



Micropathology Ltd

AN INDEPENDENT, CPA ACCREDITED, RAPID DIAGNOSIS & BIOMEDICAL RESEARCH COMPANY



Accredited Medical Laboratory
Reference No: 1926

Laboratory User Handbook

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1. Introduction

1.1 The Laboratory and outline of services

Micropathology Ltd provides a clinically supported service for the rapid diagnosis of infectious disease and host responses to infection. This service includes contract research, clinical trials for external organizations and in-house assay development.

Micropathology Ltd also provides DNA paternity testing, a forensic genetics service, molecular genetics, sequencing services and also undertakes biomedical research covering various aspects of human and veterinary pathology.

These services are offered to all hospitals, NHS laboratories, General Practitioners and private medical laboratories throughout the UK and abroad.

Ongoing contact with all our clients is welcome, both in the UK and overseas, and we are happy to discuss how we may help to meet the needs of both existing and new clients.

The laboratory is CPA accredited and participates in all appropriate external quality assurance schemes.

A 24-hour on-call clinical advice service is available for healthcare professionals to discuss specific cases or general matters concerning infectious disease or vaccination.

1.2 Laboratory policy

The directors and staff work to the highest possible standards in all aspects of the company's business. We subscribe to both UK and international standards of accreditation, 'best-practice' and quality assurance schemes in order to maintain excellence in all our undertakings. We are strongly committed to research and to the provision of training for all members of staff.

1.3 Using this handbook

This handbook is designed to assist clients in the provision of our services. Further information is available on www.micropathology.com or by telephoning the company.

2. Laboratory and Staff

2.1 Laboratory opening times

The laboratory is open between the hours of 08.30 to 17.30 Monday to Friday when staff are available for advice, information, specimen reception and processing. Outside of these hours an on-call telephone clinical advice service is provided.

We also receive samples on Saturday mornings and these will be processed the following working day.

A schedule of working arrangements over Easter, Christmas and New Year, as well as other bank holidays* throughout the year is faxed out to existing customers in advance and by email to registered website users.

*those recognised in England and Wales; we do not send out schedules for Scottish / Irish bank holidays

2.2 Location and visitors

Micropathology Ltd is located between the M6 and the M40, 4 miles outside of Coventry off the A45 (see website maps). Car parking is available at the Venture Centre and visitors are requested to report to the reception desk in the entrance foyer where they will be issued with a visitor's pass. It is essential to make an appointment in advance.

2.3 Staff

Medical / Laboratory Director	Dr Colin Fink
Scientific / Laboratory Director	Dr David Burnett
Clinical Scientist (Genetics)	Dr Sarah Ball
Clinical Scientist (Microbiology)	Dr Jenny Cottrell
Quality Manager	Dr Andrea Collins
Quality Assistant	Ms Nagela Ford
Clinical Scientist & Company Representative	Ms Heather Smith
Scientist / Health & Safety Co-ordinator	Dr Sian Davies
Scientists	Dr John Thomas, Dr Penny Reid, Dr Elli Pinnock, Dr Daniel Hand, Dr Ronan Calvez, Dr James Barnett, Dr Mark Collery, Dr Alex Esparza- Franco, Dr Leo Calvo-Bado
Scientist/Training Officer	Dr Edward Sumner
Scientist/IT manager	Dr Peter Millichap
Intercalated B.Sc Student	Miss Vicky Smith, Miss Ellie Phillips, Miss Annie Fletcher
Company accountant	Mrs Weiping Barrett
Administrative assistant	Ms Dawn Mason

3. Diagnostic and Advisory Services

3.1 Information and enquiries

For general information, consultation on appropriate investigation and sample testing, or enquiries regarding results and their interpretation please contact Micropathology Ltd on +44 (0) 2476 323222, or alternatively email info@micropathology.com where enquiries can be answered or referred to the appropriate personnel.

Clinical advice for hospital based personnel, General Practitioners and their nursing staff is also available on the above number, including out of hours.

3.2 Sending samples to the laboratory

The packaging of clinical specimens whether using a courier service, or the Royal Mail, is based upon the principle of triple containment to prevent exposure to potential infection hazard. Please follow the instructions below for safe transportation of your samples.

The clinical material itself must be contained within a sealed specimen container which is placed within a sealed plastic specimen bag with sufficient absorbent wadding to soak up any fluid should a breakage occur. This must then be placed with the request form(s) in the outer screw-top plastic specimen carrier and the lid secured to form a seal. These are then placed within the outer shipping container (usually a cardboard box). The outside of the package must be clearly labelled with: **PATHOLOGICAL SPECIMEN; FRAGILE – WITH CARE**. The UN standards (3373) allow compliance with these containment requirements. Transport boxes of these standards are commercially available.

