Micropathology Ltd

An independent, UKAS accredited, diagnostics and biomedical research laboratory

Accreditation number 9622

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9622%20Medical%20Single.pdf

Laboratory User Handbook

August 2019

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Reviews

26th June 2017 – A reviews section added. Details added to the 'Sending samples to the laboratory' section detailing that it is the responsibility of the referring laboratories to ensure all samples are received to preserve their integrity. Details added of respiratory screen panel, Measles IgG antibodies and Lymphogranuloma venereum tests to test table. Updated external referral laboratories list. Staff list and external referral laboratory list updated.

6th July 2017 – Correction to spelling of Lymphogranuloma venereum in review section and test table. Also addition of throat swab to list of sample types for LGV.

21st July 2017 – Addition of a new test, HCV NS5a resistance, addition of a new member of staff and clarification of inhibitory urine samples for HSV and Chlamydia trachomatis in section 3.6iv. Clarification of urines as an unacceptable sample type for HSV testing and removal of 'first pass' urines as a sample type for Neisseria gonorrhoeae in the test table.

12th February 2018 - Amend TAT table following TAT audit. Replacement of CPA logo to UKAS accreditation logo. UKAS details added into the introduction section. Amended staff details. Added details into the transportation of samples area. Correction of sample types for HIV drug resistance. HBV AB detection sample types updated. Removal of External Referral laboratories section and removal of external serology tests from test table. Removal of Burkholderia cepacia detection and typing, Measles and Rubella IgG testing. Burkholderia cepacia typing removed from sequencing services. Updated EQA panel participation for 2017. Information added into the genetic testing that required for paternity testing. Formatting update of entire document.

15th March 2018 – Update to sample requirements for Hepatitis B E antigen, addition of whole blood as a sample type to Mycoplasma pneumoniae test. Added details to results section for release of results by telephone to other hospital departments. Details included re addition of tests from hospital departments to requesting tests sections. Amendment to retention of samples from several months to 6 weeks. Formatting of section titles to accurately reflect content in the contents table.

14th May 2018 – Changes to the test table include addition of Klebsiella pneumoniae test , addition of scheduling of serology tests, update of Streptococcus pneumoniae sample details, requirements to separate HBV, HCV and HDV serum / plasma from EWB within 24hours of taking blood sample to the test table. Detailed regarding of shipment of these samples also added.

Removal of external referral laboratories as the laboratory no longer refers samples. Sentence added to direct clients to ensure outer packaging box for samples is sealed.

21st May 2018 – Change of test name from 18srRNA fungal gene detection and sequencing to Pan fungal DNA detection / sequencing. Additional test requests - Request to users to ask them to confirm request for an additional sent by email, if they have not received a reply within 24hours.

6th July 2018 – Amendment to size of UKAS logo on front page to 20mm.
Addition of user feedback to section to include the companies house registration number and details of how to provide feedback on the service.
Update of test table HHV6 and HHV6 quantitation to remove requirement to send whole blood as preferred by removal of ***. Addition of 'research only' to particular tests in test table.
Removal of Burkholderia cepacia and cervical cytology from test table.

Update of sample requirements for tests.
Serology sample stability data added for antigens and antibodies.
Addition of ' at users request' to the HSV typing assay for eye and oral swab samples and clarification of exactly what samples can be tested for HSV typing.
Clarification of additional test requests to test requests table. Non-critical to be made by email. Critical test requests to be made by telephone.
Updated staff list.
Update of information required on request form and sample based on IBMS criteria.
Rework of the factors affecting assays section to added clarity.

3rd October 2018 revisions
Section 2.3 - Updated staff list.
Test table - Change to limit of sensitivity for HCV RNA and HCV RNA quantitation assays. Alterations to antibodies to HepE antigen assay sample requirements and associated stability in relevant stability table. BAL removed from HHV6.
Section 3.2 - Sending samples to the laboratory section reworked for clarity to detail modes of sample transportation and sample packaging.
Additional examination section in table in section 3.3 clarified to denote critical and non-critical tests.
Table 3.3 Addition of text 'strongly recommended' added to URGENT test section in table.
Section 3.6 addition of Category III organisms to samples that will undergo additional extraction procedures.
Creation of new section 3.7 – addition of preferable sample volume 500µL to facilitate additional extraction and testing, and instructions to send sufficient sample if requesting multiple tests.
Section 3.8i nucleic acid based tests - Addition of low sample volume details for nucleic acid tests in factors affecting samples section.
Section 3.8i nucleic acid based tests inhibition section - Removal of urines which may exhibit inhibition.
Section 3.8i nucleic acid based tests HIV-1, HBV and HCV section – Further detail in HIV-1, HBV and HCV section regarding separation of plasma from EDTA whole blood within 24hours of blood draw.
Reformatting of headings throughout document.
Removal of rubella antibody ranges from table in section 3.10.

4th October 2018 – Addition of Bartonella genus test to test table.

5th October 2018 – Addition of laboratory manager role in staff section. Addition of further details for sample volume required for HCV detection and quantitation tests to test table.

