### **Schedule of Accreditation**

issued by

## **United Kingdom Accreditation Service**

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



**LABex Analytics LLP** 

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**LABex Analytics LLP** 

Issue No: 013 Issue date: 21 October 2021

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Accredited to ISO 15189:2012

Testing performed by the Organisation at the locations specified below

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

#### **Laboratory locations:**

Location details		Activity	Location code
Address	Local contact		
Department of Blood Sciences / Microbiology London North West Healthcare NHS Trust Northwick Park Hospital Watford Road Harrow HA1 3UJ	Sally Curtis	General Microbiology Virology Biochemistry Haematology Blood Transfusion	A
Department of Cellular Pathology London North West Healthcare NHS Trust St Marks Hospital (Northwick Park Campus) Watford Road Harrow HA1 3UJ	Sally Curtis	Histology Cytology (gynae & non-gynae)	В
Department of Blood Sciences Central Middlesex Hospital Acton Lane Park Royal NW10 7NS	Sally Curtis	Virology Biochemistry Haematology Blood Transfusion	C
Pathology Laboratory Ealing Hospital Uxbridge Road Southall Middlesex UB1 3HW	Sally Curtis	Biochemistry Haematology Blood Transfusion Serology Histology	D

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

Location details	Activity	Location code
Blood Fridge Main Theatre Block Northwick Park Hospital Watford Road Harrow HA1 3UJ	Blood issue fridge for storage of blood products only; no testing occurs at this site	Е
Blood Fridge Maternity Block Level 4 Room 4N144 Northwick Park Hospital Watford Road Harrow HA1 3UJ	Blood issue fridge for storage of blood products only; no testing occurs at this site	F

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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
	Microbiology		
	General Bacteriology		
HUMAN BODY SAMPLES	Examination activities for the purposes of clinical diagnosis	In-house documented procedures as referenced and based on PHE SMIs	
Specimens from wounds, eyes, ears, nose, throat, mouth, pus, tissue, joint fluids, CSF, valves, sputum, bronchial washings, bronchial lavage, genitalia, cannulae, shunts, CSF	General isolation of micro- organisms of clinical significance	Culture onto selected media for manual and automated inoculation of samples onto culture media using BD Kiestra TDL-GM-046-ET-001	A
Bacterial cultures isolated inhouse	General identification of micro- organisms of clinical significance	General biochemical methods TDL-GM-046-ET-001	А
Bacterial cultures isolated inhouse	General identification of micro- organisms of clinical significance	Matrix Assisted Laser Desorption Ionisation ToF using Bruker MALDI TDL-M-6-136	А
Bacterial cultures isolated inhouse	Antimicrobial susceptibility testing	Manual disc diffusing with antimicrobial discs using BSAC and EUCAST guidelines TDL-M-6-34, TDL-M-6-127	A
		Automated using BD Phoenix AP and M50 systems with EUCAST guidelines TDL-M-6-139	A
Bacterial cultures isolated inhouse	Antimicrobial susceptibility testing determination of minimum inhibitory concentration (MIC)	Gradient MIC using E-Tests and MIC Evaluators	A
Blood	Detection of microbial growth and general isolation of micro- organisms of clinical significance	Fluorescence detection using Bactec FX followed by isolation onto selected media TDL-M-6-138	A, D
		Positive bottles from Location D are transferred to Location A for culture	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES	General Bacteriology  Examination activities for the purposes of clinical diagnosis	In-house documented procedures as referenced and based on PHE SMIs	
Blood, fluids and respiratory samples	Detection and isolation of Mycobacterium sp.	Fluorescence detection using BD MGit 960 (automated) and culture on Lowenstein-Jensen slopes manual) TDL-M-6-138	А
Blood, fluids and respiratory samples	Detection of acid fast bacilli	Manual staining using Auramine Phenol and Ziehl Neelsen stains and microscopy TDL-M-6-79	A
CSF and joint fluids	Quantification of white and red blood cells and qualitative demonstration of bacteria	Manual microscopy TDL-M-6-20	A
Faeces	General isolation and characterisation of Salmonella, Shigella, Campylobacter & E. coli 0157, Vibrio sp., Listeria sp. and Yersinia sp.	Manual and automated culture using BD Kiestra and selective culture media TDL-M-6-38	A
Faeces	Detection of <i>Clostridium</i> difficile GDH antigen and toxins A & B	Immunochromatography using Quik Chek Complete TDL-M-6-80	A
Faeces	Detection of Helicobacter pylori antigen	ELISA using Premier Platinum Plus HpSA and DS2 analyser TDL-M-6-14	A
Faeces	Detection of Rotavirus antigen	Immunochromatography using Immunocard Stat Rotavirus TDL-M-6-43	A
Urine	Quantification of white and red blood cells, and qualitative demonstration of bacteria, epithelial cells, yeast cells and casts	Manual microscopy and Sedimax automated analyser TDL-M-6-63	A