Appropriate address labels for destination and senders should be attached to this box. We will supply mailing or DX labels, as appropriate, if you require them. Packaging materials will be returned for reuse if requested. Standard postal rates will apply to this service.

It is the responsibility of the sender to comply with UK postal, courier or international safety regulations for clinical specimens transport.

Please note that samples sent by post may arrive after the days sample processing has begun. In these instances samples may be processed on the next working day and not on the day of receipt into the laboratory. This may therefore affect the test turnaround time between receipt into the laboratory and results reporting.

3.3 Requesting tests

TEST REQUEST	Service provided	Additional information
ROUTINE	We accept and test many different kinds of clinical samples including fresh and fixed tissue samples. Please refer to the specimen tables for a list of appropriate samples for test types.	Late arriving samples (After midday) will not be processed until the next working day unless by prior arrangement or are considered urgent.
ADDITIONAL examinations Samples received within 24hrs (already under investigation)	Additional examinations can be requested by telephone, fax or email info@micropathology.com . Additional test requests received after midday, on samples currently under investigation, will be subject to processing and testing on the next working day.	Please do not send requests to personal email accounts as this may result in a delay in responding to your request and subsequent testing
ADDITIONAL examinations Samples received <u>more than 48 hours ago</u> (archived samples)	Specimens are archived at -20°C for several months. Additional examinations may be requested on these samples where there is sufficient volume remaining.	Additional requests on samples received more than 48hours previously will require full sample extraction and processing and will attract full sample costs.
URGENT requests	We offer an 8-hour urgent turnaround and reporting service for clinical specimens for double the normal sample analysis price.	Please enquire BEFORE requesting this service; we may be able to offer a routine assay that is as fast on the day at no extra cost.
WEEKEND analysis	For weekend urgent analysis, please telephone to make special arrangements.	We place a weekend premium charge for urgent analysis; please enquire by telephone if you are considering using this service

Please note: If you do NOT refer anything to us on a routine basis please contact info@micropathology.com or telephone +44 (0) 2476 323222, to confirm we hold the correct result destinations (Fax numbers, email addresses etc).

3.3 Request forms and sample identification

In all requests for testing, clinical information is an aid to laboratory diagnosis.

A request form must accompany and identify all specimens. Your own locally available pathology form is acceptable or a customisable Micropathology Ltd request form is available to download from our web site. **The origin of the request must be**

an authorised body and not an individual member of the public. Evidence of informed consent by patient or parent/guardian is required for clinical genetics tests.

To ensure unequivocal identification, samples and request forms **MUST** contain the minimum essential identification criteria. If insufficient information is not provided to ensure unequivocal traceability, samples may be rejected without analysis or referred back to the requesting practitioner.

The sample and request form must contain matching information and contain the following:

	Essential	Desirable
Sample	<ol style="list-style-type: none"> 1. Patient's full name or unique code identifier 2. Date of birth 3. Lab reference number 	<ol style="list-style-type: none"> 1. Date and time of sampling 2. Nature of sample i.e. left eye swab
Request form	<ol style="list-style-type: none"> 1. Patients full name or unique code identifier 2. Date of birth 3. Gender 4. Lab reference number 5. Sample type 6. Investigation(s) required 7. The full postal address of the requesting authority 8. A contact telephone number 9. A contact name, or consultant's name where possible 10. Secure email/fax/postal details to which the results will be sent. 	<ol style="list-style-type: none"> 1. Clinical information including relevant treatment/medication 2. Date and time of sample 3. Hospital number

3.4 Patient confidentiality

All samples received are treated in the strictest confidence and are anonymised upon receipt into the laboratory. Dr Colin Fink is responsible for protecting the confidentiality of the patient and service-user information. We are registered with the Information Commissioners Office and comply with the obligations and duties under the Data Protection Act and Freedom of Information Act.

3.5 List of tests available, target turnaround times, sample types and prices

We offer a comprehensive range of assays for the rapid detection of pathogens and host responses. Please refer to the following table on pages 10-14 for details of tests offered, test turnaround time and appropriate sample types tested. Please note: Test turnaround time is based on a Monday to Friday working week. Saturday/Sundays are not included in TAT calculations.

Prices can be accessed by registered users via the company website.

Unless stated otherwise, please send at least **200µL** of liquid sample for testing. Low volume samples may be tested, but reports will bear a caveat regarding the potential effect on assay sensitivity.

For tissue samples; please send a matchstick sized piece of the appropriate tissue in a sterile container. If you are unsure of the suitability of a particular sample, please contact us.

