Schedule of Accreditation

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UKAS MEDICAL **9546** **Accredited to ISO 15189:2022**	**NHS Lothian** **Issue No:** 015 **Issue date**: 10 January 2025	
	Royal Infirmary of Edinburgh **51 Little France Crescent** **Edinburgh** **EH16 4SA**	**Contact: Bernard Lawless** **E-Mail: Bernard.lawless@nhs.scot** **Website: www.edinburghlabmed.co.uk**
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address: Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA	**Local contact:** Bernard Lawless	**Microbiology:** Molecular Virology Molecular Haematology Molecular Pathology	A

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Western General Hospital	**Local contact:** Bernard Lawless	Haematological Malignancy Diagnostic Service (HMDS) Immunophenotyping	B
Scottish Bacterial Sexually Transmitted Infection Reference Laboratory (SBSTIRL)		National reference service for the management of sexually transmitted infection	C
Scottish E. coli O157/VTEC Reference Laboratory (SERL)		Identification and typing of *E. coli* O157 and Shiga toxin-producing *E. coli*	D
Scottish HPV Reference Laboratory (SHPVRL)		Screening and typing of Human Papillomavirus	E
Scottish Mycobacteria Reference Laboratory (SMRL)		Identification, drug susceptibility testing and strain typing of *Mycobacterium tuberculosis* complex (MTBC) and non-tuberculous mycobacteria (NTM)	F
Blood Borne Virus Specialist Testing Service (BBVSTS)		Sequencing of Blood Borne viruses	G
Viral Sequencing Service (VSS) - RIE		Genome sequencing of viruses and other pathogens	H

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES and FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis	In-house documented procedures:	
Enrichment broths from the following sample types: Faeces and isolates of E. coli. Mixed cultures of bacterial growth submitted as slopes or pellets from centrifuged culture broth	DNA Extraction	Measurement Principle: Manual DNA extraction using SOP: SERL 50	D
Nucleic Acid	Detection of stx1 stx 2 and rfbO157 genes	Real-Time PCR using BioRad C1000 Touch Thermal Cyclers using SOP: SERL 50	D
Cultures isolates of *E. coli*	Identification of *E. coli*	Identification by BioMerieux API 20E, using SOP: SERL 58, SERL 53	D
	Determination of MLST (7 loci), virulence gene profile, serotype (O:H antigen), cgMLST (2513 loci) and SNP analysis for outbreak investigation and surveillance of *E. coli* O157 and non-O157 STEC.	DNA extraction using the Qiagen DNeasy Blood and Tissue Kit using SOP: SERL137	D
		Use of the Qubit 3.0 Fluorometer using SOP: SERL144	D
		Nextera XT DNA Library Preparation using SOP: SERL 141	D
		Whole genome sequencing on the Illumina MiSeq using SOP: SERL 145	D
		Analysis of Whole Genome Sequencing Data using the UKHSA pipeline using SOP: SERL140	D
		Analysis of Whole Genome Sequencing Data using BioNumerics (BioMérieux) using SOP: SERL139	D

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HUMAN TISSUES and FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
Swabs, isolates	Culture and identification of *Neisseria gonorrhoeae*	Culture on agar followed by phenotypic identification using Gram stain, sugar utilisation, using SOPs: SBSTIRL39, SBSTIRL40	C
Isolates	Antibiotic susceptibility of *Neisseria gonorrhoeae*	Antibiotic susceptibility testing by agar dilution method and E tests using SOP: SBSTIRL41	
Swabs, urine, and aspirates	DNA Extraction	BioMerieux EasyMag or eMAG automated extractor, or manual method by Qiagen QIAamp DNA kit using SOPs: VIRM-3, SBSTIRL34	A, C
DNA	Screening for *Chlamydia trachomatis* LGV serovars	Real-time PCR by ABI 7500 using SOP: SBSTIRL31	C
Rectal, Genital, and Urines.	Screening for *Chlamydia trachomatis* LGV serovars	Real-Time PCR using the ABI7500 using SOP: SBSTIRL31	C
Male urine, male anal swabs, female urine, cervical swabs, endocervical swabs, vaginal and high vaginal swabs	Detections of mutations in *Mycoplasma Genitalium* that correlate to macrolide and fluroquinolone resistance	Automated extraction using EasyMag, eMAG, or manual extraction using QIAmp. PCR using Gel Electrophoresis visualisation or Sanger Sequencing using SOP SBSTIRL74, VSS-16	C
Urine, Urogenital Swabs and Rectal Swabs	Detection of *Mycoplasma genitalium* and key mutations associated with macrolide resistance	ResistancePlus MG FleXible assay on the Cepheid GeneXpert using SOP: VIRM355	A
Rectal, cervical, throat Swabs/Urine	Detection of N. gonorrhoeae DNA	Seegene Allplex STI4 Kit using SOP VIRM-337	A
Hologic Liquid based cytology cervical samples (Thinprep Preservcyt)	Detection of high-risk HPV types: 16 & 18/45 and pool: 31,33,35,39,51,52,56,58,59 ,66 and 68.	Cepheid GeneXpert PCR Using SOP HPV112	E