6th December 2018 – Addition of new staff. Addition of new test, UL54 for CMV drug resistance in test table. Addition of missing 'unaccredited logo' from Bartonella and HCV assay in test table. Correction of spelling of Tropheryma whipplei in test table. Updated EQA panels for 2018. Amended payment details to request BACS payments only in section 8. Clarification of testing urgent samples in section 3.2i and addition of request for users to inform the laboratory of possible infection with Cat3 organisms in request tests section.

7th December 2018 – Correct spelling of Tropheryma whipplei in test table.

13th February 2019 – Addition of new member of staff Dr Frances Pitt. Addition of details regarding sample retention. Increase in TAT for EV.Rh differentiation details added to subtext for Test table. Details for additional CtNg testing to LGV testing also specified in test table additional text. Section 3.6 and 3.7 switched around. Removal of Q80K from test table as no longer offered.

14th February 2019 - Addition of Michael Steele to staff list. Addition of whole blood to validated sample types in CMV drug resistance UL54 and UL97. Update of table page references.

1st April 2019 – Update of staff list to include Dr Mark Atkins and update job roles. Update of pan fungal test name to include (18S) in test table. Clarified that users should ensure samples are received by 9.30am to ensure that samples results will be released within the expected test turnaround times. Formatting of section 3.3. Add details of testing in combination of Ct and Ng into test table information.

26th April 2019 – Additional test added to test table to include *Mycoplasma genitalium* macrolide resistance. HHV6 test now detailed as detecting 6A and 6B types. Update of CMV drug resistance tests. Test table pagination reference in handbook updated throughout.

1st May 2019 – Addition of HHV7 quantitation tests to test table and Legionella pneumophila as a 'research only' test to test table.

7th May 2019 – Addition of a new staff member to staff list and amendment to Respiratory screen tests.

3rd June 2019 – Add details to the test table key that a maternal blood sample should be sent when testing infants <18 months old for HIV-1 proviral DNA / RNA. HBV assay details updated as new assay awaiting accreditation. Additional volume details added to hepatitis related tests in the test table.

12th June 2019 – Amended limit of detection of the HBV quantitation assay from 50IU/mL to 16IU/mL as detailed incorrectly.

6th August 2019 – Amendment to staff list and job titles. Alteration to sample volumes in test table. Change of name of forensic tests to human identification and removal of paternity test.

15th August 2019 - Amendment to name of test from "Human identification DNA profiling" to "Genetic profiling for human identification and relationship testing (Human ID DNA profiling)" and amendment of accompanying comment to "for identification of human remains, comparison of clinical samples and relationship testing (e.g. paternity, sibship or zygosity testing)". Removed forensic DNA profiling and paternity testing from list under 3.11 and replaced with genetic profiling for human identification and relationship testing. Detailed that genetic profiling for human identification and relationship testing can be performed on various sample types, but users should contact the laboratory for advice.

Contents

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 genetic profiling for human identification and relationship testing 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. The service is also available to HM Coroners (body identification) and University research groups.

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

The laboratory is UKAS accredited to ISO15189:2012 (Laboratory reference number 9622) and participates in all appropriate external quality assurance schemes. The published scope is available on https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9622%20Medical%20Single.pdf.

An 'out of hours' on-call clinical advice service is available for healthcare professionals to discuss specific 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 ISO15189:2012 international standard of accreditation 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, with telephone service in the laboratory from 9.00 – 17.45 hrs, when staff are available for advice, information, specimen reception and processing. Outside of these hours a

telephone service is provided for results and clinical advice. We also receive samples on Saturday mornings which are processed the following working day.

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

2.2 Location and visitors

Micropathology Ltd is located between the M6 and the M40, 4 miles outside of Coventry off the A45. Car parking is available at the Venture Centre and visitors are requested to report to reception 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	Prof. Colin Fink
Scientific / Laboratory Director	Dr David Burnett
Consultant Virologist / Microbiologist	Dr Mark Atkins
Clinical Scientist (Genetics)	Dr Sarah Ball
Clinical Scientist (Microbiology)	Dr Jennifer Morris-Cottell
Clinical Scientist (Virology)	Dr Paul Scott
Quality Manager	Dr Andrea Collins
Quality Lead	Ms Nagela Ford
Clinical Scientist & Company Representative	Ms Heather Smith
Laboratory Manager / Accession manager	Dr Mark Collery
Post-doctoral scientist	
Post-doctoral Scientist / Health & Safety Co-ordinator	Dr Sian Davies
Microbiology manager / Post-doctoral Scientist	Dr John Thomas
Virology Manager / Training officer	Dr Edward Sumner
Post-doctoral Scientist	
Serology Manager / Post-doctoral Scientist	Dr Penny Reid
Sequencing manager / Post-doctoral Scientist	Dr Jennie Holden
Equipment manager / Post-doctoral Scientists	Dr Ronan Calvez, Dr James Barnett

Post-doctoral Scientists	Dr Emily Hudson, Dr James Edwards-Smallbone, , Dr Jennifer Holden, Dr Michael Steele, Dr Frances Pitt , Dr Ollie Smith.
Post-doctoral Scientist/IT manager	Dr Peter Millichap
Research Post-doctoral Scientists	Dr Leo Calvo-Bado, Dr Marie Voice, Dr Richard Fetherston
IT systems architect	Mr Pete Matthews
Post-graduate scientists	Ms Rhiannon Weale, Miss Amelia Brett, Miss Annie Fletcher, Miss Ellie Philips.
Intercalated year students	Ms Meghan Strong, Ms Safah Parkar, Thamara Jeganathan Margaret McGroary, Robert Newell Karishma Supeda, Anis Uddin, Sophie Morris
Company accountant	Mrs Weiping Barrett
Administrative assistant	Ms Dawn Mason
Administration support	Dr Sue Webster
Administration and accounting support	Zhiwen Luo

