Schedule of Accreditation

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UKAS MEDICAL **9546** **Accredited to ISO 15189:2022**	**NHS Lothian** **Issue No:** 018 **Issue date:** 21 August 2026	
	Lothian NHS Board Headquarters **Mainpoint** **102 Westport** **Edinburgh** **EH3 9DN**	**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 Microbiology 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	Molecular Pathology 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/STEC Reference Laboratory (SERL)		Identification and typing of *E. coli* O157 and Shiga toxin-producing *E. coli* (STEC)	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
Infection Genomic Service (IGS) - RIE		Genome sequencing of viruses and other pathogens	H
Infection Genomic Service (IGS) BioQuarter		Genome sequencing of viruses and other pathogens	I

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	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 and Prolex O157 Latex Kit using SOP: SERL 58, SERL 53	D
	Determination of MLST (7 loci), virulence gene profile, serotype (O:H antigen), MLST (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
		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	C
Swabs, urine, and aspirates	DNA Extraction	BioMerieux eMAG automated extractor, or manual method by Qiagen QIAamp DNA kit using SOPs: VIRM-3, SBSTIRL34	A, C
Respiratory secretions, respiratory swabs, genital swabs, vesicle fluids, vesicle swabs, tissues, whole blood, blood spots, urine, swabs, body fluids, faeces, vomit, CSF, Vesicle / Skin Swab, Nose and Throat swabs in VTM or MSS, Stool, Dried Blood Spot	Nucleic acid extraction	Biomerieux eMAG Automated Extractors or Qiagen Manual Extraction SOP: VIRM-3, VIRM-71, VSS-16	A

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HUMAN TISSUES and FLUIDS	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	Detection of Influenza A, B, Respiratory Syncytial virus (RSV), Para-influenza type 1-3, Adenovirus, Mycoplasma pneumoniae, Rhinovirus, Human Metapneumovirus	SOP: VIRM-67, VIRM-5, VIRM-11, VIRM-19, VIRM-20	A
DNA Extracts	Detection of Mpox Virus DNA	SOP: VIRM-392	A
DNA Extracts	Detection of Orthopoxvirus DNA	SOP: VIRM-358	A
RNA/DNA Extracts	Detection of enteric parasites: *Cryptosporidium* spp, *Giardia lamblia* *Entamoeba histolytica*	SOP: SBSTIRL31 Reporting SOP: VIRM 247	A
RNA Extracts	Detection of HCV RNA	SOP VIRM-258, VSS-16	A
RNA Extracts	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; • E and S	Altona RealStar SARS-CoV-2 kit using ABI 7500 Fast Dx SOP: VIRM-290, VSS-16	A
RNA/DNA Extracts	Typing of Swine Dublin H1N1	SOP: VIRM-38	A
	H1N1 H275Y Resistance testing	SOP VIRM-68	A
	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	A
	Detection of Mumps	SOP: VIRM-18, VIRM-62	A

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HUMAN TISSUES and FLUIDS	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 Measles	SOP: VIRM-61	A
	Detection of Syphilis	SOP: VIRM-40, VIRM-50	A
	Detection of *Bordetella pertusis*	SOP: VIRM-46, VIRM-48	A
	Detection of Enterovirus/Parecho	SOP: VIRM-8, VIRM-13, VIRM-14, VIRM-28	A
	Detection of Enterovirus Typing (EVD68)	SOP: VIRM-14	A
	Detection of Herpes Simplex Virus (HSV), Varicella Zoster Virus (VZV), Adenovirus	SOP: VIRM-20, VIRM-26, VIRM-31, VIRM-58, VIRM-104	A
	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

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HUMAN TISSUES and FLUIDS	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 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)	SOP: VIRM-2, VIRM27	A
	Detection of Plasmodium spp	Altona Real Star Pan-Malaria assay and ABI 7500 FAST using SOP VIRM-253	A
Bronchial Washings, BAL, Sputum, Induced Sputum samples	Detection of Pneumocystis jirovecii specific DNA	Altona RealStar Pneumocystis jirovecii PCR Kit SOP: VIRM-64	A
	Enterovirus Typing (VP1)	Sanger sequencing using ABI 3500xl Genetic Analyzer.	A
Urine	Detection of *Legionella pneumophilia* serotype 1 antigen	BinaxNow Legionella kit by membrane immunochromatographic assay using SOP: VIRM-86	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
Nasopharyngeal swabs, Sputum BAL	Detection of Influenza A, Influenza B, RSV and SARS-CoV-2 RNA (RdRP and N gene target sequences)	Respiratory-4-Plex assay by Real-Time PCR using Abbott Alinity M Platform SOP: VIRM-317	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES and FLUIDS	Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures: ABI 7500 Real-Time PCR analyser using:	A
Endocervical swab Vaginal swab Urine Rectal swab Oropharyngeal swab	Detection of Chlamydia trachomatis RNA (CT) and Neisseria gonorrhoeae (NG) DNA	Real-Time PCR using Abbott Alinity M Platform SOP: VIRM-331	A
Nose and Throat Swabs in VTM or MSS	Detection of SARS-CoV-2 RNA (RdRp and N gene target sequences)	Abbott Alinity M platform, Real-Time PCR using the Abbott Resp-4-Plex assay on the Abbott Alinity M using SOP: VIRM 330	A
Plasma	Detection of CMV, BKV and EBV DNA	Abbott Alinity M platform, Real-time PCR using Abbott Alinity M platform SOP: VIRM-302	A
EDTA	Viral Load for HIV, HCV and HBV	Abbott Alinity M platform, Abbott Alinity System – Real-Time PCR extraction and amplification analyser using SOP: VIRM-302	A
Nose and Throat Swabs in VTM or MSS	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; • N2 and E	Cepheid GeneXpert real-time system SOP: VIRM-299	A
Urine, Urogenital Swabs and Rectal Swabs	Detection of *Mycoplasma genitalium* and key mutations associated with macrolide resistance	Cepheid GeneXpert, ResistancePlus MG FleXible assay on the Cepheid GeneXpert using SOP: VIRM355	A
Rectal, cervical, throat Swabs/Urine	Detection of N. gonorrhoeae DNA	Hamilton STARlet Seegene Allplex STI4 Kit GC NAAT and BioRad CFX 96 using SOP VIRM-337	A