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HUMAN TISSUES and FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
Liquid based cytology cervical samples (Thinprep Preservcyt) and Formalin Fixed Paraffin material – head and neck, and anogenital biopsies	Detection of HPV types: 19 high-risk types (16,18,26,31,33,35,39,45,51,52,53,56,58,59, 66,68,69,73,82) and 9 low-risk HPV types (6,11,40,42,43,44,54,61, 70)	SeeGene Allplex HPV28 kit SOP HPV157 Manual extraction using QIAamp DNA mini kit or automated extraction using Seegene STARMag 48 kit Combination of manual and automated stages and PCR set up using the Seegene Nimbus platform Detection using BioRad CFX and Seegene software	E
Positive Mycobacterium culture	DNA extraction	Genomic DNA extraction from a positive Mycobacterium culture for whole genome sequencing using SOP: SMRL139	F
Nucleic acids obtained from Respiratory specimens	Molecular detection of *M. tuberculosis* complex (MTBC) and its resistance to rifampicin (RIF)	Real time nested PCR via Cepheid GeneXpert platform using SOP: SMRL69	F
Mycobacteria growth indicator tube (MGIT) cultures	Detection of MTBC	Rapid immunochromatographic assay for MTBC antigen using SOP: SMRL19	F

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HUMAN TISSUES and FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
DNA	Mycobacteria Whole Genome Sequencing	Use of the Qubit 3.0 Fluorometer using SOP: SERL144	F
		Nextera XT DNA Library Preparation using SOP: SERL 141	F
		Whole genome sequencing on the Illumina MiSeq using SOP: SERL 145	F
		MTB phenotypic drug susceptibility testing based on WGS results using SOP: SMRL 151	F
		WGS result verification and reporting using SOP: SMRL 152, SERL149	F
		WGS data transfer to UKHSA server using FileZilla SOP: SMRL150	F
Cultures	Susceptibility testing of *Mycobacterium tuberculosis* complex (MTBC)	BACTEC MGIT TM 960 fluorometric system using SOP: SMRL9	F
Raw sputum or concentrated sediments prepared from sputum or MGIT culture	Detection of M. tuberculosis and resistance genes (katG, fabG1, oxyR-ahpC, inhA, gyrA, gyrB, rrs and eis)	Cepheid GeneXpert MTB/XDR assay using SOP SMRL 171	F
Respiratory samples, pleural fluids, aspirates, pus, tissue, stools, CSF, and bone marrow.	Detection of Acid Fast Bacilli (AFB)	Fluorescent microscopy stained with Auramine Phenol using SOP: SMRL3 & SMRL17	F

