


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>9546</p> <p>Accredited to ISO 15189:2012</p>	<p>NHS Lothian</p> <p>Issue No: 005 Issue date: 16 April 2021</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>Address: Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA</p> <p>Local contact: Nadine Wilkinson Tel: +44 (0)131 242 6809</p>	<p>Microbiology: Bacteriology Mycology 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>Local contact: 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 E. coli 0157 and verotoxigenic 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)		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>Swabs, Pus, Tissues and bone, Fluids: Ascitic, Peritoneal dialysis, Eye humour, Seminal, Joint, Bursa, Contact lens fluid, Fluid from wounds/deep sites, Gastric aspirate, Respiratory type samples, Blood cultures, Enteric samples, Urines, CSF, Arterial and venous catheter tips, gall stones, prosthesis, drain tips, stents, sutures, IUCD's, CSF shunt and access devices, MRSA screens, Carbapenemase Producing Enterobacteriaceae Screen (CPE) screens</p> <p>Blood cultures</p> <p>Pus, Tissue, Bone, Fluids, CSF, Blood cultures & Genito-urinary samples for bacterial vaginosis</p> <p>CSF, Ascitic fluids & PD Fluids</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation of microorganisms of clinical significance</p> <p>General isolation of microorganisms of clinical significance</p> <p>Detection and characterisation of micro-organisms</p> <p>Detection & quantification of white & red blood cells (including WBC differentiation)</p>	<p>In-house documented procedures:</p> <p>Manual or automated inoculation, incubation and image capture of culture media using: SOP: BACT-R-20, BACT-R-22, BACT-R-23, BACT-R-25, BACT-R-33, BACT-R-34, BACT-R-37, BACT-R-39, BACT-R-198, BACT-R-162, And Kit Identification & Bruker Matrix Assisted Laser Desorption Ionisation Time of Flight Biotyper (MALDI-tof) using SOP: BACT-R-29 & BACT-R-31 And Automated BD Kiestra platform using SOP: BACT-R-293</p> <p>Automated method via Biomerieux BacTALERT 3D using SOP: BACT-R-71 and BACT-R-20</p> <p>Microscopy & staining (Gram stain) Using SOP: BACT-R-28, BACT-R-23, BACT-R-20, BACT-R-34 & BACT-R-25</p> <p>Cell counts: Manual & Microscopy using SOP: BACT-R-23, BACT-R-25, BACT-R-28</p>	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:	A
Genito urinary samples	Detection and quantification of white blood cells, Trichomonas vaginalis and clue cells	Wet film: Manual & Light Microscope using SOP: BACT-R-28, BACT-R-37	
Urines	Detection & quantification of white & red blood cells, casts and bacteria	Manual & Inverted Microscopy using SOP: BACT-R-39	
Enteric samples	Ova, cysts & Parasites	Manual & Phase Contrast Microscopy using formal ether concentrate method (Parasept) using SOP: BACT-R-200	
Joint Aspirates	Detection of White blood cells, red blood cells, crystals and bacteria	Manual & Microscopy using SOP: BACT-R-28 BACT-R-34	
Enteric samples	Cryptosporidium	Auramine phenol staining and incident-light fluorescence microscopy using SOP: BACT-R-200	
Bacterial cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual and/or automated antimicrobial susceptibility testing using EUCAST methodology and: Biomerieux Vitek 2, Mastscan Elite using in-house procedure SOP: BACT-R-229, BACT-R-230, BACT-R-231, BACT-R-235, BACT-R-236, BACT-R-238, BACT-R-240	
Enteric samples	Clostridium difficile glutamate dehydrogenase (GDH) C. difficile toxins A & B	Automated Techlab Toxin A&B II ELISA kit and Techlab C.Diff Check 60 (GDH) kit via Dynex DS2 using SOP: BACT-R-201	
Yeast isolates	Antifungal disc sensitivity testing	Manual disc sensitivities using SOP: MYCOL7, 8, 9 and 24	
	Processing of Air Samples	Manual culture reading using SOP: MYCOL-10	



