


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>	<h3>Micropathology Ltd</h3> <p>Issue No: 001 Issue date: 30 November 2017</p>	
	<p>University of Warwick Science Park, Venture Centre Sir William Lyons Road Coventry CV4 7EZ United Kingdom</p>	<p>Contact: Prof Colin G. Fink Tel: +44 (0) 2476 323222 Fax: +44 (0) 2476 323333 E-Mail: colinfink@micropathology.com Website: www.micropathology.com</p>
<p>Testing performed at the above address only</p>		

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>MDx biorobot S-4 M-887 Manual extraction S-14 M-252 QiaSymphony S- 392 M-1043 ROCHE High Pure Viral Nucleic acid kit M-252 QIAamp DNA blood biorobot MDx kit handbook M-1345</p> <p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>PeqSTART M-971 Biometra Trio M-1211 MJ-200 M-1209 MJ-100 M-1210 Biometra T3000 M-1223 Biometra Professional TRIO M-1224 MJ research PTC-100 M-970 ROCHE Carousel Lightcycler model 1.1 M-1338, model 1.5 M-876, model 2.0 M-877 & M-878</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>ROCHE Lightcycler 480 model I/II M-879 Qiagen ROTORGENE M-882 Biomolecular Sciences Magnetic induction cyler (MIC) M-1243 SimpliAMP thermal cyler M-1242 Eppendorf Mastercycler Pro thermal cyler M-1334</p> <p>Hamilton STARTLET M-890 and S-968 Qiagility - M-1339 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</p> <p>1.0M Magnesium chloride solution M-1282 2.0M Magnesium chloride solution M-1283 Bovine serum albumin M-1284 EvaGreen dye M-1285 Immolase M-1286</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Any respiratory specimen</p> <p>NPA and nasopharyngeal swabs</p> <p>EDTA/citrated whole blood, CSF, skin biopsy</p> <p>EDTA/citrated whole blood, CSF</p> <p>Any respiratory specimen</p>	<p><u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><i>Bordetella</i> genus DNA</p> <p><i>Bordetella pertussis</i> DNA</p> <p><i>Borrelia</i> genus DNA</p> <p><i>Brucella</i> genus DNA</p> <p><i>Chlamydia pneumoniae</i> DNA</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>S-1221 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.</p> <p>S-1186 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.</p> <p>S-1222 Nested PCR assay or a single round assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.</p> <p>S-1208 Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel.</p> <p>S-1197 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.</p>



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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
Any respiratory specimen	<i>Chlamydia psittaci</i> DNA	S-1169 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.
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	<i>Chlamydia trachomatis</i> DNA	S-942 Nested PCR assay using block thermal cyclers in the first round and real time PCR machine Qiagen Rotorgene with intercalating dye in the second round.
Stool	<i>Clostridium difficile</i> DNA	S-915 Two round PCR assay performed on block thermal cyclers and visualisation on agarose gel.
Whole blood, BAL, tissue	<i>Coxiella burnetti</i> DNA	S -951 Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel.
CSF, EDTA whole blood, citrated whole blood	<i>Escherichia coli</i> DNA	S-1332 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.



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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, EDTA whole blood, citrated whole blood	Group A <i>Streptococcus</i> DNA	S-1225 Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel.
CSF, EDTA whole blood, citrated whole blood	Group B <i>Streptococcus</i> DNA	S-1225 Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel.
Swab	<i>Haemophilus ducreyi</i> DNA	S-943 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.
CSF, EDTA whole blood, citrated whole blood	<i>Haemophilus influenzae</i> / <i>Haemophilus parainfluenzae</i> DNA	S-1226 Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel.
CSF, EDTA whole blood, citrated whole blood, urine	<i>Leptospira interrogans</i> DNA	S-1227 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>CSF, EDTA whole blood, citrated whole blood</p> <p>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</p> <p>Sputum, tissue, fixed tissue, CSF, BAL</p> <p>Sputum, tissue, fixed tissue, CSF, BAL</p>	<p><u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><i>Listeria monocytogenes</i> DNA</p> <p>Lymphogranuloma venereum</p> <p><i>Mycobacterium avium</i> complex / TB complex DNA</p> <p><i>Mycobacterium</i> genus</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>S-1228 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.</p> <p>S-1275 Single round assay using real time PCR on ROCHE lightcycler 480s using probe based technology.</p> <p>S-1229 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.</p> <p>S-1230 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel and subsequent sequencing for identification of positives.</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Urine, genital swab</p> <p>CSF, EDTA whole blood, citrated whole blood, tissue culture</p> <p>Any respiratory sample</p> <p>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</p>	<p><u>Molecular bacteriology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><i>Mycoplasma genitalium</i> DNA</p> <p><i>Mycoplasma</i> genus DNA</p> <p><i>Mycoplasma pneumoniae</i> DNA</p> <p><i>Neisseria gonorrhoeae</i> DNA</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>S-945 Semi-nested PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round.</p> <p>S-1152 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel and subsequent sequencing for identification of positives.</p> <p>S-1199 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.</p> <p>S-946 Semi-nested PCR assay using block thermal cyclers in the first round and real time PCR machine Qiagen Rotorgene with intercalating dye in the second round.</p>