Bilateral eye swabs, and nose and throat swabs may be combined in the same tube with the same accession number if the clients has assigned them the same laboratory number and we cannot distinguish between them. If they have the same laboratory number but are clearly labeled 'left' and 'right' eye then they will be assigned different accession numbers. If this is not preferred please state this on the sample request form.

We will consider any project for the development of new molecular diagnostic assays, with the aim of improving the sensitivity or speed of diagnosis over existing methods. Please contact the laboratory for further information/discussions.

3.6 Factors affecting assays

The sensitivity of DNA/RNA detection tests depends on the quality/type of the sample and the test performed.

3.6i Extracted samples

These samples may be subject to testing but the laboratory cannot guarantee the efficiency of detection in the laboratory assays on samples extracted by a procedure not validated by ourselves. Extracts of insufficient volume may also be subject to dilution for testing.

3.6ii Serum/plasma samples for blood borne-virus detection

HBV, HCV and HIV-1 RNA Viral load testing require serum/EDTA plasma samples, which are as fresh as possible. Viral loads may decrease after storage in poor conditions.

The presence of red blood cells in EDTA plasma samples indicates the possible presence of white blood cell contamination. This may affect the results of HIV-1 viral load assays. EDTA plasma should be separated as soon as possible.

3.6iii Li-heparin or Na-heparin whole blood samples

Li Heparin/Na heparin has inhibitory effects in PCR. Please provide an alternative sample if molecular detection of viral / bacterial targets or human genetics tests are required.

3.6iv Inhibitory samples

All clinical samples are processed with a nucleic acid extraction procedure that has been shown to overcome the potential inhibition of assays associated with some samples. Urine samples however, may still contain enough inhibitors, even after extraction, to affect the detection of low levels of target nucleic acid. Please bear

this in mind when sending urine samples for *Chlamydia trachomatis* and HSV testing, for example. We are able to detect if inhibition has occurred and report accordingly.

3.6v Serology samples

Fresh blood in plain or gel tubes is best left at room temperature to clot. DO NOT FREEZE or OVER COOL ANY WHOLE BLOOD SAMPLES as this may result in haemolysis of the red blood cells. This is particularly important as severe haemolysis of red blood cells may compromise the results of serology assays.

3.6vi Sample instability

Significant delay in sending and/or receiving samples can result in sample instability and thus may hinder detection of the requested target.

3.7 Criteria for accepting / rejecting samples

Samples are accepted for testing if they are:

- 1 Of appropriate sample type for tests required, as detailed in this handbook (pages 11-15).
- 2 Of sufficient volume for testing.
- 3 Correctly matched information on sample and request form.
- 4 Sufficient patient/source identification (Table on page 7).

Samples may be rejected if:

- 1 Inappropriate sample type.
- 2 Leakage has occurred.
- 3 Low volume.
- 4 Badly haemolysed (serum/plasma samples for HIV-Q and serological assays).
- 5 Misdirected.
- 6 Mismatched sample and request form.
- 7 Insufficient or incorrect information on sample and / or request form.

On occasion, rejected samples are tested. In these instances, result reports will bear an appropriate caveat indicating the nature of the problem (if sample related) and that results should be interpreted with caution.

If the sample is rejected and not subject to testing, the referring laboratory will be notified of the rejection of the sample and reasons why, by either telephone or fax.

Micropathology Ltd will contact clients if samples are misdirected, contain insufficient / incorrect information or have a mismatched sample / request form.

3.8 Reference values for Serological assays

Reference values for the serology assays provided at Micropathology Ltd are detailed below.

Qualitative assays

TEST	Cut-off	Reactive	Non-reactive	Borderline
Anti-HCV	1.0	≥ 1.0	< 0.9	$\geq 0.9 - < 1.0$
HIV combi	1.0	≥ 1.0	< 0.9	$\geq 0.9 - < 1.0$
HBsAg II	1.0	≥ 1.0	< 0.9	$\geq 0.9 - < 1.0$
Anti-HBc	1.0	≤ 1.0	> 1.0	
Anti-HBe	1.0	≤ 1.0	> 1.0	
HBeAg	1.0	≥ 1.0	< 1.0	

Please contact the laboratory for additional information regarding these reference values.

