for Sebia Capillary Electrophoresis: HA.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 HA.S008	A
Whole Blood	G6PD (Quantitative) assay	Abbott Architect using Pointe Scientific kit to HA.S931	A
Whole Blood	Sickle solubility test for presence of sickle haemoglobin (HbS)	Streck Sickledex Kit: HA.S400	A, B
CSF	Production of Cytospin and Staining Preparations	Shandon Cytospin Centrifuge. HA.S176	A
Bone marrow peripheral blood	Acute Leukaemias	Documented In-house Methods and Manufacturer's instructions for Navios Flow Cytometer: 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:	
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. – (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
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





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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. 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 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 SPA <sup>PLUS</sup> Turbidimeter: CIT.X650 CIT.I650 CIT.X263 CIT.I651	A
Serum	IgG Subclasses (IgG, IgG1, IgG2, IgG3, IgG4)	CIT.X256 CIT.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>		
Whole blood	Lymphocyte proliferation studies using the following stimuli to measure cell proliferation by incorporation of <sup>3</sup> H thymidine. To evaluate T-lymphocyte function.	Documented In-house Methods and Manufacturer's instructions for Beta Counter: CIT.S1695:	A
	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)		
Serum/plasma		Documented In-house Methods and Manufacturer's instructions for DS2 Automated ELISA workstation ST.S163 and:	A
	Intrinsic factor antibodies (IFAB)	ST.S340	
	Diphtheria antibodies (DIPH)	ST.S146	
	Haemophilus influenza type B antibodies (HIBAB)	ST.S147	
	Pneumococcal antibodies (PNEUAB)	ST.S148	
Plasma	Quantiferon TB Plus (QFTPL)	CIT.S1696	



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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 DS2 Automated ELISA workstation ST.S163 and:	A
Serum/plasma	Salmonella typhii antibody quantification	CIT.S1148	
	Tetanus antibodies (TETAB)	ST.S149	
Plasma		Documented In-house Methods and Manufacturer's instructions for manual ELISA using the Multiskan plate reader:	
	Detection of latent TB (QFT)	Quantiferon TB Gold (QFT)ST.S046	A
	Detection of CMV antibodies (QFCMV)	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.S1640	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	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
Serum	Anti-Cardiolipin antibodies (IgG+IgM)	Documented In-house Methods and Manufacturer's instructions for Phadia Immunocap 250: CIT.S1512	A
	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.faei (MFG)		
	Anti-Myeloperoxidase antibodies (MPOS)		



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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-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 Immucap 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-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: 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



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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 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: ST.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) methylene tetrahydrofolate 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)  Whole blood	<u>Molecular (Chemistry) examination activities for the purposes of clinical diagnosis:</u>  TPMT- genotype	Documented In-house Methods and Manufacturer's instructions for Step-One RT-PCR (PCR – Allelic discrimination methods): CIT.S1014	A



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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. Roche HE600 Haematoxylin and Eosin staining machine 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</p>	A
<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 &amp; Eosin stain: HI.S083 Tissue Tek Prisma Staining Machine / Coverslipper. Roche HE600</p>	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis</u> (cont'd)		
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	
	Melanin	Masson Fontana	
	Basophil/Eosinophol/Neutorphil granules	Masson's Trichrome Stain	



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HUMAN BODY TISSUE (cont'd)	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis</u> (cont'd)		
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 (cont'd):	Documented In-house Methods for special stains HI.S216 (cont'd):	A
	Neutral mucins	Mucicarmine (Manual) Mucicarmine (Benchmark Special Stainer BSS)	
	Neutral lipids	Oil Red O	
	Hepatitis B Antigen	Orcein	
	Basement Membranes	Periodic Acid Silver Method for Basement Membranes (Manual) Periodic Acid Silver Method for Basement Membranes (Benchmark Special Stainer BSS)	
	Ferric iron	Perl's Prussian Blue (Manual) Perl's Prussian Blue (Benchmark Special Stainer BSS)	
	Fibrin, neuroglia, muscle striations	Phosphotungstic acid Haematoxylin PTAH	
	Reticulin fibres	Reticulin Method (Manual) Reticulin Method (Benchmark Special Stainer BSS)	
	Copper	Rubeanic Acid	
	Calcium	Von Kossa Method	
	Spirocheates	Warthin-Starry (Manual) Method (Benchmark Special Stainer BSS)	