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HUMAN TISSUES and FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
Respiratory samples, pleural fluids, aspirates, pus, tissue, stools, CSF, bone marrow, urine, whole & citrated blood culture	Culture, identification for Mycobacteria	Culture via solid and/or liquid media followed by BD BACTEC MGIT 960 or BD BACTEC Fx using SOP: SMRL17, SMRL6	F
		Kinyoun modification of Ziehl-Neelsen staining using SOP: SMRL21	F
	Molecular Microbiological examination activities for the purpose of clinical diagnosis	In-house documented procedures:	
Nose and Throat Swabs in VTM or MSS	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; • N2 and E	GeneXpert real-time system SOP: VIRM-299	A
Nose and Throat Swabs in VTM or MSS	Detection of SARS-CoV-2 RNA (RdRp and N gene target sequences)	Real-Time PCR using the Abbott Resp-4-Plex assay on the Abbott Alinity M using SOP: VIRM 330	A
Nose and Throat Swab in VTM or MSS	Detection of SARS-CoV-2 (N gene target sequences x2)	Real-Time PCR using the RP2 Panel on the Genmark ePlex using SOP: VIRM 314	A
Dried Blood Spot	Detection of HCV RNA	In-house RT-PCR assay using EasyMag or eMAG automated extraction and ABI 7500 FAST using SOP VIRM-258, VSS-16	A
Viral RNA	HCV genotyping	Sanger sequencing of HCV (various regions) via ABI 3500xl Genetic Analyser using SOP: BBV1, BBV4, BBV 33	G
Viral RNA or DNA	HIV sequencing	Sanger sequencing of HIV (various regions) via ABI 3500xl Genetic Analyser using SOP: BBV1, BBV8, BBV5, BBV7, BBV11	G

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HUMAN TISSUES and FLUIDS (cont'd)	Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
Plasma/serum/CSF	Viral nucleic acid extraction	Biomerieux EasyMag or eMAG automated nucleic acid extraction platform using SOP: VIRM-3, VSS-16	G
Whole EDTA blood, Peripheral blood mononuclear cell's (PBMC's)	Viral DNA extraction	Manual DNA extraction via QIAGEN QIAamp DNA Blood Mini kit using SOP: BBV2	G
Vesicle / Skin Swab	Detection of Orthopoxvirus DNA	EasyMag extraction platform and Altona RealStar Zoonotic Orthopoxvirus PCR kit 1.0 and ABI 7500 thermocycler. SOP: VIRM-358	A
Vesicle / Skin Swab	Detection of Monkeypox virus DNA	In-house assay and EasyMag extraction platform and ABI 7500 thermocycler. SOP: VIRM-392	A
Faeces	Detection of Norovirus (G1 and G2), Rotavirus, Adenovirus (F40/41), Astrovirus, Sapovirus (G1, 2, 4,5) nucleic acids	Hamilton STARlet, Seegene Allplex GI Plus kit and BioRad CFX 96 thermocycler. SOP: VIRM-337	A
Respiratory secretions, respiratory swabs, genital swabs, vesicle fluids, vesicle swabs, tissues, whole blood, blood spots, urine, swabs, body fluids, faeces, vomit, CSF	Nucleic acid extraction	Biomerieux Easymag or eMAG Automated Extractors or Qiagen Manual Extraction SOP: VIRM-3, VIRM-71, VSS-16	A
RNA/DNA Extracts	Detection of Influenza A, B, Respiratory Syncytial virus (RSV), Para-influenza type 1-3, Adenovirus, Mycoplasma pneumoniae, Rhinovirus, Human Metapneumovirus	Respiratory Multiplex PCR via ABI 7500 using SOP: VIRM-67, VIRM-5, VIRM-11, VIRM-19, VIRM-20	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES and FLUIDS (cont'd)	Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
Respiratory samples	SARS-CoV-2 whole genome sequencing	SARS-CoV-2 whole genome sequencing (Oxford Nanopore) using Oxford Nanopore Technologies GridION using SOPS: VSS-3. VSS-9, VSS-11, VSS-12, VSS-15)	H
		ABI 7500 Real-Time PCR analyser using	A
		In-house RT-PCR assay using EasyMag or eMAG automated extraction and ABI 7500 FAST and associated SOP:	
RNA/DNA Extracts	Typing of Swine Dublin H1N1	SOP: VIRM-38	
	H1N1 H275Y Resistance testing	SOP VIRM-68	
	Influenza virus Typing and Confirmation (H1/H3/H5/H7)	SOP: VIRM-55, H1/H3 SOP VIRM-55, H5 SOP VIRM-30, H7 SOP VIRM-105	
	Detection of Mumps	SOP: VIRM-18, VIRM-62	
	Detection of Measles	SOP: VIRM-61	
	Detection of Syphilis	SOP: VIRM-40, VIRM-50	
	Detection of *Bordetella pertusis*	SOP: VIRM-46, VIRM-48	
	Detection of Enterovirus/Parecho	SOP: VIRM-8, VIRM-13, VIRM-14, VIRM-28	
	Detection of Enterovirus Typing (EVD68)	SOP: VIRM-14	
	Detection of Herpes Simplex Virus (HSV), Varicella Zoster Virus (VZV), Adenovirus	SOP: VIRM-20, VIRM-26, VIRM-31, VIRM-58, VIRM-104	