Quantitative assays

TEST	Measuring Range	Reactive	Non-reactive	Equivocal	Dilution
Rubella	0.17 – 500 IU/mL (10,000 IU/mL if diluted 1:20)	≥ 10 IU/mL	< 10 IU/mL		Samples > 500 IU/mL can be diluted 1:20
Toxoplasma	0.13 – 650 IU/mL (13,000 IU/mL if diluted 1:20)	≥ 3 IU/mL	< 1 IU/mL	$\geq 1 - < 3$ IU/mL	Samples > 650 IU/mL can be diluted 1:20
Anti-HBs	2.00 – 1,000 IU/L (100,000 if diluted 1:100)	≥ 10 IU/L	< 10 IU/L		Samples $> 1,000$ IU/L can be diluted 1:100
HBsAg II quant	5 – 13,000 IU/mL for 100-fold diluted samples (mandatory). 0.05 – 130 IU/mL for undiluted samples.	> 0.05	Values of < 0.05 are considered to be below the Limit of Detection.		It is mandatory for samples to be diluted on-board at 1:100. Samples $> 13,000$ IU/mL can be further diluted manually 1:100 to achieve a final 1:10,000 dilution.

Tests available		
Test	Target turnaround	Sample types
16S rRNA bacterial gene detection	3 days	Any (inc. fixed tissue) preferably from normally sterile sites
16S rRNA bacterial gene sequencing	3 days	PCR product (see detection above) or bacterial culture
18S rRNA fungal gene detection	3 days	Any (inc. fixed tissue) preferably from normally sterile sites
18S rRNA fungal gene sequencing	3 days	PCR product (see detection above) or fungal culture
Acanthamoeba DNA	2 days	Corneal scrape, swab or contact lens, contact lens solution
Adenovirus DNA	Next day	EDTA/citrated whole blood, stool or any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc). BAL and NPA preferred, eye swab, tissue, urine
Adenovirus DNA quantitation	Next day	EDTA/citrated whole blood
Adenovirus typing	3 days	PCR product generated in-house from the sample types detailed for Adenovirus DNA
Alpha-1 antitrypsin genotyping	5 days	EDTA/citrated whole blood
Aspergillus genus DNA	3 days	EDTA/citrated whole blood/respiratory
Bocavirus	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Bordetella genus DNA	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Bordetella pertussis DNA	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Borrelia burgdorferi antibody (externally referred)	14 days	Serum
Borrelia burgdorferi DNA	Next day	EDTA/citrated whole blood, CSF, skin biopsy
Borrelia genus	Next day	EDTA/citrated whole blood, CSF, skin biopsy
Brucella antibody (externally referred)	14 days	Serum
Brucella genus DNA	3 days	EDTA/citrated whole blood, CSF, tissue
Burkholderia cepacia complex	3 days	Sputum, culture
Burkholderia cepacia complex typing	5 days	Sputum, culture
Candida albicans DNA	2 days	EDTA/citrated whole blood, CSF, tissue
Cervical cytology (externally referred)	10 days	'Thin prep' endocervical cellular specimens.
Chlamydia pneumoniae DNA	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Chlamydia psittaci DNA	2 days	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Chlamydia trachomatis DNA	3 days	Eye swab, throat swab For genitourinary: Female: Endocervical, vaginal or rectal swab, first pass urine, 'Thin prep' endocervical cellular specimens Male: Urethral swab, first pass urine, semen, rectal swab
Clostridium difficile	3 days	Stool
Coronavirus 229E, HKU1, NL63 or OC43	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Coxiella burnetii	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred

Tests available		
Test	Target turnaround	Sample types
		and tissues, whole blood. We do not accept cultures.
Cryptococcus neoformans DNA	Next day	CSF
Cytomegalovirus DNA	Same day	EDTA/citrated whole blood, urine, serum/EDTA plasma, eye fluid, tissue, biopsy or respiratory specimen - BAL preferred Pregnancy – EDTA whole blood, amniotic fluid, cervical swab, serum/plasma
Cytomegalovirus DNA quantitation	Same day	EDTA/citrated whole blood, urine, serum/EDTA plasma, eye fluid
Cytomegalovirus ganciclovir resistance	5 days	As for CMV DNA
Enterovirus RNA	Next day	CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood - may be useful in suspected meningitis cases
Enterovirus typing	3 days	CSF, EDTA/citrated whole blood, stool, respiratory samples, tissue, serum, plasma
Epstein Barr Virus DNA	Same day	EDTA/citrated whole blood, CSF, urine, serum, plasma, eye fluid, biopsy, respiratory samples
Epstein Barr Virus DNA quantitation	Same day	EDTA/citrated whole blood, CSF, urine, serum, plasma, eye fluid
Escherichia coli DNA	2 days	CSF, EDTA/citrated whole blood
Factor V Mutation + Prothrombin	5 days	EDTA / citrated whole blood
Forensic DNA Profiling – tissue extraction	10 days	Muscle
Forensic DNA Profiling - extraction from bone or teeth	15 days	Bone/teeth
Forensic DNA Profiling	10 days	Cheek swab, EDTA/citrated whole blood, tissue, serum, fixed tissue (least preferred sample), personal items (Hairbrush, comb, razor)
Group A Streptococcus (S.pyogenes) DNA	Next day	CSF, EDTA/citrated whole blood, tissue
Group B Streptococcus (S. agalactiae) DNA	Next day	CSF, EDTA/citrated whole blood, tissue
Haemochromatosis H63D C282Y	5 days	EDTA / citrated whole blood
Haemophilus ducreyi DNA	Next day	Swab
Haemophilus influenzae/parainfluenzae DNA	Next day	CSF, EDTA/citrated whole blood (may be useful in suspected meningitis cases) or any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA are preferred.
HBV Core/PreCore Mutations	5 days	Serum/plasma
Hepatitis B core antibody	3 days	Serum preferred or Na-heparin*, EDTA, sodium citrate plasma
Hepatitis B e antibody	3 days	Serum preferred or Na-heparin*, EDTA, sodium citrate plasma
Hepatitis B e antigen	3 days	Serum preferred or Na-heparin*, EDTA, sodium citrate plasma
Hepatitis B drug resistance mutation screen	5 days	Serum/plasma
Hepatitis B surface antibody	3 days	Serum preferred or EDTA plasma **
Hepatitis B surface antigen	3 days	Serum preferred or Li-heparin*, EDTA, citrate plasma
Hepatitis B surface antigen quantitation	3 days	Serum preferred or Li-heparin*, Na-heparin*, EDTA, citrate plasma
Hepatitis B virus DNA (<10IU/mL)	Next day	At least 0.3ml serum/plasma
Hepatitis B virus DNA quantitation (<10IU/mL)	Next day	At least 0.3ml serum/plasma

