


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p><b>8217</b></p> <p>Accredited to ISO 15189:2012</p>	<b>University Hospitals Birmingham NHS Foundation Trust</b>	
	<b>Issue No: 014    Issue date: 23 August 2021</b>	
<b>Birmingham Heartlands Hospital</b> <b>Bordesley Green Road</b> <b>Bordesley Green East</b> <b>Birmingham</b> <b>B9 5SS</b>	<b>Contact: Michelle Waterworth</b> <b>Tel: +44 (0)121 424 2035</b> <b>E-Mail: michellewaterworth@heartofengland.nhs.uk</b> <b>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 MOHS Clinica	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 MOHS Clinic	C
<b>Address</b> PHEPLB Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	<b>Local contact</b> Hannah Tanner Tel: +44 (0)121 424 3194	Processing Patient Samples	D



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**Site activities performed away from the locations listed above:**

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



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Location details	Activity	
<b>Address</b> Mortuary, Birmingham Heartlands Hospital Bordesley Green Road Bordesley Green East Birmingham B9 5SS	<b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235	Body storage Post Mortem
<b>Address</b> Body store Good Hope Hospital Rectory Rd, Sutton Coldfield, B75 7RR	<b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235	Body storage
<b>Address</b> Body store Solihull Hospital Lode Lane Solihull B91 2JL	<b>Local contact</b> Louise Fallon Tel: +44 (0)121 424 1235	Body storage
<b>Address</b> Dermatology Department, Solihull Hospital Lode Lane Solihull B91 2JL	<b>Local contact</b> 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>  <u>Quantitative determination of:</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry and with specific reference to: CIT.S110 and CIT.S112 for Alinity analysers at site A; CIT.S001 and CIT.S002 for Architect analysers at sites B and C and:	
Serum/Plasma	Alpha-Feto Protein (AFP)	CIT.X402 CITS.I002	A
Serum/Plasma	Alanine Aminotransferase (ALT)	CIT.X447, CITS.I005 CIT.X009; CIT.I009	A B,C
Serum/Plasma	Albumin	CIT.X403, CITS.I003 CIT.X200; CIT.I200	A, B,C
Fluid	Albumin	CIT.X473 CITS.I003	A
Serum/Plasma	Alkaline Phosphatase (ALP)	CIT.X424, CITS.I004 CIT.X005, CIT.I005	A, B,C
Serum/Plasma	Amikacin	CIT.S2021 CIT.I318 CIT.X318	A
Plasma	Ammonia	CIT.X452 CITS.I006	A,
Serum/Plasma	Amylase	CIT.X407; CITS.I007 CIT.X017, CIT.I017	A, B,C
Fluid	Amylase	CIT.X473 CITS.I007	A
Urine	Amylase	CIT.X755, CITS.I007	A



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (CONT'D)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>  <u>Quantitative determination of:</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry and with specific reference to: CIT.S110 and CIT.S112 for Alinity analysers at site A; CIT.S001 and CIT.S002 for Architect analysers at sites B and C and:	
Serum	Angiotensin Converting Enzyme (ACE)	CIT.X418 CIT.I282	A
Serum/Plasma	Aspartate Transaminase (AST)	CIT.X408 CITS.I008	A
Serum/Plasma	Beta HCG (not tumour marker)	CIT.X409, CITS.I009 CIT.X233, CIT.I233	A, B,C
Serum/Plasma	Bicarbonate	CIT.X420, CITS.I020 CIT.X021, CIT.I021	A, B,C
Serum	Bile Acids	CIT.X320, CIT.I320 CIT.X025, CIT.I025	A, B
Serum/Plasma	CA 15-3	CIT.X411 CITS.I011	A
Serum/Plasma	CA-125	CIT.X413 CITS.I013	A
Serum/Plasma	Caeruloplasmin	CIT.X280 CIT.I280	B
Serum/Plasma	Calcium	CIT.X415, CITS.I015 CIT.X037, CIT.I037	A, B,C
Urine	Calcium	CIT.X755, CITS.I015	A
Faeces	Calprotectin	CIT.X2010, CIT.S890	A,



