


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 9546</p> <p>Accredited to ISO 15189:2012</p>	<h3>NHS Lothian</h3> <p>Issue No: 008 Issue date: 19 April 2022</p>	
	<p>Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA</p>	<p>Contact: Nadine Wilkinson Tel: +44 (0)131 242 6809 E-Mail: Nadine.Wilkinson@nhslothian.scot.nhs.uk Website: www.edinburghlabmed.co.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

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

#### Laboratory locations:

Location details	Activity	Location code
<p><b>Address:</b> Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA</p> <p><b>Local contact:</b> Nadine Wilkinson Tel: +44 (0)131 242 6809</p>	<p><b>Microbiology:</b> Molecular Virology Molecular Haematology Molecular Pathology</p>	A

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

Location details	Activity	Location code	
Western General Hospital	<p><b>Local contact:</b> Nadine Wilkinson Tel: +44 (0)131 242 6809</p>	Haematological Malignancy Diagnostic Service (HDMS) 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 <i>E. coli</i> O157 and verotoxigenic <i>E. coli</i>	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 <i>Mycobacterium tuberculosis</i> complex (MTBC) and non-tuberculous mycobacteria (NTM)	F
Blood Borne Virus Specialist Testing Service (BBVSTS)		Confirmation and Sequencing of Blood Borne viruses	G



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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
<p>HUMAN TISSUES AND FLUIDS</p> <p>Enrichment broths from the following sample types: Faeces and isolates of <i>E. coli</i>. Mixed cultures of bacterial growth submitted as slopes or pellets from centrifuged culture broth and tissue</p> <p>Nucleic Acid</p> <p>Cultures isolates of <i>E. coli</i></p> <p>Enrichment broths from the following sample types: Faeces and isolates of <i>E. coli</i>. Mixed cultures of bacterial growth submitted as slopes or pellets from centrifuged culture broth and tissue</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>DNA Extraction</p> <p>Detection of vtx1, vtx2 and rfbO157 genes</p> <p>Identification of <i>E. coli</i></p> <p>Detection of <i>E. coli</i> O157</p>	<p>In-house documented procedures:</p> <p>Measurement Principle: Manual DNA extraction using SOP: SERL 49, SERL 50</p> <p>Real-Time PCR using BioRad CFX Thermal Cycler C1000 and C1000 Touch using SOP: SERL 50</p> <p>Identification by BioMerieux API 20E, Wellcolex O157 Latex Kit and Mast E. coli O157 antisera using SOP: SERL 58, SERL 53</p> <p>Immunomagnetic Separation (IMS) by Thermo Scientific KingFisher mL Magnetic Particle Processor using SOP: SERL 55</p>	D