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HUMAN TISSUES and FLUIDS	Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures: ABI 7500 Real-Time PCR analyser using:	A
Nasopharyngeal aspirate Nasopharyngeal swab BAL Sputum	Detection of Adenovirus, Metapneumovirus, Enterovirus, Parainfluenza 1, 2 and 3 (RP2) Bocavirus, Rhinovirus, Coronavirus 229E, Coronavirus NL63, Coronavirus OC43 (RP3) Nucleic acids	Hamilton STARlet Seegene Allplex Respiratory RP2/3 assay and BioRad CFX 96 using SOP VIRM-337	A
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 eMAG, or manual extraction using QIAmp. PCR using Gel Electrophoresis visualisation or Sanger Sequencing using SOP SBSTIRL74, VSS-16	C
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	E
		Manual extraction using QIAamp DNA mini kit or automated extraction using Seegene STARMag 48 kit	E
		Combination of manual and automated stages and PCR set up using the Seegene Nimbus platform	E
		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
Positive Mycobacterium culture	Identification of Mycobacteria species	MALDITOF Mass Spectrometry for Mycobacteria SOP: SMRL 182	F
DNA	Mycobacteria Whole Genome Sequencing	WGS result verification and reporting using SOP: SMRL 152, SERL149	F
Cultures	Susceptibility testing of *Mycobacterium tuberculosis* complex (MTBC)	BACTEC MGIT TM 960 fluorometric system using SOP: SMRL9	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:	
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
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

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HUMAN TISSUES and FLUIDS (cont'd)	Molecular Microbiological examination activities for the purpose of clinical diagnosis	In-house documented procedures:	
Viral RNA	HCV genotyping	Sanger sequencing of HCV (various regions) via ABI 3500xl Genetic Analyser using SOP: BBV1, BBV4	G
Viral RNA or DNA	HIV sequencing	Sanger sequencing of HIV (various regions) via ABI 3500xl Genetic Analyser using SOP: BBV1, BBV8, BBV5, BBV7	G
Plasma/serum/CSF	Viral nucleic acid extraction	Biomerieux 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
Respiratory samples	SARS-CoV-2 nucleic acid extraction, reverse transcription, and genome amplification	Nucleic acid extraction, reverse transcription, and SARS-CoV-2 genome amplification using BioRad C1000 touch, ThermoFisher Kingfisher, ThermoFisher Multidrop, Hamilton Starlet SOP: IGS-3, IGS-6, IGS-9, IGS-11, IGS-12, IGS-15, IGS-19	H
Nucleic acid extracts and PCR products from microbiological agents	Illumina whole genome sequencing	Whole genome sequencing using COVIDSeq library preparation, Hamilton NGS STAR, BioRad C1000 Touch, Thermofisher Qubit 3.0 Fluorometer, Illumina NextSeq 2000 SOP: IGS-18, IGS-19, IGS-20, IGS-27, IGS-28, SERL-144	H, I
Nucleic acid extracts and PCR products from microbiological agents	Nanopore whole genome sequencing	Whole genome sequencing using ligation library preparation, BioRad C1000 Touch, Thermofisher Qubit 3.0 Fluorometer, Oxford Nanopore Technologies GridION SOP: IGS-3, IGS-6	H

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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-974	B
Whole Blood and Bone Marrow	Lymphoid panel BD OneFlow LST: CD45, CD3, CD4, CD5, CD8, CD19, CD20, CD38, CD56, IgK, IgL and TCRgd.	BDFACS Lyric flow cytometers with BDFACSClinical software. HAEM-W-983	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES	Immunophenotyping Testing for use in clinical diagnosis (cont'd)	Documented In-house methods using:	
Whole Blood and Bone Marrow	Lymphoid panel BD OneFlow C-LPD T1: CD45, CD10, CD19, CD20, CD23, CD43, CD79b and CD200	BDFACS Lyric flow cytometers with BDFACSClinical software. Main SOP reference HAEM-W-983	

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 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 DPYD kit, SOP PATH-R-399	A
DNA extracted from FFPE	Detection of MLH1 promoter hypermethylation status	PCR/Fragment Length Analysis using MRC Holland ME011-D1 SALSA Methylation Specific Multiplex Ligation-dependent Probe amplification (MS-MLPA) kit SOP: PATH-R-496	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)	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	DNA Extraction	Automated extraction using the Maxwell RSC Blood DNA kit on 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 Fast RT PCR system and Hamilton Liquid Handler 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

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 (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 B-cell Clonality tests • IGH • IGL • IGK • IGKDEL	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
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
Synthesised cDNA	Detection of KMT2A Fusion genes	Real time PCR assay using ABI 7500 using SOP:HAEM-W-236	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 (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

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 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
DNA extracted from blood, bone marrow, plasma and FFPE blocks	Patient Identity Testing	GenePrint 24 system, Thermal Cyclers and ABI 3500 PCR and Fragment Length Analysis SOP: PATH-R-572	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

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	FOXO1 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	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