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	General Bacteriology		
HUMAN BODY SAMPLES	Examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures as referenced and based on PHE SMIs with manufacturers instructions	
Urine	General isolation, characterisation and sensitivity testing of micro-organisms of clinical significance	Culture using Mast Uri microtitre culture system WSL-MIC-001	A
Urine	General isolation and characterisation of micro-organisms of clinical significance	Culture onto selected media using manual and automated culture using BD Kiestra TDL-M-6-63	A
Urine	Detection of <i>Legionella</i> pneumophila serotype 1 antigen	Immunochromatography using Binax NOW rapid card TDL-M-6-65	A
	Detection of Streptococcus pneumoniae	Immunochromatography using Binax NOW rapid card TDL-M-6-66	A
	<u>Parasitology</u>		
	Examination activities for the purposes of clinical diagnosis	In-house documented procedures based on PHE SMIs	
Faeces, rectal swabs, sputum, urine & aspirates	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Concentration using MIDI Parasep SF and manual microscopy or by direct microscopy TDL-M-6-39	A
Clear adhesive tape slides	Enterobius sp	Direct microscopy TDL-M-6-39 by	А
Faeces	Cryptosporidium sp	Staining using modified Ziehl- Neelsen and microscopy TDL-M-6-39	A

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#### 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
	<u>Mycology</u>		
Skin, hair and nail	Examination activities for the purposes of clinical diagnosis		
	General isolation and characterisation of fungi of human clinical significance	Manual culture onto selective culture media and microscopic / macroscopic identification TDL-M-6-53	A
Yeast cultures isolated inhouse	Susceptibility testing	Using Sensititre Yeastone TDL-M-6-56	А
CSF, blood	Detection of Cryptococcal antigen	Lateral flow using IMMY kit TDL-M-6-140	А
	Molecular Biology		
HUMAN BODY SAMPLES	Examination activities for the purposes of clinical diagnosis	In house documented procedures based on and in conjunction with manufacturers instructions	
Sputum, bronchial washings / lavage, pus, aspirates, CSF, tissue and biopsies	Detection of Mycobacterium tuberculosis complex and genes encoding for rifampicin resistance	PCR using Cepheid GeneXpert TDL-M-6-60	A
Throat, nasal and nasopharyngeal swabs, nasopharyngeal aspirate (NPA) and NPA in universal transport medium	Detection of Influenza A, Influenza B & Respiratory Syncytial Virus (RSV)	PCR using Cepheid GeneXpert TDL-M-6-135	A
Nasopharyngeal swabs and combined nose / throat swabs in viral transport media	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: ORF1a, N	Polymerase chain reaction using SAMBA II analyser and SRAS-CoV-2 kit MIC-NWP6-123	A

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Materials/Products tested	Type of test/Properties	Standard specifications/	Location
	measured/Range of measurement	Equipment/Techniques used	Code
	<u>Viral Serology</u>		
Serum / Plasma unless otherwise stated	Examination activities for the purposes of clinical diagnosis. Detection of:	In house documented procedures based on and in conjunction with manufacturers instructions	
	Hepatitis A IgM & IgG total	Immunoassay using Roche Cobas 8000 (Location A) & 6000	Α
	Hepatitis B core IgM, core total antibody, e antigen, e antibody	(Locations C & D) TDL-NWLH-CB-037	А
	Hepatitis B surface antigen, Hepatiis B surface antibody and Core antibody		A&C
	Hepatitis B surface antigen		D
	Hepatitis C antibody		Α
	Detection of HIV 1 & 2 antibody and p24 antigen		A, C & D
	Rubella IgG antibody		Α
	Syphilis antibody		A, C & D
Serum / plasma	Confirmation of Syphilis antibody	Manual agglutination (TPPA) TDL-NWLH-CB-060	А
		Floculation test (RPR) TDL-NWLH-CB-061	

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#### 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
	Cytopathology (Non-Gynae)	In house documented procedures based on and in conjunction with manufacturers instructions	
FNAs, needle washings, fluids, urine, sputum, BAL	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis	Processing, Staining and reporting of Diagnostic Specimens using documented in-house procedures with reference to the following procedures and equipment TDL-NWLH-C-011 Sputum TDL-NWLH-C-012 Bronchial Brushings TDL-NWLH-C-013 Bronchial Washings TDL-NWLH-C-015 Serous & Cyst fluids TDL-NWLH-C-016 Urine  TDL-NWLH-C-010 Cytocentrifuge TDL-NWLH-C-030 ThinPrep 2000 processor TDL-NWLH-C-044 ThinPrep 5000 processor	В
		Interpretive/diagnostic microscopy (qualitative analysis) HIS-NWP4-2	В