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Isolates of <i>E. coli</i> O157</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>E. coli Phage Typing</p> <p>Determination of MLST (7 loci), virulence gene profile, serotype (O:H antigen), antibiotic resistance gene profile, cgMLST (2513 loci) and SNP analysis for outbreak investigation and surveillance of <i>E. coli</i> O157 and non-O157 STEC.</p>	<p>In-house documented procedures:</p> <p>Phage Typing panel provided by PHE measuring the pattern of bacterial lysis by phages using SOP: SERL 59</p> <p>DNA extraction using the QIASymphony using SOP: SERL138</p> <p>DNA extraction using the Qiagen DNeasy Blood and Tissue Kit using SOP: SERL137</p> <p>Use of the NanoDrop ND-1000 Spectrophotometer using SOP: SERL143</p> <p>Use of the Qubit 3.0 Fluorometer using SOP: SERL144</p> <p>Nextera XT DNA Library Preparation using SOP: SERL 141</p> <p>Use of the Illumina Experiment Manager using SOP: SERL 142</p> <p>Whole genome sequencing on the Illumina MiSeq using SOP: SERL 145</p> <p>Analysis of Whole Genome Sequencing Data using the Public Health England pipeline using SOP: SERL140</p> <p>Analysis of Whole Genome Sequencing Data using BioNumerics (Applied Maths) using SOP: SERL139</p>	<p>D</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures:	
Swabs, isolates	Culture and identification of <i>Neisseria gonorrhoeae</i>	Culture on agar followed by phenotypic identification using Gram stain, sugar utilisation, Phadebact monoclonal antibody using SOPs: SBSTIRL39, SBSTIRL40	C
Isolates	Antibiotic susceptibility of <i>Neisseria gonorrhoeae</i>	Antibiotic susceptibility testing by agar dilution method and E tests using SOP: SBSTIRL41	
Swabs, urine, and aspirates	DNA Extraction	BioMerieux EasyMag automated extractor or manual method by Qiagen QIAamp DNA kit using SOPs: VIRM-3, SBSTIRL34	
DNA	Confirmation of <i>Neisseria gonorrhoeae</i>	Real-time PCR confirmation by ABI 7500 using SOP: SBSTIRL33	
DNA	Confirmation of <i>Chlamydia trachomatis</i>	Real-time PCR confirmation by ABI 7500 using SOP: SBSTIRL31	
DNA	Screening for <i>Chlamydia trachomatis</i> LGV serovars	Real-time PCR by ABI 7500 using SOP: SBSTIRL31	
DNA	Screening for <i>Mycoplasma genitalium</i>	Real time PCR using the SpeedX kit by ABI7500 using SOP: SBSTIRL64, SBSTIRL74	
Male urine, male anal swabs, female urine, cervical swabs, endocervical swabs, vaginal and high vaginal swabs	Detections of mutations in <i>Mycoplasma Genitalium</i> that correlate to macrolide and fluoroquinolone resistance	Automated extraction using EasyMag, or manual extraction using QIAmp. PCR using Gel Electrophoresis visualisation or Sanger Sequencing using SOP SBSTIRL74	A
Swabs, urine, and isolates	<i>Neisseria gonorrhoeae</i> molecular epidemiology	NG-MAST Sanger sequencing by ABI 3500xl Genetic Analyzer using SOPs: SBSTIRL32, SBSTIRL29	
Serum and CSF	Detection of Cryptococcal antigen	Lateral flow assay using SOP MYCOL-11	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures:	
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
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 Anyplex HPV28 kit SOP HPV138  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 Anyplex software	E
Respiratory specimens, FFPE tissue, and Cultures	Extraction of nucleic acid	HAIN Lifescience GenoLyse® manual method using SOP: SMRL7	
Nucleic acids obtained from both Respiratory specimens & FFPE tissue.	Detection of MTBC ( <i>Mycobacterium tuberculosis</i> Complex)	Real-time multiplex PCR by IS6110 gene detection using ABI Prism 7500 using SOP: SMRL2, SMRL53	F
Nucleic acids obtained from Cultures	Typing MTBC.	24 locus MIRU-VNTR via GeneAmp (Applied Biosystems) PCR system & ABI 3500 xl capillary sequencer using SOP: SMRL1	
Nucleic acids obtained from: cultures, FFPE & respiratory specimens	Resisting testing of MTB complex to rifampicin (RIF), isoniazid (INH) and other second line agents	Molecular detection by Multiplex PCR via Proflex PCR system & HAIN Lifescience GTBlot 48 using SOP: SMRL7	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures:	
Nucleic acids obtained from Respiratory specimens	Molecular detection of MTBC and its resistance to rifampicin (RIF)	Real time nested PCR via Cepheid GeneXpert platform using SOP: SMRL69	
Nucleic acids obtained from Cultures.	Molecular identification of Non-Tuberculi Mycobacteria (NTM) and identification of members of the MTBC	Multiplex PCR via Gene Amp 2700 PCR & HAIN Lifescience GTBlot 48 using SOP: SMRL7	
Mycobacteria growth indicator tube (MGIT) cultures	Detection of MTBC	Rapid chromatographic immunoassay by Cartridge based chromatographic immunoassay for MTBC antigen using SOP: SMRL19	
Cultures	Susceptibility testing of <i>Mycobacterium tuberculosis</i> complex (MTBC)	BACTEC MGIT TM 960 fluorometric system using SOP: SMRL9	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 & 17	
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 BACTEC MGIT TM 960 or BACTEC Fx using SOP: SMRL17, SMRL6  Presumptive confirmation using Kinyoun Ziehl-Neelsen staining using SOP: SMRL21	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular Microbiological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures:	
Serum/plasma	HIV-1 RNA detection	Quantitative PCR method via Cepheid GeneXpert, Xpert® HIV-1 Viral Load kit using SOP: VIRM - 140	G
Nose and Throat Swabs in VTM	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; <ul style="list-style-type: none"> <li>• N2 and E</li> </ul>	GeneXpert real-time system SOP: VIRM-299	A
Viral DNA	HIV-1 proviral DNA testing	Qualitative Real Time PCR for detection of HIV-1 Proviral DNA via Bio-Rad CFX using SOP: BBV15	G
Viral RNA	Hepatitis C genotyping	Sanger sequencing of HCV (various regions) via ABI 3500xl Genetic Analyser using SOP: BBV1, BBV4, BBV 33	
Viral RNA or DNA	HIV sequencing	Sanger sequencing of HIV (various regions) via ABI 3500xl Genetic Analyser using SOP: BBV1, BBV8, BBV5, BBV7, BBV11	
Dried Blood Spot	Detection of HCV RNA	In-house RT-PCR assay using EasyMag automated extraction and ABI 7500 FAST using SOP VIRM-258	



