Micropathology Ltd

An independent diagnostics and biomedical research laboratory

UKAS MEDICAL
9622

Laboratory User Handbook

28th April 2026

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Review

April 2026

Removed Dr Paul Scott, Dr Heather Ison-Scott and Alison Scheuermann from staff list.
Test table – added *Kingella kingae* PCR.
Test table – added Hepatitis A virus PCR.

Table of contents

1. Introduction

1.1 The Laboratory and outline of services

Micropathology Ltd is a ISO15189:2022 UKAS accredited medical diagnostic service, No. 9622. Please refer to the test table on pages 14-23 for details of UKAS accredited and unaccredited activities.

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.

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 ISO15189:2022 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, and other bank holidays (those recognised in England and Wales only) throughout the year is emailed 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
Consultant Virologist / Microbiologist	Dr Mark Atkins
Senior Scientist	Dr David Burnett
Clinical Scientist (Microbiology)	Dr Jennifer Morris-Cottell
Training & Quality Support	Mrs Nicola Mullen
Company Representative	Ms Heather Smith
Laboratory Lead / Post-graduate Scientist	Mrs Alison Jackson
Post-doctoral Scientist / Health & Safety Co-ordinator	Dr Paul Hunter
Post-graduate Scientist / Deputy Health & Safety Co-ordinator	Miss Phooja Nandi
Senior Manager / Microbiology Manager / Post-doctoral Scientist	Dr John Thomas
Senior Manager / Virology Manager / Post-doctoral Scientist / Training officer	Dr Edward Sumner
Senior Manager / Sequencing Manager / Post-doctoral Scientist	Dr Jennifer Holden
Accessions Lead / Post-doctoral Scientist	Dr Julia Manning
Accessions Lead / Manuals Lead / Post-doctoral Scientist	Dr Rachel Clewes
Serology Lead / Post-doctoral Scientist	Dr Penny Reid
Equipment Lead / Nucleic Acid Extraction Lead / Post-doctoral Scientist	Dr Ronan Calvez
	Dr Ollie Smith

Equipment Lead / Bioinformatics / Post-doctoral Scientist	Dr Jess Palmer
Bioinformatician Lead / Post-doctoral Scientist	Dr Andrew Taylor
Research & Development Lead / Post-doctoral Scientist	Dr Emma Johnstone
Principal Bioinformatician Post-doctoral Scientists	Dr Sally Hilton, Dr Naznin Choudhury, Dr Steven Ryder, Dr Kishlay Kumar, Dr Jinyu Shan, Dr Ana Dominguez Ferreras, Dr Luke Cadd, Dr Sam Dawson, Dr Sameeksha Mishra, Dr Ying Jia
IT Lead / Post-doctoral Scientist	Dr Peter Millichap
Research Post-graduate Scientist	Miss Catherine Davis
Senior Software Engineer	Mr Kyle Billing
Software Developer	Mr George Harding
IT systems Quality Assurance Specialist	Mr Ian Faulkner
Post-graduate Scientists	Miss Amelia Brett, Miss Jay Drury, Mr Gary Keane, Mrs Alison Jackson, Mr Oliver Judge, Miss Ciara Ryder, Mr Oliver Ivison, Mr Thomas Payne, Mr Jake Stevens
Senior Manager / Company accountant	Mrs Weiping Barrett
Laboratory Office Administrator	Ms Dawn Mason
Administration support	Dr Sue Webster
Administration and accounting support	Miss Zhiwen Luo
Human Resources / Deputy Training Officer	Mrs Helen Healy

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 Prompt transport of specimens

It is the responsibility of the sender to comply with courier, UK postal or international safety regulations for clinical specimen transport.
To ensure prompt testing of samples and release of results within the published test turnaround times (pages 14-23), samples should arrive at 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.

3.2ii Packaging and sending samples

To preserve the continued integrity of the specimen, it is the customer's 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

Infectious substances assigned to Category B (UN3373) can be transported by specialised couriers or the Royal Mail, provided they comply with the required packaging instruction. Please refer to https://www.un3373.com/category-biological-substances/category-b/ for further details. Always clarify with your provider before shipping.

Request forms must be placed between the secondary container and the outer shipping container. Request forms **should not** be placed inside the secondary container.

Users sending samples containing, or suspected to contain Category III organisms or are from a patient suspected to have Creutzfeld-Jakob disease, should clearly mark the referral form with the details of the potential hazard. This ensures that the sample can be handled appropriately upon receipt into the laboratory. In addition, the

secondary specimen container can be marked with a hazard sticker to alert staff of potential hazards prior to opening.

Please ensure the outer packaging is addressed correctly to ensure prompt delivery of specimens. We will supply mailing or DX labels, if required. Details of senders should be attached to this box. Secondary and outer packaging materials will be returned for reuse if requested. This service does incur a standard rate postal charge.

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.

The laboratory will also contact users to clarify any request on any sample. Requests from hospital departments other than the referring laboratory must ensure the referring laboratory is aware of the additional request.