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HUMAN TISSUES and FLUIDS (cont'd)	Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
		ABI 7500 Real-Time PCR analyser using	A
RNA/DNA Extracts (cont'd)	Detection of Rotavirus	SOP: VIRM-35, VIRM-70	A
	Detection of Middle eastern respiratory syndrome (MERS)	SOP: VIRM-136	A
	Detection of Bocavirus	SOP: VIRM-92	A
	Detection of Coronavirus	SOP: VIRM-103	A
	Detection of Bacterial Meningitis (*Neisseria meningiditis*, *Haemophilus pneumoniae*, and *Streptococcus pneumoniae*)	SOP: VIRM-47, VIRM-39	A
	Detection of Viral Haemorrhagic Fever (Malaria, Ebola, Marburg, Lassa, Crimean Congo, and Dengue)	SOP: VIRM-111, VIRM113	A
	Detection of Astrovirus and Sapovirus	SOP: VIRM-242	A
	Detection of Parvovirus B19	SOP: VIRM-123, VIRM-124	A
	Detection of Hepatitis E	SOP: VIRM-12, VIRM-56	A
	Detection of *Chlamydia pneumophilia*	SOP: VIRM-114, VIRM-115, VIRM-116	A
	Detection of Legionella (*L. pneumophila*/species)	SOP: VIRM-16, VIRM-49	A
	Detection of Epstein-Barr Virus (EBV)	ABI 7500 Quantitative Real-Time PCR analyser using SOP: VIRM-2, VIRM27	A
	Detection of Plasmodium spp	Altona Real Star Pan-Malaria assay using EasyMag, or eMAG automated extraction and ABI 7500 FAST using SOP VIRM-253, VSS-16	A

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HUMAN TISSUES and FLUIDS (cont'd)	Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures:	
		ABI 7500 Real-Time PCR analyser using	A
Nose and Throat swabs in VTM or MSS	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; • E and S	EasyMag, or eMAG extraction and Altona RealStar SARS-CoV-2 kit using ABI 7500 Fast Dx SOP: VIRM-290, VSS-16	A
RNA/DNA Extracts	Detection of BK virus	Quantitative Real-time PCR via VELA Santosa SX using SOP: VIRM-177	A
	Enterovirus Typing (VP1)	Sanger sequencing using ABI 3500xl Genetic Analyzer.	A
Clotted Blood/EDTA	CMV Quantitation	Vela Diagnostics Sentosa Real-time PCR using SOP: VIRM 119	A
Stool	Detection of enteric parasites • *Cryptosporidium* spp, • *Giardia lamblia* • *Entamoeba histolytica*	BioMerieux EasyMag, or eMAG automated extractor and Qiagen QIAamp DNA kit using SOP: VIRM-3, VSS-16 with detection by real-time PCR using the ABI 7500 thermocycler using SOP: SBSTIRL31 Reporting SOP: VIRM 247	A
Boiled Crude lysate	Carbapenemase Producing/ Resistant Enterobacteriaceae	Biorad C1000 TouchReal-Time PCR analyser using SOP: VIRM-33, VIRM-73, VIRM-138, VIRM-139	A
EDTA	Viral Load for HIV, HCV and HBV	Abbott Alinity System – Real-Time PCR extraction and amplification analyserusing SOP: VIRM-302	A
Urine	Detection of *Legionella pneumophilia* serotype 1 antigen	BinaxNow Legionella kit by membrane immunochromatographic assay using SOP: VIRM-86	A