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Plasma/serum/CSF	Viral RNA extraction	Biomerieux easyMag automated nucleic acid extraction platform using SOP: VIRM-3	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	
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 Automated Extractors or Qiagen Manual Extraction SOP: VIRM-3, VIRM-71	A
Formalin Fixed Tissue (FFPE)	Nucleic acid extraction	VELA Sentosa SX Platform using SOP: VIRM-117	
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	
RNA/DNA Extracts	Detection of Influenza A, H1, H3, Influenza B, Respiratory Syncytial virus (RSV A&B), Parainfluenza 1-4, Adenovirus, <i>Mycoplasma pneumoniae</i> , Rhinovirus, Enterovirus, Human Metapneumovirus, Coronavirus, Bocavirus, <i>Legionella pneumophila</i> , <i>Chlamydomphila pneumoniae</i>	NxTAG Respiratory PCR panel via Luminex MAGPIX using VIRM-189	





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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures:	A
RNA/DNA Extracts	Typing of Swine Dublin H1N1	ABI 7500 Real-Time PCR analyser using 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 <i>Bordetella pertusis</i>	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	
RNA/DNA Extracts	Detection of Pneumocystis Jirovecii (PJP)	SOP: VIRM-34, VIRM-64	
	Detection of Rotavirus	SOP: VIRM-35, VIRM-70	
	Detection of Middle eastern respiratory syndrome (MERS)	SOP: VIRM-136	
	Detection of Bocavirus	SOP: VIRM-92	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures:	
RNA/DNA Extracts	Detection of Coronavirus	ABI 7500 Real-Time PCR analyser using SOP: VIRM-103	A
	Detection of Bacterial Meningitis ( <i>Neisseria meningitidis</i> , <i>Haemophilus pneumoniae</i> , and <i>Streptococcus pneumoniae</i> )	SOP: VIRM-47, VIRM-39	
	Detection of Viral Haemorrhagic Fever (Malaria, Ebola, Marburg, Lassa, Crimean Congo, and Dengue)	SOP: VIRM-111, VIRM113	
	Detection of Astrovirus and Sapovirus	SOP: VIRM-242	
	Detection of Parvovirus B19	SOP: VIRM-123, VIRM-124	
	Detection of Hepatitis E	SOP: VIRM-12, VIRM-56	
	Detection of <i>Chlamydia pneumophilia</i>	SOP: VIRM-114, VIRM-115, VIRM-116	
	Detection of Legionella ( <i>L. pneumophila</i> /species)	SOP: VIRM-16, VIRM-49	
	Detection of Epstein-Barr Virus (EBV)	ABI 7500 Quantitative Real-Time PCR analyser using SOP: VIRM-2, VIRM27	A
	<u>Detection of Plasmodium spp</u>	Altona Real Star Pan-Malaria assay using EasyMag automated extraction and ABI 7500 FAST using SOP VIRM-253	A
Nose and Throat swabs in VTM	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; <ul style="list-style-type: none"> <li>RdRp</li> </ul>	Extraction using the EasyMag and detection using the ABI 7500 Fast Dx SOP: VIRM-267	
RNA extract from Nose and Throat swabs	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; <ul style="list-style-type: none"> <li>E gene</li> </ul>	ABI 7500 Fast Dx SOP: VIRM-267	