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CSF and serum	Cryptococcal antigen testing	Manual latex agglutination test using SOP: MYCOL-11	
CSF	Cell counts	Manual microscopy using SOP: BACT-R-23	
Skin, nail and hair	Isolation and identification of clinically significant dermatophyte fungi	Microscopy by KOH/DMSO and lactophenol cotton blue using SOP: MYCOL-18	
Skin tapes	Isolation and identification of clinically significant dermatophyte fungi	Manual microscopy by Parkers blue/black 'Quink' Ink using SOP: MYCOL-19	
Respiratory samples/deep tissues		Manual fluorescent microscopy by Calcofluor white and Evans blue using SOP: MYCOL-20, 22	
CSF, Environmental samples, Stools, Fluids, Oesophageal brushings, Peritoneal dialysis fluid, Swabs, Deep tissues	Culture of yeast of clinical significance	Manual methods using SOP: MYCOL-12, MYCOL-13, MYCOL-14, MYCOL-15, MYCOL-16, MYCOL-17, MYCOL-21, MYCOL-22	
Respiratory samples	Culture for filamentous fungi of clinical significance	Manual methods using SOP: MYCOL-20	
Skin, nail and hair	Culture for dermatophytes of clinical significance	Manual methods using SOP: MYCOL-18, 19	
Yeast isolates	Identification of yeasts of clinical significance	Manual methods using SOP: MYCOL-25, 26	
	Identification of Filamentous fungi of clinical significance	Manual methods by phase contrast microscopy using SOP: MYCOL-20	
	Identification of Dermatophytes of clinical significance	Manual methods by phase contrast microscopy using SOP: MYCOL-18	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures:	D
Yeast isolates	Susceptibility of yeasts of clinical significance	YeastOne Sensitre plate test by EUCAST methodology using SOP: MYCOL-33	
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 and tissue.	DNA Extraction	Measurement Principle: Manual DNA extraction using SOP: SERL 49, SERL 50	
Nucleic Acid	Detection of vtx1, vtx2 and rfbO157 genes	Real-Time PCR using BioRad CFX Thermal Cycler C1000 and C1000 Touch using SOP: SERL 50	
Cultures isolates of E. coli	Identification of E.coli	Identification by BioMerieux API 20E, Wellcolex O157 Latex Kit and Mast E. coli O157 antisera using SOP: SERL 58, SERL 53	
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 and tissue.	Detection of E.coli O157	Immunomagnetic Separation (IMS) by Thermo Scientific KingFisher mL Magnetic Particle Processor using SOP: SERL 55	



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



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (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, Phadebact monoclonal antibody 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 automated extractor or manual method by Qiagen QIAamp DNA kit using SOPs: VIRM-3, SBSTIRL34	
DNA	Confirmation of Neisseria gonorrhoeae	Real-time PCR confirmation by ABI 7500 using SOP: SBSTIRL33	
DNA	Confirmation of Chlamydia trachomatis	Real-time PCR confirmation by ABI 7500 using SOP: SBSTIRL31	
DNA	Screening for Chlamydia trachomatis LGV serovars	Real-time PCR by ABI 7500 using SOP: SBSTIRL31	
DNA	Screening for Mycoplasma genitalium	Real time PCR using the SpeedX kit by ABI7500 using SOP: SBSTIRL64, SBSTIRL74	
Swabs, urine, and isolates	Neisseria gonorrhoeae molecular epidemiology	NG-MAST Sanger sequencing by ABI 3500xl Genetic Analyzer using SOPs: SBSTIRL32, SBSTIRL29	
Cervical liquid based cytology samples.	Screening for Human Papillomavirus (HPV) Types assessed - 16,18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68	Abbott M2000 target PCR amplification assay using SOP: CELLSC-3, CELLSC-4, HPV 41	E
Cervical liquid based cytology samples.	DNA extraction	Qiagen MDX (automated) using SOP: HPV 2 or Qiagen Minelute Kit (manual) using SOP: HPV 45	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures:	
Formal fixed paraffin embedded tissue sections (FFPE).	DNA extraction	Manual extraction by Qiagen Mini Kit using SOP: VIRM-71 or Automated extraction by BioMerieux EasyMag using SOP: HPV 98	E
Formal fixed paraffin embedded tissue sections (FFPE).	Molecular genotyping of HPV	PCR genotyping by Luminex system followed by Diamex Optiplex HPV Genotyping Test using Luminex Xmap platform using SOP: HPV 43	
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 (Mycobacterium tuberculosis 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	
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	



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Cultures	Susceptibility testing of Mycobacterium tuberculosis 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	
	<u>Molecular Microbiological examination activities for the purpose of clinical diagnosis</u>	Presumptive confirmation using Kinyoun Ziehl-Neelsen staining using SOP: SMRL21	
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"> • N2 and E 	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	



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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, Mycoplasma pneumoniae, Rhinovirus, Enterovirus, Human Metapneumovirus, Coronavirus, Bocavirus, Legionella pneumophila, Chlamydomphila pneumoniae	NxTAG Respiratory PCR panel via Luminex MAGPIX using VIRM-189	