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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, EDTA whole blood, citrated whole blood	<i>Neisseria meningitidis</i> DNA	S-1194 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.
Positive <i>Neisseria meningitidis</i> samples	<i>Neisseria meningitidis</i> typing	S-1231 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel using in-house methodology.
Bronchial lavage, nasopharyngeal aspirate and sputum	<i>Pneumocystis jiroveci</i> DNA	S-1232 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve Analysis.
Eye sample, tissue, CSF	<i>Propionibacteria/Actinomyces</i> DNA	S-625 Nested PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round.
CSF, EDTA whole blood, citrated whole blood	<i>Salmonella enterica</i> DNA	S-601 Single round PCR performed on block thermal cyclers with visualisation using agarose gel.



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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, eye sample, tissue	<i>Staphylococcus</i> genus DNA	S-1233 Semi-nested PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round.
CSF, whole blood, respiratory specimens	<i>Streptococcus pneumoniae</i> DNA	S-1193 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.
CSF, genital swab	<i>Treponema pallidum</i> DNA	S-947 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.
Genital swab	<i>Trichomonas vaginalis</i> DNA	S-948 Single round PCR performed on block thermal cyclers with visualisation using agarose gel.
CSF and almost any cellular material including whole blood	<i>Tropheryma whippelii</i> DNA	S-1239 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel and melt curve analysis.
Urine, genital swab, respiratory sample (neonates)	<i>Ureaplasma urealyticum/parvum</i> DNA	S-949 Semi-nested PCR assay using block thermal cyclers in the first round and real time PCR machine Qiagen Rotorgene with intercalating dye in the second round.