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Serum/Plasma/	Carcinoembryonic Antigen (CEA)	CIT.X416, CITS.I016 CIT.I193	A
Serum/Plasma/	Chloride	CIT.X323, CIT.I323 CIT.X065, CIT.I065	A, B,C
Urine	Chloride	CIT.X755, CIT.I501 CIT.X065, CIT.I065	A B
Serum/plasma	Cholesterol	CIT.X417, CITS.I017 CIT.X045, CIT.I045	A, B,C
Fluid	Cholesterol	CIT.X473, CITS.I017	A
Serum/Plasma	Conjugated Bilirubin (Synermed reagents)	CIT.X426, CIT.I061 CIT.X061, CIT.I061	A, B
Serum/Plasma	Cortisol	CIT.X422, CITS.I022 CIT.X197, CIT.I197	A, B
Serum/Plasma	C-reactive protein (CRP)	CIT.X421, CITS.I021 CIT.X053, CIT.I053	A, B,C
Serum/Plasma	Creatine Kinase (CK)	CIT.X419, CITS.I019 CIT.X043, CIT.I043	A, B,C
Serum/Plasma	Creatinine (Enzymatic)	CIT.X423, CITS.I023 CIT.S310, CIT.I049	A, B,C
Fluid	Creatinine (Enzymatic)	CIT.X473, CITS.I023	A



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Urine	Creatinine (Enzymatic)	CIT.X755, CITS.I023	A
Serum/Plasma	Digoxin	CIT.X425, CITS.I025 CIT.X057, CIT.I057	A B
Serum/Plasma	Ethanol	CIT.X428 CITS.I028	A
Serum/Plasma	Ferritin	CIT.X429, CITS.I029 CIT.X213 CIT.I213	A, B,C
Serum/Plasma	Folate	CIT.X430, CITS.I030 CIT.X217 CIT.I217	A B
Serum/Plasma	Follicle Stimulating Hormone (FSH)	CIT.X432, CITS.I032 CIT.X221 CIT.I221	A B
Serum/Plasma	Free Thyroxine (FT4)	CIT.X434, CITS.I034 CIT.X229 CIT.I229	A B,C
Serum/Plasma	Free Triiodothyronine (FT3)	CIT.X433, CITS.I033 CIT.X225 CIT.I225	A B
Serum/Plasma	Gamma G.T. (GGT)	CIT.X437, CITS.I037 CIT.X254 CIT.I254	A B
Serum/Plasma	Gentamicin (GENT)	CIT.X435, CITS.I035	A



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CSF	Glucose	CIT.X472, CITS.I038 CIT.X073 CIT.I073	A B
Serum/Plasma	Glucose	CITS.I038, CIT.X438 CIT.X073 CIT.I073	A B,C
Fluid	Glucose	CITS.I038, CIT.X473	A
Serum/Plasma	Haptoglobin	CIT.X436, CITS.I036	A
Serum/Plasma	High Density Lipoprotein (HDL)	CIT.X439, CITS.I039 CIT.X077 CIT.I077	A B,C
Serum/Plasma	hs-Troponin I	CIT.X465, CITS.I065 CIT.X199 CIT.I199	A B,C
Serum/Plasma	Iron	CIT.X440, CITS.I040 CIT.X097 CIT.I097	A B,C
Plasma/	Lactate	CIT.X327 , CIT.I327 CIT.X101 CIT.I101	A B
CSF	Lactate	CIT.I327, CIT.X472 CIT.X101 CIT.I101	A B
Serum/Plasma	Lactate Dehydrogenase (LDH)	CITS.I041, CIT.X441	A