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Tests available		
Test	Target turnaround	Sample types
Hepatitis B genotyping	3 days	Serum/plasma
Hepatitis C antibody (EIA)	3 days	Serum preferred or Li-heparin*, Na-heparin*, EDTA, citrate plasma
Hepatitis C antibody (RIBA)	3 days	Serum preferred or Li-heparin*, citrate or EDTA plasma
Hepatitis C NS3 Q80K polymorphism	3 days	At least 0.3ml serum/plasma
Hepatitis C genotyping	3 days	Serum/plasma
Hepatitis C virus RNA (<18IU/ml)	Next day	At least 0.3ml serum/plasma
Hepatitis C virus RNA quantitation (<18IU/ml)	Next day	At least 0.3ml serum/plasma
Hepatitis D virus RNA	3 days	Serum/plasma. This assay should always be reviewed in conjunction with HBV investigations.
Hepatitis D virus RNA quantitation	3 days	Serum/plasma. This assay should always be reviewed in conjunction with HBV investigations.
Hepatitis E virus RNA	4 days	Serum/plasma
Herpes Simplex virus DNA	Next day	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) 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 types I & II typing	Next day	Performed routinely on positive HSV sample (Except oral and eye samples)
HIV I & II antibody and p24 antigen (EIA)	3 days	Serum preferred or Li-heparin*, EDTA plasma
HIV I & II antibody (LIA)	3 days	Serum preferred or Li-heparin*, citrate or EDTA plasma
HIV I & II antibody (LIA) - saliva	3 days	Saliva
HIV-1 LTR, env, gag and pol genes	2 days	EDTA whole blood preferred or serum/plasma/semen/cell lines
HIV-1 RNA drug resistance	9 days	Serum/plasma. This test requires at least 500µL of sample. Use EDTA whole blood, separate the plasma within 24 hours of blood collection. Ship at ambient temperature for next day delivery. Please supply viral load if available.
HIV-1 RNA Integrase drug resistance	5 days	Serum/plasma. This test requires at least 500µL of sample. Use EDTA whole blood, separate the plasma within 24 hours of blood collection. Ship at ambient temperature for next day delivery. Please supply viral load if available.
HIV-1 RNA quantitation	3 days	Serum/plasma. This test requires at least 1mL of sample. Use EDTA whole blood, separate the plasma within 24 hours of blood collection. Ship at ambient temperature for next day delivery.
HIV-2 LTR and pol DNA/RNA	2 days	EDTA whole blood preferred or serum/plasma/semen/cell lines
HTLV I & II antibody	2 days	Serum preferred or EDTA, citrate plasma
HTLV DNA or RNA	3 days	EDTA/citrated whole blood or CSF
Human Herpesvirus 6 DNA	Same day	EDTA/citrated whole blood (CSF in encephalitis), bone marrow biopsies, BAL, plasma***, serum***
Human Herpesvirus 6 DNA quantitation	Next day	EDTA/citrated whole blood (CSF in encephalitis), bone marrow, plasma***, serum***
Human Herpesvirus 7 DNA	Next day	EDTA/citrated whole blood, CSF, plasma***, serum***