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 within 24hrs (already under investigation)	Additional test requests can be requested by telephone 02476 323222, or email info@micropathology.com. It is recommended that **critical** test requests should be made by telephone. 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 an 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 more than 48 hours ago (archived samples)	Specimens are archived at -20^{O}C for 4-6 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 of our samples are reported the same day. However, if something is especially urgent please advise us by marking the request form as such or telephoning the laboratory. **PLEASE DO NOT SEND URGENT SAMPLES BY POST DUE TO THE LATE ARRIVAL OF THIS SERVICE. A COURIER IS STRONGLY RECOMMENDED AS A MORE TIMELY MODE OF TRANSPORT.**	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

* Additional test requests made by telephone will be recorded on a telephone message form and within the laboratories LIMS system. This will serve as written confirmation of the test request from the requestor, in accordance with ISO15189:2022 7.2.3.2.

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 (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**. For clinical genetic testing it is the responsibility of the requesting clinician to obtain informed consent from the patient or parent/guardian.

To ensure unequivocal identification, samples and request forms **MUST** contain the minimum essential identification criteria. If sufficient 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 and / or hospital number 3. NHS, CHI or health and care number 4. Sample type and if clinically relevant, anatomical origin *Barcodes on the sample do not replace full sample labelling but if used must be identical to barcodes on the request form.*	1. Date and time of sampling 2. Nature of sample including qualifying details i.e. left eye swab

Request form*	1. NHS, CHI or Health and Care Number 2. Patients full name or unique code identifier 3. Date of birth and / or hospital number 4. Biological sex 5. Lab reference number 6. Sample type including anatomical site 7. Investigation(s) required 8. Clinical details / history 9. The full postal address of the requesting authority * 10. A contact name, or consultant's name where possible 11. Secure email details to which the results will be sent.	1. Clinical information including relevant treatment/medication 2. Date and time of sample 3. A contact telephone number 4. Of a female is known to be pregnant

**Information taken from IBMS guidance on patient sample and request form identification criteria 2024*

The Health and Care Number is a 10 digit number randomly selected and allocated to everyone in Northern Ireland. Individuals registered with a Scottish GP practice has their own unique ten-digit number Community Health Index (CHI) 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.

Only relevant data related to the patient and specimen should be supplied in accordance with GDPR. Personal data pertinent to any sample submitted for testing is held on our LIMS. Samples and associated data are retained held in line with Royal College guidelines for Retention and Storage of Pathological Records and Specimens 5th edition and the HTA guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment. If this data is to be deleted from the medical record, a formal request in writing is required. Copies of our data protection policies can be supplied upon request.

3.5 Medico-legal samples

Please note on the form if this sample is a medico-legal sample. We advise the requesting laboratory to retain some of the sample sent to the laboratory if required for medico-legal purposes. We, Micropathology Ltd, are unable to undertake long term storage of samples. If the sample is sent to us in its entirety, please advise within 5 working days of receiving the results whether you require any medico-legal sample to be returned. If the request form with the receiving sample clearly states that the sample is to be returned, there is no requirement to contact us further to request this.

3.6 Human identification samples

Coroners should inform the laboratory if sample(s) sent to us for human identification are to be returned as soon as possible.

3.7 Patient confidentiality

All samples received are treated in the strictest confidence and are anonymised upon receipt into the laboratory. All samples are handled with due care and respect. 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. Any request to release confidential patient information into the public domain must be made to Prof. Fink or Dr Mark Atkins.

3.8 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 1 week to facilitate repeat or additional testing. The exception to this is 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.

3.9 Formalin fixed/wax embedded tissues

Please send at least **5-10 block shavings** for formalin fixed/wax embedded tissues. Please ensure that each curl contains a visible amount of tissue.

The laboratory does accept wax blocks, but block shavings are preferred. The laboratory does not have a microtome to generate wax curls from blocks, and instead uses disposal scalpels to produce curls which may affect the uniformity of wax block surfaces.

Any block shavings remaining after extraction and testing is completed are stored for 1 week to facilitate any repeat or additional testing before being discarded, in line with the company's sample retention procedure. All wax blocks are returned to the requesting laboratory after testing is complete.

3.10 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 14-23 for details of UKAS accredited and non-accredited tests offered, test turnaround time and appropriate UKAS accredited and non-accredited sample types. Please refer to the UKAS accreditation schedule (Micropathology Ltd accreditation number 9622) available on the UKAS website www.UKAS.com for further information.

Result reports will bear details of the nature of the same type tested. Unless explicitly stated by the presence of the symbol ▲ in the test table, all assays/samples are UKAS accredited. Reports bearing the 'Not UKAS accredited' indicates that the assay / sample type has not been assessed and accredited to ISO15189:2022 by UKAS.

Test turnaround time is based on a Monday to Friday working week. Saturday/Sundays and bank holidays are not included in TAT calculations. Some tests are scheduled throughout the week, and these are detailed in the test table but may be performed at other time points depending on test requests. All other assays are run daily.

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, postmortem samples, stools, eye samples, sputums, BALs and those suspected or known to contain 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. Tests requiring a manual extraction are detailed below:

16S rRNA bacterial gene
18S rRNA fungal gene
Acanthamoeba DNA
Aspergillus DNA
Brucella genus DNA
Candida albicans DNA
Chlamydia psittacii DNA
Coxiella burnetti DNA
Cutibacterium (formerly Propionibacteria) DNA
Escherichia coli DNA
Mycobacterium avium complex DNA

Mycobacterium genus DNA
Mycobacterium TB complex DNA
Mycoplasma genus DNA
Proprionibacteria/Cutibacteria
Staphylococcus genus DNA

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.

Users will be contacted if Micropathology Ltd do not offer a requested test.

