

issued by

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





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Micropathology Ltd
Issue No: 007 Issue date: 13 June 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Amplification and visualisation of specific amplicon from bacterial, fungal, parasitic, viral and human genetics targets</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant Biometra TProfessional TRIO M-2586 PTC-100 M-970 PTC-200 M1209 ROCHE Carousel Lightcycler TRIO M- ROCHE Lightcycler 480 M-879 ROCHE carousel centrifuge M-1470 ROCHE Lightcycler 96 M-2582 Biomolecular Sciences Magnetic induction cyclor (MIC)– M-1243 SimpliAMP thermal cyclor M-1242 Eppendorf mastercycler Pro M-Mastercycler X50 M-1630 Luminex MagPix manual M-1160 QX200 Droplet Generator M-1663 QX200 Droplet reader M-1664, PX1 Plate sealer M-2591 QX200 ddPCR EvaGreen SuperMix M-1665 ddPCR Supermix for Probes M-1666 One Step RT PCR Kit M-1667 SensiFAST SYBR NoRox One Step Kit M-499 MyTaq HS DNA polymerase kit insert M-500 MAGPIX Calibration M-1144 MAGPIX Performance Verification M -1145 NxTag resp Pathogen Panel M-1146 MyTaq mix kit M-1149



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Amplification and visualisation of specific amplicon from bacterial, fungal, parasitic, viral and human genetics targets</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant 1.0M Magnesium chloride solution M-1282 Bovine serum albumin M-1284 EvaGreen dye M-1285 Immolase M-1286 LabMaster Taq and buffer M-1287 LC480 probe master M-1288 Qiagen OneStep RT-PCR kit M-1289 Bioline dNTPs M-1290 TaqMan Fast Virus 1-step master M-1291 Qiagen QuantiTect reverse transcription kit M-1292 MyTaq mix kit M-1149 Meridian Fast 1-step RT-PCR Mix M-1945 Bioline HyperLadder 100bp kit insert S-803 MultiNA M-1192 S-470 Agarose gel S-48 UV Fire reader M-1710 Analysis and interpretation of real-time pathogen PCR experiments S-560
Any sample preferably from a sterile site	<u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> Bacterial 16S rRNA gene detection	In House documented methods incorporating manufacturers' instructions, where relevant S-49 In-house, single round assay performed on real time PCR (polymerase chain reaction) machine BioSciences MIC



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
EDTA/citrated whole blood, CSF, skin biopsy	Borrelia genus DNA	Nested PCR assay performed on Block thermal cyclers and visualisation on an agarose gel or PCR with intercalating dye in the second round and visualisation on ROCHE LC 480 using procedure: S-1222
Nasopharyngeal swab, NPA, BAL, sputum	Chlamydia pneumoniae DNA	S-1197
Nasopharyngeal swab, BAL	Chlamydia psittaci DNA	S-1169
CSF, EDTA whole blood, urine	Leptospira interrogans DNA	S-1227
CSF, EDTA whole blood,	Listeria monocytogenes DNA	S-1228
Sputum, tissue, CSF, BAL, NPA	Mycobacterium avium complex / TB complex DNA	S-1229
Positive Neisseria meningitides samples	Neisseria meningitidis typing	S-2260, S-1231
CSF, whole blood, respiratory specimens	Streptococcus pneumoniae DNA	S-1193
CSF, genital swab	Treponema pallidum DNA	S-947
CSF and almost any cellular material including whole blood	Tropheryma whippelii DNA	S-1239



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
Eye swab, throat swab, For genitourinary: Female: Endocervical, vaginal or rectal swab, 'Thin prep' endocervical cellular specimens Male: Urethral swab, first pass urine, rectal swab, semen	Chlamydia trachomatis DNA	Nested PCR assay using block thermal cyclers in the first round and real time PCR machine ROCHE LC 480 with intercalating dye in the second round S-942
NPA and perinasal and nasopharyngeal swabs	Bordetella pertussis DNA	Semi-nested PCR assay performed on block thermal cyclers and visualisation on an agarose gel or PCR with intercalating dye in the second round and visualisation on ROCHE LC 480 using procedures: S-1186
CSF, EDTA whole blood	Escherichia coli DNA	S-1332
Swab	Haemophilus ducreyi DNA	S-943
NPA, BAL, EDTA whole blood, sputum, swabs and ET secretions	Mycoplasma pneumoniae DNA	S-1199