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Fluid	Lactate Dehydrogenase (LDH)	CIT.X473, CITS.I041	A
Serum/Plasma	Lipoprotein (a) (Lp(a))	CIT.X469, CIT.I283	A
Serum/Plasma	Lithium	CIT.X443, CITS.I043 CIT.X111 CIT.I111	A, B
Serum/Plasma	Luteinising Hormone (LH)	CIT.X442, CITS.I042 CIT.X249 CIT.I249	A, B
Serum/Plasma	Monomeric Prolactin (Investigation of Macroprolactin)	CIT.S200	A
Serum/Plasma	Magnesium	CIT.X444, CITS.I044 CIT.X113 CIT.I113	A, B,C
Urine	Magnesium	CITS.I044, CIT.X755	A
Serum	Methotrexate (MTX)	CIT.S2026, CIT.X445, CITS.I045	A
Urine	Microalbumin	CIT.I1171, CIT.X755	A
Serum/Plasma	NT-ProBNP (BNP)	CIT.X446, CITS.I046	A
Serum/Plasma	Oestradiol	CIT.X427, CITS.I027	A
Serum/Plasma	Paracetamol	CIT.X470, CIT.I203 CIT.S203, CIT.I203	A B,C



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (CONT'D)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>  <u>Quantitative determination of:</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry and with specific reference to: CIT.S110 and CIT.S112 for Alinity analysers at site A; CIT.S001 and CIT.S002 for Architect analysers at sites B and C and:	
Serum/Plasma	Parathyroid Hormone (PTH)	CIT.X454, CITS.I054	A
Serum/Plasma	Phenytoin	CIT.X448, CITS.I048	A
Serum/Plasma	Phosphate	CIT.X449, CITS.I049 CIT.X125 CIT.I125	A, B,C
Urine	Phosphate	CITS.I049. CIT.X755	A
Serum/Plasma	Potassium	CIT.X457, CIT.I501 CIT.X065 CIT.I065	A, B,C
Urine	Potassium	CIT.I501. CIT.X755 CIT.X065 CIT.I065	A, B
Serum/Plasma	Progesterone	CIT.X450, CITS.I050 CIT.X253 CIT.I253	A, B,C
Serum/Plasma	Prolactin	CIT.X451, CITS.I051 CIT.X257 CIT.I257	A, B
Serum/Plasma	Prostate Specific Antigen (PSA)	CIT.X474, CITS.I053 CIT.X273 CIT.I273	A, B,C
Serum/Plasma	Salicylate	CIT.X455, CITS.I055 CIT.X133 CIT.I133	A, B,C



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HUMAN BODY FLUIDS / TISSUE (CONT'D)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>  <u>Quantitative determination of:</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry and with specific reference to: CIT.S110 and CIT.S112 for Alinity analysers at site A; CIT.S001 and CIT.S002 for Architect analysers at sites B and C and:	
Serum/Plasma	Sex Hormone Binding Globulin (SHBG).	CIT.X456, CITS.I056	A
Serum/Plasma	Sodium	CIT.X459, CIT.I501 CIT.X065 CIT.I065	A, B,C
Urine	Sodium	CIT.I501, CIT.X755 CIT.X065 CIT.I065	A, B
Serum/Plasma	Testosterone (Male)	CIT.X332, CIT.I332	A
Serum/Plasma	Theophylline	CIT.X458, CITS.I058 CIT.X137 CIT.I137	A, B
Serum/Plasma	Thyroid Stimulating Hormone (TSH)	CIT.X462, CITS.I062 CIT.X281 CIT.I281	A, B,C
Serum/Plasma	Tobramycin	CIT.X340, CIT.I340	A
Serum/Plasma	Total Bilirubin	CIT.X410, CITS.I010 CIT.X141 CIT.I141	A, B,C
Fluid	Bilirubin	CIT.X473, CITS.I010	A
Serum/Plasma	Total Protein	CIT.X341, CIT.I341 CIT.X258 CIT.I258	A, B,C