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

3.2i Modes of transport

It is the responsibility of the sender to comply with courier, UK postal or international safety regulations for clinical specimens transport. To ensure the continued integrity of the specimen, it is the customers responsibility that samples

sent to Micropathology Ltd arrive safely and securely in a prompt manner. The results obtained for testing of samples is based upon the quality of the sample(s) as they are received at the laboratory

To ensure prompt testing of samples and release of results within the published test turnaround times (Pages 14-22), samples should arrive into the laboratory by 9.30a.m. The use of a courier service (Dx) is recommended, especially for URGENT and CRITICAL samples.

Samples sent by post arrive after the days sample processing has begun. In these instances samples will be processed on the next working day and not on the day of receipt into the laboratory. This will affect the test turnaround time between receipt into the laboratory and results reporting. Exceptions to this are CSF and whole blood samples requesting *Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae*, HSV, VZV and EV. These samples may undergo urgent processing and testing.

3.2ii Packaging samples

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**. **Please ensure that the outer box for transporting the specimen is also sealed.**

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, if required. Packaging materials will be returned for reuse if requested. Standard postal rates will apply to this service.

3.3 Requesting tests

Each test requested shall be considered an agreement. The company have a service level agreement for users and will consider any external service level agreements. Micropathology Ltd. shall inform users of any change to service which will impact on the examination result.

* Requests from hospital departments other than the referring laboratory must ensure the referring laboratory is aware of the additional request.

If it is suspected that the patient is positive for any Category 3 organism, please indicate this on the accompanying request form so that the sample can be handled appropriately upon receipt into the laboratory.

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. This will therefore affect the expected TAT.**
ADDITIONAL examinations * **Samples received <u>within</u> 24hrs (already under investigation)**	Additional **<u>non -urgent</u>** test requests can be requested by telephone, fax or email info@micropathology.com. Additional **<u>critical</u>** test requests should be made by telephone 024 76323222. Additional test requests received after midday, on samples currently under investigation, may be subject to processing and testing on the next working day. If sending a request by email, please contact to the laboratory within 24 hours if you have not received a email reply to your request.	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</u> 48 hours ago (archived samples)**	Specimens are archived at -20^{o}C for 6 weeks. Additional examinations may be requested on these samples where there is sufficient volume remaining.	Additional requests on samples received more than 48hours previously may require full sample extraction and processing and will attract full sample costs.
URGENT requests	Many off our samples are reported the same day. If something is especially urgent please advise. **PLEASE DO NOT SEND URGENT SAMPLES BY POST DUE TO THE LATE ARRIVAL OF THE POST. A COURIER IS STRONGLY RECOMMENDED AS A MORE TIMELY MODE OF TRANSPORT FOR URGENT SAMPLES.**	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).

3.4 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	1. Patient's full name or unique code identifier 2. Date of birth 3. NHS reference number	1. Date and time of sampling 2. Nature of sample i.e. left eye swab 3. Lab reference number
Request form	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.	1. Clinical information including relevant treatment/medication 2. Date and time of sample 3. Hospital number

* Failure to provide sufficient contact referral laboratory details will result in samples being enter into the LIMS as 'Micropathology Ltd 'unidentified source' until such time as a client contacts the laboratory seeking results.

3.5 Patient confidentiality

All samples received are treated in the strictest confidence and are anonymised upon receipt into the laboratory. Prof. 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 General Data Protection Regulation (EU) 2016/679 and Freedom of Information Act.

3.6 Sample volume and handling

Unless stated otherwise in the test table, please send at least **200µL** of liquid sample for testing**, preferably 500µL to facilitate additional extraction and testing**,. Low volume samples may be diluted and tested, but reports will bear a caveat regarding the potential effect on assay sensitivity. Sending sufficient sample is imperative when requesting multiple tests.

For tissue samples; please send a matchstick head 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 client 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.

Portions of samples are retained for 6 weeks to facilitate repeat or additional testing. The exception to this are wax embedded samples which are retained indefinitely. We do however, advise sending block shavings rather than the whole wax block.

Samples may be stored for longer if there is an explicit agreement between the user and Micropathology Ltd. This can be achieved through a service level agreement. Please contact the laboratory for further information.

3.7 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 14-22 for details of tests offered, test turnaround time and appropriate validated sample types. Other unvalidated sample types can be tested but the sensitivity cannot be guaranteed to be at the same limit of detection.

Test turnaround time is based on a Monday to Friday working week. Saturday/Sundays are not included in TAT calculations. Some tests are scheduled throughout the week and these are detailed in the test table. All other assays are run on a daily basis.

The company expect that 90% of test results will be available with the defined TAT. However, a proportion of tests require repeat for confirmation of rare / weak or 'off scale' positives and will result in a delay in reporting results. Additional tests may be added late in the day (Post midday) due to external or internal factors and requests. In these instances results for tests may incur a delay in results being made available to users and will affect TAT.