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Sputum, tissue, , CSF, BAL	Mycobacterium genus DNA	Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel and subsequent sequencing for identification of positives using procedures: S-1230 and S-1657
CSF, EDTA whole blood, tissue	Mycoplasma genus DNA	S-1152 and S-1776
Eye swab, throat swab, For genitourinary: Female: Endocervical, vaginal or rectal swab, 'Thin prep' endocervical cellular specimens. Male: Urethral swab, first pass urine, rectal swab Urine, genital swab, NPA, semen	Neisseria gonorrhoeae DNA	Semi-nested PCR assay using block thermal cyclers in the first round and real time PCR machine ROCHE LC480 with intercalating dye in the second round using procedure: S-946
Urine, genital swab, NPA, thin preps, semen	Ureaplasma urealyticum and Ureaplasma parvum DNA	S-949
Positive throat swabs	Neisseria gonorrhoeae sequencing	S-1811 Automated pipeline analysis for NG PCR products
EDTA whole blood, tissue, vitreous fluid, aqueous fluid, pus	Bartonella genus DNA	S-1523



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
CSF, joint fluid, pleural fluid, tissue, eye swab, vitreous fluid and aqueous fluid	Staphylococcus genus DNA	Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel using procedures: S-1233
EDTA/citrated whole blood, CSF	Brucella genus DNA	S-1474
Whole blood, BAL, tissue	Coxiella burnetti DNA	S -951
CSF, EDTA whole blood, tissue, joint fluid, pleural fluid	Group A Streptococcus DNA	S-1225, S-1868,
CSF, EDTA whole blood, citrated whole blood, tissue	Group B Streptococcus DNA	S-1225, S-1870
CSF, EDTA whole blood,tissue	Haemophilus influenzae / Haemophilus parainfluenzae DNA	S-1226
Genital swab	Trichomonas vaginalis DNA	S-948
Female: Endocervical vaginal or rectal swab, rectal tissue / biopsy, lymph biopsy, throat swab. Male: Genital swab, rectal swab, throat swab, first catch urine, rectal tissue / biopsy, lymph biopsy	Lymphogranuloma venereum	Single round assay using real time PCR on ROCHE LC480s using probe based technology using procedures: S-1275
Urine, genital swab,	Mycoplasma genitalium DNA	S-1539



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular bacteriology examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Molecular fungal/parasitic examination activities for the purpose of clinical diagnosis</u>	In House documented methods incorporating manufacturers' instructions, where relevant In House documented methods incorporating manufacturers' instructions, where relevant Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel PCR with intercalating dye in the second round and visualisation on ROCHE LC 480 using procedures:
EDTA, BAL, , sputum, corneal scrape	Aspergillus genus DNA	S-1236
EDTA whole blood, corneal scrape, eye swab and contact lens soaking fluid	Pseudomonas aeruginosa	S-1365
CSF, EDTA, amniotic fluid,	Toxoplasma gondii DNA	S-1123 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or PCR with intercalating dye in the second round and visualisation on ROCHE LC 480 using procedures:
BAL, NPA, sputum	Pneumocystis jirovecii DNA	S-1232 Single round PCR assay utilising block thermal cyclers and visualisation on agarose gel using procedures:
EDTA, CSF, eye fluid, corneal scrape, eye swabs	Candida albicans DNA	S-1237
CSF / EDTA whole blood	Cryptococcus neoformans DNA	S -1201
Any (inc. fixed tissue) preferably from normally sterile sites	Pan-Fungal 18srRNA gene detection	S-1001



