


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Micropathology Ltd	
	Issue No: 004 Issue date: 13 January 2021	
	University of Warwick Science Park, Venture Centre Sir William Lyons Road Coventry CV4 7EZ United Kingdom	Contact: Prof Colin G. Fink Tel: +44 (0) 2476 323222 Fax: +44 (0) 2476 323333 E-Mail: colinfink@micropathology.com Website: www.micropathology.com

Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	<p><u>Extraction of DNA, RNA from bacterial, fungal, parasitic, viral and human genetics targets</u></p> <p><u>Amplification and visualisation of specific amplicon from bacterial, fungal, parasitic, viral and human genetics targets</u></p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>Sample pretreatment Manual extraction S-14 M-252 High Pure Column extraction S-1541 QiaSymphony S- 392 ROCHE High Pure Viral Nucleic acid kit M-1043 Blood biorobot kit insert M-252 Tissue Lyser LT M-977 Tissue Lyser II M-1529</p> <p>Kingfisher Flex extractionsystem M-1616, S-1642 VIAFLO pipette M-1617 VOYAGER pipette M-1618 MaxWell HT 96g blood isolation system M-1619</p> <p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>Hamilton MicroLab StarLET M-980, M-981 S-968 PeqSTAR M-971 Biometra Trio M-1211 MJ-200 M-12097MJ-100 M-1210 Biometra T3000 M-1223</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p>	<p><u>Amplification and visualisation of specific amplicon from bacterial, fungal, parasitic, viral and human genetics targets</u> (cont'd)</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>Biometra Professional TRIO M-1224 PTC-100 M-970 PTC-200 M1209 ROCHE Carousel Lightcycler model 1.5 M-876 and M-877, 2.0 M-878 ROCHE Lightcycler 480 M-879 ROCHE carousel centrifuge M-1470 Biomolecular Sciences Magnetic induction cycler (MIC)– M-1243 SimpliAMP thermal cycler M-1242 Eppendorf mastercycler Pro M-1334 and M-1630 Luminex MagPix manual M-1160 QX200 Droplet Generator M-1663 QX200 Droplet reader M-1664 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 ROCHE Master HybProbe kit M-631 1.0M Magnesium chloride solution M-1282 Bovine serum albumin M-1284 EvaGreen dye M-1285 Immolase M-1286</p>



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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 mehods incorporating manufacturers' instructions, where relevant 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 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
Any respiratory specimen	Chlamydia pneumoniae DNA	S-1197
Any respiratory specimen	Chlamydia psittaci DNA	S-1169
CSF, EDTA whole blood, citrated whole blood, urine	Leptospira interrogans DNA	S-1227
CSF, EDTA whole blood, citrated whole blood	Listeria monocytogenes DNA	S-1228
Sputum, tissue, fixed tissue, CSF, BAL	Mycobacterium avium complex / TB complex DNA	S-1229
CSF, EDTA whole blood, citrated whole blood	Neisseria meningitidis DNA	S-1194
Positive Neisseria meningitides samples	Neisseria meningitidis typing	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	Chlamydia trachomatis DNA	Nested PCR assay using block thermal cyclers in the first round and real time PCR machine Qiagen Rotorgene or ROCHE LC 480 with intercalating dye in the second round S-942
Eye sample, tissue, CSF	Propionibacteria/Actinomyces DNA	S-625 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel with sequencing for confirmation of positives using procedures: 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:
NPA and perinasal and nasopharyngeal swabs	Bordetella pertussis DNA	S-1186
CSF, EDTA whole blood, citrated whole blood	Escherichia coli DNA	S-1332
Swab	Haemophilus ducreyi DNA	S-943
Any respiratory sample	Mycoplasma pneumoniae DNA	S-1199



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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
Sputum, tissue, fixed 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, citrated whole blood, tissue culture	Mycoplasma genus DNA	S-1152 and S-1776 Semi-nested PCR assay using block thermal cyclers in the first round and real time PCR machine Qiagen Rotorgene or ROCHE LC480 with intercalating dye in the second round using procedure:
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, respiratory sample (neonates)	Neisseria gonorrhoeae DNA Ureaplasma urealyticum and Ureaplasma parvum DNA	S-946 S-949
CSF, eye sample, tissue	Staphylococcus genus DNA	Semi-nested PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round and procedures: S-1233