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HUMAN BODY FLUIDS and TISSUES	<u>Immunophenotyping Testing for use in clinical diagnosis</u>	Documented In-house methods using:	
Whole Blood	• BD TBNK AssayCD3 • CD4 • CD8 • CD16 • CD19 • CD56	BD FACS Lyric flow cytometer SOP: HAEM-W-927 and HAEM-W-928	B
Whole Blood and Bone Marrow	Leukaemia/Lymphoma Immunophenotyping Antibodies listed in cocktails for CLL and Acute Leukaemia Panels: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD13, CD15, CD16, CD19, CD20, CD22, CD23, CD25, CD33, CD34, CD45, CD56, CD79b, CD103, CD117, FMC7 HLADR, Oncomark reagent CD14/CD64, Kappa and Lambda	BD FACS Lyric flow cytometer HAEM-W-927 and HAEM-W-929	B
	Intracytoplasmic marker in panels: Oncomark reagent CD3, MPO, CD79a, TdT		B
Whole Blood	Investigation of Paroxysmal Nocturnal Haemoglobinuria (CD59, CD235a, CD14, CD15, CD24, CD45. CD64, FLAER)	BD FACS Lyric flow cytometer HAEM-W-947	B

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HUMAN BODY FLUIDS and TISSUES (cont'd)	Molecular Haematology activities for the purpose of clinical diagnosis	Documented In-house methods using:	
Whole Blood EDTA and NaCitrate	Extraction of nucleic acid	QiaSymphony SP: Purification of DNA according to SOP HAEM-R32	A
DNA Extracted from whole blood/ bone marrow	Detection of JAK2 V617F mutation	Applied Biosystems Fast 7500 real time PCR Analyser using manufacturers' instructions and SOP: HAEM-R109	A
	Detection of JAK2 exon 12 mutations and MPL exon 10 mutations	Real-time PCR amplification using the Rotorgene and analysis by High resolution melt curve analysis (HRM). SOP: HAEM R115, R126	A
	Detection of JAK2 exon 12 mutations and MPL exon 10 mutations	PCR Amplification using thermal cyclers and direct DNA sequence analysis using Applied Biosystems 3500xl analyser using manufacturers' instructions SOP: HAEM R115, R126	A
	Detection of prothrombin G20210A and Factor V Leiden mutations	Real-time amplification using the Applied Biosystems® Fast 7500 real time PCR analyser using SOP: HAEM-R19	A
	Detection of CALR mutations.	PCR Amplification using thermal cyclers, and fragment analysis of PCR product by Applied Biosystems 3500xl analyser using manufacturers' instructions and SOP: HAEM-R113	A
	Detection of CALR mutations.	PCR Amplification using thermal cyclers, and Sanger sequencing by Applied Biosystems 3500xl analyser using manufacturers' instructions and SOP: HAEM-R113	A
DNA/RNA extracted from blood/bone marrow	NGS Myeloid panel	ThermoFisher Oncomine Myeloid Assay by NGS by Ion Chef and Ion Torrent S5 Sequencer using SOP HAEM-W-857 and HAEM-W-724	A
	DPYD	DPYD testing using the Elucigene DPYD kit, SOP PATH-R-399	A