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular fungal/parasitic examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods incorporating manufacturers' instructions, where relevant
Corneal scrape, swab, contact lens solution, CSF	Acanthamoeba DNA	Single round assay using real time PCR on ROCHE LC 480s using probe based technology and procedures: S-1649
CSF, EDTA whole blood, nasopharyngeal swabs, joint fluid	Neisseria meningitidis DNA	S-1734
	<u>Molecular virology examination activities for the purpose of clinical diagnosis</u>	In House documented methods incorporating manufacturers' instructions, where relevant
EDTA whole blood preferred, serum/plasma or CSF	HIV-2 LTR and pol	Nested round PCR assay performed on block thermal cyclers and visualisation on agarose gel using procedures: S-1464
EDTA/Citrated whole blood, CSF, plasma, serum	Human Herpesvirus 8 DNA detection and quantitation	Real-time PCR on Roche LC 480 using probe-based technology using procedures: S-2134
CSF, blood, plasma, serum, skin swabs, throat swabs	Monkeypox virus DNA	S-2273
EDTA/citrated whole blood, CSF, serum, plasma	Polyoma BK virus DNA Detection and Quantitation	S-1894



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swab, tissue For genital samples: Female: Endocervical swab sent in VTM or endocervical cellular specimens. Male: Penile swab placed into VTM or fresh biopsy tissue</p> <p>EDTA whole blood preferred, serum/plasma or CSF</p> <p>Any upper / lower respiratory sample</p> <p>Nasopharyngeal/throat swabs, Nasal aspirates and washes, Tracheal aspirates, Sputum and BAL</p>	<p><u>Molecular virology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Human Papillomavirus DNA and in house typing of positive samples</p> <p>HIV-1 LTR, env, gag and pol genes</p> <p>Bocavirus DNA</p> <p>Coronavirus 229E, HKU1, NL63 or OC43 RNA</p> <p>Human metapneumovirus RNA</p> <p>Influenza A virus RNA</p> <p>Influenza B virus RNA</p> <p>Parainfluenza 1,2,3 and 4 virus RNA</p> <p>Respiratory Syncytial Virus RNA</p> <p>Rhinovirus RNA</p> <p>Adenovirus DNA</p> <p>Chlamydia pneumoniae DNA</p> <p>Legionella pneumophila</p> <p>Mycoplasma pneumoniae DNA</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>Semi-nested PCR assay using standard thermal cyclers followed by visualisation on agarose gel and subsequent sequencing of positives using procedures:</p> <p>S-944 S-1678</p> <p>A combination of nested and semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel using procedures:</p> <p>S-1389</p> <p>Luminex assay - Single round thermal block PCR followed by analysis on the MAGPIX using procedure S-1147</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular virology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
Any upper / lower respiratory sample (cont'd)	Respiratory Virus Screen	(Note: Picornavirus positives are differentiated between Enterovirus and Rhinovirus using in-house nested PCR assays S-1669. Products are generated on thermal cyclers in the first round and LC480 in the second round using intercalating dye)
Swabs, NPA, BAL	Detection of RNA from SARS-CoV-2 specifically the N1 region of the N gene	Extraction of RNA using Kingfisher extraction platform with PROMEGA chemistry followed by real-time PCR amplification of viral RNA using probe-based technology on the Roche LC480 platform S-1642 S-1851
Nose and Throat swabs	Detection of RNA from SARS-CoV-2 specifically the N1 region of the N gene	Heat extraction of viral RNA using calibrated thermal blocks followed by real-time PCR amplification or viral RNA using probe-based technology on the Roche LC480 or LC96 platform S-1886 Single round assay using real time PCR ROCHE LC 480s and probe based technology and procedures:



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular virology examination activities for the purpose of clinical diagnosis (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
Vitreous fluid, eye fluid, serum, skin swab, blood plasma, urine, bronchial washings, NPA, swab(Nose, throat, eye), CSF, pericaridal fluid, bone marrow	Adenovirus DNA	S-939
EDTA, CSF and plasma	Adenovirus DNA quantitation	S-939
CSF, EDTA, urine, serum/EDTA plasma, saliva, respiratory specimen - BAL preferred. Pregnancy – EDTA whole blood, amniotic fluid, , serum/plasma	Cytomegalovirus DNA	S-937
CSF, EDTA/citrated whole blood, urine, serum/EDTA plasma,	Cytomegalovirus DNA quantitation	S-937
CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood	Enterovirus RNA	S-952
EDTA/citrated whole blood, CSF, , serum, plasma,	Epstein Barr Virus DNA	S-937
EDTA/citrated whole blood, CSF, serum, plasma	Epstein Barr Virus DNA quantitation	S-937