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Nose and Throat swabs in VTM	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; <ul style="list-style-type: none"> <li>E and S</li> </ul>	ABI 7500 Real-Time PCR analyser using  EasyMag extraction and Altona RealStar SARS-CoV-2 kit using ABI 7500 Fast Dx SOP: VIRM-290	
RNA/DNA Extracts	Detection of BK virus  Enterovirus Typing (VP1)	Quantitative Real-time PCR via VELA Santosa SX using SOP: VIRM-177  Sanger sequencing using ABI 3500xl Genetic Analyzer.	
Clotted Blood/EDTA	CMV Quantitation	Vela Diagnostics Sentosa Real-time PCR using SOP: VIRM 119	
Stool	Detection of enteric parasites <ul style="list-style-type: none"> <li><i>Cryptosporidium</i> spp,</li> <li><i>Giardia lamblia</i></li> <li><i>Entamoeba histolytica</i></li> </ul>	BioMerieux EasyMag automated extractor and Qiagen QIAamp DNA kit using SOP: VIRM-3 with detection by real-time PCR using the ABI 7500 thermocycler using SOP: SBSTIRL31 Reporting SOP: VIRM 247	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures:	
Boiled Crude lysate	Carbapenemase Producing/ Resistant Enterobacteriaceae	Biorad C1000 TouchReal-Time PCR analyser using SOP: VIRM-33, VIRM-73, VIRM-138, VIRM-139	
Faeces/Vomit	Detection of Norovirus	BDmax extraction and Real-Time PCR analyser using SOP: VIRM-32 VIRM-99	
EDTA	Viral Load for HIV, HCV and HBV	Abbott Alinity System – Real-Time PCR extraction and amplification analyser using SOP: VIRM-302	A
High vaginal swabs, endocervical swabs, urethral swab, rectal swab, urine, throat swab	Chlamydia trachomatis and Neisseria gonorrhoeae	Abbott M2000sp and real-time (RT) PCR extraction and amplification analyser using SOP: CHL-2, CHL-13	
Nose and Throat Swabs in VTM	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences <ul style="list-style-type: none"> <li>• RdRp and N genes</li> </ul>	Abbott m2000 real-time system (extraction and detection) SOP: VIRM-286	
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen	BinaxNow Legionella kit by membrane immunochromatographic assay using SOP: VIRM-86	
Nose and Throat Swabs in VTM	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences <ul style="list-style-type: none"> <li>• RdRp/S gene</li> <li>• N gene</li> <li>• E genes</li> </ul>	Seegene Allplex 2019-nCoV assay using Seegene Nimbus, Seegene Starlet or Easymag extraction platforms* and Biorad CFX real-time PCR SOP: VIRM-271	A