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Andrology  Andrological examination activities for the purposes of clinical diagnosis	In house documented procedures based on and in conjunction with the following guidelines	
	Post-Vasectomy:		
Ejaculate	Detection of Spermatazoa	Manual microscopy based on WHO Laboratory Manual for Examination and Processing of Human Semen 5 <sup>th</sup> Edition 2010 TDL-NWLH-C-026	В
Ejaculate	Fertility Testing:	Manual methods based on WHO Laboratory Manual for Examination and Processing of Human Semen 5 <sup>th</sup> Edition 2010	В
	Volume	Volume/weight TDL-NWLH-C-021	
	Sperm motility	Manual microscopy TDL-NWLH-C-022	
	Detection of IgA	MAR Test TDL-NWLH-C-023	
	Sperm concentration	Manual microscopy TDL-NWLH-C-024	
	Sperm morphology	Manual microscopy TDL-NWLH-C-025	
	Fructose	Seliwanoffs method TDL-NWLH-C-064	

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#### 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
	Routine Histopathology		
Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis	Macroscopic and Microscopic examination. In house documented procedures in conjunction with equipment as specified below:	
Formalin fixed tissues samples (as above)		Specimen dissection	B&D
Samples (as above)		Using manual methods TDL-NWLH-HP-006 Assisting in Consultant Led Specimen Dissection TDL-NWLH-HP-080 Procedure for BMS Specimen Transfer TDL-NWLH-HP-081 Procedure and assisting BMS specimen dissection Ext-1044 Pathologist cut-up SOPs	
		<u>Decalcification</u>	B & D
		SOP TDL-NWLH-HP-018	
Formalin fixed tissues		Tissue Processing	В
samples (as above)		Thermo Scientific Excelsior, Leica Peloris II, and Sakura Tissue Tek VIP5 & VIP6 tissue processors tissue processor TDL-NWLH-HP-011	
Formalin fixed and		Tissue embedding	В
processed tissues samples (as above)		Thermo and Leica EG1150 H embedding stations TDL-NWLH-HP-012	
Formalin fixed and		Tissue sectioning (microtomy)	В
embedded tissues samples (as above)		Thermo Finesse microtomes TDL-NWLH-HP-013	
Fresh tissue samples – frozen section		Frozen Sections	В
HOZEH SECHOH		Leica CM1860 Cryostat TDL-NWLH-HP-088	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Routine Histopathology		
Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis	In house documented procedures in conjunction with equipment as specified below:	
	Routine and Special Staining		
Formalin fixed slides	Detection of:	Documented in-house procedure for staining using Sakura Tissue Tek Prisma Autostainer and Coverslipper (automated) and by manual method TDL-NWLH-HP-014 TDL-NWLH-HP-088	В
	Identification of basophilic and eosinophilic structures	Haemotoxylin & Eosin	
	Gycogen & mucins	Periodic Acid Schiffs (PAS)	
	Mucins & neutral mucins	Alcian Blue Diastase PAS	
	Mucins	Alcian Blue PAS	
	Glycogen	PAS Diastase	
	Special Staining	Documented in-house procedure	
	Detection of:	for manual staining TDL-NWLH-HP-088	
	Glycogen	Alcian Blue	
	Glycogen	Alcian Blue PAS	
	Glycogen	Alcian Blue PAS Diastase	
	Mast cells and mucopolysaccharides	Azure A	
	Amyloid	Congo red	
	Haemopoetic cells	Giemsa	
	Helicobacter pylori	Giemsa	

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#### 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
Fixed, fresh and frozen	Routine Histopathology  Examination of tissues to	In house documented procedures	
tissue; excisional and incisional biopsies and surgical resection specimens	identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	in conjunction with equipment as specified below:	
Formalin fixed slides	Routine and Special Staining  Detection of:	Documented in-house procedure for staining using Sakura Tissue Tek Prisma Autostainer and Coverslipper (automated) and by manual method TDL-NWLH-HP-014 TDL-NWLH-HP-088	В
	Reticulin	Gordons & Sweets Reticulin	
	Fungi	Grocott	
	Gram positive / negative bacteria	Gram stain	
	Collagen / smooth muscle	Haematoxylin Van Geison	
	Fibrin	Martius Scarlet Blue	
	Melanin pigment	Masson Fontana	
	Connective tissue	Masson Trichrome	
	Connective tissue	Melanin Bleach	
	Elastic fibres	Millers Elastic	
	Glycogen	PAS +/- Diastase Digestion	
	Iron (Haemosiderin)	Perls	
	Lipofuchsin	Schmori Reaction	
	Copper associated protein	Victoria Blue	
	Calcium	Von Kossa	
	Tubercle bacilli	Ziehl Neelsen	
	Mycobacterium leprae	Wade Fite	