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular virology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
Serum / plasma	Hepatitis B virus DNA detection and quantitation	Single round assay using real time PCR ROCHE LC 480s and probe based technology and procedures: S-1641
Serum/plasma, CSF, Stool, EDTA, whole blood	Hepatitis E virus RNA detection	S-1076
Serum/plasma, CSF, EDTA, whole blood	Hepatitis E virus RNA quantitation	S-1076
CSF, AC tap, EDTA/citrated whole blood, corneal scrape, vesicle fluid, skin/eye/vesicle/ swab, tissue, BAL, Genitourinary - For female: vulval lesions sample area with a swab and place into viral transport media (VTM). Male: Penile lesions - Penile swab placed into VTM. Pregnancy – vulval/vaginal swab	Herpes Simplex virus DNA	S-1379
Performed routinely on positive HSV samples (Except oral and eye samples)	Herpes Simplex virus types I & II typing	S-1468
EDTA, (CSF in encephalitis), bone marrow, plasma	Human Herpesvirus 6A, 6B DNA detection and quantitation	S-1612
EDTA,, CSF, plasma	Human Herpesvirus 7 DNA detection and quantitation	S-1612
CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood	Parechovirus RNA	S-952
EDTA,, CSF, urine	Polyoma JC virus DNA and quantitation	S-908
Serum. plasma	Hepatitis D virus detection and quantitation	Altona Realstar kit using single round RT-PCR using probe based technology and visualisation on ROCHE LC480s using procedures: S-1959
CSF, urine, plasma, EDTA whole blood	West Nile Fever virus RNA	S-1905



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular virology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
CSF, AC tap, EDTA/citrated whole blood, corneal scrape, vesicle fluid, skin/eye/vesicle/lesion swab, tissue. Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc)	Varicella Zoster virus DNA	Single round assay using real time PCR ROCHE LC 480s & LC 96 and probe based technology and procedures: S-1379
Whole blood, CSF, plasma, serum, nose and throat swabs, skin swabs and urine	Measles virus RNA	S-2378
	Mumps virus RNA	S-2382
Whole blood, serum, nose and throat swabs, skin swabs, urine, aqueous humour, amniotic fluid, CSF, plasma and tissue	Rubella virus RNA	S-2402
CSF, serum, semen, plasma and whole blood	HTLV-1	S-2432
Female: Endocervical swab sent in VTM or 'thin prep' endocervical cellular specimens	Human Papillomavirus DNA genotyping (High risk)	Liferiver HPV genotyping kit M-1189 utilising probe technology on LC 480s SOP S-1536
Serum / plasma	Hepatitis C virus RNA detection and quantitation	S-2348 Roche COBAS 5800 HCV test kit M-2314
EDTA plasma/CSF	HIV-1 RNA quantitation	S-2351 Roche COBAS 5800 HIV test kit M-2316