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Whole Blood</p> <p>Whole Blood and Bone Marrow</p> <p>Whole Blood</p>	<p><u>Immunophenotyping Testing for use in clinical diagnosis</u></p> <p>Immune Monitoring – HIV and suspected immunodeficiency:</p> <ul style="list-style-type: none"> <li>• CD3</li> <li>• CD4</li> <li>• CD8</li> </ul> <p>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, CD79b, FMC7, CD33, CD34, CD45, CD56, CD103, HLADR, Oncomark reagent CD14/CD64, Kappa and Lambda</p> <p>Intracytoplasmic marker in panels: Oncomark reagent CD3, MPO, CD79a, TdT</p> <p>Investigation of Paroxysmal Nocturnal Haemoglobinuria (FLAER, CD16, CD33, CD14)</p>	<p>Documented In-house methods using:</p> <p>FACS CANTO 11 Flow Cytometer</p> <p>SOP: HAEM-W-509</p> <p>FACS CANTO 11 Flow Cytometer SOP: HAEM-W-518 &amp; HAEM-W-153 by multi parameter flow cytometry.</p> <p>FACS CANTO 11 Flow Cytometer SOP: HAEM-W-184</p>	<p>B</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Whole Blood EDTA and NaCitrate</p> <p>DNA Extracted from whole blood leucocytes</p>	<p><u>Molecular Haematology activities for the purpose of clinical diagnosis</u></p> <p>Molecular genetic analysis for genetic mutations and variants</p> <p>F8 gene intron 1 and 22 inversion analysis</p> <p>Detection of JAK2 V617F mutation</p> <p>Detection of JAK2 exon 12 mutations and MPL exon 10 mutations</p> <p>Detection of JAK2 exon 12 mutations and MPL exon 10 mutations</p>	<p>Documented In-house methods using:</p> <p>QiaSymphony SP: Purification of DNA Qiagen Manual Extraction using manufacturers' instructions using SOP: HAEM-R32</p> <p>PCR Amplification using thermal cyclers, and fragment analysis of PCR product by gel-electrophoresis (intron 1 and 22) and by Applied Biosystems 3500xl analyser (intron 22) using manufacturers' instructions and SOP: HAEM-R27, R25</p> <p>Applied Biosystems Fast 7500 real time PCR Analyser using manufacturers' instructions and SOP: HAEM-R109</p> <p>Real-time PCR amplification using the Rotorgene and analysis by High resolution melt curve analysis (HRM). SOP: HAEM R115, R126</p> <p>PCR Amplification using thermal cyclers and direct DNA sequence analysis using Applied Biosystems 3500xl analyser using manufacturers' instructions SOP: HAEM R115, R126</p>	<p>A</p>



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**NHS Lothian**

**Issue No:** 008 **Issue date:** 19 April 2022

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<p>HUMAN BODY FLUIDS</p> <p>DNA extracted from Whole blood Leucocytes</p>	<p><u>Molecular Haematology activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Multiple screening for pathogenic sequence variants in various factor genes, (full gene screening and screening for known familial variants) for all the following genes:</p> <p>SERPINC1 gene LMAN1 and MCFD2 genes</p> <p>F5 gene F7 gene F8 gene F9 gene F10 gene F11 gene FGA, FGB and FGG genes ITGA2B and ITGB3 genes GP1BA gene MYH9 gene (targeted screen)</p> <p>VWF gene PROC gene PROS1 GP1BA, GP1BB, GP9</p> <p>Screening for exonic deletions/duplications in the F8, F9, PROC, SERPINC1, VWF, F7, PROS1, F11, F10 genes (full gene screening and screening for known familial variants)</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:</p> <p>PCR Amplification using thermal cyclers and direct DNA sequence analysis using Applied Biosystems 3500xl analyser using manufacturers' instructions and SOP: HAEM R34, R138</p> <p>SOP: HAEM-R6 SOP: HAEM-R10 SOP: HAEM-R11 SOP: HAEM-R12 SOP: HAEM-R13 SOP: HAEM-R14 SOP: HAEM-R15 SOP: HAEM-R16 SOP: HAEM-R18 SOP: HAEM-R22, R23, R29. SOP: HAEM-R30 SOP: HAEM-R31 SOP: HAEM-R107 SOP: HAEM-R117</p> <p>MLPA analysis using thermocyclers and Applied Biosystems 3500xl analyser using SOP: HAEM-R26</p>	<p>A</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Haematology activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	A
DNA extracted from whole blood Leucocytes (cont'd)	Multiple screening for pathogenic sequence variants in various factor genes, (full gene screening and screening for known familial variants) for the following genes: (cont'd)	PCR Amplification using thermal cyclers and direct DNA sequence analysis using Applied Biosystems 3500xl analyser using manufacturers' instructions and SOP: HAEM R34, R138	
	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	
	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	
	Detection of CALR mutations.	PCR Amplification using thermal cyclers, and Sanger sequencing by Applied Biosystems 3500xl analyser using manufacturers' instructions and SOP: HAEM-R113	
DNA/RNA extracted from blood/bone marrow	Myeloid panel	ThermoFisher Oncomine Myeloid Assay by NGS by Ion Chef and Ion Torrent S5 Sequencer using SOP HAEM-W-857	
	Cancer Hotspot	ThermoFisher AmpliSeq Cancer Hotspot version 2 NGS by Ion Chef and Ion Torrent S5 sequencer using SOP PATH-R-358	
	DPYD	DPYD testing using the Elucigene DPYD kit, SOP PATH-R-399	
DNA extracted from FFPE	Microsatellite Instability Testing	PCR/Fragment length analysis using Promega MSI kit and Thermocycler ABI 3500, SOP MOLG-R-62	
	FOXL2 c402C>G analysis	Sanger sequencing using Thermocycler ABI 3500, SOP PATH-R-184	