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## LABex Analytics LLP

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#### 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
	Immunocytochemistry		
Paraffin tissue section	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis	In-house procedures in conjunction with manufacturers instructions using Leica Bond III and the following antibodies: TDL-NWLH-HP-089	В
	Cytokeratin cocktail for CK1-8, 10, 14-16 and 19	AE1/AE3	
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.	BCI-2	
	Prognostic marker in some B-cell Non-Hodgkins lymphomas.	BCL-6	
	Epithelial cell types	Ber-EP4	
	Normal cortical thymocytes, Langerhan cells, dendritic reticulum cells	CD1A	
	T cells	CD3	
	T cells (helper+mature)	CD4	
	Mature T cells, T cell lymphomas	CD5	
	T cells	CD8	
	Mature B cells, follicular dentritic cells, CALLA	CD10	
	Granulocytes, Reed-Sternberg cells	CD15	
	B cells	CD20	
	Adenocarcinoma of intestinal origin	CDX2	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Immunocytochemistry		
Paraffin tissue section	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	In-house procedure with pre-fixed Q Cards as stated) in conjunction with manufacturers instructions using Leica Bond III and the following antibodies: TDL-NWLH-HP-089	В
	Mature B cells, Follicular dentritic cells	CD21	
	B cells, some T cells	CD23	
	Reed-Sternberg cells, plasma cells	CD-30	
	Endothelial cells	CD31	
	Haematopoetic cells, vascular endothelium	CD34	
	Leukocyte common antigen (LCA)	CD45	
	Natural killer cells, neuroendocrine tissues	CD56	
	Macrophages, monocytes, myeloid cells	CD68	
	B cells	CD79a	
	Mast cells	CD117	
	Differentiating B cells	CD138	
	Tissues of neuroendocrine origin	Chromogranin A	
	Cytokeratin 5	CK5	
	Stratified squamous epithelium, basal cells, mesotheliomas	CK5/6	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Immunocytochemistry		
Paraffin tissue section	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	In-house procedure with pre-fixed Q Cards as stated) in conjunction with manufacturers instructions using Leica Bond III and the following antibodies: TDL-NWLH-HP-089	В
	Normal and neoplastic epithelia	CK7	
	Epithelial cells	CK14	
	Cytokeratin 5	CK19	
	Adenocarcinomas, columnar epithelial cells	CK20	
	CMV	CMV	
	Tumours	CYC-D1	
	Normal duct epithelial cells, ductal carcinoma	E-cad	
	Normal and neoplastic epithelium	ЕМА	
	Oestrogen receptors	ER	
	V.W factor in endothelial cells	FACTOR VIII	
	Placental trophoblasts	HCG	
	Melanoma, melanocyte differentiation	Hmb45	
	B cells and plasma cells	Карра	
	B cell follicles	Lambda	
	Melanoma marker	Melan A	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	<u>Immunocytochemistry</u>		
Paraffin tissue section	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	In-house procedure with pre-fixed Q Cards as stated) in conjunction with manufacturers instructions using Leica Bond III and the following antibodies: TDL-NWLH-HP-089	В
	Differential identification of colorectal carcinoma	MLH1	
	MNF116	MNF116	
	Myeloperoxidase	MPO	
	Mismatch repair protein	MSH2	
	Mismatch repair protein	MSH6	
	Multiple myeloma oncogene	MUM1	
	Myosin	Myosin	
	Peripheral nerves, neuroendocrine tumours	NSE	
	Postmeitotic segregation increased 2	pms2	
	Progesterone receptors	pgr	
	Prostate basal cells, profliferative cells	P63	
	Prostate secretory and ductal epithelium	PSA	
	Schwann cells, nerve processes, S100 +ve neoplasms	S100	
	Smooth muscle cells, myoepithelial cells	SMA	

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Materials/Products tested Type of test/Properties measured/Range of measurement  Standard specifications/ Equipment/Techniques used  Immunocytochemistry	Location Code
<u>Immunocytochemistry</u>	
Paraffin tissue section  Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)  In-house procedure with pre-fixed Q Cards as stated) in conjunction with manufacturers instructions using Leica Bond III and the following antibodies:  TDL-NWLH-HP-089	3
Neuroendocrine cells Synaptophysin	
Lining blood vessels, lymphatic vessels, mesothelial cells	
Thyroglobulin containing cells Thyroglobulin	
Lung and thyroid (thyroid follicular cells)	
Cells of mesenchymal origin Vim	
Breast carcinoma Her 2 (TDL-NWLH-HP-025 )	
Kras mutation & Epidermal KRAS & EGFR (TDL-NWLH-HP-027)	
Endometrial glands, ovarian tumours, adenocarcinoma	
Epithelial cells, Adenocarcinoma  CA 19-9	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Smooth muscle. Leiomyosarcomas.	Calponin	
	Apocrine epithelia of skin and breast. Breast tumours	GCDFP-15	
	Cytoplasm of pneumocytes and alveolar macrophages of lung and renal tubules	Napsin A	
	Tumour suppressor protein. Mucosal crypts and lymphatic aggregates of bowel, basal epithelial cells and germinal centres of tonsil	P53	
	Nuclear staining of epithelial and smooth muscle cells. Wilms tumour, malignant mesotheliomas	WT-1	