Micropathology Ltd do not currently refer work to 3rd party laboratories. Samples will be returned or forwarded to a laboratory for further testing at a user's request. In this instance samples will incur a postal charge as detailed in the test table.

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, sample types.

Tests available		
Test	**Target turn-around**	**Sample types**
Client sample postage: returns and forwarding to UKHSA	Next day	AnyΨ
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, contact lens solution Meningitis - CSF
Adenovirus DNA See Θ below	Next day	Vitreous fluid, eye fluid, serum, swab (Nose, throat, eye and skin), blood, plasma, urine, bronchial washings, NPA, CSF, pericardial fluid, bone marrow.
Adenovirus DNA quantitation	Next day	EDTA/citrated whole blood, CSF, urine and plasma
Adenovirus typing (Research only)	5 days	PCR product generated in-house from the sample types detailed for Adenovirus DNA
Aspergillus genus DNA	5 days	EDTA/citrated whole blood, BAL, sputum, corneal scrape
Aspergillus antigen (Galactomannan)	This test is scheduled on Wednesdays	Serum, BAL This test requires at least 300µL of sample
Bartonella henselae / quintana	2 days	EDTA whole blood, tissue, vitreous fluid, aqueous fluid and pus.
Bocavirus	Next day	Any upper / lower respiratory specimen (sputum, BAL, NPA, nasopharyngeal swab etc), BAL and NPA preferred
Bordetella pertussis DNA Ψ	2 days	NPA, upper respiratory swabs
Borrelia genus	2 days	EDTA whole blood, CSF, tissue
Brucella genus DNA	3 days	EDTA whole blood, CSF. **We do not accept cultures for safety reasons**
Candida albicans DNA	2 days	EDTA whole blood, CSF, eye fluid, corneal scrape, eye swabs.
Capnocytophaga canimorsus ▲	Next day	EDTA whole blood, blood culture
Carbapenem Resistance Gene ▲	3 days	EDTA WB, urine, eye fluid, joint fluid, faeces, faecal swabs, tissues and cultures
Chlamydia pneumoniae DNA See Θ below	Next day	NPA, BAL, swab and sputum
Chlamydia psittaci DNA	2 days	BAL or nasopharyngeal swab
Chlamydia trachomatis DNA ▲	2 days	Eye swab, throat swab

Tests available		
Test	**Target turn-around**	**Sample types**
If sending for confirmation in accordance with BASHH guidelines, please telephone the laboratory for further information. *Individual requests for Ct are always tested in combination with Ng respectively.*		For genitourinary: Female: Endocervical, vaginal or rectal swab, 'Thin prep' endocervical cellular specimens. Male: Urethral swab, first pass urine, rectal swab, semen
Clostridium difficile (Research only)	3 days	Stool
Coronavirus 229E, HKU1, NL63 or OC43	Next day	Any upper / lower respiratory sample
Coronavirus – SARS-CoV-2	Same day	Any respiratory swab, BAL and NPA Sputum is not validated for this assay.
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
Cutibacterium acnes (formerly Propionibacterium) ▲	2 days	Eye sample, tissue, CSF
Cytomegalovirus DNA	Same day	EDTA whole blood, urine, serum/EDTA plasma, CSF, saliva or respiratory specimen - BAL preferred. Pregnancy – EDTA whole blood, amniotic fluid, serum/plasma
Cytomegalovirus DNA quantitation	Same day	EDTA whole blood, urine, serum/EDTA plasma, CSF, amniotic fluid
Cytomegalovirus drug resistance (ganciclovir, foscarnet, cidofovir and maribavir) (UL97 and UL54) *All samples requesting this assay will be tested for CMV viral load first.* ●	9 days	EDTA/citrated whole blood, EDTA plasma
CMV letermovir drug resistance (UL56 and UL89) ● *All samples requesting this assay will be tested for CMV viral load first.*	9 days	EDTA/citrated whole blood, EDTA plasma
Enterovirus RNA	Next day	CSF, swab, stool, tissue, serum, plasma, NPA, pericardial fluid, 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	Next day	EDTA whole blood, CSF, serum, plasma
Epstein Barr Virus DNA quantitation	Next day	EDTA whole blood, CSF, serum, plasma
Escherichia coli DNA	2 days	CSF, EDTA/citrated whole blood

Tests available		
Test	**Target turn-around**	**Sample types**
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 - For identification of human remains, comparison of clinical samples and relationship testing (e.g. paternity, sibship or zygosity testing)	15 days	Bone It may be necessary for us to request further specimens for genetic profile analysis in circumstances where our investigations are inconclusive.
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) It may be necessary for us to request further specimens for genetic profile analysis in circumstances where our investigations are inconclusive
Group A Streptococcus (S.pyogenes) DNA Ψ	Next day	CSF, EDTA/citrated whole blood, tissue, joint fluid and pleural fluid
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	Genital Swab
Haemophilus influenzae/parainfluenzae DNA	Next day	CSF, EDTA/citrated whole blood.
Hepatitis A virus RNA▲	2 days	**At least 0.6mL** serum/plasma, stool
Hepatitis B core antibody (Tests schedule Monday and Thursday)	4 days	serum preferred or Li-heparin*, Na-heparin*, K2/K3-EDTA, CPDA, CPD, CP2D, ACD, sodium citrate plasma
Hepatitis B e antibody (Tests schedule Monday and Thursday)	4 days	serum preferred or Li-heparin*, Na-heparin*, K2/K3-EDTA, CPDA, CPD, CP2D, ACD, sodium citrate plasma
Hepatitis B e antigen (Tests schedule Monday and Thursday)	4 days	serum preferred or Li-heparin*, Na-heparin*, K2/K3-EDTA, CPDA, CPD, CP2D, ACD, sodium citrate plasma