Additionally, those samples requiring special extraction procedures (Tissues, post mortem samples, stools, eye samples, Category III organisms) due to the nature of the sample or test requested, may incur a delay in reporting results to that of the published TAT.

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.

Prices can be accessed by users registered on our website.

Key for test table

▲ Currently not UKAS accredited

♦ EDTA Plasma separated within 24 hours of initial collection of blood. Ship at ambient temperature for next day delivery.

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

**** - Individual requests for Ct or Ng are always tested in combination with Ng or Ct respectively.

***** - All LGV requests are also tested for Ct and Ng.

****** - A paired maternal blood sample should be sent when testing infants <18 months old for HIV-1 proviral DNA / RNA.

Θ- Respiratory panel comprising of Influenzae A and B, Respiratory syncytial virus A and B, Parainfluenza 1 – 4, Human metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Human Bocavirus. The extended respiratory screen is comprised of the aforementioned organisms with Coronavirus OC43, 229E, NL63 and HKU1 additional testing. Please note, Influenza A positives▲ can be differentiated between H1 and H3 subtypes. If required this can be reported. Differentiation of Rhinovirus/Enterovirus will incur an extra day TAT to facilitate additional testing.

Ψ Please note; when Measles RNA, Rubella RNA, *Neisseria meningitidis* DNA or *Bordetella pertussis* DNA are detected within a specimen, the sample will be forwarded to Public Health England to comply with their requirements.

Abbreviations used in test table

ACD – Acid citrate dextrose
BAL – Bronchioalveolar lavage
CPD – Citrate phosphate dextrose
CPDA – Citrate phosphate dextrose adenine
CP2D - Citrate phosphate double dextrose
CSF – Cerebrospinal fluid
EDTA - Ethylenediaminetetraacetic acid

Test repertoire, test turnaround, validated sample types.

Tests available		
Test	**Target turn-around**	**Validated Sample types**
Client sample postage: returns and forwarding to PHE	Next day	Any$^{\Psi}$
16S rRNA bacterial gene detection	2 days	Any (inc. fixed tissue) preferably from normally sterile sites
16S rRNA bacterial gene sequencing	2 days	PCR product (see detection above) or bacterial culture
Pan fungal (18S) DNA detection	3 days	Any (inc. fixed tissue) preferably from normally sterile sites
Pan fungal (18S) DNA sequencing	3 days	PCR product (see detection above) or fungal culture
Acanthamoeba DNA	2 days	For eyes - Corneal scrape, swab or contact lens, contact lens solution Meningitis - CSF
Adenovirus DNA	Next day	Vitreous fluid, eye fluid, serum, skin swab, blood, plasma, urine, bronchial washings, NPA, swab (Nose, throat, eye), CSF, pericardial fluid, bone marrow.
Adenovirus DNA quantitation	Next day	EDTA/citrated whole blood, CSF and plasma
Adenovirus typing (Research only)	5 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	5 days	EDTA/citrated whole blood/ lower respiratory sample ((BAL, bronchial washings, sputum)
Bartonella genus ▲	2 days	EDTA whole blood, tissue
Bocavirus	Next day	Any upper / lower respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Bordetella pertussis DNA	2 days	NPA, perinasal and nasopharyngeal swab
Borrelia genus	2 days	EDTA/citrated whole blood, CSF, skin biopsy
Brucella genus DNA	3 days	EDTA/citrated whole blood, CSF, tissue. **We do not accept cultures for safety reasons**
Candida albicans DNA	2 days	EDTA/citrated whole blood, CSF, eye fluid
Chlamydia pneumoniae DNA	Next day	Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Chlamydia psittaci DNA	2 days	BAL, nasopharyngeal swab
Chlamydia trachomatis DNA ****	2 days	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

Tests available		
Test	**Target turn-around**	**Validated Sample types**
If sending for confirmation in accordance with BASHH guidelines, please telephone the laboratory for further information.		
Clostridium difficile (Research only)	3 days	Stool
Coronavirus 229E, HKU1, NL63 or OC43	Next day	Any upper / lower respiratory sample
Coxiella burnetii	Next day	EDTA whole blood, BAL and tissues. **We do not accept cultures for safety reasons.**
Cryptococcus neoformans DNA	Next day	CSF, EDTA whole blood
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 drug resistance (ganciclovir, foscarnet or cidofovir) (UL97 and UL54)	5 days	Whole blood, serum / plasma
Enterovirus RNA	Next day	CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood - may be useful in suspected meningitis cases
Enterovirus typing (Research only)	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, biopsy,
Epstein Barr Virus DNA quantitation	Same day	EDTA/citrated whole blood, CSF, urine, serum, plasma
Escherichia coli DNA	2 days	CSF, EDTA/citrated whole blood
Factor V Mutation + Prothrombin	5 days	EDTA / citrated whole blood
Genetic profiling for human identification and relationship testing (Human ID DNA Profiling)- extraction from bone or teeth - For identification of human remains, comparison of clinical samples and relationship testing (e.g. paternity, sibship or zygosity testing)	15 days	Bone/teeth