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HUMAN BODY FLUIDS / TISSUE (CONT'D)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>  <u>Quantitative determination of:</u>	Documented In-house Methods and Manufacturer's instructions for Abbott Chemistry and with specific reference to: CIT.S110 and CIT.S112 for Alinity analysers at site A; CIT.S001 and CIT.S002 for Architect analysers at sites B and C and:	
Urine	Total Protein	CITS.I059, CIT.X755 CIT.X258 CIT.I258	A, B
CSF	Total Protein		A B
CSF	Total Protein	CITS.I059, CIT.X472 CIT.I258 CIT.X258	A B
Fluid	Total protein	CIT.X473, CIT.I341	A
Serum/Plasma	Triglycerides	CIT.X461, CITS.I061 CIT.X258 CIT.I258	A, B,C
Fluid	Triglycerides	CIT.X473, CITS.I061	A
Serum/plasma	Transferrin	CIT.X460, CITS.I060	A
Serum/Plasma	Urate	CIT.X467, CITS.I067 CIT.X157 CIT.I157	A, B,C
Urine	Urate	CITS.I067, CIT.X755	A
Serum/Plasma	Urea	CIT.X466, CITS.I066 CIT.X153 CIT.I153	A, B,C
Urine	Urea	CITS.I066, CIT.X755	A
Fluid	Urea	CIT.X473, CITS.I066	A



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Serum/Plasma	Vancomycin	CIT.S2021, CIT.X468, CITS.I068	A
Serum/Plasma	Valproate	CIT.X471, CIT.I330	A
Serum/Plasma	Vitamin B12	CIT.X463, CITS.I063 CIT.X177 CIT.I177	A, B,C
Serum/plasma	25 – hydroxyvitamin D	CIT.X464, CITS.I064 CIT.S505	A B
Serum/Plasma/urine	Osmolality — Solute concentration of the sample	Documented In-house Methods and Manufacturer's instructions for Advanced Instruments with specific reference to CIT.S221	A,B
Serum/Plasma	Sodium (Direct ISE)	Documented In-house Methods and Manufacturer's instructions for IL Lab – Ilyte with specific reference to CIT.S220	A,B,
Urine	Urinary metanephrines Metanephrine, 3MT - 3-methoxytyramine	Documented In-house Methods and Manufacturer's instructions for API 5000 Tandem Mass Spectrometer:  CIT.S455	A
Plasma	Homocysteine	CIT.S585	A
Serum/ Plasma	Female testosterone	CIT.S171	A



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HUMAN BODY FLUIDS / TISSUE (CONT'D)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented In-house Methods and Manufacturer's instructions:	
Serum/ Plasma	Prednisolone Prednisolone, Prednisone, Cortisol and Cortisone, Dexamethasone	API 5000 Tandem Mass Spectrometer:  CIT.S1066	A
Serum/ Plasma	Urinary cortisol	CIT.S1044	A
Urine	Urinary 5HIAA	Documented In-house Methods and Manufacturer's instructions for Sciex 6500Q Tandem Mass Spectrometer:  Chromsystems kit CIT.S1060	A
Plasma Urine	Metanephrines Urinary Free Catecholamines Noradrenaline, Adrenaline and Dopamine	CIT.S1020 Documented In-house Methods and Manufacturer's instructions API65000 LC-MS/MS with specific reference to CIT.S1004	A A
Blood	Thiopurine metabolites	Documented In-house Methods and Manufacturer's instructions API65000 LC-MS/MS with specific reference to CIT.X250	A
Serum/ Plasma	Vitamin D Vitamin D2, Vitamin D3 Total Vitamin D	Documented In-house Methods and Manufacturer's instructions for the API 4500 and API 5000 Tandem Mass Spectrometer CIT.S1011	A
Serum/Plasma	TPMT – phenotype	Documented In-house Methods and Manufacturer's instructions for Shimadzu HPLC: CIT.S1008 CIT.S1014, ST.S464	A