Tests available		
Test	**Target turn-around**	**Sample types**
Hepatitis B drug resistance mutation screen ♦ ●	9 days	**At least 0.6mL** Serum/plasma Please supply viral load if available.
Hepatitis B surface antibody (Tests schedule Monday and Thursday)	4 days	Serum preferred or K2/K3EDTA plasma **
Hepatitis B surface antigen (Tests schedule Monday and Thursday)	4 days	Serum preferred or Li-heparin*, Na-heparin, Na-citrate, K2/K3- EDTA, CPDA, CPD, CP2D, ACD, citrate plasma.
Hepatitis B surface antigen quantitation (Tests schedule Monday and Thursday)	4 days	Serum preferred or Li-heparin*, Na-heparin*, K2-EDTA, citrate plasma
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 ♦	9 days	**At least 0.6mL** serum/plasma. Please supply viral load if available.
Hepatitis C antibody (EIA) (Tests schedule Monday and Thursday)	4 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)	4 days	Serum preferred or Li-heparin*, citrate or EDTA plasma
Hepatitis C genotyping ♦	3 days	**At least 0.6mL** serum/plasma Please supply viral load if available.
Hepatitis C virus RNA **(<15IU/ml)** ♦	2 days	**At least 2ml serum/plasma is essential**. Please send more sample if other tests are required.
Hepatitis C virus RNA quantitation **(<15IU/ml)** ♦	2 days	**At least 2ml serum/plasma is essential**. Please send more sample if other tests are required.
Hepatitis D virus RNA ♦	5 days	**At least 0.6mL** serum/plasma This assay should always be reviewed in conjunction with HBV investigations.
Hepatitis D virus RNA quantitation ♦	5 days	**At least 0.6mL** serum/plasma. This assay should always be reviewed in conjunction with HBV investigations.
Hepatitis E virus RNA *Serum/plasma, CSF and whole blood samples will be reported as quantitative results by default. Please specify on the request form if you require a qualitative result specifically.*	2 days	**At least 0.6mL** serum/plasma, CSF, whole blood, stool

Tests available		
Test	**Target turn-around**	**Sample types**
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, Aqueous/Vitreous humour, Corneal Scrape, EDTA/citrated whole blood, vesicle fluid, skin/eye/vesicle swab, tissue (Biopsy), BAL, NPA. Genitourinary - For female: Vaginal 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
Herpes Simplex Acyclovir drug resistance (UL23 and UL30) ●	9 days	HSV-1 positive samples, including CSF, EDTA whole blood, plasma and swabs.
Herpes Simplex virus types I & II typing	Next day	Performed routinely on positive HSV samples. Please refer to the HSV detection assay for list of validated sample types
HIV I & II antibody and p24 antigen (EIA) (Tests schedule Monday and Thursday)	4 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)	4 days	Serum preferred or Li-heparin*, citrate or EDTA plasma
HIV I & II antibody (LIA) – saliva (Tests schedule Monday and Thursday)	4 days	Saliva
HIV-1 proviral LTR, env, gag and pol genes	2 days	EDTA whole blood preferred or serum/plasma A paired maternal blood sample should be sent when testing infants <18 months old for HIV-1 proviral DNA / RNA.
HIV-1 RNA drug resistance ♦ ●	9 days	EDTA Plasma**. This test requires at least 600µL of sample**. Please supply viral load if available.
HIV-1 RNA Integrase drug resistance ♦ ●	9 days	EDTA 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/CSF.**
HIV-2 proviral LTR and pol DNA/RNA	2 days	EDTA whole blood preferred or serum/plasma, CSF
HTLV I & II antibody	Tests scheduled Wednesdays 5 days	Serum preferred or EDTA, citrate plasma
HTLV-1 DNA or RNA	3 days	EDTA whole blood, serum, plasma or CSF

Tests available		
Test	**Target turn-around**	**Sample types**
Human Herpesvirus 6A and 6B DNA	Next day	EDTA whole blood (CSF in encephalitis), bone marrow. plasma
Human Herpesvirus 6 DNA quantitation	Next day	EDTA whole blood (CSF in encephalitis), bone marrow, plasma.
Human Herpesvirus 7 DNA	Next day	EDTA whole blood, CSF, bone marrow. Plasma may be tested but whole blood is preferred.
Human Herpesvirus 7 DNA quantitation	Next day	EDTA whole blood, CSF, bone marrow. Plasma may be tested but whole blood is preferred.
Human Herpesvirus 8 DNA	Next day	EDTA whole blood. CSF, Plasma or serum may be tested but whole blood is preferred.
Human Herpesvirus 8 DNA quantitation	Next day	EDTA whole blood. CSF, Plasma or serum may be tested but whole blood is preferred.
Human metapneumovirus RNA See ʘ below	2 days	Any upper / lower respiratory specimen
Human Papillomavirus DNA detection and typing ▲ *Please note that all positive results are also typed by sequence analysis.* *This assay is run in parallel with the HPV high risk typing probe-based assay (below).*	10 days	Swabs: vulva, vagina, cervix, penis, rectum, eye, throat, skin. Please state site of swab type.
Human Papillomavirus DNA **selected high risk typing (Genital samples only)** ■ *This assay is run in parallel with the HPV typing assay (above).*	10 days	Genital swabs and endocervical specimens. Please state site of swab.
Influenza A virus RNA	Same day	Any upper / lower respiratory specimen
Influenza B virus RNA	Same day	Any upper / lower respiratory specimen
Kingella kingae	Next day	Joint fluid▲
Legionella pneumophila See ʘ below	Next day	Any upper / lower respiratory specimen
Leptospira interrogans DNA	3 days	CSF, EDTA whole blood, urine
Lymphogranuloma venereum *All LGV requests are also tested for Ct and Ng.*	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 whole blood - may be useful in suspected meningitis cases
Measles virus RNA Ψ	Next day	CSF, urine, nose & throat swabs, skin swabs, whole blood, plasma, serum