Tests available		
Test	**Target turn-around**	**Validated Sample types**
Genetic profiling for human identification and relationship testing (Human ID DNA Profiling) - For identification of human remains, comparison of clinical samples and relationship testing (e.g. paternity, sibship or zygosity testing)	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	2 days	Swab
Haemophilus influenzae/parainfluenzae DNA	Next day	CSF, EDTA/citrated whole blood.
HBV Core/PreCore Mutations	5 days	Serum/plasma
Hepatitis B core antibody (Tests schedule Monday and Thursday)	3 days	Li-heparin, Na-heparin, K2-EDTA, K3-EDTA, ACD, CPD, CP2D, CPDA and Na-citrate plasma
Hepatitis B e antibody (Tests schedule Monday and Thursday)	3 days	Li-heparin, Na-heparin, K2-EDTA, K3-EDTA, ACD, CPD, CP2D, CPDA and Na-citrate plasma
Hepatitis B e antigen (Tests schedule Monday and Thursday)	3 days	Serum preferred or Na-heparin*, Li-heparin*, K2-EDTA, K3-EDTA, ACD, CPD, CP2D, CPDA and Na-citrate plasma.
Hepatitis B drug resistance mutation screen ♦	5 days	Serum/plasma Please supply viral load if available.
Hepatitis B surface antibody (Tests schedule Monday and Thursday)	3 days	Serum preferred or K2/K3EDTA plasma **
Hepatitis B surface antigen (Tests schedule Monday and Thursday)	3 days	Serum preferred or Li-heparin*, Na-citrate, K2/K3- EDTA, CPDA, CPD, CP2D, ACD, citrate plasma.
Hepatitis B surface antigen quantitation	3 days	Serum preferred or Li-heparin*, Na-heparin*, K2-EDTA, citrate plasma

Tests available		
Test	**Target turn-around**	**Validated Sample types**
(Tests schedule Monday and Thursday)		
Hepatitis B virus DNA **(<16IU/mL)** ♦ ▲	Next day	**At least 0.6mL** serum/plasma
Hepatitis B virus DNA quantitation **(<16IU/mL)** ♦ ▲	Next day	**At least 0.6mL** serum/plasma
Hepatitis B genotyping ♦	3 days	**At least 0.6mL** serum/plasma
Hepatitis C antibody (EIA) (Tests schedule Monday and Thursday)	3 days	serum preferred or Li-heparin*, K2/K3-EDTA, Na-heparin, Na-citrate, CPDA, CPD, CP2D, and ACD plasma.
Hepatitis C antibody (RIBA) (Tests schedule Monday and Thursday)	3 days	Serum preferred or Li-heparin*, citrate or EDTA plasma
Hepatitis C NS5A resistance testing ♦	4 days	**At least 0.6ml** serum/plasma Please supply viral load if available.
Hepatitis C genotyping ♦	3 days	**At least 0.6mL** serum/plasma Please supply viral load if available.
Hepatitis C virus RNA **(<15IU/ml)** ♦ ▲	Next day	**At least 0.7ml serum/plasma, 1ml is preferable**. Please send more sample if other tests are required.
Hepatitis C virus RNA quantitation **(<15IU/ml)** ♦ ▲	Next day	**At least 0.7ml serum/plasma, 1ml is preferable**. Please send more sample if other tests are required.
Hepatitis D virus RNA ♦	3 days	**At least 0.6mL** serum/plasma This assay should always be reviewed in conjunction with HBV investigations.
Hepatitis D virus RNA quantitation ♦	3 days	**At least 0.6mL** serum/plasma. This assay should always be reviewed in conjunction with HBV investigations.
Hepatitis E virus RNA	2 days	**At least 0.6mL** serum/plasma, CSF, whole blood, stool
Hepatitis E virus RNA quantitation	2 days	**At least 0.6mL** serum/plasma, CSF, whole blood
Herpes Simplex virus DNA ▲	Next day	CSF, AC tap, EDTA/citrated whole blood, vesicle fluid, skin/eye/corneal vesicle/lesion swab, tissue (Biopsy and fixed included). Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc) . aqueous / vitreous humour. 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. Urine is not a recommended sample type for diagnosis of infection in male or females. Pregnancy – vulval/vaginal swab