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Serum	Vitamin A and E	Shimadzu HPLC: CIT.S1450	A
Serum	Vitamin E:Cholesterol ratio Derived test based on ratio of Vitamin E to Cholesterol	Vitamin E-HPLC with florescence detection: CIT.S049	A
Sweat	Sodium	Documented In-house Methods and Manufacturer's instructions ICP/MS: CIT.S1001, CIT.S2008	A
Sweat	Chloride	Documented In-house Methods and Manufacturer's instructions ICP/MS: CIT.S1001, CIT.S2008	A
Serum/Plasma	Non-HDL Cholesterol	Derived Tests in Clinical Chemistry: CIT.S049	A, B, C
Serum/Plasma	Free Testosterone	CIT.S049	A, B, C
Urine	Albumin: Creatinine Ratio	CIT.X117 CIT.I117 CIT.X049 CIT.I049 CIT.S049	A,B,C
Serum/Plasma	Corrected Calcium	CIT.X037 CIT.I037 CIT.S049	A,B,C
Serum/Plasma	Globulins	CIT.X258 CIT.I258 CIT.X200 CIT.I200 CIT.S049	A,B,C
Serum/Plasma	Glomerular Filtration Rate (GFR)	CIT.X049 CIT.I049 CIT.S049	A,B,C



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS / TISSUE (CONT'D)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>		
Serum/Plasma	LDL-Cholesterol	Derived Tests in Clinical Chemistry: 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 Serum/Plasma	Albumin: Globulin Ratio Creatinine Clearance	CIT.S049 CIT.S049	A, B, C A, B, C
	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Serum, Plasma, Blood, Urine	Quantitative measurement of the following elements:  Aluminium,  Arsenic,  Cadmium,  Chromium,  Cobalt,	Documented In-house Methods and Manufacturer's instructions for ICP-MS: CIT.S2008	A





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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>		
Serum, Plasma, Blood, Urine	Copper, Lead, Manganese, Selenium, Zinc	Documented In-house Methods and Manufacturer's instructions for ICP-MS: CIT.S2008	A
Sweat	Quantitative measurement of Sodium and Chloride		
Urine	Opiates - Morphine, Codeine, Dihydrocodeine & 6-monoacetyl morphine (6MAM)	Documented In-house Methods and Manufacturer's instructions for API 4000 (Tandem Mass Spectrophotometer) CIT.S2017	A
Urine	Targeted drugs of abuse screen in urine. The method will detect the following compounds:  Opioids - Methadone and metabolite EDDP), Buprenorphine and metabolite (norbuprenorphine)  Amphetamines – Amphetamine (Amfetamine)  Methamphetamine (Metamfetamine),  MDA, MDMA & MDEA	Documented In-house Methods and Manufacturer's instructions for API 4000 (Tandem Mass Spectrophotometer) CIT.S2017	A



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)  Urine	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>  Benzodiazepines – Diazepam and metabolite (nordiazepam), oxazepam, temazepam, lorazepam, nitrazepam & midazolam  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)	Documented In-house Methods and Manufacturer's instructions for API 4000 (Tandem Mass Spectrophotometer) CIT.S2017:	A



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



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)	<u>Biochemistry (toxicology) examination activities for the purposes of clinical diagnosis:</u>	Documented methods and manufactures instructions for Liquid Chromatography Quadrupole Time of Flight Mass Spectrometry (LC-QToF MS) using Waters Acquity UPLC with Waters Xevo G2-XS QToF (CIT.S2023)	
Blood, Plasma, Serum, Urine	<u>Presumptive screening and confirmation for the presence of drugs from the following drug classes (cont'd):</u>  Novel psychoactive substances Opiates Opioids Paracetamol Psychedelics Renin Inhibitors Salicylates Statins Stimulants Sulphonylureas Synthetic Cannabinoids THC and related compounds Z-drugs	Flexible scope for LC-QToF MS limited to the application of additional drugs boundaried within the named classes in accordance with documented in-house procedure GEN.S003  The verified scope of the screens is identified within laboratory controlled Waters Toxicology Library	A
Urine only	<u>Presumptive screening and confirmation of cardiovascular disease modifying drugs from the following drug classes:</u>  ACE inhibitors Angiotensin II Receptor Antagonists (ARBs) Alpha receptor agonists Alpha Blockers, Beta Blockers Calcium Channel blockers Diuretics Metformin Renin Inhibitors Statins Sulphonylureas	Flexible scope for LC-QToF MS limited to the application of additional drugs boundaried within the named classes in accordance with documented in-house procedure GEN.S003  The verified scope of the screens is identified within laboratory controlled Waters Toxicology Library	A



