



Micropathology Ltd

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



Accredited Medical Laboratory
Reference No: 1926

Laboratory User Handbook

2010

University of Warwick Science Park, Venture Centre
Sir William Lyons Road, Coventry
CV4 7EZ, United Kingdom

DX address: Micropathology Ltd
Coventry 93CV DX6784501

www.micropathology.com

Tel: +44 (0) 2476 323 222
Fax: +44 (0) 2476 323 333

Contents

1. Introduction	3
1.1 The Laboratory and outline of services	3
1.2 Laboratory policy.....	3
1.3 Using this handbook.....	3
2. Laboratory and Staff.....	4
2.1 Laboratory opening times.....	4
2.2 Location and visitors	4
2.3 Staff.....	4
3. Diagnostic and Advisory Services	5
3.1 Information and enquiries.....	5
3.2 Requesting tests routinely and urgently	5
3.3 List of tests available and target turnaround times	6
3.4 Sensitivity of DNA/RNA Detection Methods	9
3.5 Genetic testing	9
3.6 Suitable sample types and volumes	9
3.7 Specimen transport.....	11
4. Additional services	12
5. Quality Assurance	12
5.1 External QA schemes	12
5.2 Accreditation	13
6. Results and Reports.....	14
7. Payment for services.....	14
7.1 Terms of Payment.....	14
7.2 Acceptable Methods of payment.....	14

1. Introduction

1.1 The Laboratory and outline of services

Micropathology Ltd provides a clinically supported service for the rapid diagnosis and management of infectious and genetic disease.

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

Micropathology Ltd also provides DNA paternity testing, a forensic genetics service and undertakes biomedical research covering various aspects of human and veterinary pathology. This service includes contract research and clinical trials for external organizations, as well as continuing in-house assay development.

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

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 use of the services we offer. Further information is available on the web site 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 the Easter, Christmas and New Year holidays is faxed out to existing customers in advance.

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 Director	Dr Colin Fink
Scientific Director	Dr David Burnett
Finance Director	Mr David Morris-Jones
Clinical Scientist/Microbiologist, Safety officer & Quality manager	Dr Joanne Mitchell
Clinical Scientist/Molecular geneticist & Training Officer	Dr Phil Bennett
Clinical Scientist/Virologist	Mr Steven Read
Clinical Scientist & Company representative	Ms Heather Smith
Biomedical Scientist	Dr Andrea Collins
Scientists	Dr Edward Sumner, Dr Joanna Brown, Dr John Thomas, Mr Alec Bowden, Mr John Beekman, Dr Peter Millichap, Dr Penny Reid

3. Diagnostic and Advisory Services

3.1 Information and enquiries

For consultation on appropriate investigation and sample testing, interpretation of results and general information, please contact Micropathology Ltd on +44 (0) 2476 323222, from 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 this number, including out of hours.

3.2 Requesting tests routinely and urgently

We accept and test many different kinds of clinical samples including fresh and fixed tissue samples. 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.

Additional examinations can be requested by telephone or fax. We archive specimens at -20°C (when there is sufficient volume) for several months.

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 and will cost no extra.

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.

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

The request form must include a minimum of three of the following:

- The patient's full name
- Date of birth
- The patient's hospital or clinic number
- Your laboratory's reference number

Additionally, your request form must contain the following information:

- Investigation required
- The full postal address of the originator
- A contact telephone number
- A contact name, or consultant's name where possible
- A FAX number to which the results will be sent.

You may supply an e-mail address as an alternative for reporting results, which will be sent as PDF attachments.

Please ensure that the details on the specimen match those on the request form.

The origin of the request must be an authorised body and not an individual member of the public.

3.3 List of tests available and target turnaround times

We offer a comprehensive range of assays for the rapid detection of pathogens and host responses. We also offer viral load quantitation, genotyping and drug resistance typing for certain pathogens, please see the list below for details.

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.

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

Test	Target turnaround
16S rRNA bacterial gene	3 days
16S rRNA bacterial gene sequencing	3 days
Acanthamoeba DNA	Next day
Adenovirus DNA	Same day
Adenovirus DNA quantitation	Same day
Adenovirus typing	3 days
Aspergillus genus DNA	2 days
Bordetella genus DNA	Same day
Bordetella pertussis DNA	Same day
Borrelia burgdorferi antibody	6 days
Borrelia burgdorferi DNA	Same day
Brucella antibody	6 days
Brucella genus DNA	Next day
Candida albicans DNA	2 days
Chlamydia pneumoniae DNA	Next day
Chlamydia psittaci DNA	2 days
Chlamydia trachomatis DNA	2 days
Cryptococcus neoformans DNA	Next day
Cytomegalovirus DNA	Same day
Cytomegalovirus DNA quantitation	Same day
Cytomegalovirus ganciclovir resistance	2 days
Enterovirus RNA	Same day
Epstein Barr Virus DNA	Same day
Epstein Barr Virus DNA quantitation	Same day