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HUMAN BODY FLUIDS and TISSUES (cont'd)	Molecular Haematology activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
DNA extracted from peripheral blood	DPYD variant testing	PCR and Sanger sequencing using ABI 3500X according to SOP- PATH-R-184	A
DNA extracted from FFPE	Microsatellite Instability Testing	PCR/Fragment length analysis using Promega MSI Oncomate kit thermocyclers and Applied Biosystems 3500xl analyser using SOP PATH-R-473	A
	NGS Caner Hotspot	ThermoFisher AmpliSeq Cancer Hotspot version 2 NGS by Ion Chef and Ion Torrent S5 sequencer using SOP PATH-R-358 and PATH-R-364	A
Blood, Bone Marrow		Automated extraction of genomic DNA using the Promega Maxwell RSC instrument using SOP: HAEM-W-948	B
		Automated extraction of RNA using the Promega Maxwell RSC instrument as described in SOP HAEM-W-581 and HAEM-W-937	B
Extracted RNA	cDNA synthesis	cDNA synthesis using the VILO mastermix performed on Thermal Cyclers using SOP: HAEM-W-731	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES (cont'd)	Molecular Haematology (HMDS) Testing for use in clinical diagnosis	Documented In-house methods using:	
Synthesised cDNA	Detection of: • FIPL1-PDGFRA fusion gene	Reverse transcriptase PCR on Thermo cyclers and Gel electrophoresis SOP: HAEM-W-578 SOP: HAEM-W-286	B
Synthesised cDNA	Detection of: • BCR: ABL 1 fusion gene	Realtime RT-PCR ABI 7500	B
Nucleic Acid	Detection of • FLT3 internal tandem duplication and tyrosine kinase domain mutation	multiplex PCR on Thermal cyclers and capillary electrophoresis and the ABI 3500 genetic analyser using SOP: HAEM-W-586	B
Synthesised cDNA	Relative Quantification of • BCR: ABL 1	Quantitative realtime RT-PCR using the ABI 7500 SOP: HAEM-W-205 (E13A2 and E14A2 fusion transcript) and SOP HAEM-W-586 (E1A2 fusion transcript)	B
	BCR: ABL 1 TKD mutation	Nested PCR and ABI 3500XL genetic analyser Sanger sequencing using SOP:HAEM-W-791	B
Nucleic Acid	IGHV mutation status	PCR and Sanger sequencing using ABI 3500XL according to SOP: HAEM-W-796	B
Nucleic Acid	NPM1 mutation	PCR and capillary electrophoresis using the ABI 3500XL genetic analyser using SOP: HAEM-W-835	B
Nucleic Acid	Quantification of NPM1 mutation	Quantitative realtime RT-PCR using the ABI 7500 according to SOP HAEM-W-907	B
Blood/Bone Marrow	Isolation of human mononuclear cells	Centrifugation for sample separation sing Lymphoprep using HAEM-W-806	B
Nucleic Acid	Quantification of Nucleic Acid	Use of Nanodrop ND1000 according to HAEM-R3	B
Synthesised cDNA	PCR amplification	Veriti Thermocycler	B

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HUMAN BODY FLUIDS and TISSUES (cont'd)	Molecular Haematology (HMDS) Testing for use in clinical diagnosis (cont'd)	Documented In-house methods using:	
Synthesised cDNA	Acute Myeloid Leukaemia (AML) and Acute Lymphoblastic Leukaemia (ALL) fusion gene Panel RUNX1::RUNX1T1 CBFB::MYH11 PML::RARA ETV6::RUNX1 TCF3::PBX1 BCR::ABL1 (E1A2) • BCR::ABL1 (E13A2; E14A2)	Realtime RT-PCR using the ABI 7500 according to SOP HAEM-W-619 (AML fusion panel) Realtime RT-PCR using the ABI 7500 according to SOP HAEM-W-635 (ALL fusion panel) Realtime RT-PCR using the ABI 7500 according to SOP HAEM-W-636 (ALL and AML fusion follow up)	B
Synthesised cDNA	Quantification of RUNX1::RUNX1T1	Quantitative realtime RT-PCR using the ABI 7500 according to SOP HAEM-W-915	B
Synthesised cDNA	Quantification of PML::RARA	Quantitative realtime RT-PCR using the ABI 7500 according to SOP HAEM-W-916	B
Synthesised cDNA	Quantification of CBFB::MYH11	Quantitative realtime RT-PCR using the ABI 7500 according to SOP HAEM-W-917	B
Extracted DNA	T-cell Clonality tests • TCRB • TCRG • TCRD	Multiplex PCR with Invivoscrobe Identiclone Kits on Thermal cyclers, ABI 3500 Genetic Analyser and using SOP: HAEM-W-569, SOP:HAEM-W-570	B
	B-cell Clonality tests • IGH • IGL • IGK • IGKDEL		B
Extracted DNA	MYD88 L265P Mutation screening	Real-time PCR using the ABI 7500 by Allele Specific PCR using SOP: HAEM-W-720	B
Extracted DNA	KIT D816V Mutation screening	Real-time PCR using the ABI 7500 by Allele Specific PCR using SOP: HAEM-W713	B