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Corneal scrape, swab or contact lens, contact lens solution, CSF</p> <p>EDTA/citrated whole blood/ lower respiratory sample (BAL, bronchial washings, sputum)</p> <p>EDTA/citrated whole blood, CSF, eye fluid</p> <p>CSF / EDTA whole blood</p> <p>Any (inc. fixed tissue) preferably from normally sterile sites</p> <p>CSF, EDTA/citrated whole blood, amniotic fluid, aqueous/vitreous humours, tissue</p>	<p><u>Molecular fungal/parasitic examination activities for the purpose of clinical diagnosis</u></p> <p><i>Acanthamoeba</i> DNA</p> <p><i>Aspergillus</i> genus DNA</p> <p><i>Candida albicans</i> DNA</p> <p><i>Cryptococcus neoformans</i> DNA</p> <p>Fungal 18srRNA gene detection</p> <p><i>Toxoplasma gondii</i> DNA</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>S- 1234 Semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.</p> <p>S-1236 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.</p> <p>S-1237 Single round PCR assay utilising block thermal cyclers and visualisation on agarose gel.</p> <p>S -608 Single round PCR assay performed on block thermal cyclers and visualisation on agarose gel.</p> <p>S-1001 Single round PCR assay utilising block thermal cyclers and visualisation on agarose gel.</p> <p>S-1123 Nested PCR assay performed on block thermal cyclers and visualisation on agarose gel or melt curve analysis.</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (Cont'd)</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>EDTA/citrated whole blood, CSF and plasma</p> <p>Any upper / lower respiratory sample</p> <p>Any upper / lower respiratory sample</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>Amniotic fluid, CSF, saliva, EDTA/citrated whole blood, urine, serum/EDTA plasma</p>	<p><u>Molecular virology examination activities for the purpose of clinical diagnosis</u></p> <p><i>Adenovirus</i> DNA</p> <p><i>Adenovirus</i> DNA quantitation</p> <p><i>Bocavirus</i> DNA</p> <p><i>Coronavirus</i> 229E, HKU1, NL63 or OC43 RNA</p> <p><i>Cytomegalovirus</i> DNA</p> <p><i>Cytomegalovirus</i> DNA quantitation</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>S-939 Single round assay using real time PCR ROCHE 480 Lightcyclers and probe based Technology.</p> <p>S- 939 Single round real time assay using real time PCR ROCHE 480 Lightcyclers and probe based Technology.</p> <p>S-1147 Luminex assay - Single round thermal block PCR followed by analysis on the MAGPIX.</p> <p>S-1147 Luminex assay - Single round thermal block PCR followed by analysis on the MAGPIX.</p> <p>S-937 Single round PCR using ROCHE Lightcycler 480 and probe based Technology.</p> <p>S-937 Single round real time PCR using ROCHE Lightcycler 480 and probe based technology.</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
CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood	<i>Enterovirus</i> RNA	S-952 Single round PCR using ROCHE Lightcycler 480 and probe based technology.
EDTA/citrated whole blood, CSF, urine, serum, plasma, biopsy	<i>Epstein Barr Virus</i> DNA	S-937 Single round real time PCR using ROCHE Lightcycler 480 and probe based technology.
EDTA/citrated whole blood, CSF, urine, serum, plasma	<i>Epstein Barr Virus</i> DNA quantitation	S-937 Single round real time PCR using ROCHE Lightcycler 480 and probe based technology.
serum/plasma	<i>Hepatitis B virus</i> DNA detection and quantitation	S-1264 Nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers or LC480 and intercalating dye in the second round.
serum/plasma	<i>Hepatitis C virus</i> RNA detection and quantitation	S-1168 Single round PCR assay using ROCHE 480 lightcyclers and intercalating dye.
serum/plasma	<i>Hepatitis D virus</i> RNA detection and quantitation	S-836 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.
Serum/plasma, CSF, Stool, EDTA whole blood	<i>Hepatitis E virus</i> RNA detection	S-1076 Single round PCR assay using ROCHE 480 Lightcyclers and probe based technology.



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/plasma, CSF, EDTA whole blood</p> <p>CSF, AC tap, EDTA/citrated whole blood, corneal scrape, vesicle fluid, skin/eye/ vesicle/ lesion swab, tissue, BAL Genitourinary – female: vulval Or endocervical 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</p> <p>Performed routinely on positive HSV samples (Except oral and eye samples)</p> <p>EDTA whole blood preferred or serum/plasma</p> <p>Serum/plasma, CSF</p>	<p><u>Molecular virology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><i>Hepatitis E virus</i> RNA quantitation</p> <p><i>Herpes Simplex virus</i> DNA</p> <p><i>Herpes Simplex virus</i> types I & II typing</p> <p><i>HIV-1</i> LTR, env, gag and pol genes</p> <p><i>HIV-1</i> RNA quantitation</p>	<p>In House documented methods incorporating manufacturers' instructions, where relevant</p> <p>S-1076 Single round PCR assay using ROCHE 480 Lightcyclers and probe based technology.</p> <p>S-987 Nested PCR assay using block thermal cyclers in the first round and ROCHE 480 lightcyclers and intercalating dye in the second round.</p> <p>S-863 Semi-nested PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round.</p> <p>S-286 A combination of nested and semi-nested PCR assay performed on block thermal cyclers and visualisation on agarose gel.</p> <p>S-220 ROCHE COBAS assay using COBAS Ampliprep / Taqman and oligonucleotide probes COBAS Ampliprep M-891 COBAS Ampliprep/Taqman HIV-1 Test kit M-251.</p>