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



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



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



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Whole Blood:EDTA	Blood Films - morphology of the red cells, platelets and white cells. Manual differential of white cells	Documented in-house visual examination method using microscopy: Manual HA.S610 and automated XN Track SP50 HA.S604 staining, followed by microscopy.	A, B
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: Automated RAL Stainer HA.S604 staining, followed by microscopy.	A,B,C
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 BHH (A): XN9100 track (3x XN10, 3x XN20)GHH (B) XN2000, Sol (C) XN1000:  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 Starrsed (Interrliner on XN9100 track and stand alone autocompact)HA.S608	A





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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Plasma :EDTA	Glandular Fever Screen for heterophile antibodies	Documented In-house methods and manufacturer's instructions for DiaQUICK Mononucleosis Cassette HA.S540	A, B, C
Plasma: EDTA	Plasma viscosity	Documented in-house method for Capillary resistance, Benson BV1 analyser: HA.S028	A
Whole Blood	Haemoglobinopathy screen to confirm or exclude presence of haemoglobin variant and / or thalassaemia	Documented -in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements	A
Whole Blood	Hb variant confirmation	Documented In-house Methods and Manufacturer's instructions for TOSOH G8 HPLC analyser with specific reference to HA.S600	A
Bone Marrow Aspirates	Bone marrow slide staining for microscopic examination for evidence of haematological disease	Documented in-house method based on May Grunwald and Giemsa stain HA.S008	A



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



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented In-house Methods and Manufacturer's instructions for Navios Flow Cytometer:	A
Bone marrow/ Peripheral blood	MDS/Leukaemia screen. Short panel to identify presence of blast cells.	HA.S509	
Bone marrow/ Peripheral blood	Minimal Residual Disease (MRD)	HA.S358	
Bone marrow/Peripheral blood	Myeloma /MGUS	HA.S506	
Whole Blood	Paroxysmal Nocturnal Haemoglobinuria	HA.S063	
Blood	HbA1c	Documented In-house Methods and Manufacturer's instructions for TOSOH G11 HPLC analyser with specific reference to CIT.S1015	A
	<u>Transfusion examination activities for the purposes of clinical diagnosis:</u>		
Plasma	Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma antibody	Compatibility testing using LISS/Coombs gel column agglutination and centrifugation BB.S119. Automated and Manual techniques	A, B, C
Plasma	Antibody Screening: Screening of anti-D, C, E, c, e, Cw, K, k, Kp(a),Kp(b), Fy(a), Fy(b), Jk(a), Jk(b), Le(a), Le(b), P1, M, N, S, s, Lu(a) and Lu(b).	Automated Antibody screening using LISS/Coombs gel column agglutination and centrifugation BB.S205 Antenatal BB.S201	A, B, C
Whole blood	Red Cell Phenotyping	LISS/Coombs gel column agglutination and Centrifugation. BB.S109	A, B, C