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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	Brucella genus DNA	Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel using procedures: S-1474
Whole blood, BAL, tissue	Coxiella burnetti DNA	S -951
CSF, EDTA whole blood, citrated whole blood, tissue	Group A Streptococcus DNA Group B Streptococcus DNA	S-1225, S-1868, S-1870
CSF, EDTA whole blood, citrated 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
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-1844



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Nose and Throat swabs	<u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> (cont'd) Detection of RNA from SARS-CoV-2 specifically the N1 region of the N gene	In House documented methods incorporating manufacturers' instructions, where relevant 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
	<u>Molecular fungal/parasitic examination activities for the purpose of clinical diagnosis</u>	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/citrated whole blood/ lower respiratory sample (BAL, bronchial washings, sputum)	Aspergillus genus DNA	S-1236
CSF, EDTA/citrated whole blood, amniotic fluid, aqueous/vitreous humours, tissue	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/citrated whole blood, CSF, eye fluid	Candida albicans DNA	S-1237
CSF / EDTA whole blood	Cryptococcus neoformans DNA	S -1201



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Any (inc. fixed tissue) preferably from normally sterile sites	Pan-Fungal 18srRNA gene detection	S-1001 Single round assay using real time PCR on ROCHE LC 480s using probe based technology and procedures:
Corneal scrape, swab or contact lens, contact lens solution, CSF	Acanthamoeba DNA	S- 1234
	<u>Molecular virology examination activities for the purpose of clinical diagnosis</u>	In House documented methods incorporating manufacturers' instructions, where relevant
		Nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round using procedures:
CSF, urine, saliva, mouth/throat swab, whole blood	Measles virus RNA	S-1660
CSF, EDTA/citrated whole blood, throat swab, urine, amniotic fluid	Rubella virus RNA	S-1805 Nested round PCR assay performed on block thermal cyclers and visualisation on agarose gel using procedures:
EDTA whole blood preferred, serum/plasma or CSF	HIV-2 LTR and pol	S-1464 Nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel Lightcyclers or ROCHE LC480 and intercalating dye in the second round using procedures:
EDTA/citrated whole blood, plasma, serum	Human Herpesvirus 8 DNA detection and quantitation	S-1190



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EDTA/citrated whole blood, amniotic fluid, serum/plasma, post-mortem samples (Foetal), CSF, bone marrow	Parvovirus B19 DNA	S-931
EDTA/citrated whole blood, amniotic fluid, serum/plasma, CSF, bone marrow	Parvovirus B19 DNA quantitation	S-931 Semi-nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers or ROCHE LC480s and intercalating dye in the second round and procedures:
EDTA/citrated whole blood, CSF, serum, plasma	Polyoma BK virus DNA detection and quantitation	S-1066 Nested round PCR assay performed on block thermal cyclers and visualisation on agarose gel using procedures:
EDTA whole blood preferred, serum/plasma or CSF	HIV-2 LTR and pol	S-1464 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or PCR with intercalating dye in the second round using ROCHE Carousel lightcyclers using procedures:
EDTA/citrated whole blood, serum or plasma	HTLV-1 DNA or RNA	S-938
CSF, whole blood	West Nile Fever virus RNA	S-611 Semi-nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round and procedures:
Serum/plasma	Hepatitis D virus RNA detection and quantitation	S-1679



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CSF, urine, saliva, mouth/throat swab	Mumps virus RNA	S-1760 Semi-nested PCR assay using standard thermal cyclers followed by visualisation on agarose gel and subsequent sequencing of positives using procedures:
Swab, tissue (including fixed tissue). For genital samples: Female: Endocervical swab sent in VTM or 'thin prep' endocervical cellular specimens. Male: Penile swab placed into VTM or fresh biopsy tissue	Human Papillomavirus DNA and typing	S-944 A combination of nested and semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel using procedures:
EDTA whole blood preferred, serum/plasma or CSF	HIV-1 LTR, env, gag and pol genes	S-1389
Any upper / lower respiratory sample	Bocavirus DNA Coronavirus 229E, HKU1, NL63 or OC43 RNA Human metapneumovirus RNA Influenza A virus RNA Influenza B virus RNA Parainfluenza 1,2,3 and 4 virus RNA Respiratory Syncytial Virus RNA Rhinovirus RNA	Luminex assay - Single round thermal block PCR followed by analysis on the MAGPIX using procedure S-1147