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EDTA whole blood preferred or serum/plasma	<i>HIV-2</i> LTR and pol	S-286 Nested round PCR assay performed on block thermal cyclers and visualisation on agarose gel.
EDTA/citrated whole blood	<i>HTLV</i> DNA or RNA	S-938 Nested PCR assay performed on block thermal cyclers and visualisation on ROCHE capillary lightcyclers.
EDTA/citrated whole blood (CSF in encephalitis), bone marrow, plasma, serum	<i>Human Herpesvirus 6</i> DNA detection and quantitation	S-1212 Nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel and LC480 lightcyclers and intercalating dye in the second round.
EDTA/citrated whole blood, CSF, plasma, serum	<i>Human Herpesvirus 7</i> DNA	S-950 Nested PCR assay using block thermal cyclers in the first round and ROCHE carousel and LC480 Lightcyclers and intercalating dye in the second round.
EDTA/citrated whole blood, plasma, serum	<i>Human Herpesvirus 8</i> DNA detection and quantitation	S-1052 Nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel and LC480 lightcyclers and intercalating dye in the second round.
Upper and lower respiratory samples	<i>Human metapneumovirus</i> RNA	S-1147 Luminex assay - Single round thermal block PCR followed by visualisation on the MAGPIX.



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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	<i>Human Papillomavirus</i> DNA and typing	S-944 Nested PCR assay using standard thermal cyclers followed by visualisation on agarose gel and subsequent sequencing of positives.
Female: Endocervical swab sent in VTM or 'thin prep' endocervical cellular specimens	<i>Human Papillomavirus</i> DNA genotyping (High risk)	M-1189 Liferiver HPV genotyping kit utilising probe technology on Lightcycler 480 PCR machines.
Upper and lower respiratory samples	<i>Influenza A virus</i> RNA	S-1147 Luminex assay - Single round thermal block PCR followed by visualisation on the MAGPIX.
Upper and lower respiratory samples	<i>Influenza B virus</i> RNA	S-1147 Luminex assay - Single round thermal block PCR followed by visualisation on the MAGPIX.
CSF, urine, saliva, mouth/throat swab, whole blood	<i>Measles virus</i> RNA	S-935 Nested round PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round.
CSF, urine, saliva, mouth/throat swab	<i>Mumps virus</i> RNA	S-935 Nested PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round.
Upper and lower respiratory samples	<i>Parainfluenza 1,2,3 and 4 virus</i> RNA	S-1147 Luminex assay - Single round thermal block PCR followed by visualisation on the MAGPIX.



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CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood	<i>Parechovirus</i> RNA	S-952 Single round PCR assay using ROCHE480 lightcyclers and probe technology.
EDTA/citrated whole blood, amniotic fluid, serum/plasma, post-mortem samples (Foetal), CSF, bone marrow	<i>Parvovirus B19</i> DNA	S-931 Nested PCR assay using block thermal cyclers in the first round and ROCHE carousel and LC480 lightcyclers and intercalating dye in the second round.
EDTA/citrated whole blood, amniotic fluid, serum/plasma, CSF, bone marrow	<i>Parvovirus B19</i> DNA quantitation	S-931 Nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel and LC480 lightcyclers and intercalating dye in the second round.
EDTA/citrated whole blood, urine, CSF, serum, plasma	<i>Polyoma BK virus</i> DNA detection and quantitation	S-1066 Semi-nested real time PCR assay using block thermal cyclers in the first round and ROCHE carousel and LC480 lightcyclers and intercalating dye in the second round.
Urines only	<i>Polyoma BK virus</i> single assay	S-1069 Single round PCR assay using ROCHE 480 lightcyclers and intercalating dye.
EDTA/citrated whole blood, CSF, urine	<i>Polyoma JC virus</i> DNA detection and quantitation	S-908 In-house single round PCR assay using ROCHE 480 lightcyclers and probe technology.