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



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (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	AP50	Documented In-house Methods and Manufacturer's instructions for Binding Site Optilite Turbidimeter: Binding Site using Radial Immunodiffusion (RID) CIT.S1977	A
Serum	Free Light Chains (Kappa & Lambda)	CIT.X1112, CIT.S112	A
Serum	IgG Subclasses (IgG, IgG1, IgG2, IgG3, IgG4)	CIT.S207	A
Serum/plasma	C1 Esterase Inhibitor (CIN)	CIT.S205	A
Serum	CH50	CIT.S1978	A
Serum	PLA2 receptor antibodies	CIT.S1125	A



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (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	ACRA -Acetylcholine Receptor Antibody	Documented In-house Methods and Manufacturer's instructions for the Wizard Gamma Counter CIT.S1971	A



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
Serum/plasma	Intrinsic factor antibodies (IFAB)	Documented In-house Methods and Manufacturer's instructions for DS2 Automated ELISA workstation ST.S163 and:  ST.S340	A
	Diphtheria antibodies (DIPH)	CIT.S146	
	Haemophilus influenza type B antibodies (HIBAB)	CIT.S147	
	Pneumococcal antibodies (PNEUAB)	CIT.S148	
	PLA2 receptor antibodies		
Plasma	Quantiferon TB Plus (QFTPL)	CIT.S1696	
Serum/plasma	Salmonella typhii antibody quantification	CIT.S1148	
	Tetanus antibodies (TETAB)	CIT.S149	
		Documented In-house Methods and Manufacturer's instructions for manual ELISA	
Plasma	GAD antibodies	CIT.X1116, CIT.S1514	A
Whole blood	TB TSpot. Elispot to measure Interferon gamma production by TB antigens in investigation of latent TB.	Elispot to measure Interferon gamma production by TB antigens CIT.S109	A



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





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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)  Serum	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>  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)	Documented In-house Methods and Manufacturer's instructions for Phadia Immunocap 250: CIT.S1512	A



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



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented In-house Methods and Manufacturer's instructions for immunofluorescence using QL 3000 Quantalyser slide staining workstation UV microscope and QUANTALink reporting software: CIT.S164, CIT.S100, CIT.S104	A
Serum/plasma	Anti-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)		
Serum/plasma	Anti-adrenal antibodies (ADR) Anti-epidermal antibodies (EPI) Anti-neuronal antibodies screen (NEURO) Anti-pancreatic islet cell antibodies (PIC)	Documented In-house Methods and Manufacturer's instructions for Manual Indirect Immunofluorescence and use of UV microscope: CIT.S1581	A
Blood	Detection of myositis IgG antibodies Detection IgG antibodies for autoimmune liver disease.	Immunoblot using EUROLINE Myositis Antigens Profile and EUROLINE Autoimmune Liver disease profile. CIT.S165, CIT.X1113	A



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



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HUMAN BODY FLUIDS / TISSUE (CONT'D) (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): CIT.S1014	A, D
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	A, C
Body Fluids: Urines, sputum, bronchial washings, bronchial washings, serous fluids, CSF	Routine diagnostic examination of non-cervical cytological specimens	Hologic T5000 Benchtop Processor CY.S343 Hologic T2000 Processor CY.S306 Prisma automated stainer and coverslipper Non – gynae Sample Preparation Manual CY.S301	A
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



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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>Special staining of Histopathology examinations to assist in detection of clinical abnormalities.</p> <p>Acid mucins</p> <p>Glycogen and neutral mucins</p> <p>Acid and neutral mucins</p> <p>Glycogen and mucins</p> <p>Gram positive and negative bacteria</p> <p>Amyloid</p> <p>H.pylori</p> <p>Elastic fibres</p> <p>Malarial parasites</p> <p>Fungi</p> <p>Connective tissue and fibrin</p> <p>Melanin</p> <p>Basophil/Eosinophil/Neutrophil granules</p>	<p>Documented In-house Methods for special stains HI.S216</p> <p>Alcian Blue pH 1.0, pH2.5 (AB)</p> <p>Periodic Acid Schiff (PAS) (Diastase PAS)</p> <p>Alcian Blue pH 2.5 PAS</p> <p>Alcian Blue pH 2.5 Hyaluronadase</p> <p>Brown Brenn Gram Gram stain</p> <p>Congo Red</p> <p>Cresyl Fast violet (CFV)</p> <p>Elastic Van Gieson Haematoxylin Van Gieson</p> <p>Geimsa</p> <p>Grocotts Silver Stain (Manual) Grocotts Silver Stain (Benchmark Special Stainer BSS)</p> <p>Martius Scarlet Blue</p> <p>Masson Fontana</p> <p>Masson's Trichrome Stain</p>	<p>A</p>