Tests available		
Test	Target turnaround	Sample types
Human Herpesvirus 8 DNA	Same day	EDTA/citrated whole blood, plasma ^{***} , serum ^{***}
Human Herpesvirus 8 DNA quantitation	Next day	EDTA/citrated whole blood, plasma ^{***} , serum ^{***}
Human metapneumovirus RNA	Same day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Human Papillomavirus DNA detection	5 days	Swab, tissue (including fixed). Please state site of swab / tissue type. 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 typing.	5 days	Any positive detected from samples detailed for HPV detection.
Human Papillomavirus DNA high risk typing (Genital samples only)	5 days	Female: Endocervical swab sent in VTM or 'thin prep' endocervical cellular specimens. Male: Penile swab placed into VTM.
IL28B gene (rs12979860)	4 days	EDTA / citrated whole blood
Influenza A virus RNA	Same day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Influenza A H1N1 confirmation	2 days	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Influenza B virus RNA	Same day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Leptospira genus DNA	2 days	CSF, EDTA/citrated whole blood, urine
Listeria monocytogenes DNA	Next day	CSF, EDTA/citrated whole blood - may be useful in suspected meningitis cases
Measles virus RNA	Same day	CSF, urine, saliva, mouth/throat swab, whole blood
Mumps IgG antibody	3 days	Serum preferred or citrate plasma
Mumps virus RNA	Same day	CSF, urine, saliva, mouth/throat swab
Mycobacterium avium complex/TB complex DNA	Next day	Sputum, tissue, fixed tissue, CSF, BAL
Mycobacterium genus DNA	4 days	Sputum, tissue, fixed tissue, CSF, BAL
Mycobacterium TB rifampicin resistance	3 days	Sputum, tissue, fixed tissue, CSF, BAL
Mycoplasma genitalium DNA	2 days	Urine/genital swab
Mycoplasma genus DNA	3 days	CSF, EDTA/citrated whole blood, tissue culture
Mycoplasma pneumoniae DNA	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Neisseria gonorrhoeae DNA	3 days	Eye swab For genitourinary: Female: Endocervical, vaginal or rectal swab, first pass urine, 'Thin prep' endocervical cellular specimens. Male: Urethral swab, first pass urine, semen, rectal swab
Neisseria meningitidis DNA	Same day	CSF, EDTA/citrated whole blood (may be useful in suspected meningitis cases)
Neisseria meningitidis DNA typing	2 days	Performed routinely on positive Neisseria meningitidis samples
Parainfluenza 1,2,3 and 4 virus RNA	Same day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Parechovirus RNA	Next day	CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood - may be useful in suspected meningitis cases
Parvovirus B19 DNA	Same day	EDTA/citrated whole blood, amniotic fluid, serum/plasma, post-mortem samples (Foetal), CSF, bone marrow

Tests available		
Test	Target turnaround	Sample types
Parvovirus B19 DNA quantitation	Next day	EDTA/citrated whole blood, amniotic fluid, serum/plasma, CSF
Paternity Testing	7 days	Cheek swab
Pneumocystis carinii (aka jiroveci) DNA	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Polyoma BK virus DNA	Next day	EDTA/citrated whole blood, urine, CSF
Polyoma BK virus DNA quantitation	Next day	EDTA/citrated whole blood, urine, CSF
Polyoma JC virus DNA	Next day	EDTA/citrated whole blood, CSF, urine
Propionibacteria/Actinomyces DNA	2 days	Eye swab, tissue, CSF, vitreous fluid
Respiratory Syncytial Virus RNA	Same day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Respiratory Virus Screen	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Rhinovirus RNA	Same day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Rhinovirus typing	3 days	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Rubella IgG antibody	3 days	Serum preferred or Li-heparin, EDTA, sodium citrate plasma. Plasma treated with sodium fluoride and potassium oxalate should not be used
Rubella virus RNA	Same day	CSF, EDTA/citrated whole blood, throat swab, urine, amniotic fluid
Salmonella enterica	Next day	CSF, EDTA/citrated whole blood – may be useful in suspected meningitis cases, tissue, abscess fluid.
Staphylococcus genus DNA	Next day	CSF, aqueous/vitreous humour, tissue
Streptococcus pneumoniae DNA	Same day	CSF, whole blood – may be useful in suspected meningitis cases. Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc). BAL and NPA preferred
Toxoplasma gondii DNA	Same day	CSF, EDTA/citrated whole blood, amniotic fluid, aqueous/vitreous humours, tissue
Toxoplasma IgG antibody	5 days	Serum preferred or Li-heparin*, EDTA or citrate plasma
Treponema pallidum (syphilis) antibody (externally referred)	14 days	Serum
Treponema pallidum DNA	Next day	CSF, genital swab
Trichomonas vaginalis DNA	Next day	Genital swab
Tropheryma whippelii DNA	Next day	CSF and almost any cellular material including whole blood. PLEASE DO NOT SEND SERUM.
Ureaplasma urealyticum/parvum DNA	2 days	Urine, genital swab, respiratory (neonates)
Varicella Zoster virus DNA	Next day	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) 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
West Nile Fever virus RNA	Next day	CSF

* - Li Heparin/Na heparin has inhibitory effects in PCR. Please provide an alternative sample if molecular detection of viral / bacterial targets or human genetics tests are additionally required.