Tests available		
Test	**Target turn-around**	**Sample types**
Mpox virus DNA	Next day	Blood, skin swabs, throat swabs
Mumps IgG antibody	Tests schedule Wednesdays	Serum preferred or citrate/heparin plasma
Mumps virus RNA	Next day	Whole blood, CSF, serum/plasma, nose & throat swab, skin swab, urine
Mycobacterium avium complex\TB complex DNA	4 days	Sputum, CSF, BAL, tissue, NPA
Mycobacterium genus DNA	4 days	CSF, BAL, sputum and tissues
Mycobacterium TB rifampicin resistance All rifampicin requests are tested on the Mycobacterium avium complex\TB complex DNA assay first	5 days	Sputum, tissue, CSF, BAL
Mycoplasma genitalium DNA	2 days	Males - first catch urine. Females - vaginal swab. Semen▲, thin preps▲
Mycoplasma genitalium macrolide resistance *All Mycoplasma genitalium macrolide requests are also tested in-house for confirmation of Mycoplasma genitalium positivity.*	4 days	Males - first catch urine. Females - vaginal swab
Mycoplasma genitalium (ParC) fluoroquinolone resistance *All Mycoplasma genitalium fluoroquinolone requests are also tested in-house for confirmation of Mycoplasma genitalium positivity.*	4 days	Males - first catch urine. Females - vaginal swab
Mycoplasma genus DNA	4 days	CSF, EDTA whole blood, tissue
Mycoplasma pneumoniae DNA See ʘ below	Next day	EDTA whole blood, BAL and NPA, sputum, swabs and ET secretions
Neisseria gonorrhoeae DNA *Positive samples are sequenced for confirmation. Individual requests for Ng are always tested in combination with Ct respectively.*	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, semen

Tests available		
Test	**Target turn-around**	**Sample types**
If sending for confirmation in accordance with BASHH guidelines, please telephone the laboratory for further information.		
Neisseria meningitidis DNA Ψ	Same day	CSF, EDTA whole blood (may be useful in suspected meningitis cases), swabs, joint fluid
Neisseria meningitidis DNA B serogroup typing	4 days	Performed routinely first on positive Neisseria meningitidis samples
Neisseria meningitidis DNA ACWY typing	7 days	Performed routinely on positive Neisseria meningitidis samples if negative for serogroup B
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, NPA, pericardial fluid, EDTA/citrated whole blood - may be useful in suspected meningitis cases
Parvovirus B19 DNA and quantitation	Next day	EDTA whole blood, amniotic fluid, serum/plasma, CSF, bone marrow, tissue
Pneumocystis jirovecii (aka carinii) DNA	Next day	Sputum, BAL, NPA, whole blood ▲
Polyoma BK virus DNA	Next day	EDTA whole blood, serum/ plasma, urine
Polyoma BK virus DNA quantitation	Next day	EDTA whole blood, serum / plasma, urine
Polyoma JC virus DNA	Next day	EDTA whole blood, urine, CSF, serum/plasma▲
Polyoma JC virus DNA quantitation	Next day	EDTA whole blood, urine, CSF, serum/plasma▲
Pseudomonas aeruginosa	Next day	EDTA whole blood, corneal scrape, eye swab, contact lens solution
Respiratory Syncytial Virus RNA	Same day	Any upper / lower respiratory specimen
Respiratory Virus Screen See Θ below	Next day	Any upper / lower respiratory specimen
Rhinovirus RNA	Same day	Any upper / lower respiratory specimen
Rhinovirus typing (Research only)	3 days	Any positive Rhinovirus respiratory specimen
Rubella virus RNA	3 days	CSF, EDTA/citrated whole blood, throat swab, urine, amniotic fluid, serum
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, Tissues, joint fluid and pleural fluid eye swab, aqueous fluid, vitreous fluid and corneal tissue
Streptococcus pneumoniae DNA	Next day	Whole blood, CSF and pleural fluid
Toxoplasma gondii DNA	Next day	CSF, EDTA whole blood, amniotic fluid, vitreous ▲ and aqueous fluid ▲
Treponema pallidum DNA	2 days	CSF, genital swab

Tests available		
Test	**Target turn-around**	**Sample types**
Trichomonas vaginalis DNA	2 days	Genital swab, semen▲, male urine▲, thin preps▲
Tropheryma whipplei DNA	5 days	CSF and almost any cellular material including whole blood and tissue. PLEASE DO NOT SEND SERUM.
Ureaplasma urealyticum/parvum DNA	2 days	Urine, genital swab, thin preps, semen Neonates- NPA, ET secretions▲
Varicella Zoster virus DNA	Next day	CSF, AC tap, aqueous / vitreous humour, EDTA/citrated whole blood, corneal scrape, vesicle fluid, skin/eye swab, tissue (Biopsy), BAL, NPA, Genitourinary - For female: Vaginal 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, urine, plasma EDTA whole blood

Key for test table

▲ Not UKAS accredited.