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HUMAN BODY FLUIDS AND TISSUES	<u>Molecular Haematology (HMDS) Testing for use in clinical diagnosis</u>	Documented In-house methods using:	B
Blood, Bone Marrow and FFP slides		Automated DNA extraction via 12GC Magtration system. MagDEA DNA 200 (GC) Kit using SOP: HAEM-W-260	
Blood, Bone Marrow		Automated Extraction of RNA using Maxwell 16 LEV Robot. Total RNA Preparation MAXWELL Simply Blood RNA kit using SOP: HAEM-W-581	
Nucleic acid	DNA and RNA quantitation	Promega Quantus fluorometer using SOP: HAEM-W-599	
Extracted RNA	cDNA synthesis	Biometra Thermal Cyclers using SOP: HAEM-W-255	
Synthesised cDNA	Detection of: <ul style="list-style-type: none"> <li>BCR-ABL 1 fusion gene</li> <li>KMT2A Fusion</li> <li>FIPL1-PDGFR4</li> </ul>	Reverse transcriptase PCR on Biometra Thermo cyclers and Gel electrophoresis SOP: HAEM-W-238 SOP: HAEM-W-236 SOP: HAEM-W-578 SOP: HAEM-W-286	
Nucleic Acid	Detection of <ul style="list-style-type: none"> <li>FLT3</li> <li></li> </ul>	multiplex reverse transcriptase (RT) – PCR on on Biometra Thermal cyclers and capillary electrophoresis and the ABI 3130 genetic analyser using SOP: HAEM-W-586	
Extracted RNA	Relative Quantification of <ul style="list-style-type: none"> <li>BCR-ABL 1</li> <li>ABL 1</li> </ul>	RQ-PCR (realtime RT-PCR) and ABI 7500 Realtime PCR System SOP: HAEM-W-205	
Nucleic Acid	BCR ABL I TKD mutation	Nested PCR and ABI 3130 genetic analyser Sanger sequencing using SOP:HAEM-W-791	
Nucleic Acid	IGHV	ABI 3130 genetic analyser Sanger Sequencing using SOP: HAEM-W-796	
Nucleic Acid	NPM1 exon 12 mutation	PCR and capillary electrophoresis using SOP: HAEM-W-835	
Blood/Bone Marrow	Isolation of human mononuclear cells	Centrifugation for sample separation sing Lymphoprep using HAEM-W-806	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular Haematology (HMDS) Testing for use in clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Extracted RNA	Acute Myeloid Leukaemia fusion gene Panel <ul style="list-style-type: none"> <li>• RUNx1-RUNXT1 (AML1 ETO)</li> <li>• E1a2-BCR-ABL-1</li> <li>• Ex13/14 BCL-ABL-1</li> <li>• PML-RARA</li> <li>• CFBF-MYH11 (INV 16)</li> </ul>	RQ-PCR (realtime RT-PCR) ABI 7500 SOP: HAEM-W-619 & HAEM-W-620	
Extracted DNA	T-cell Clonality tests <ul style="list-style-type: none"> <li>• TCRB</li> <li>• TCRG</li> <li>• TCRD</li> </ul> B-cell Clonality tests <ul style="list-style-type: none"> <li>• IGH</li> <li>• IGL</li> <li>• IGK</li> <li>• IGKDEL</li> </ul>	Multiplex PCR with Invivoscribe Identiclone Kits on Biometra Thermal cyclers, ABI 3130 Genetic Analyser and using SOP: HAEM-W-569, SOP:HAEM-W-570	
Extracted DNA	MYD88 L265P Mutation screening	Real-time PCR via ABI 7500 by Allele Specific PCR using SOP: HAEM-W-720	
Extracted DNA	KIT D816V Mutation screening	Real-time PCR via ABI 7500 by Allele Specific PCR using SOP: HAEM-W713	
Extracted DNA	Detection of TP 53 mutation	Multiple PCR and Sanger sequencing on Biometra thermal cyclers and ABI 3130XL Genetic Analyzer according to SOP: HAEM-W-721. Analysis of TP53 sequencing according to HAEM-W-722	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular Pathology tests to assist in detection of clinical abnormalities</u>	In house, manual methods and manufacturer's instructions documented	A
FFPE various tissue samples	DNA profiling for detection of abnormal gene sequences:	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	
	EGFR	PCR amplification of DNA using Roche COBAS for mutation detection using in-house method SOP: PATH-R-174	
	KRAS	Pyromark Q24 pyrosequencing for mutation detection using SOP: PATH-R-134, PATH-R-334	
	NRAS	Pyromark Q24 pyrosequencing for mutation detection using SOP- PATH-R-134, PATH-R-334	
	BRAF	Pyromark Q24 pyrosequencing for mutation detection and COBAS BRAF mutation detection using SOP- PATH-R-134, PATH-R-334	
	<ul style="list-style-type: none"> <li>• KIT</li> <li>• PDGFRA</li> <li>• EGFR</li> <li>• KRAS</li> </ul>	Capillary electrophoresis by in house methods (Sanger Sequencing) using ABI 3500 genetic analyser using SOP: PATH-R-184	
	MGMT	Pyromark Q24 pyrosequencing for methylation analysis using SOP- PATH-R-144	
	Molecular identity testing	Multiplex PCR followed by capillary electrophoresis using the ABI 3500 genetic analyser using SOP-PATH-R-149	
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	B