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#### Testing performed by the Organisation at the locations specified

Immunocytochemistry   Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)   Interpretive/diagnostic microscopy SOP TDL-E-HP-020   D      FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides stained on-site   Interpretive/diagnostic microscopy SOP TDL-E-HP-020   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed paraffin embedded) tissue on   D      FFPE slides (Formalin fixed par				
Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)  FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides stained on-site  FFPE slides (Formalin fixed paraffin embedded) tissue on SOP TDL-E-HP-020  Interpretive/diagnostic microscopy SOP TDL-E-HP-020	Materials/Products tested	measured/Range of		Location Code
paraffin embedded) tissue on glass slides stained on-site  FFPE slides (Formalin fixed paraffin embedded) tissue on  SOP TDL-E-HP-020  Interpretive/diagnostic microscopy SOP TDL-E-HP-020		Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes		
paraffin embedded) tissue on SOP TDL-E-HP-020	paraffin embedded) tissue on		Interpretive/diagnostic microscopy SOP TDL-E-HP-020	В
glass slides stained at an external source	FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides stained at an			D

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## **LABex Analytics LLP**

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#### 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
	<u>Haematology</u>		
HUMAN BODY FLUIDS	Haematology examination activities for the purposes of clinical diagnosis:	In house documented procedures based on equipment manuals and standard methods as specified below:	
EDTA Blood	Full Blood Count:	Using Sysmex XE-5000 WSL-AH-001	А
	White Blood Cells (WBC) Red Blood Cells (RBC) Haemoglobin (HGB) Haematocrit (HCT) Mean Cell Volume (MCV) Mean Cell Haemoglobin (MCH) Mean Cell Haemoglobin Concentration (MCHC) Platelets (PLT) Red Cell Distribution (RDW) Neutrophils (NEUT) Lymphocytes (LYMP) Monocytes (MONO) Eosinophils (EO) Basophils (BASO) Nucleated Red Blood Cells (NRBC) Reticulocytes (RET)	Using Sysmex XE-2100 WSL-AH-001 TDL-E-H-048	C&D
EDTA Blood	Blood film assessment & cell differential	May-Grunwald & Giemsa stains using:	
		Sysmex Sp-1000i & Hematak staining machines or manual hand staining and microscopy	A & D
		Hematek staining machine and microscopy TDL-E-H-053, TDL-NWLH-H-037 & WSL-AH-052	C & D
EDTA Blood	Erythrocyte Sedimentation Rate	Vescube Optical Electronic method SOP TDL-E-H-057	D
		Dispette 11 Westergren method SOP TDL-E-H-004	D

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	<u>Haematology</u>		
HUMAN BODY FLUIDS	Haematology examination activities for the purposes of clinical diagnosis:	In house documented procedures based on equipment manuals and standard methods as specified below:	
EDTA Blood	Erythrocyte Sedimentation Rate	Using Sysmex Interrliner TDL-NWLH-H-002	А
		Using StaRRsed Autocompact TDL-NWLH-H-044	С
EDTA Blood	Detection of Infectious Mononucleosis heterophile antibodies	Immunochromatography using Biokit Monogen rapid antigen detection cards TDL-NWLH-H-006	A & C
EDTA Blood	Detection of Infectious Mononucleosis heterophile antibodies	Immunochromatography using Clearview IM Screen SOP TDL-E-H-051	D
EDTA Blood	P. falciparum and non P. falciparum (excl knowlesi) malarial antigens	Rapid Diagnostic Testing using CareStart Malaria Rapydtest. pLDH/HRP2 Combo (Pan/Pf) by lateral flow immunochromatography SOP HAE-NWP5-38 (Loc A) SOP E-H-001 (Loc D)	A & D
EDTA Blood	Detection of intra-erythrocyte parasites	Giemsa pH 7 stain & light microscopy SOP HAE-EAL3-1	D
EDTA Blood	Sickle Cell Haemoglobin Screening Test	Solubility test using Streck Sickledex Solubility SOP TDL-NWLH-H-007 SOP HAE-EAL3-21	A & D