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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 Bordetella Pertusis	SOP: VIRM-46, VIRM-48	
	Detection of Enterovirus/Parecho	SOP: VIRM-8, VIRM-13, VIRM-14, VIRM-28	
	Detection of Entervirus 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 (cont'd)</u>	In-house documented procedures:	A
RNA/DNA Extracts	Detection of Coronavirus	ABI 7500 Real-Time PCR analyser using SOP: VIRM-103	
	Detection of Bacterial Meningitis (Neisseria meningitidis, Haemophilus pneumoniae, and Streptococcus pneumoniae)	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 Chlamydia pneumophillia	SOP: VIRM-114, VIRM-115, VIRM-116	
	Detection of Legionella(Pneumophila/species)	SOP: VIRM-16, VIRM-49	
	Detection of Epstein-Barr Virus (EBV)	ABI 7500 Quantitative Real-Time PCR analyser using SOP: VIRM-2, VIRM27	
Nose and Throat swabs in VTM	<u>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences:</u> • <u>RdRp</u>	Extraction using the EasyMag and detection using the ABI 7500 Fast Dx SOP: VIRM-267	
RNA extract from Nose and Throat swabs	<u>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences:</u> • <u>E gene</u>	ABI 7500 Fast Dx SOP: VIRM-267	



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Nose and Throat swabs in VTM	<u>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences;</u> • <u>E and S</u>	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 • Cryptosporidium spp, • Giardia lamblia Entamoeba histolytica	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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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 M2000sp and M2000rt – Real-Time PCR extraction and amplification analysers using SOP: VIRM-1, VIRM-54	
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"> RdRp and N genes 	Abbott m2000 real-time system (extraction and detection) SOP: VIRM-286	
Urine	Detection of Legionella pneumophila serotype 1 antigen	BinaxNow Legionella kit by membrane immunochromatographic assay using SOP: VIRM-86	
Nose and Throat Swabs in VTM	<u>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences</u> <ul style="list-style-type: none"> <u>RdRp/S gene</u> <u>N gene</u> <u>E genes</u> 	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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunophenotyping Testing for use in clinical diagnosis</u>	Documented In-house methods using:	B
Whole Blood	Immune Monitoring – HIV and suspected immunodeficiency: <ul style="list-style-type: none"> • CD3 • CD4 • CD8 	FACS CANTO 11 Flow Cytometer SOP: HAEM-W-509	
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, CD79b, FMC7, CD33, CD34, CD45, CD56, CD103, HLADR, Oncomark reagent CD14/CD64, Kappa and Lambda Intracytoplasmic marker in panels: Oncomark reagent CD3, MPO, CD79a, TdT	FACS CANTO 11 Flow Cytometer SOP: HAEM-W-518 & HAEM-W-153 by multi parameter flow cytometry.	
Whole Blood	Investigation of Paroxysmal Nocturnal Haemoglobinuria (FLAER, CD16, CD33, CD14)	FACS CANTO 11 Flow Cytometer SOP: HAEM-W-184	



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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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<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</p> <p>F7 gene</p> <p>F8 gene</p> <p>F9 gene</p> <p>F10 gene</p> <p>F11 gene</p> <p>FGA, FGB and FGG genes</p> <p>ITGA2B and ITGB3 genes GP1BA gene MYH9 gene (targeted screen)</p> <p>VWF gene</p> <p>PROC gene</p> <p>PROS1</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</p> <p>SOP: HAEM-R11</p> <p>SOP: HAEM-R12</p> <p>SOP: HAEM-R13</p> <p>SOP: HAEM-R14</p> <p>SOP: HAEM-R15</p> <p>SOP: HAEM-R16</p> <p>SOP: HAEM-R18</p> <p>SOP: HAEM-R22, R23, R29.</p> <p>SOP: HAEM-R30</p> <p>SOP: HAEM-R31</p> <p>SOP: HAEM-R107</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>DNA extracted from whole blood Leucocytes (cont'd)</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 the following genes: (cont'd)</p> <p>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>Detection of prothrombin G20210A and Factor V Leiden mutations.</p> <p>Detection of CALR mutations.</p> <p>Detection of CALR mutations.</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-R117</p> <p>MLPA analysis using thermocyclers and Applied Biosystems 3500xl analyser using SOP: HAEM-R26</p> <p>Real-time amplification using the Applied Biosystems® Fast 7500 real time PCR analyser using SOP: HAEM-R19</p> <p>PCR Amplification using thermal cyclers, and fragment analysis of PCR product by Applied Biosystems 3500xl analyser using manufacturers' instructions and SOP: HAEM-R113</p> <p>PCR Amplification using thermal cyclers, and Sanger sequencing by Applied Biosystems 3500xl analyser using manufacturers' instructions and SOP: HAEM-R113</p>	<p>A</p>



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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"> BCR-ABL 1 fusion gene KMT2A Fusion FIPL1-PDGFR A 	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"> FLT3 	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"> BCR-ABL 1 ABL 1 	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	



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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"> • RUNx1-RUNXT1 (AML1 ETO) • E1a2-BCR-ABL-1 • Ex13/14 BCL-ABL-1 • PML-RARA • CBFβ-MYH11 (INV 16) 	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"> • TCRB • TCRG • TCRD B-cell Clonality tests <ul style="list-style-type: none"> • IGH • IGL • IGK • IGKDEL 	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	
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	A
	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"> • KIT • PDGFRA • EGFR • KRAS 	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
END			