** - For the Hepatitis B surface antibody assay, if plasma treated with lithium heparin, sodium citrate, sodium fluoride or potassium oxalate is used, values obtained are 25% lower compared with serum. Additionally, lithium heparin plasma tubes containing separating gel should not be used for this test.

*** - Serum and plasma may be tested but whole blood is preferred.

3.9 Human genetic testing

Genetic services provide the following tests:

- Forensic DNA Profiling
- Haemochromatosis: HFE Gene Mutations
- Paternity Testing: Including Twin Zygosity Testing
- Prothrombin and Factor V Mutations
- IL28B gene (rs12979860 polymorphism associated response to the combination of pegylated-interferon and ribavirin for the treatment of HCV)
- Alpha-1 antitrypsin deficiency genotyping.

A minimum of 200µL of EDTA or citrated whole blood is required for these tests with the exception of paternity testing, which can be performed on cheek swabs, and forensic DNA profiling for which we accept a wide range of sample types. Please refer to the website (www.micropathology.com) or contact the laboratory for advice.

In addition to the specific tests listed, our molecular genetic services are also available for contract research projects in any relevant area of human or animal diagnosis and screening. We would be very pleased to hear from prospective clients who may have requirements for specific genetic tests.

3.9i Consent for Genetic Testing

It is the responsibility of the clinician requesting a genetic test to obtain informed consent for testing from the patient or and individual with parental/legal responsibility for the patient. Guidelines on consent for genetic testing are provided by the Joint Committee on Medical Genetics and are available at http://www.bsgm.org.uk/media/39563/consent_and_confidentiality_2011_1_.pdf

3.10 Sequencing service

Micropathology Ltd provides the following sequencing services in support of the diagnosis and management of infectious disease:

- Adenovirus typing
- Burkholderia cepacia complex typing
- Cytomegalovirus ganciclovir resistance
- Enterovirus typing

- H1N1 confirmation
- HBV Genotyping
- HBV Core/PreCore Mutation screening
- HBV drug resistance mutation screening
- HCV Genotyping
- HIV-1 drug resistance mutation analysis
- HPV genotyping
- Rhinovirus typing
- 16srRNA and 18srRNA sequencing for species determination
- Mycobacterium tuberculosis Rifampicin resistance
- Mycobacterium genus
- Mycoplasma genus

Please refer to the list of tests and sample types for further information regarding suitable sample types.

3.11 External referral laboratories

When necessary, the following external referral laboratories may be used:

Laboratory	CPA/UKAS ref	Accreditation status
Rare and Imported Pathogen Laboratory, HPA, Porton Down, Salisbury, Wiltshire, SP4 OJG	1612	CPA Accredited
Brucella reference unit, Duncan Building, 7 th Floor, Virology Department, Daulby Street, Liverpool, L69 3GA	1864	CPA Accredited
University Hospital Birmingham NHS Trust, Clinical Laboratory Sciences – Biochemistry, Level 1, Queen Elizabeth Hospital, Middleson Way, Birmingham. B15 2WB.	0333	CPA Accredited
Clinical Microbiology & Virology UCLH NHS Foundation Trust 60 Whitfield Street, London W1T 4EU	0543	CPA Accredited
TDL Cytology, The Doctors Laboratory, 60 Whitfield Street, London W1T 4EU	8511	ISO15189:2012 Accredited
Rare and Imported Pathogen Laboratory, HPA, Porton Down, Salisbury, Wiltshire, SP4 OJG	1612	CPA Accredited
Sexually Transmitted Bacteria Reference Laboratory (STBRL), HPA, 61 Colindale Avenue, London, NW9 5HT	1834	CPA Accredited

To ensure unequivocal linking of the sample and request form for any sample to be directly referred by Micropathology Ltd, referring laboratories are expected to provide the minimum information required as detailed in section 3.3.

4. Additional services

- Cell culture reagent testing for infection
- Medico-legal investigations of infection or genetic studies
- Contract and collaborative research services

Please see our web site for further information.