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	<u>Haematology</u>		
HUMAN BODY FLUIDS	Haematology examination activities for the purposes of clinical diagnosis:	In house documented procedures based on equipment manuals and standard methods as specified below:	
Bone marrow aspirate	Bone marrow for detection of microscopic cell contents and structure	Manual staining and microscopy using May-Grunwald and Giemsa stains TDL-NWLH-H-008	A & D
	Iron deposits	Manual staining and microscopy using GCC Iron stain kit TDL-NWLH-H-035	A
		Perls iron stain and light microscopy TDL-E-H-045	D
EDTA Blood	Quantitation of HbF, HbS & HbA2	Using Biorad high performance liquid chromatography TDL-NWLH-H-025	С
Dried blood spot	Sickle Cell Haemoglobin Screening Test	High performance liquid chromatography using VNBS HPLC system TDL-MWLH-H-045	С
EDTA Blood	Identification of Haemoglobin variants	Iso-electric focusing using Perkin Elmer TDL-NWLH-H-023	С
		Acid gel electrophoresis using Helena kit TDL-NWLH-H-029	С
		Capillary electrophoresis using Sebia Capillarys TDL-NWLH-H-034	С
		Mass spectrometry using Quattro Premier XE Tandem Quadropole Mass Spectrometer TDL-NWLH-H-028	А

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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	<u>Haematology</u>		
	Haematology examination activities for the purposes of clinical diagnosis:	In house documented procedures based on equipment manuals and standard methods as specified below:	
EDTA Blood	G6PD quantitation	Spectrophotomtetry using Jenway Spectrophotometer TDL-NWLH-H-031	С
		By immunochromatography using Pointe Scientific kit SOP TDL-NWLH-H-061	С
EDTA Blood	G6PD screen	By immunochromatrography using Binax NOW G6PD SOP TDL-NWLH-H-051	С
Citrated blood	<u>Coagulation</u>		
	International Normalised ratio (INR)	Using Sysmex CS5100 WSL-AH-035, WSL-AH-044 & WSL-AH-047, WSL-AH-050	А
	Prothrombin time	Using Sysmex CS2100	С
	Fibrinogen-Clauss	WSL-AH-035, WSL-AH-044 & WSL-AH-047, TDL-NWLH-H-020	
	Activiated Partial Thromboplastin time		
	D-Dimer		
Citrated blood	Prothrombin time	Sysmex CA1500 by optical clot detection unless stated:	D
	Thrombin time	SOP TDL-E-H-050	
	Activated partial thromboplastin time (APTT)	By calculation	
	Fibrinogen	Immunoturbidimetry	
	APTT ratio		
	D-Dimer		
	International Normalised Ratio		

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#### 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	Blood Transfusion  General examination activities for the purposes of clinical diagnosis:	In house documented procedures in conjunction with equipment manuals and standard methods as specified below:	
EDTA Blood	Blood group:  A RhD Positive A RhD Negative B RhD Positive	Using Grifols Eflexis analyser and Gel-based microtyping system and reagents (automated) BTF-EAL3-1	A & D
	B RhD Positive AB RhD Positive AB RhD Negative O RhD Positive O RhD Negative	Using Grifols Wadiana analyser and Gel-based microtyping system and reagents (automated) BTF-EAL3-10	C&D
	O THIS Hogalive	Using Grifols Gel-based microtyping system and reagents (manual) BTF-EAL3-25	A, C & D
EDTA Blood	Antibody detection and identification  Rh: D,C,E,c,e,Cw Kell: K,k,Kpa,Kpb	Using Grifols Eflexis analyser, Gel- based microtyping system, screening & panel cells and NHSBT panels (automated) BTF-EAL3-1	A & D
	Duffy: Fya,Fyb Kidd: Jka,Jkb Lewis: Lea,Leb P: P1 MNS: M,N,S,s Lutheran: Lua,Lub	Using Grifols Wadiana analyser, Gel-based microtyping system, screening & panel cells (automated) BTF-EAL3-10	C&D
		Using Grifols Gel-based microtyping system and reagents (manual) BTF-EAL3-25	A, C & D
EDTA Blood	Compatibility testing of patient's plasma with donor cells	Using Grifols Gel-based microtyping system and Indirect Antiglobulin test (manual) BTF-EAL3-58	A, C & D

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#### 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
	Blood Transfusion		
HUMAN BODY FLUIDS	General examination activities for the purposes of clinical diagnosis:	In house documented procedures in conjunction with equipment manuals and standard methods as specified below:	
EDTA Blood	Direct Antiglobulin test (automated)  Direct Antiglobulin test (manual)	Using Grifols Eflexis analyser and Gel-based microtyping system (automated) BTF-EAL3-24	A & D
		Using Grifols Wadiana analyser, Gel-based microtyping system, screening & panel cells (automated) BTF-EAL3-24	C&D
		Using Grifols Gel-based microtyping system (manual) BTF-EAL3-24	A, C & D
EDTA Blood	Antigen Phenotyping: Rh: C,E,c,e, Cw Kell: K	Using Grifols Eflexis analyser and Gel-based microtyping system (automated) BTF-EAL3-26	A & D
		Using Grifols Wadiana analyser, Gel-based microtyping system, screening & panel cells (automated) BTF-EAL3-26	C&D
		Using Grifols Gel-based microtyping system (manual) BTF-EAL3-26	A, C & D
EDTA Blood	Measurement of Foetal Rbc in maternal blood for FMH determination	By modified Kleihauer-Betke test using Source Bioscience Fetal Red Cell Detection kit and Fixol TDL-BT-077	A