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Any upper / lower respiratory sample (cont'd)</p>	<p><u>Molecular virology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Respiratory Virus Screen</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>(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)</p> <p>Single round assay using real time PCR ROCHE LC 480s and probe based technology and procedures:</p>
<p>Vitreous fluid, eye fluid, serum, skin swab, blood plasma, urine, bronchial washings, NPA, swab(Nose, throat, eye), CSF, pericaridal fluid, bone marrow</p>	<p>Adenovirus DNA</p>	<p>S-939</p>
<p>EDTA/citrated whole blood, CSF and plasma</p>	<p>Adenovirus DNA quantitation</p>	<p>S-939</p>
<p>CSF, EDTA/citrated whole blood, urine, serum/EDTA plasma, eye fluid, saliva, tissue, biopsy or respiratory specimen - BAL preferred. Pregnancy – EDTA whole blood, amniotic fluid, cervical swab, serum/plasma</p>	<p>Cytomegalovirus DNA</p>	<p>S-937</p>
<p>Amniotic fluid, CSF, saliva, EDTA/citrated whole blood, urine, serum/EDTA plasma,</p>	<p>Cytomegalovirus DNA quantitation</p>	<p>S-937</p>
<p>CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood</p>	<p>Enterovirus RNA</p>	<p>S-952</p>
<p>EDTA/citrated whole blood, CSF, urine, serum, plasma, biopsy</p>	<p>Epstein Barr Virus DNA</p>	<p>S-937</p>
<p>EDTA/citrated whole blood, CSF, urine, serum, plasma</p>	<p>Epstein Barr Virus DNA quantitation</p>	<p>S-937</p>



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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/lesion swab, tissue, BAL, Genitourinary - For female: Endocervical or 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/citrated whole blood (CSF in encephalitis), bone marrow, plasma, serum	Human Herpesvirus 6A, 6B DNA detection and quantitation	S-1612
EDTA/citrated whole blood, CSF, plasma, serum	Human Herpesvirus 7 DNA detection and quantitation	S-1612
CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood	Parechovirus RNA	S-952
EDTA/citrated whole blood, CSF, urine	Polyoma JC virus DNA and quantitation	S-908



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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 and probe based technology and procedures: S-1379
Urines only	Polyoma BK virus single assay	Single round PCR assay using ROCHE capillary lightcyclers and intercalating dye using procedure: S-1069
Female: Endocervical swab sent in VTM or 'thin prep' endocervical cellular specimens	Human Papillomavirus DNA genotyping (High risk)	Liferiver HPV genotyping kit utilising probe technology on LC 480s using procedures: M-1189
Serum/plasma, CSF	HIV-1 RNA quantitation	ROCHE COBAS assay using COBAS Ampliprep / Taqman and oligonucleotide probes COBAS Ampliprep M-891 using: COBAS Ampliprep/Taqman HIV-1 Test kit M-251 and procedure S-220
Serum/plasma	Hepatitis C virus RNA detection and quantitation	COBAS Ampliprep / Taqman HCV test kit M1500 and procedure S-1532



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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 e</i> antibody	Antibodies to Hepatitis B E Antigen M-490.
Serum preferred or Na-heparin, K3-EDTA, sodium citrate plasma	<i>Hepatitis B e</i> 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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Serum preferred or Li-heparin, citrate or EDTA plasma	<i>Toxoplasma</i> IgG antibody	IgG antibodies to <i>Toxoplasma gondii</i> M-486.
	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.