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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	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 Phosphotase	
	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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<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>Identify patients eligible for PD-L1 positive treatments - Clones SP263</p> <p>High grade prostatic intraepithelial neoplasm (HGPIN) &amp; prostate adenocarcinoma</p> <p>Subtypes of endometrioid &amp; 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>Clear cell carcinoma of the kidney</p> <p>C cell abnormalities of the thyroid</p> <p>Pulmonary subtypes - mesothelioma</p> <p>Categorisation of lymphoid, renal, liver, connective tissue, and endometrial tumours</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry- Routine Ventana Benchmark to HI.S078 (cont'd):</p> <p>PD-L1 Antibody</p> <p>Racemase - AMACR</p> <p>Beta Catenin</p> <p>BCL2</p> <p>BCL6</p> <p>BerEP4/MOC31</p> <p>CKIT/CD117</p> <p>CA125</p> <p>Carbonic Anhydrase IX</p> <p>Calcitonin</p> <p>Calretinin/Thrombomodulin</p> <p>CD10</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
	Monocytic leukaemia	CD14	
	Characterization of lymphoid tumours – Hodgkins disease	CD15	
	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	
	T cell disease entities	CD4/8	
	Bladder epithelium	CD44	
	Small cell carcinoma of the lung & Carcinoids/neuroendocrine tumours	CD56	
	Natural Killer cells	CD57	



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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
	Megakaryocytes	CD61	
	Macrophages	CD68/CD68PG	
	Erythroid precursor cells	CD71	
	Ewings Sarcoma	CD99	
	Distinguish between adenocarcinoma (+ve) and malignant mesothelioma (-ve).	CarcinoEmbryonic Antigen	
	Neuroendocrine tumours	Chromogranin/Synaptophysin	
	Epithelial Cells	Cytokeratin pan (CK)	
	Identifying primary site of a carcinoma – used in a panel	CK5/CK7/CK8/CK14/CK17/CK18/CK19/CK20	
	Cytomegalovirus	Cytomegalovirus	
	Mantle Cell Lymphoma	CyclinD1/SOX11	
	Lymphatic endothelium	D2-40	
	Smooth Muscle Cells – Normal/Neoplastic	Desmin/ H-Caldesmon/ Smooth Muscle Actin/ Smooth Muscle Myosin	
	Gastrintestinal stromal tumours (GISTs)	DOG 1	





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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
	Epstein Bar Virus	EBER/Epstein Bar Virus (LMP)	
	Breast Carcinoma Subtype - Ductal	ECaderin	
	Tumour subtyping – Skin, Lymphoid	Epithelial Membrane Antigen	
	Dermatofibromas	Factor 13a	
	Reed-Sternberg cells/dendritic cells	FACSIN	
	Thyroid tumour subtyping	Galactin 3/ HBME (mesothelial cell)	
	Astrocytes – Normal/Neoplastic	Glial Fibrillary Protein	
	Erythrocytes - Normal/Neoplastic	Glycophorin A	
	Metastatic Breast Cancer	Gross Cystic Disease Fluid Protein-15	
	Subtyping Germ cell tumours and Molar Pregnancies	Human Chorionic Gonadotropin	
	Hepatocytes – Normal/Neoplastic	Hepatocyte	
	Kaposi Sarcoma	Human Herpes Virus 8	
	Basal cells in Prostate/Thyroid tumour Subtyping	High Molecular Weight Cytokeratin	
	Melanomas	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>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</p> <p>Tumours showing neural differentiation</p> <p>Expression levels for directed therapies</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</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</p> <p>Neuro filament protein</p> <p>Oestrogen/Progesterone Receptor</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
	Sub typing tumours of Mullerian origin	PAX8	
	Identification HPV associated neoplastic lesions – Cervix/Oral cavity	P16	
	Subtyping Genitourinary tract tumours/ Prognostic indicator	P53	
	Complete Molar pregnancies	P57	
	Malignant prostatic/breast glands, and Squamous cell carcinoma	P63	
	Malignant Prostatic glands	P63/AM (double stain)	
	Angioimmunoblastic lymphoma	PD1	
	Pneumocystis Carinii	Pneumocystis	
	Prostate glands – Normal/Neoplastic	Prostatic Specific Antigen/	
	Melanomas/nerve tumours	Prostatic Acid Phosphotase	
	Smooth Muscle and Myoepithelial cells	S100	
	Smooth Muscle and Myoepithelial cells	Smooth muscle actin/ Smooth muscle myosin	
	Acute lymphoblastic lymphoma	Terminal Deoxynucleotidyl Transferase	
	Thyroid epithelium – normal/neoplastic	Thyroglobulin	



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**Issue No:** 006 **Issue date:** 08 August 2018

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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
	Primary adenocarcinoma of the Lung/Thyroid epithelium – normal/neoplastic	Thyroid Transcription Factor 1	
	Metastatic Colorectal tumours	Villin	
	All mesenchymal cells/co expression with CK in wide variety of tumours	Vimentin	
	Ovarian tumours/mesothelioma/sarcomas	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 Papanicolau 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 <sup>th</sup> 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			