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological analysis for the purpose of clinical diagnosis</u>	Detection of antibodies and antigens to various viral markers using CE marked kits or inhouse protocols developed in accordance with manufacturers instructions
Serum preferred or Na-heparin, K3-EDTA, sodium citrate plasma	<i>Hepatitis B</i> core antibody	M-890 S-474 ROCHE COBAS Electrochemiluminescence immunoassay 'ECLIA' performed on COBAS E411. Antibodies to Hepatitis B core antigen M-489.
Serum preferred or Na-heparin, K3-EDTA, sodium citrate plasma	<i>Hepatitis B</i> e antibody	Antibodies to Hepatitis B E Antigen M-490.
Serum preferred or Na-heparin, K3-EDTA, sodium citrate plasma	<i>Hepatitis B</i> e antigen	Detection of Hepatitis B E Antigen M-492.
Serum preferred or K2/K3EDTA plasma	<i>Hepatitis B</i> surface antibody	Antibodies to Hepatitis B surface antigen M-491.
Serum preferred or Li-heparin, Na-citrate, K2/K3-EDTA, CPDA, CPD, CP2D, ACD, citrate plasma.	<i>Hepatitis B</i> surface antigen	Detection of Hepatitis B surface antigen M-493.
Serum preferred or Li-heparin, Na-heparin, K2-EDTA, citrate plasma	<i>Hepatitis B</i> surface antigen quantitation	Quantitation of Hepatitis B surface antigen M-578.
Serum preferred or Li-heparin, K2/K3-EDTA, ACD, CPD, CP2D, Na-heparin, Na-citrate plasma	<i>Hepatitis C</i> antibody	Antibodies to Hepatitis C virus M-488.
Serum preferred or Li-heparin, K2/K3-EDTA, Na-heparin, Na-citrate, CPDA, CPD, CP2D, ACD plasma	<i>HIV I & II</i> antibody and p24 antigen	Detection of HIV-1 antigen and total antibodies to HIV-1 and HIV-2 M-497.



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological analysis for the purpose of clinical diagnosis (cont'd)</u>	Detection of antibodies and antigens to various viral markers using CE marked kits or inhouse protocols developed in accordance with manufacturers instructions
Serum preferred or Li-heparin, citrate or EDTA plasma	<i>Toxoplasma</i> IgG antibody	IgG antibodies to <i>Toxoplasma gondii</i> M-486.
Serum preferred or Li-heparin, citrate or EDTA plasma, saliva	Serological analysis for the purpose of clinical diagnosis (cont'd)	In House method, developed in accordance with manufacturers instructions Line Immunoassay using the enzyme immune assay (EIA) principle
Serum preferred or Li-heparin, citrate or EDTA plasma, saliva	<i>Hepatitis C</i> antibody (RIBA)	INNO-LIA HCV score kit M-1087 using S-23.
Serum preferred or Li-heparin, citrate or EDTA plasma, saliva	<i>HIV I & II</i> antibody (LIA)	INNO-LIA HIV I/II score M-1088 S-122.
Saliva	<i>HIV I & II</i> antibody (LIA) - saliva	INNO-LIA HIV I/II score M-1088 S-122. ELISA assays performed in accordance with the manufacturer's instructions using TECAN plate reader M-1561 and M-1562 and platewasher M888
Serum preferred or EDTA, citrate plasma	<i>HTLV I & II</i> antibody	Murex HTLV I and II M-239.
Serum preferred or citrate plasma	<i>Mumps</i> IgG antibody	Novatec NovaLisa mumps virus IgG ELISA M-244.
BAL and serum	<i>Aspergillus</i> (Galactomannan) antigen	PlateLIA <i>Aspergillus</i> Antigen kit using M-1745, S-1775



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Dideoxynucleotide sequencing examination activities for the characterisation of phylogenetics and drug resistance mutations with bacterial, fungal and viral samples	Dideoxynucleotide sequencing performed on ABI 3500 xl using in-house methodology Sequencing of PCR products using the 3500xl genetic analysers S - 1889 Sequence data analysisS-1809 Sequence data analysis for Phylogenetic typing PeqSTART M-971 Biometra Trio M-1224 MJ-200 M-1209 MJ-100 M-1210 Biometra T3000 M-1223 Biometra Professional TRIO M-1224 MJ research PTC-100 M-970
Any positive product produced in 16S rRNA bacteria assay	16S rRNA bacterial gene sequencing	Single round PCR products produced on Biosciences MIC S-49 S-1758. Positive subject to sequencing.