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#### 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
	General Biochemistry		
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum / plasma unless stated		Using Roche Cobas 8000 (Location A) and 6000 (Locations C & D) with reference to the following measurement principles: WSL-AB-COB-006 & TDL-NWLH-CB-043	
Serum / plasma	Albumin	by photometry	A, C & D
Urine only	Tina-quant Albumin	by imunoturbidimetry	D
	Alanine transaminase	by photometry	A, C & D
Urine also	Alkaline phosphatase	by photometry	A, C & D
	Alpha fetoprotein	by immunoassay	A & C
	Amikacin	by immunoassay	A, C & D
	Ammonia	by photometry	A, C & D
Serum / plasma	Amylase	by photometry	A, C & D
	Aspartate aminotransferase	by photometry	A & D
	Bicarbonate	by photometry	A & C
	Bilirubin (total)	by photometry	A, C & D
Serum / plasma	Ca125	by immunoassay	А
Serum / plasma, urine	Calcium	by photometry	A & D
Serum / plasma	Calcium	by photometry	С
Serum / plasma	Carbamazepine	by photometry	A & D

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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	General Biochemistry		
	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum / plasma unless stated		Uusing Roche Cobas 8000 (Location A) and 6000 (Locations C & D) with reference to the following measurement principles: WSL-AB-COB-006 & TDL-NWLH-CB-043	
	Carcinoembryonic antigen	by immunoassay	А
	Chloride	by ion sensitive electrode	A & D
	Cholesterol	by photometry	A, C & D
Urine only	Cholesterol	by photometry	D
	Complement C3	by turbidimetry	
	Complement C4	by turbidimetry	
Urine also	Creatinine (jaffe method)	by photometry	A, C & D
Serum / plasma	Conjugated Bilirubin	by photometry	A & D
	Cortisol	by immunoassay	A & D
	CO2	by immunoassay	D
	C-reactive protein	by turbidimetry	A & D
	Creatinine (enzymatic method)	by photometry	A, C & D
	Creatinine kinase	by photometry	A, C & D
	Digoxin	by immunoassay	A & D
Plasma	Ethanol	by spectrophotometry	A & D

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	General Biochemistry		
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
		Using Roche Cobas 8000 (Location A) and 6000 (Locations C & D) with reference to the following measurement principles: WSL-AB-COB-006 & TDL-NWLH-CB-043	
	Ferritin	by immunoassay	A, C & D
	Free Triiodothyronine	by immunoassay	A & C
	Free Thyroxine (FT) 3 & 4	by immunoassay	A, C & D
	Folate	by immunoassay	A & D
	Follicle stimulating hormone	by immunoassay	A & D
Serum / plasma	Fructosamine	by photometry	А
	Gamma glutamyl transferase	by photometry	A & D
	Gentamicin	by immunoassay	A & D
CSF also	Glucose	by photometry	A, C & D
	HDL-Cholesterol	by photometry	A, C & D
	Human chorionic gonadotrophin	by immunoassay	A, C & D
	Iron	by spectrophotometry	A & D
	Immunoglobulins A, G, M	by immunoturbidimetry	А
Plasma & CSF	Lactate	by photometry	A, C & D
	Lactate dehydrogenase	by photometry	A, C & D
Serum / plasma	Lithium	by photometry	A & D