Test	Target turnaround
Factor V Mutations + Prothrombin	4 days
Familial Mediterranean Fever	Same day
Forensic DNA Profiling - from swabs or tissue	10 days
Forensic DNA Profiling - from bone or teeth	10 days
Group A Streptococcus (<i>S.pyogenes</i>) DNA	Next day
Group B Streptococcus (<i>S. agalactiae</i>) DNA	Next day
Haemochromatosis	2 days
Haemophilus ducreyi DNA	Next day
Haemophilus influenzae/parainfluenzae DNA	Same day
Hepatitis B core antibody	2 days
Hepatitis B drug resistance mutation screen	2 days
Hepatitis B e antibody	2 days
Hepatitis B e antigen	2 days
Hepatitis B surface antibody	2 days
Hepatitis B surface antigen	2 days
Hepatitis B virus DNA	Next day
Hepatitis B virus DNA quantitation	Next day
Hepatitis B genotyping	3 days
Hepatitis C antibody (EIA)	2 days
Hepatitis C antibody (RIBA)	2 days
Hepatitis C genotyping	3 days
Hepatitis C virus RNA	Next day
Hepatitis C virus RNA quantitation	Next day
Hepatitis D virus RNA	4 days
Herpes Simplex virus DNA	Same day
Herpes Simplex virus types I & II typing	Next day
Herpes Simplex virus DNA on GUM swabs	Next day
Herpes Simplex virus typing on positive swabs	Next day
HIV I & II antibody and p24 antigen (EIA)	2 days
HIV I & II antibody (LIA)	2 days
HIV I & II antibody (LIA) - saliva	2 days
HIV-1 LTR, env, gag and pol genes	2 days
HIV-1 RNA drug resistance	9 days
HIV-1 RNA quantitation	Next day
HTLV I & II antibody	2 days
Human Herpesvirus 6 DNA	Same day
Human Herpesvirus 6 DNA quantitation	Same day
Human Herpesvirus 7 DNA	Same day
Human Herpesvirus 8 DNA	Same day
Human Herpesvirus 8 DNA quantitation	Same day
Human metapneumovirus RNA	Same day
Influenza A/B virus RNA	Same day
Influenza virus typing i.e. H1N1 pandemic strain	2 days

Test	Target turnaround
Leptospira genus DNA	Next day
Listeria monocytogenes DNA	Same day
Measles IgG antibody	2 days
Measles virus RNA	Same day
Mumps IgG antibody	2 days
Mumps virus RNA	Same day
Mycobacterium avium complex\TB complex DNA	Next day
Mycobacterium genus DNA	4 days
Mycobacterium TB rifampicin resistance	3 days
Mycoplasma genitalium DNA	2 days
Mycoplasma genus DNA	Next day
Mycoplasma pneumoniae DNA	Next day
Neisseria gonorrhoeae DNA	2 days
Neisseria meningitidis DNA	Same day
Neisseria meningitidis DNA typing	3 days
Papillomavirus DNA	3 days
Papillomavirus DNA typing	3 days
Parainfluenza 1 viruses (1,2,3,4) RNA	Same day
Parechovirus RNA	Same day
Parvovirus B19 DNA	Same day
Parvovirus B19 DNA quantitation	Next day
Paternity Testing	7 days
Pneumocystis carinii (aka jiroveci) DNA	Next day
Polyoma BK virus DNA	Same day
Polyoma BK virus DNA quantitation	Same day
Polyoma JC virus DNA	Same day
Propionibacteria/Actinomyces DNA	2 days
Prothrombin Mutations + Factor V Mutations	4 days
Respiratory Syncytial Virus RNA	Same day
Rhinovirus RNA	Same day
Rubella IgG antibody	2 days
Rubella virus RNA	Same day
Staphylococcus genus DNA	2 days
Streptococcus pneumoniae DNA	Same day
Toxoplasma gondii DNA	Same day
Toxoplasma IgG antibody	2 days
Treponema pallidum (syphilis) antibody	2 days
Treponema pallidum DNA	Same day
Trichomonas vaginalis DNA	Next day
Tropheryma whippelii DNA	Next day
Ureaplasma urealyticum/parvum DNA	2 days
Varicella Zoster virus DNA	Same day
West Nile Fever virus RNA	Same day

3.4 Sensitivity of DNA/RNA Detection Methods

The sensitivity of such tests depends on the quality of the sample and the test performed.

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* testing, for example.

3.5 Genetic testing

Genetic services provide the following tests:

- Familial Mediterranean Fever
- Forensic DNA Profiling
- Haemochromatosis: HFE Gene Mutations
- Paternity Testing: Including Twin Zygosity Testing
- Prothrombin and Factor V Mutations

A minimum of 200ul 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 our website (www.micropathology.com) or contact the laboratory for further 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.

3.6 Suitable sample types and volumes

If you are unsure of the suitability of a particular sample, please contact us.

Wherever possible, please send at least 200µl of liquid sample for testing unless otherwise stated (see table on following pages). We will test low volume samples but reports will bear a caveat regarding the potential effect on assay sensitivity.