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Dideoxynucleotide sequencing examination activities for the characterisation of phylogenetics and drug resistance mutations with bacterial, fungal and viral samples (cont'd)</u>	Dideoxynucleotide sequencing performed on ABI 3500 xl using in-house methodology
EDTA/citrated whole blood, EDTA plasma	<i>Cytomegalovirus (UL54)</i> ganciclovir, foscarnet or cidofovir resistance	S-1445, S-1546 Single round PCR assay, performed on thermal cycler blocks in which positives are subject to sequencing
EDTA/citrated whole blood, EDTA plasma	<i>Cytomegalovirus (UL56/UL89)</i> letermovir resistance	S-2047 Nested PCR using thermal cyclers followed by sequencing of positives on ABI 3500 xl using Sanger Sequencing S-1889, S-2069
Serum/plasma	<i>Hepatitis B</i> genotyping and drug resistance assay	S-1555, S-1570 S-1838 Semi-nested PCR assay, performed on thermal cycler blocks in which positives are subject to sequencing.
Serum/plasma	<i>Hepatitis C</i> genotyping	S-1437, S-1841 Single round and nested PCR assays, performed on thermal cycler blocks used alone or in combination. Positives are subject to sequencing
Plasma	<i>HIV-1</i> RNA drug resistance	S-169, S-1765 Single round and semi-nested PCR assays, in which positives are subject to sequencing



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Dideoxynucleotide sequencing examination activities for the characterisation of phylogenetics and drug resistance mutations with bacterial, fungal and viral samples (cont'd)</u>	Dideoxynucleotide sequencing performed on ABI 3500 xl using in-house methodology
Plasma	<i>HIV-1</i> RNA Integrase drug resistance	S-169, S-1765 Nested PCR assay, in which positives are subject to sequencing using the above methodology.
Any positive product produced in 18srRNA fungal assay	18S rRNA fungal gene sequencing	S-1001, S-1583 Single round PCR assay performed on thermal cycler blocks in which positives are subject to sequencing using the above methodology.
Any positive product produced	<i>Neisseria meningitidis</i> Rifampicin	S-1556 S-1621 Nested PCR assay, in which positives are subject to sequencing using the above methodology. Extraction on KingFisher instrument or Manual extraction S-14-n on QiaSymphony instrument. Single round PCR using thermal cyclers with visualisation on an agarose. Sanger Sequencing of Positives on ABI3500xl using SOPs:
First catch urine, vaginal swab	<i>Mycoplasma genitalium</i> macrolide resistance	S-1625, S-1626
	<i>Mycoplasma genitalium</i> fluoroquinolone resistance	S-2067, S-2068



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Micropathology Ltd
Issue No: 007 Issue date: 13 June 2024

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Human genetic mutation detection for clinical diagnostic purposes</u>	In House documented methods incorporating manufacturers' instructions, where relevant
EDTA or citrate whole blood specimens	Detection of Factor V Leiden and Factor II (Prothrombin mutations)	DNA Extraction on Roche HighPure extraction kits or automated ThermoFisher Kingfisher extraction platform. Real-time PCR and melt curve analysis on LightCycler 480 II LightMix Factor V Leiden and Kit LightMix Factor II (Prothrombin) Kit. SOP S-1971



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Cheek swab, EDTA/citrated whole blood, tissue, serum, fixed tissue (least preferred sample), personal items (Hairbrush, comb, razor) bone EDTA, citrate whole blood specimens Cheek swab	<u>Human genetic profiling</u> Human identification DNA Profiling HFE H63D S65C C282Y gene, mutations; c.845G>A p.(Cys282Tyr), c.187C>G p.(His63Asp) and c.193A>T p.(Ser65Cys) Paternity Testing	In House documented methods incorporating manufacturers' instructions, where relevant Powerplex STR profile kit insert M-1185 Powerplex16HS system instructions for use M-1185. S-218 Generation of Human STR Profiles using Promega PowerPlex 16HS and the ABI 3500xl genetic analyser S-219 DNA Extraction on Roche HighPure extraction kits or automated ThermoFisher Kingfisher and Qiasymphony. Real-time PCR and melt curve analysis on LightCycler 480 II using CE marked (TIB MOL BIO) LightMix kit (for HFE gene mutations) SOP – S2292 3500xl Genetic Analyzer user guide M-993 3500xl Genetic Analyzer Data Collection guide M-994 SimpliAmp thermal cycler user guide M-1242 MJ research PTC-100 M-970 S-260 Direct Sequencing of PCR products S-56 Sequence data analysis
END		