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HUMAN BODY FLUIDS and TISSUES (cont'd)	Molecular Haematology (HMDS) Testing for use in clinical diagnosis (cont'd)	Documented In-house methods using:	
Extracted DNA	Detection of TP53 mutation Detection of POLE mutation Detection of NPM1 mutation	PCR and Sanger sequencing using ABI 3500XL according to SOP: HAEM-W-721 and HAEM-W-722	B
	Molecular Pathology tests to assist in detection of clinical abnormalities	In house, manual methods and manufacturer's instructions documented	A
Plasma	DNA profiling for detection of abnormal gene sequences:	Manual Isolation of Cell-Free DNA from Plasma Using the COBAS cfDNA Sample Preparation Kit (MOLG-R-14)	A
FFPE various tissue samples	Extraction of nucleic acid	Documented in- house methods: Manual DNA extraction using one or a combination of the techniques below by In-house procedures using commercial kits and manual extraction SOP: PATH-R-120	A
		Extraction of DNA & RNA using the Promega Maxwell 16 Instrument and associated kits (PATH-R-379)	A
DNA extracted from FFPE and cell free DNA from plasma	EGFR	PCR amplification of DNA using Roche COBAS for mutation detection using in-house method SOP: PATH-R-174	A
DNA extracted from FFPE	KRAS	Pyromark Q24 pyrosequencing for mutation detection using SOP: PATH-R-134, PATH-R-334	A
	NRAS	Pyromark Q24 pyrosequencing for mutation detection using SOP- PATH-R-134, PATH-R-334	A
	BRAF	Pyromark Q24 pyrosequencing for mutation detection BRAF using SOP- PATH-R-134, PATH-R-334	A

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HUMAN BODY FLUIDS and TISSUES (cont'd)	Molecular Pathology tests to assist in detection of clinical abnormalities (cont'd)	In house, manual methods and manufacturer's instructions documented	
DNA extracted from FFPE	• KIT • PDGFRA • EGFR • KRAS • TERT Promoter • FOXL2 c.402C>G	PCR and Sanger sequencing using ABI 3500XL according to SOP: PATH-R-184	A
	MGMT promoter methylation	Pyromark Q24 pyrosequencing for methylation analysis using SOPs PATH-R-134 and PATH-R-144	A
	Molecular identity testing	Multiplex PCR followed by capillary electrophoresis using the ABI 3500 genetic analyser using SOP-PATH-R-149	A
DNA extracted from FFPE	IDH 1 and IDH 2 somatic mutations	Pyromark Q24 pyrosequencing for mutation detection using SOP- PATH-R-134, PATH-R-334	A
	FISH analysis to assist in detection of clinical abnormalities	In House manual methods and manufacturer's instructions documented	
FFPE tissue samples and cell blocks	ALK rearrangement using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A
FFPE tissue samples and cell blocks	DDIT3 using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A
FFPE tissue samples and cell blocks	EWSR1 rearrangement using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A
FFPE tissue samples and cell blocks	FOXO1 rearrangement using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES (cont'd)	FISH analysis to assist in detection of clinical abnormalities (cont'd)	In House manual methods and manufacturer's instructions documented	
FFPE tissue samples and cell blocks	FUS rearrangement using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A
FFPE tissue samples and cell blocks	HER2 amplification for therapy stratification in gastric cancer	FISH Analysis Manual staining procedures (gastric): ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	A
FFPE tissue samples and cell blocks	ROS1 rearrangement using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A
FFPE tissue samples and cell blocks	USP6 rearrangement using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A
FFPE tissue samples and cell blocks	MDM2 amplification by enumeration FISH	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A
FFPE tissue samples and cell blocks	SS18 rearrangement using breakapart FISH probe	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy: ICC-R25 Interpretation and scoring: MOLG-R-107	A

END