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p>	<p><u>Dideoxynucleotide sequencing examination activities for the characterisation of phylogenetics and drug resistance mutations with bacterial, fungal and viral samples</u></p>	<p>Dideoxynucleotide sequencing performed on ABI 3500 xl using in-house methodology</p> <p>S-260 Direct Sequencing of PCR products S-56 Sequence data analysis S-1809 Sequence data analysis for Phylogenetic typing 3500xl Genetic Analyzer user guide M-993 3500xl Genetic Analyzer Data Collection guide M-994 PeqSTART M-971 Biometra Trio M-1211 MJ-200 M-1209 MJ-100 M-1210 Biometra T3000 M-1223</p> <p><i>Dideoxynucleotide sequencing performed on ABI 3500 xl using in-house methodology</i> Biometra Professional TRIO M-1224 MJ research PTC-100 M-970</p>
<p>Any positive product produced in 16S rRNA bacteria assay</p>	<p>16S rRNA bacterial gene sequencing</p>	<p>Single round PCR products produced on Biosciences MIC M-882 S-49 S-1758. Positive subject to sequencing.</p>
<p>PCR product generated in-house</p>	<p><i>Adenovirus</i> typing</p>	<p>S-594, S-1647 Nested PCR assay performed on thermal cycler blocks, in which positives are subject to sequencing.</p>



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Micropathology Ltd

Issue No: 004 Issue date: 13 January 2021

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>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, serum/EDTA plasma	<i>Cytomegalovirus</i> ganciclovir resistance	S-584, S-1546 Semi-nested PCR assay, performed on thermal cycler blocks in which positives are subject to sequencing
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> NS5A resistance	S-1295, S-1880 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
Any positive Herpes Simplex type 1 sample	<i>Herpes Simplex</i> type 1 Acyclovir drug resistance	S-1336, S-1784 Nested PCR assay performed on thermal cycler blocks in which positives are subject to sequencing
Serum/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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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/plasma</p> <p>Any positive product produced in 18srRNA fungal assay</p> <p>Any positive product produced</p>	<p><u>Dideoxynucleotide sequencing examination activities for the characterisation of phylogenetics and drug resistance mutations with bacterial, fungal and viral samples (cont'd)</u></p> <p><i>HIV-1</i> RNA Integrase drug resistance</p> <p>18S rRNA fungal gene sequencing</p> <p>Neisseria meningitidis Rifampicin</p>	<p>Dideoxynucleotide sequencing performed on ABI 3500 xl using in-house methodology</p> <p>S-169, S-1765 Nested PCR assay, in which positives are subject to sequencing using the above methodology.</p> <p>S-1001, S-1583 Single round PCR assay performed on thermal cycler blocks in which positives are subject to sequencing using the above methodology.</p> <p>S-1556 S-1621 Nested PCR assay, in which positives are subject to sequencing using the above methodology.</p>



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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/citrated whole blood	Alpha-1 antitrypsin genotyping	<p>ROCHE Carousel Lightcycler model 1.1 M-1338, model 1.5 M-876, model 2.0 M-877 & M-878.</p> <p>S-874 Analysis and interpretation of Real time PCR for genotyping</p> <p>S-927 Single round PCR using ROCHE carousel lightcyclers and probe based technology utilising in-house methodology and ROCHE Master HybProb kit M-631.</p>
EDTA / citrated whole blood	Factor V Mutation + Prothrombin	<p>S-21 Single round PCR using ROCHE carousel Lightcyclers and probe based technology using in-house methodology in accordance with manufacturer's instructions Factor V Leiden Kit M-766 Factor II (Prothrombin) kit GA20210A Kit M-767.</p>
EDTA / citrated whole blood	Haemochromatosis H63D C282Y	<p>S-22 Single round PCR assay using in-house methodology and ROCHE carousel Lightcyclers and FRET probe based technology and ROCHE Master HybProb kit M-631.</p>
EDTA / citrated whole blood	IL28B gene (rs12979860)	<p>S-303 Single round PCR using in-house methodology ROCHE carousel Lightcyclers and FRET probe based technology and ROCHE Master HybProb kit M-631.</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Cheek swab, EDTA/citrated whole blood, tissue, serum, fixed tissue (least preferred sample), personal items (Hairbrush, comb, razor) bone</p> <p>Cheek swab</p>	<p><u>Human genetic profiling</u></p> <p>Human identification DNA Profiling</p> <p>Paternity Testing</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>Powerplex STR profile kit insert M-790 Powerplex16HS system instructions for use M-1185.</p> <p>S-218 Generation of Human STR Profiles using Promega PowerPlex 16HS and the ABI 3500xl genetic analyser S-219 Statistical analysis and Interpretation of Genescan Data generated in-house S-260 Direct Sequencing of PCR products S-56 Sequence data analysis</p> <p>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</p> <p>S-260 Direct Sequencing of PCR products S-56 Sequence data analysis</p>
END		