● - Drug resistance profiles produced by Next generation sequencing are Not UKAS accredited. A nucleotide variant is reported if it occurs in a proportion of the reads at or above the minimum nucleotide frequency threshold which was set at **5%**. The relative frequencies of drug resistance mutations are denoted only where a heterogeneous population is present at a particular site.

♦ Non-separated whole blood samples must be centrifuged and plasma collected within 24 hours of collection to provide relevant results. Ship at ambient temperature for next day delivery. For HIV-1 RNA quantitation samples may be tested within 72 hours if the EDTA plasma is refrigerated upon separation or up to 6 weeks if frozen.

* - 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.

⊙ - Respiratory panel comprising of Influenzae A and B, Respiratory syncytial virus A and B, Parainfluenza 1 – 4, Coronavirus OC43, 229E, NL63, HKU1 and new Coronavirus-SARS-CoV-2, Human metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Human Bocavirus. *Chlamydia pneumoniae*, *Legionella pneumoniae* and *Mycoplasma pneumoniae* may also be reported if found to be positive on the NxTAG® Respiratory Pathogen Panel.

Please note, Influenza A positives (Research only) 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. The Rhinovirus assay in the Rh/EV assay is not UKAS accredited.

Ψ Please note; when Group A *Streptococcus*, Measles RNA, N. *meningitidis* DNA or *Bordetella pertussis* DNA are detected within a specimen, the sample will be forwarded to UKHSA, as requested, to comply with their requirements.

■ Please note that the Human Papillomavirus high risk typing only detects types 16, 18, 31, 33, 25, 39, 54, 51, 52, 56, 58, 59, 66, 68a, and 82 only. This assay does NOT detect type 68b.

3.11 Factors affecting assays

The sensitivity of DNA/RNA detection tests depends on the quality/type of the sample and the test performed. The following issues can affect this.

3.11i 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.

3.11ii 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.

3.11iii Li-heparin or Na-heparin whole blood samples
Li Heparin/Na heparin may have 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.

3.11iv Cotton-tipped/Calcium alginate swabs
Cotton-tipped or calcium alginate swabs are not acceptable and should not be used for sample collection as residues present in these materials may inhibit PCR assays (CDC, 2015).

3.11v Formalin fixed/wax embedded tissues
The extraction efficiency fixed tissue and wax embedded maybe reduced due to the effects of the manipulation of the tissue and may decrease the sensitivity of the assay. Result reports will bear a caveat if this is suspected.

3.11vi 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.

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

3.11vii Environmental contamination
Both *Cutibacterium acnes* (Formerly *Propionibacterium*) *and Escherichia coli* may be present in the human environment and on skin. This may affect results of these assays depending upon the nature and quality of sample received.

3.11viii Sample instability

Significant delay in sending and/or receiving samples, or sending incorrect sample types can result in sample instability and thus may hinder detection of the requested target. Stability for certain assays is detailed below

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**
Aspergillus antigen (Galactomannan)	Serum – Unopened samples 5 days 2 - 8^{O}C, opened samples 2 days 2 – 8^{O}C. Serum can be stored long term at -20^{O}C for 11 mths. BAL – after initial opening 24hrs at 2-8^{O}C. BAL can be stored long term -20^{O}C for 11 mths
HCV antibodies	ELISA 7 days (20-25ºC), 14 days (2 - 8ºC), 3 mths (-20ºC) RIBA 7 days 2-8^{O}C, long term -20^{O}C or lower. Repeated freeze thawing of samples (more than 3 times) and use of diluted samples may produce erroneous results.
HIV I and II antibodies	ELISA 7 days (25ºC), 4 weeks (2 - 8ºC), 3 mths (-20ºC) LIA 7 days 2-8^{O}C, long term -20^{O}C or lower. Repeated freeze thawing of samples (more than 3 times) and use of diluted samples may produce erroneous results
HBV surface antigen	7 days (20oC – 25oC) 14 days (2 - 8ºC), 6 mths (-20ºC)
HBV sAg quantitation	7 days (2 - 8ºC), 3 mths (-20ºC)
HBV Core antibody	7 days (20-25ºC), 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 mths at -20 °C (± 5 °C).
HBV surface antibodies	7 days (20-25ºC), 14 days (2 - 8ºC), 3 mths (-20ºC)
HTLV 1 and 2 antibodies	7 days 2-8^{O}C, long term -15^{O}C or lower.
Mumps IgG antibodies	5 days 2-8^{O}C, long term -20^{O}C to -70^{O}C.

HIV-1 RNA quantitation

For HIV-1 RNA quantitation on the Cobas 5800, to ensure sample stability, samples should be:

- Whole blood collected in EDTA tubes may be stored and/or transported for up to 24 hours at 2°C to 25°C prior to plasma preparation.