Tests available		
Test	**Target turn-around**	**Validated Sample types**
Herpes Simplex Acyclovir drug resistance	5 days	HSV-1 positive samples, including CSF, Corneal scrapes, vesicle fluid, swabs, and whole blood
Herpes Simplex virus types I & II typing ▲	Next day	Performed routinely on positive HSV samples (including CSF, amniotic fluid, EDTA/citrated-whole blood, vesicle fluid, skin/lesion swab, tissue samples and biopsies, any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc). HSV positive eye samples and oral swabs are typed upon request. Specific requirements for genitourinary samples: Males: Penile lesions-penile swabs placed into VTM. Females: Endocervical or vulval lesion swabs placed into VTM. In pregnancy, vulval/vaginal swabs placed into VTM. **Urine** is not a recommended sample type for the diagnosis of infection in male or female patients.
HIV I & II antibody and p24 antigen (EIA) (Tests schedule Monday and Thursday)	3 days	Serum preferred or Li-heparin*, EDTA, ACD, CPD, CP2D, CPDA and Na-citrate plasma
HIV I & II antibody (LIA) (Tests schedule Monday and Thursday)	3 days	Serum preferred or Li-heparin*, citrate or EDTA plasma
HIV I & II antibody (LIA) – saliva (Tests schedule Monday and Thursday)	3 days	Saliva
HIV-1 proviral LTR, env, gag and pol genes	2 days	EDTA whole blood preferred or serum/plasma, CSF▲
HIV-1 RNA drug resistance ♦	9 days	Serum/plasma**. This test requires at least 600µL of sample**. Please supply viral load if available.
HIV-1 RNA Integrase drug resistance ♦	9 days	Serum/plasma**. This test requires at least 600µL of sample**. Please supply viral load if available.
HIV-1 RNA quantitation ♦	3 days	EDTA Plasma, CSF. **Please supply 2mL EDTA plasma.**
HIV-2 proviral LTR and pol DNA/RNA*****	2 days	EDTA whole blood preferred or serum/plasma, CSF▲
HTLV I & II antibody (Tests scheduled Wednesday)	2 days	Serum preferred or EDTA, citrate plasma
HTLV DNA or RNA	3 days	EDTA/citrated whole blood or CSF
Human Herpesvirus 6A and 6B DNA	Next day	EDTA/citrated whole blood (CSF in encephalitis), bone marrow biopsies, , plasma, serum
Human Herpesvirus 6 DNA quantitation	Next day	EDTA/citrated whole blood (CSF in encephalitis), bone marrow, plasma, serum

Tests available		
Test	**Target turn-around**	**Validated Sample types**
Human Herpesvirus 7 DNA	Next day	EDTA/citrated whole blood, CSF, plasma***, serum***
Human Herpesvirus 7 DNA quantitation	Next day	EDTA/citrated whole blood, CSF, plasma***, serum***
Human Herpesvirus 8 DNA	Next day	EDTA/citrated whole blood, plasma***, serum***
Human Herpesvirus 8 DNA quantitation	Next day	EDTA/citrated whole blood, plasma***, serum***
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 upper / lower respiratory specimen
Influenza B virus RNA	Same day	Any upper / lower respiratory specimen
Legionella pneumophila (Research only)	Same day	Any upper / lower respiratory specimen
Leptospira genus DNA	3 days	CSF, EDTA/citrated whole blood, urine
Lymphogranuloma venereum *****	4 days	Male - first catch urine, genital swab, rectal swab, throat swab, rectal biopsy/tissue, lymph node tissue/biopsy. Female - genital swab, throat swab, rectal swab, rectal biopsy/tissue, lymph node tissue/biopsy
Listeria monocytogenes DNA	Next day	CSF, EDTA/citrated whole blood - may be useful in suspected meningitis cases
Measles virus RNA	Next day	CSF, urine, saliva, mouth/throat swab, whole blood
Mumps IgG antibody (Tests schedule Wednesday)	4 days	Serum preferred or citrate plasma
Mumps virus RNA	Next day	CSF, urine, saliva, mouth/throat swab
Mycobacterium avium complex\TB complex DNA	2 days	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 genitalium macrolide resistance	4 days	Samples positive for Mycoplasma genitalium

Tests available		
Test	**Target turn-around**	**Validated Sample types**
Mycoplasma genus DNA	4 days	CSF, EDTA/citrated whole blood, tissue culture
Mycoplasma pneumoniae DNA	Next day	EDTA whole blood and any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Neisseria gonorrhoeae DNA **** If sending for confirmation in accordance with BASHH guidelines, please telephone the laboratory for further information.	2 days	Eye swab For genitourinary: Female: Endocervical, vaginal or rectal swab, 'Thin prep' endocervical cellular specimens. Male: Urethral swab, first pass urine, 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 upper / lower respiratory specimen
Parechovirus RNA	Next day	CSF, swab, stool, tissue, serum, plasma, EDTA/citrated whole blood - may be useful in suspected meningitis cases
Parvovirus B19 DNA	Next day	EDTA/citrated whole blood, amniotic fluid, serum/plasma, post-mortem samples (Foetal), CSF, bone marrow
Parvovirus B19 DNA quantitation	Next day	EDTA/citrated whole blood, amniotic fluid, serum/plasma, CSF
Pneumocystis jirovecii (aka carinii) DNA	Next day	Sputum, BAL, 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, urine, CSF
Polyoma JC virus DNA quantitation	Next day	EDTA/citrated whole blood, urine, CSF
Propionibacteria/Actinomyces DNA	2 days	Eye sample, tissue, CSF
Pseudomonas aeruginosa▲	Next day	EDTA whole blood, corneal scrape, eye swab, contact lens or contact lens solution
Respiratory Syncytial Virus RNA	Same day	Any upper / lower respiratory specimen
Respiratory Virus Screen See Θ above	Next day	Any upper / lower respiratory specimen
Extended respiratory screen. Respiratory screen detailed above with additional Coronavirus OC43, 229E, NL63 and HKU1 testing		Any upper / lower respiratory specimen
Rhinovirus RNA	Same day	Any upper / lower respiratory specimen