5. Quality Assurance

5.1 External QA schemes

We took part in the following external quality assurance schemes (2015):

United Kingdom National External Quality Assessment Service

- Anti-HBsAg
- Blood-Borne Virus screen (serology for hepatitis C, hepatitis B and HIV (including p24)
- Blood-Borne Virus donor screen (serology for hepatitis C, hepatitis B, HIV (including p24), HTLV and Toxoplasma)
- HepB serology (Surface antigen, 'e' antigen, 'e' antibody, core antibody)
- HFE (Haemochromatosis) H63D, C282Y & S65C mutations
- HPV (molecular)
- Thrombophilia gene mutations (Factor V Leiden & Prothrombin)
- Measles & mumps IgG
- Mycobacteria (molecular)
- Toxoplasma IgG
- Rubella IgG
- Virus identification (molecular)
- Pre and post analytical EQA.

INSTAND panels

- IL-28B
- Alpha-1 antitrypsin

Quality Control for Molecular Diagnostics

- adenovirus DNA quantitation
- CMV DNA quantitation (whole blood and serum)
- CMV drug resistance (UL97/UL54)
- Coronavirus including MERS
- EBV DNA quantitation (whole blood and serum)
- enterovirus
- HBV DNA quantitation

- HBV drug resistance
- HBV genotyping
- HCV drug resistance
- HCV genotyping
- HCV RNA quantitation
- HDV RNA quantitation
- HEV
- HHV6 DNA quantitation
- HIV-1 DNA
- HIV-1 drug resistance (protease/reverse transcriptase / integrase)
- HIV-1 RNA quantitation
- HPV
- HSV
- influenza virus A and B
- measles
- MPV
- mumps
- parainfluenza virus 1-4
- parechovirus
- parvovirus B19
- polyoma virus BK
- polyoma virus JC
- rhinovirus
- RSV
- VZV
- West Nile virus

- *Aspergillus* spp.
- *Bordetella pertussis*
- *Borrelia borgdorferi*
- *Candida* spp.
- *Chlamydia pneumonia*
- *Chlamydia psittacii*
- *Chlamydia trachomatis*
- *Clostridium difficile*
- *Mycobacterium tuberculosis*
- *Mycoplasma pneumonia*
- *Mycoplasma* spp
- *Neisseria gonorrhoea*
- *Pneumocystis jirovecii*
- STI screen (Mycoplasma genitalium DNA, Ureaplasma sp DNA, Trichomonas vaginalis DNA, Mycoplasma hominis DNA, Gardnerella vaginalis DNA)
- *Toxoplasma gondii*
- *Treponema pallidum*

Informal interlaboratory exchange schemes 2015 included:

- *Tropheryma whippelii*
- *Bacterial 16srRNA*
- *Acanthamoeba*
- *Streptococcus pneumoniae*
- *Neisseria meningitidis*
- *Group AB Streptococcus*
- *16srRNA*
- *Staphylococcus genus*

5.2 Accreditation

Micropathology Ltd is an accredited medical laboratory within the Clinical Pathology Accreditation (UK) Ltd standards. Reference Number: 1926. CPA provides a means to accredit Clinical Pathology Services and External Quality Assessment Schemes (EQA) and involves an external audit of the ability to provide a service of high quality by declaring a defined standard of practice, which is confirmed by peer review.

For all Quality Management System enquiries please contact Dr Andrea Collins on a.collins@micropathology.com.

6. Results and Reports

Results are transmitted to users between 17:00 and 18:30 Monday to Friday.

The primary delivery method of results is to a designated secure fax number; however results can be emailed to designated addresses as PDF attachments. Alternatively, clients can elect to receive hard copies of results; the previous week's results are normally printed and dispatched on Mondays by first class post.

Where results are seen to be urgent, they will be faxed as soon as possible, or you may be contacted by telephone.

If you have not referred anything to us on a routine basis please contact info@micropathology.com or telephone +44 (0) 2476 323222, to confirm we hold the correct result destinations (Fax numbers, email addresses etc).

Additionally, please contact the laboratory to alter any current report destinations.

7. Complaints procedure

Complaints can be made via the following routes:

1. Contact the laboratory directly by telephoning 024 76323222
2. Email the Quality Manager Dr Andrea Collins, a.collins@micropathology.com

3. Email the laboratory, info@micropathology.com
4. Email/contact the company representative, Miss Heather Smith, heather.smith@micropathology.com

8. Payment for services

8.1 Terms of Payment

Invoices are issued at the end of each month and work is completed on the basis of an undertaking by the Client to ensure payment within 30 days from the date of the invoice.

8.2 Acceptable Methods of payment

A cheque, BACS transfers, or international money transfers are all acceptable methods of payment.