- Upon separation EDTA plasma samples may be stored in secondary tubes for up to 6 days at 2°C to 8°C or up to 12 weeks at ≤ -18°C. For long-term storage, temperatures at ≤ -60°C are recommended.
- Plasma samples are stable for up to four freeze/thaw cycles when frozen at ≤ -18°C.

HCV RNA quantitation

To ensure sample stability, samples should be:

- Whole blood collected in SST™ Serum Separation Tubes, BD Vacutainer® PPT™ Plasma Preparation Tubes or in sterile tubes using EDTA as the anticoagulant may be stored and/or transported for up to 24 hours at 2°C to 25°C prior to plasma/serum preparation. Centrifugation should be performed according to manufacturer instructions.
- Upon separation EDTA plasma or serum samples may be stored in secondary tubes for up to 6 days at 2°C to 8°C or up to 12 weeks at ≤ -18°C. For long-term storage, temperatures at ≤ -60°C are recommended.
- Plasma/serum samples are stable for up to four freeze/thaw cycles when frozen at ≤ -18°C.

Samples for HIV-1, HBV and HCV tests

To avoid inaccurate viral load measurements and issues with potential viral degradation affecting assay performance please supply separated serum or plasma as detailed in the test table. When separating plasma from EDTA whole blood by centrifugation, please perform the separation within 24 hours of sample collection. This applies to the:

HBV drug resistance, genotyping and quantitation
HCV detection, drug resistance, genotyping
HIV-1 RNA detection and drug resistances assays.

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.

Additionally, 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.

3.12 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 14-23).
2 Of sufficient volume for testing.
3 Correctly matched information on sample and request form.
4 Sufficient patient/source identification (Table on page 8).

Samples maybe rejected if:

1 Inappropriate sample type.
2 Leakage has occurred - Samples will be rejected outright if they appear to contain no sample or leaked. Users will be contacted.
3 Low volume.
4 Badly haemolysed (serum/plasma samples for HIV-1 Quant and serological assays).
5 Misdirected**.
6 Mismatched sample and request form**.
7 Insufficient or incorrect information on sample and / or request form.

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

3.13 Reference values for Serological and HBV detection 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	
Aspergillus antigen Galactomannan	0.5			

* Analysed on ROCHE COBAS E411 using various assays
- Galactomannan analysed using PLATELIA™ antigen assay

Quantitative assays

* Analysed on ROCHE COBAS E411 using various assays

Semi-quantitative

TEST	Not detected	Detected	Equivocal
Mumps IgG	<9 U/mL	>11 U/mL	9-11 U/mL

Analysed using the Novatec Mumps IgG ELISA kit.

HBV detection in pregnancy

Current European Association for the Study of the Liver (EASL) guidelines recommend antiviral therapy to prevent HBV vertical transmission in women with high HBV DNA (>200,000 IU/ml) or elevated quantitative HBsAg >4 log10 IU/ml, commencing at 24-28 weeks GA. Treatment of other high risk women during pregnancy to prevent HBV vertical transmission should be considered on an individual case basis by the specialist team. HBV DNA should be tested before 24 weeks GA, in order to assess HBV vertical transmission risk and aid decision making regarding commencing antiviral treatment and requirement of HBIG for newborns at birth . Quantitative HBsAg can also be tested at the same time, if available. If diagnosed after 24 weeks GA, test HBV DNA as soon as possible.

*Excerpt taken from the British Viral Hepatitis group Management of HBV infection in pregnancy and the exposed infant 2021. **M-2292 v1.0**

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

TEST	Measuring Range	Reactive	Non-reactive	Dilution
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.

3.14 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

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. It may be necessary to request additional samples for repeat testing for human identification and relationship testing.

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.

3.13i 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 https://www.rcpath.org/uploads/assets/c4303f87-31eb-403b-89c91cbbc7ff97b4/Consentconfidentialityworkingreportfinalonline.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.

3.15 Sequencing service

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

- Adenovirus typing – research only
- *Bartonella henselae/quintana* identification
- *Chlamydia pscittaci*
- Cytomegalovirus ganciclovir, foscarnet, cidofovir, letermovir and miribavir resistance
- Enterovirus typing- research only
- HBV Genotyping
- HBV drug resistance
- HCV Genotyping
- Herpes Simplex type 1 Acyclovir drug resistance
- HIV-1 RT/Protease/Integrase drug resistance mutation analysis
- HPV genotyping
- Rhinovirus typing - research only

- 16SrRNA and 18SrRNA gene sequencing for species determination
- *Mycobacterium tuberculosis* Rifampicin resistance
- *Mycobacterium* genus
- *Mycoplasma* genus
- *Mycoplasma genitalium* Macrolide and fluoroquinolone resistance
- *Neisseria gonorrhoeae* confirmation – throat swabs only
- *Pseudomonas* genus confirmation

Please refer to the list of tests and sample types for further information regarding suitable sample types, next generation sequencing and status of UKAS accreditation.