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	General Biochemistry		
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
		Using Roche Cobas 8000 (Location A) and 6000 (Locations C & D) with reference to the following measurement principles: WSL-AB-COB-006 & TDL-NWLH-CB-043	
	Luteinizing hormone	by immunoassay	А
	Magnesium	by photometry	A, C & D
Urine only	Magnesium	by photometry	D
Urine	Microalbumin	by photometry	A
	NT Pro-Brain natriuretic peptide	by immunoassay	А
	Oestradiol	by immunoassay	A & D
	Parathyroid hormone	by immunoassay	A, C & D
	Paracetamol	by photometry	A & D
	Phenytoin	by photometry	A & D
Urine also	Phosphate	by photometry	A, C & D
	Potassium	by ion sensitive electrode	A, C & D
	Progesterone	by immunoassay	A & D
	Procalcitonin	by immunoassay	A & D
	Prolactin	by immunoassay	А
	Prostate specific antigen	by immunoassay	A
Urine & CSF also	Protein (total)	by photometry	A, C & D
Serum / plasma	Rheumatoid factor	by immunturbidimetry	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	General Biochemistry		
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
		Using Roche Cobas 8000 (Location A) and 6000 (Locations C & D) with reference to the following measurement principles: WSL-AB-COB-006 & TDL-NWLH-CB-043	
	Salicylate	by photometry	A & D
Urine also	Sodium	by ion sensitive electrode	A, C & D
	Sex hormone binding globulin	by immunoassay	А
	Theophylline	by photometry	A & D
	Triglycerides	by photometry	A & C
Urine only	Triglycerides	by photometry	D
	Thyroid stimulating hormone	by immunoassay	A, C & D
	Transferrin	by immunoturbidimetry	А
	hs Troponin T	by immunoassay	A, C & D
Urine only	Urate	by photometry	А
	Urate	by photometry	A & D
	Urea	by photometry	A, C & D
	Vancomycin	by immunoassay	A & D
	Valproate	by photometry	A & D
	Vitamin B12	by immunoassay	A, C & D

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	General Biochemistry		
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis.  Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
		Using Roche Cobas 8000 (Location	A & C
		A) and 6000 (Locations C & D) with reference to the following	A & C
		measurement principles: WSL-AB-COB-006 & TDL-NWLH- CB-043	A & C
	Acute kidney alert	by calculation	D
	Anion gap	by calculation	D
Urine only	Albumin:Creatinine ratio	by calculation	D
Urine also	Creatinine clearance	by calculation	D
	Calcium (adjusted)	by calculation	D
	Estimated Glomerular Filtration rate (eGFR)	by calculation	D
Urine also	Cholesterol(Total/HDL)	by calculation	D
	Cholesterol (LDL-non fasting)	by calculation	D
	Non-HDL Cholesterol	by calculation	A, C & D
	LDL Cholesterol	by calculation	A & C
	Globulins	by calculation	D
	Protein:Creatinine ratio	by calculation	D
	Tubular Phosphate Reasbsorption	by calculation	D
	Transferrin Saturation	by calculation	А
	Free Copper Index	by calculation	A

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Materials/Products tested	Type of test/Properties	Standard specifications/	Location
	measured/Range of measurement	Equipment/Techniques used	Code
	General Biochemistry		
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis.  Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum / plasma	Macroprolactin	TDL-NWLH-CB-046 by PEG precipitation followed by Roche Cobas immunoassay	A
Whole blood	HbA1c	By high performance liquid chromatography using TOSOH G8 TDL-NWLH-CB-006	A
Whole blood	HbA1c	Bio-Rad Variant II turbo using high- performance liquid chromatography SOP TDL-EHT-B-VAR-010	D
Serum / plasma & urine	Osmolality	By freezing point depression using Vitech Osmometer TDL-NWLH-CB-013	A, C & D
Sweat	Chloride	Sherwood Sweat Chloride meter by colourimetry SOP TDL-EHT-B-CHL-001	D
Sweat	Conductivity	Sweat CHEK conductivity model 3100 flow-through conductivity cell SOP TDL-EHT-B-SWT-001	D
Urine	Porphobilinogen	By ion exchange column extraction and spectrophotometry using Thermo Scientific Evo 201 TDL-NWLH-CB-024	A
Urine	Porphyrins	By scanning spectrophotometry using Thermo Scientific Evo 201 TDL-NWLH-CB-027	A
CSF	Xanthochromia	By spectrophotometry using which Thermo Scientific Evo 201 TDL-NWLH-CB-030	A
Faeces	Occult blood	By Chromatography using Hema Screen kit TDL-NWLH-CB-019	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	General Biochemistry		
HUMAN BODY FLUIDS	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum, urine	Detection of kappa & lambda light chains	By electrophoresis using Sebia Hydrasys 2 TDL-NWLH-CB-050	А
Serum, urine	Protein immunofixation	TDL-NWLH-CB-030	
Serum	Detection of normal and abnormal protein electrophoretic patterns	Protein electrophoresis using Sebia Capillarys 3 TDL-NWLH-CB-052	A
	Protein monoclonal quanitification		
	Protein immunotyping		
		By liquid chromatography and mass spectrometry using Waters Quattro and Waters Acquity with reference to:	A
Serum / plasma	Testosterone DHEAs 17-OH Progesterone Androstenodione	TDL-NWLH-CB-040	
		By liquid chromatography and mass spectrometry using Waters Xevo with reference to:	A
Urine	Free Cortisol	TDL-NWLH-CB-041	
Serum / plasma	25-hydroxyvitamin D	TDL-NWLH-CB-039	
Urine	5-Hydroxyindoleacetic acid	TDL-NWLH-CB-035	
END			

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