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>FFPE tissue samples and cell blocks</p>	<p><u>FISH analysis to assist in detection of clinical abnormalities</u></p> <p>ALK1 rearrangement for therapy stratification in NSCLC</p> <p>DDIT3 rearrangement for sarcoma classification (myxoid liposarcoma)</p> <p>EWSR1 rearrangement for sarcoma classification (Ewing's sarcoma)</p> <p>FOXO1 rearrangement for sarcoma classification (alveolar rhabdomyosarcoma)</p> <p>FUS rearrangement for sarcoma classification (myxoid/fibro myxoid sarcoma)</p> <p>HER2 amplification for therapy stratification in breast and gastric cancer</p>	<p>In House manual methods and manufacturer's instructions documented</p> <p>FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p> <p>FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p> <p>FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p> <p>FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p> <p>FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p> <p>FISH Analysis Manual staining procedures (gastric): ICC-R41 Leica Bond automated staining procedures (breast): ICC-R39 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p>	<p style="text-align: center;">A</p>



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>FFPE tissue samples and cell blocks</p>	<p><u>FISH analysis to assist in detection of clinical abnormalities</u></p> <p>MDM2 amplification for sarcoma classification (well differentiated liposarcoma)</p> <p>SS18 rearrangement for sarcoma classification (synovial sarcoma)</p>	<p>In House manual methods and manufacturer's instructions documented</p> <p>FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p> <p>FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46</p>	<p>A</p>
<p>END</p>			