Fresh blood in plain or gel tubes is best left at room temperature to clot. **DO NOT FREEZE OR OVERCOOL ANY WHOLE BLOOD SAMPLES.**

Severe haemolysis may compromise the results of serology assays.

Red blood cells are markers for white blood cell contamination of the sample. This may affect the results of HIV-1 viral load assays.

Target	Preferred Sample
Blood-borne viral infections	
HCV and HBV (including detection, quantitation, genotyping and resistance screening)	Plasma or serum
HIV-1 proviral DNA or RNA (i.e. for primary diagnosis)	EDTA whole blood
HIV-1 RNA Quantitation	This test requires at least 1mL of sample. Blood should be taken into EDTA tubes. The plasma should be separated within 24 hours of blood collection and shipped at room temperature for next day delivery.
HIV-1 Anti-Retroviral drug resistance screening	This test requires at least 500µl of sample. Blood should be taken into EDTA tubes. The plasma should be separated within 24 hours of blood collection and shipped at room temperature for next day delivery.
Respiratory infections	
Respiratory viruses or bacteria	Any respiratory specimen is acceptable e.g. sputum, BAL, NPA, nasopharyngeal swab etc.
Genitourinary infections	
Chlamydia/gonococcus (female)	Endocervical swab + first pass urine*
Chlamydia/gonococcus (male)	Urethral swab + first pass urine*
Chlamydia/gonococcus and HPV	Endocervical swab sent in plain tube or 'thin prep' endocervical cellular specimens
Herpes simplex infection	Endocervical or vulval lesions: rub a dry swab over the area and return it to a plain DRY holder
Infections associated with post-transplant or immunocompromised patients	
CMV or EBV DNA viral load	EDTA whole blood or serum (plain or gel tube). EDTA is ideal but serum will be acceptable.
Adenovirus (quantitation)	EDTA whole blood

Target	Preferred Sample
Infections associated with post-transplant or immunocompromised patients (continued)	
Adenovirus (detection and genotyping)	Any appropriate sample (please contact us if unsure)
HHV6 (detection and/or quantitation)	EDTA whole blood (CSF in encephalitis)
HHV6 (detection of integrated HHV6)	Hair follicles <u>and</u> EDTA whole blood (please contact the laboratory if you require guidance)
Polyoma BK	EDTA whole blood or urine
Polyoma JC	EDTA whole blood, CSF or urine
Infections important in pregnancy	
Parvovirus	EDTA whole blood, amniotic fluid
Toxoplasma gondii	EDTA whole blood, amniotic fluid
Cytomegalovirus	EDTA whole blood, amniotic fluid, cervical swab
Rubella	EDTA whole blood, serum (for antibodies)
Herpes Simplex Virus	Vulval/vaginal swab
Intracellular organisms	
Tropheryma whippelii	Almost any cellular material is acceptable including EDTA whole blood. PLEASE DO NOT SEND SERUM.

* We can process specimens together as one for economy: the two separate sites of sampling increase the sensitivity of the test, please state on the request form that you would like the samples combined. We will also accept single samples.

3.7 Specimen transport

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.**

Appropriate address labels for both destination and sender 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.

Please remember that it is the responsibility of the sender to comply with both UK postal regulations for clinical specimens and/or international safety regulations.

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 take part in the following external quality assurance schemes:

United Kingdom National External Quality Assessment Service

- Anti HBs detection
- HBV serology
- Blood borne virus serology
- HIV1 RNA Quantitation
- HPV DNA
- Rubella IgG serology
- Toxoplasma IgG serology
- Virus identification
- HFE typing (Haemochromatosis)
- Molecular genetics of thrombophilia

Quality Control for Molecular Diagnostics

- Adenovirus DNA
- Aspergillus DNA

- Bordetella pertussis DNA
- Chlamydia pneumoniae DNA
- Chlamydia trachomatis DNA
- Coronavirus RNA
- CMV DNA
- EBV DNA
- Enterovirus RNA
- HBV DNA
- HBV genotyping
- HCV genotyping
- HCV RNA
- HHV6 DNA
- HIV drug resistance typing
- HIV-1 DNA
- HIV-1 RNA quantitation
- HSV DNA
- Influenza A and B RNA
- Metapneumovirus RNA
- Mycobacterium DNA
- Mycoplasma pneumoniae DNA
- Neisseria gonorrhoeae DNA
- Parechovirus RNA
- Parvovirus B19 DNA
- Polyoma JC and BK virus
- RSV DNA
- Toxoplasma gondii DNA
- VZV DNA
- West Nile Virus DNA

International Society for Forensic Genetics

- Paternity testing

If you have any questions about our quality management system please contact our Quality Manager, Dr Joanne Mitchell.

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.

6. Results and Reports

Results are faxed to users between 16:00 and 18:00 daily.

The primary delivery method of results is to a designated secure fax number; however we can e-mail the results to you as PDF attachments.

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

Unless specifically requested not to do so, we will send you hard copies of the week's results by first class post. These are normally dispatched over the weekend.

7. Payment for services

7.1 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.

7.2 Acceptable Methods of payment

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