Tests available		
Test	**Target turn-around**	**Validated Sample types**
Rhinovirus typing (Research only)	3 days	Any positive Rhinovirus respiratory specimen
Rubella virus RNA	Next day	CSF, EDTA/citrated whole blood, throat swab, urine, amniotic fluid
Salmonella enterica (Research only)	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	Whole blood, CSF and pleural fluid
Toxoplasma gondii DNA	Same day	CSF, EDTA/citrated whole blood, amniotic fluid, aqueous/vitreous humours, tissue
Toxoplasma IgG antibody (Tests schedule Monday and Thursday)	5 days	Serum preferred or Li-heparin*, K3-EDTA or citrate plasma
Treponema pallidum DNA	Next day	CSF, genital swab
Trichomonas vaginalis DNA	Next day	Genital swab
Tropheryma whipplei 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 (Biopsy and fixed included). Any respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), aqueous / vitreous humour. 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, EDTA whole blood

3.8 Factors affecting assays

3.8i Nucleic acid based tests

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

Low volume samples

The laboratory may receive low volume samples. However, these may be diluted for extraction and testing. The result report will bear a suitable caveat alerting the user to this. It is recommended that users send the required volume for extraction and testing.

Extracted samples

These samples extracted elsewhere 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.

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. EDTA samples are preferred.

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.

Cotton-tipped or calcium alginate swabs are not acceptable should not be used for sample collection as residues present in these materials may inhibit PCR assays (CDC, 2015).

We are able to detect if inhibition has occurred and we report accordingly.

Sample instability

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

Handling samples for HIV-1, HBV and HCV

For test requests on HCV, HBV detection, drug resistance, genotyping and quantitation and/or HIV drug resistance and quantitation, please supply separated plasma. When separating plasma from EDTA whole blood by centrifugation, please perform the separation within 24 hours of sample collection.

This is important to provide accurate viral load measurements of cell-free circulating infectious virus. 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. Additionally HIV-1, HBV and HCV viruses are subject to degradation in blood samples in which plasma is not separated within the 24hour from blood draw which can lead to inaccurate qualitative and quantitative results.

If samples are not separated before sending to Micropathology Ltd., please ensure arrangements are in place to send the sample to us within 24 hours of collection to prevent virus degradation during transit.

Separated plasma samples should not be frozen if there is to be a short delay between separation and sending to the laboratory, as freeze-thawing samples can result in virus DNA/RNA degradation. If a delay in sending the sample is unavoidable, please refrigerate the plasma and send it to us via an appropriate cold-chain courier.

3.8 ii 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.

Antibodies and antigens are only stable for a particular length of time after sample taking and serum separation. Please take note of the test table below and the scheduling of the serology assays to ensure that samples are transported to ensure the integrity of the sample.

Assay	**Sample stability**
HCV antibodies	3 days (25ºC), 7 days (2 - 8ºC), 3 mths (-20ºC)
HIV I and II antibodies	7 days (25ºC), 4 weeks (2 - 8ºC), 3 mths (-20ºC)
HBV surface antigen	5 days (2 - 8ºC), 3 mths (-20ºC)
HBV surface antigen quantitation	7 days (2 - 8ºC), 3 mths (-20ºC)
HBV Core antibody	7 days (15-25ºC), 14 days (2 - 8ºC), 3 mths (-20ºC)
HBV E Antigen	7 days (20-25ºC), 14 days (2 - 8ºC) (plasma) 11 days (2 - 8ºC) (serum) 3 mths (-20ºC) (both)
HBV E antigen antibodies	7 days at 20-25 °C, 14 days at 2-8°C, 3 months at -20 °C (± 5 °C).
HBV surface antibodies	3 days (20-25ºC), 6 days (2 - 8ºC), 3 mths (-20ºC)
Toxo IgG Antibody	3 days (25ºC), 3 weeks (2 - 8ºC), 3 mths (-20ºC)

3.9 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 14-22).
2 Of sufficient volume for testing.
3 Correctly matched information on sample and request form.
4 Sufficient patient/source identification (Table on page 11).

Samples maybe 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.

If any of the above rejected samples are tested, 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 email.

*Samples will be rejected outright if they appear to contain no sample. Users will be contacted.

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

3.10 Reference values for Serological assays

Reference values for 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	≥ 0.9 - < 1.0
HIV combi	1.0	≥ 1.0	< 0.9	≥ 0.9 - < 1.0
HBsAg II	1.0	≥ 1.0	< 0.9	≥ 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
Toxoplasma	0.13 – 650 IU/mL (13,000 IU/mL if diluted 1:20)	≥ 3 IU/mL	< 1 IU/mL	≥ 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.

3.11 Human genetic testing

Genetic services provide the following tests:

- Genetic profiling for human identification and relationship testing
- Haemochromatosis: HFE Gene Mutations
- 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 (preferably 500µL to facilitate additional extraction and testing) of EDTA or citrated whole blood is required for these tests with the exception of genetic profiling for human identification and relationship testing, which can be performed on various sample types. Please 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.

3.11i 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 an 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

When sending samples for testing family relationships, such as paternity or maternity testing, sibship analysis and twin zygosity testing, please clearly describe the

suspected relationships including half-sibship status and provide full names and dates of birth of all individuals involved to avoid unnecessary confusion or delays caused by the need to carry out extensive fact checking.