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 (2026):

United Kingdom National External Quality Assessment Service

- Anti-HBsAg
- Blood-Borne Virus donor screen (serology for hepatitis C Ag and AB, hepatitis B (HBVSAg), 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)
- Mumps IgG
- Molecular tissue identification (GenQA)
- Mycobacteria (molecular)
- Mycology (Molecular fungal identification)

INSTAND panels

- Adenovirus DNA quantitation
- CMV DNA quantitation

- EBV DNA quantitation
- Enterovirus RNA
- HBV DNA quantitation
- HCV RNA quantitation
- HDV RNA quantitation
- HEV RNA quantitation
- HHV6 DNA quantitation
- HHV-8 DNA detection
- HIV-1 RNA quantitation
- HIV-2 RNA detection
- HPV DNA detection
- HSV 1/2 DNA detection and typing
- Measles RNA detection
- Mumps RNA detection
- Parechovirus RNA detection
- Parvovirus B19 DNA quantitation
- Polyoma virus BK DNA quantitation
- Polyoma virus JC
- Rubella RNA
- VZV DNA detection
- *Bordetella pertussis* DNA
- *Brucella* sp. DNA
- *Chlamydia pneumoniae* DNA
- *Coxiella burnetii* DNA
- *Legionella pneumophila*
- *Mycoplasma pneumoniae* DNA
- *Pneumocystis jirovecii* DNA
- *Salmonella enterica*

Quality Control for Molecular Diagnostics

- Adenovirus DNA
- CMV drug resistance (UL97/UL54/)
- CMV (Whole Blood)
- EBV (Whole Blood)
- HAV RNA
- HBV drug resistance
- HBV genotyping
- HCV genotyping
- HHV6 DNA quantitation
- HIV-1 drug resistance (protease/reverse transcriptase / integrase)
- HIV-1 DNA/RNA detection
- HSV drug resistance
- Influenza virus A and B RNA detection
- Mpox virus DNA
- Respiratory II (MPV, Adenovirus, Rhinovirus, coronavirus, enterovirus, parainfluenza viruses 1-4).

- RSV RNA detection
- SARS-CoV-2 RNA detection
- VZV DNA
- West Nile virus RNA detection
- *Aspergillus spp.*
- Bacterial 16S panel
- Bacterial sepsis (*Staphylococcus, Serratia, Escherichia coli, Staphylococcus, Enterococcus, Streptococcus* and *Klebsiella, Pseudomonas*)
- *Borrelia burgdorferi*
- *Candida spp.*
- *Central nervous system II (Listeria spp., Neisseria meningitides, Streptococcus pneumoniae, Streptococcus agalactiae, Escherichia coli, Haemophilus influenzae strains, Cryptococcus neoformans)*
- *Chlamydia pneumoniae*
- *Chlamydia psittacii*
- *Chlamydia trachomatis and LGV*
- *Clostridium difficile*
- *Group A Streptococcus*
- *Group B Streptococcus*
- *Mycobacterium tuberculosis*
- *Mycoplasma genitalium including macrolide and fluoroquinolone resistance*
- *Mycoplasma pneumoniae*
- *Neisseria gonorrhoeae*
- *Non-tuberculosis Mycobacteria spp.*
- *Pneumocystis jirovecii*
- STI screen (*Mycoplasma genitalium, Ureaplasma* sp, *Trichomonas vaginalis*, *Mycoplasma hominis*)
- Staphylococcus aureus MRSA
- Respiratory III (Bordetella *pertussis, Legionella pneumoniae, Mycoplasma pneumoniae, Streptococcus pneumoniae, Haemophilus influenzae* strains)
- *Toxoplasma gondii*
- *Treponema pallidum*
- VZV DNA detection

VETCAS - Veterinary laboratory agency

- Leptospira genus

SKML - International external quality assessment scheme

- *Acanthamoeba*

BMS Micro

- *Acanthamoeba*
- *Panton-Valentine Leukocidin*

English Speaking Working Group (of the International Society for Forensic Genetics)

- Human relationship testing proficiency scheme

Informal interlaboratory exchange schemes include:

- Bocavirus
- HTLV-1 DNA/RNA
- Human herpes 7 DNA
- *Bartonella sp.*
- *Cutibacterium (Propionibacterium) acnes*
- *Capnocytophaga canimorsus*
- *Bacterial 16S*
- *Haemophilus ducreyi*
- *Tropheryma whipplei*

5.2 Accreditation

Micropathology Ltd is a UKAS accredited medical diagnostic service, No. 9622, accredited to ISO15189:2022. 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 the Quality Team on quality@micropathology.com.

6. Results and Reports

Results are transmitted to users between 16:00 and 18:00 Monday to Friday.

The primary delivery method of results is to pre-specified email address as a PDF attachment. Where a single email address is specified, it is strongly recommended that multiple users have access to this mailbox. If the Uncertainty of measurement for any quantitative assay result is required, users may contact the laboratory for further information.

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 (email addresses etc). Additionally, please contact the laboratory to alter any current report destinations.

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. The referring laboratory will be alerted of these results as soon as

the test operator has entered them into LIMS and requested their immediate authorisation.

Results are **only** provided over the telephone to the **requesting laboratory** with the exception of results for HIV-1/2 diagnosis, HIV-1 RNA quantitation and any sexual health transmitted diseases (*CtNg, T. pallidum*, HSV on genital swabs, *Haemophilus ducreyi, Mycoplasma genitalium, Ureaplasma urealyticum / parvum*). These are not provided over the telephone and callers are asked to contact the referring laboratory for details of the final authorised report.

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 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 laboratory to the designated feedback inbox, feedback@micropathology.com
3. Email/contact the company representative, Miss Heather Smith, heather.smith@micropathology.com
4. Complaints should be resolved within 30 working days

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 may incur a 25% surcharge.

8.2 Acceptable Methods of payment

BACs is the preferred method of payment.