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Micropathology Ltd

Issue No: 001 **Issue date:** 30 November 2017

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>Molecular virology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods incorporating manufacturers' instructions, where relevant
Upper and lower respiratory sample	<i>Respiratory Syncytial Virus</i> RNA	S-1147 Luminex assay - Single round thermal block PCR followed by visualisation on the MAGPIX.
Upper and lower respiratory sample	Respiratory Virus Screen	S-1147 Luminex assay - Single round thermal block PCR followed by visualisation on the MAGPIX. Picornavirus positives are differentiated between Enterovirus and Rhinovirus using in-house nested PCR assays S-1347. Products are generated on thermal cyclers in the first round and LC480 in the second round using intercalating dye.
Upper and lower respiratory sample	<i>Rhinovirus</i> RNA	S-1147 Luminex assay - Single round thermal block PCR followed by visualisation on the MAGPIX.
CSF, EDTA/citrated whole blood, throat swab, urine, amniotic fluid	<i>Rubella virus</i> RNA	S-935 Nested PCR assay using block thermal cyclers in the first round and ROCHE carousel lightcyclers and intercalating dye in the second round.
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)	<i>Varicella Zoster virus</i> DNA	S-987 Nested PCR assay using block thermal cyclers in the first round and ROCHE 480 lightcyclers and visualisation on the agarose gel.
CSF, whole blood	<i>West Nile Fever virus</i> RNA	S-611 In-house assay using standard thermal cyclers followed by real time PCR machines and intercalating dye.



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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>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.
Serum preferred or Li-heparin, K3-EDTA, Na citrate plasma	<i>Rubella</i> IgG antibody	IgG antibodies to Rubella virus M-487.



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological analysis for the purpose of clinical diagnosis</u> (cont'd)	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.
	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
		Plate reader M-889
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>Measles</i> IgG antibody	Novatec NovaLisa measles virus IgG ELISA M-245.
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</p> <p>Any positive product produced in 16S rRNA bacteria assay</p> <p>PCR product generated in-house</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>16S rRNA bacterial gene sequencing</p> <p><i>Adenovirus</i> typing</p>	<p>Dideoxynucleotide sequencing performed on ABI 3130 xl using in-house methodology</p> <p>S-260 Direct Sequencing of PCR products S-56 Sequence data analysis 3130/3130xl Genetic Analyzer user guide M-993 3130xl 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 <i>Dideoxynucleotide sequencing performed on ABI 3130 xl using in-house methodology</i> Biometra Professional TRIO M-1224 MJ research PTC-100 M-970</p> <p>Single round PCR products produced on Qiagen Rotorgene / Biosciences MIC M-882 S-49 subject to sequencing.</p> <p>S-594 Nested PCR assay performed on thermal cycler blocks, in which positives are subject to sequencing.</p>



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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 3130 xl using in-house methodology
Sputum, culture	<i>Burkholderia cepacia</i> complex typing	S- 238 Single round PCR on block thermal cycler with visualisation on agarose gel.
EDTA/citrated whole blood, urine, serum/EDTA plasma, eye fluid, tissue, biopsy or respiratory specimen. Pregnancy – EDTA whole blood, amniotic fluid, cervical swab, serum/plasma	<i>Cytomegalovirus</i> ganciclovir resistance	S-584 Semi-nested PCR assay, performed on thermal cycler blocks in which positives are subject to sequencing
Serum/plasma	<i>HBV</i> Core/PreCore Mutations	S-585 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-617 Semi-nested PCR assay, performed on thermal cycler blocks in which positives are subject to sequencing.
Serum/plasma	<i>Hepatitis C</i> NS3 Q80K polymorphism	S-782 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 Nested PCR assay, performed on thermal cycler blocks 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 3130 xl using in-house methodology
Serum/plasma	<i>Hepatitis C</i> genotyping	S-595 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-133 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 Single round and semi-nested PCR assays, in which positives are subject to sequencing.
Serum/plasma	<i>HIV-1</i> RNA Integrase drug resistance	S-169 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	Single round PCR assay S-1001, performed on thermal cycler blocks in which positives are subject to sequencing using the above methodology.



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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 ROCHE Carousel Lightcycler model 1.1 M-1338, model 1.5 M-876, model 2.0 M-877 & M-878.
EDTA/citrated whole blood	Alpha-1 antitrypsin genotyping	S-927 Single round PCR using ROCHE carousel lightcyclers and probe based technology utilising in-house methodology and ROCHE Master HybProb kit M-631.
EDTA / citrated whole blood	Factor V Mutation + Prothrombin	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.
EDTA / citrated whole blood	Haemochromatosis H63D C282Y	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.
EDTA / citrated whole blood	IL28B gene (rs12979860)	S-303 Single round PCR using in-house methodology ROCHE carousel Lightcyclers and FRET probe based technology and ROCHE Master HybProb kit M-631.



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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>Forensic 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 3130xl 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>3130/3130xl Genetic Analyzer user guide M-993 3130xl 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		