3.12 Sequencing service

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

- Adenovirus typing
- Cytomegalovirus ganciclovir, foscarnet and cidofovir resistance
- Enterovirus / Rhinovirus typing
- H1N1 confirmation
- HBV Genotyping
- HBV Core/PreCore Mutation screening
- HBV drug resistance mutation screening
- HCV Genotyping
- HCV NS5A drug resistance
- Herpes Simplex Acyclovir drug resistance
- HIV-1 RT/Protease/Integrase drug resistance mutation analysis
- HPV genotyping
- Rhinovirus typing
- 16srRNA and 18srRNA gene 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.

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 (2018):

United Kingdom National External Quality Assessment Service

- Anti-HBsAg
- Blood-Borne Virus donor screen (serology for hepatitis C Ag and AB, hepatitis B (HBVSAg, Anti-HBV Core), HIV 1 and 2 Ag and AB (including p24), HTLV 1 and 2 AB
- Fungal biomarkers
- HepB serology (Surface antigen, 'e' antigen, 'e' antibody, core antibody)
- HFE (Haemachromatosis) H63D, C282Y & S65C mutations
- Thrombophilia gene mutations (Factor V Leiden & Prothrombin)
- Measles & mumps IgG
- Molecular tissue identification
- Mycobacteria (molecular)
- Mycology (Molecular fungal identification)
- Toxoplasma IgG
- Virus identification (molecular)

INSTAND panels

- IL-28B
- Alpha-1 antitrypsin
- Rubella RNA
- *Coxiella burnetii* DNA
- *Salmonella* detection
- HIV-2 detection

Quality Control for Molecular Diagnostics

- Adenovirus DNA quantitation
- CMV DNA quantitation (whole blood)
- CMV drug resistance (UL97/UL54)
- Coronavirus including MERS
- EBV DNA quantitation (whole blood)
- Enterovirus RNA
- Enterovirus typing
- HBV DNA quantitation
- HBV drug resistance
- HBV genotyping
- HCV drug resistance
- HCV genotyping
- HCV RNA quantitation
- HDV RNA quantitation
- HEV RNA quantiation
- HHV6 DNA quantitation
- HIV-1 DNA/RNA
- HIV-1 drug resistance (protease/reverse transcriptase / integrase)
- HIV-1 RNA quantitation

- HPV
- HSV
- HSV drug resistance
- influenza virus A and B
- measles
- MPV
- Mumps
- parainfluenza virus 1-4
- parechovirus
- parvovirus B19
- polyoma virus BK
- polyoma virus JC
- Respiratory II (MPV, Adenovirus, Rhinovirus, coronavirus, enterovirus, parainfluenza viruses).
- Rhinovirus
- RSV
- VZV
- West Nile virus

- *Aspergillus spp.*
- Bacterial 16S panel
- Bacterial sepsis (*Staphylococcus, Serratia, Escherichia coli, Staphylococcus, Enterococcus, Streptococcus* and *Klebsiella, Pseudomonas*)
- *Bordetella pertussis*
- *Borrelia burgdorferi*
- *Candida spp.*
- *Central nervous system II (Listeria spp., Neisseria meningitides, Streptococcus pneumoniae, Streptococcus agalactiae, Escherichia coli, Aspergillus spp., Haemophilus influenzae strains)*
- *Chlamydia pneumoniae*
- *Chlamydia psittacii*
- *Chlamydia trachomatis*
- *Clostridium difficile*
- *Group B Streptococcus*
- *Mycobacterium tuberculosis*
- *Mycoplasma pneumoniae*
- *Mycoplasma sp.*
- *Neisseria gonorrhoeae*
- *Pneumocystis jirovecii*
- STI screen (*Mycoplasma genitalium, Ureaplasma* sp, *Trichomonas vaginalis*, *Mycoplasma hominis, Gardnerella vaginalis*)
- Respiratory III (*Pertussis, Legionella pneumoniae, Mycoplasma pneumoniae, Streptococcus pneumoniae, Haemophilus influenzae* strains)
- *Toxoplasma gondii*
- *Treponema pallidum*

Informal interlaboratory exchange schemes 2018 included:

- *Acanthamoeba*
- Brucella genus
- *Leptospira* genus
- *Trophyremena whippleii*

5.2 Accreditation

Micropathology Ltd is an accredited medical laboratory to ISO15189:2012 standard. UKAS Reference Number: 9622. UKAS provides a means to accredit Medical Laboratories 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.

It may be important to transmit the results of a test as soon as possible e.g. positive test results of clinical significance or where the results of an examination falls within a critical interval (This includes results sent to referral laboratories for testing). These results will be telephoned as soon as the test operator enters them into LIMS and requests their immediate authorisation.

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.

Results can be provided over the telephone by request from any hospital department / ward from where the primary source originated following confirmation of patient identity. If you are contacting us from the source of the primary sample and not the referring laboratory, we request that you contact the referring laboratory for confirmation of the results provided in the final report.

7. User Feedback and Complaints procedure

Feedback and Complaints regarding the service provided by Micropathology Ltd (Companies house registration No. 3022426) 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 working days (6 weeks) from the date of the invoice. Since August 2018 any invoices not paid within this time will incur a 25% surcharge.

8.2 Acceptable Methods of payment

BACs is the preferred method of payment.