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



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





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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>High grade prostatic intraepithelial neoplasm (HGPIN) &amp; prostate adenocarcinoma</p> <p>Most cells / Loss of in subset of Mesotheliomas</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>Most epithelial CXells / Pagets disease</p> <p>Clear cell carcinoma of the kidney</p> <p>C cell abnormalities of the thyroid</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT &amp; Ultras to HI.S078 (cont'd):</p> <p>Racemase - AMACR</p> <p>BAP1</p> <p>Beta Catenin</p> <p>BCL2</p> <p>BCL6</p> <p>BerEP4/MOC31</p> <p>CKIT/CD117</p> <p>CA125</p> <p>CAM5.2</p> <p>Carbonic Anhydrase IX</p> <p>Calcitonin</p>	<p>A</p>



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



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



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<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>Smooth Muscle Cells – Normal/Neoplastic</p> <p>Gastrintestinal stromal tumours (GISTs)</p> <p>Epstein Bar Virus</p> <p>Breast Carcinoma Subtype - Ductal</p> <p>Tumour subtyping – Skin, Lymphoid</p> <p>Dermatofibromas</p> <p>Reed-Sternberg cells/dendritic cells</p> <p>Thyroid tumour subtyping</p> <p>Erythrocytes - Normal/Neoplastic</p> <p>Metastatic Breast Cancer</p> <p>Subtyping Germ cell tumours and Molar Pregnancies</p> <p>Hepatocytes – Normal/Neoplastic</p> <p>Kaposi Sarcoma</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT &amp; Ultras to HI.S078 (cont'd):</p> <p>Desmin/ H-Caldesmon /Smooth Muscle Actin / Smooth Muscle Myosin</p> <p>DOG 1</p> <p>EBER/Epstein Bar Virus (LMP)</p> <p>ECaderin</p> <p>Epithelial Membrane Antigen</p> <p>Factor 13a</p> <p>FACSIN</p> <p>HBME (mesothelial cell)</p> <p>Glycophorin A</p> <p>Gross Cystic Disease Fluid Protein-15</p> <p>Human Chorionic Gonadotrhpin</p> <p>Hepatocyte</p> <p>Human Herpes Virus 8</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>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 Leukaemia</p> <p>Mast cells</p> <p>Mismatch repair proteins – Lynch Syndrome</p> <p>Skeletal muscle differentiation</p> <p>Striated muscle differentiation</p> <p>Expression levels for directed therapies</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry-Routine Ventana Benchmark XT &amp; Ultras to HI.S078 (cont'd):</p> <p>High Molecular Weight Cytokeratin</p> <p>HMB45/ MELA – Melanosome</p> <p>IgA/IgD/IgG/IgM</p> <p>IGG4</p> <p>Inhibin</p> <p>Kappa/Lambda</p> <p>KI67</p> <p>Leucocyte Common Antigen</p> <p>Lysozyme/ Myeloperoxidase</p> <p>MAST cell tryptase</p> <p>MLH1 MSH2 MSH6 PMS2</p> <p>Myogenin/Sarcometric</p> <p>Myoglobin</p> <p>Oestrogen/Progesterone Receptor</p>	<p>A</p>



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



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



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





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## Schedule of Accreditation

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## University Hospitals Birmingham NHS Foundation Trust

Issue No: 014 Issue date: 23 August 2021

Testing performed by the Organisation at the locations specified

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