Micropathology Ltd

Tel 24hrs: +44 (0) 24 - 76 – 323222

Fax / Ans: +44 (0) 24 - 76 - 323333

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

Website: www.micropathology.com E-mail: info@micropathology.com

QUALITY MANUAL

ISO15189:2012

4th October 2024

This document, together with specified procedures, represents the Quality Management System of Micropathology Limited. It has been compiled to meet the United Kingdom accreditation service requirements of a Quality Management system and appropriate national and international standards including ISO15189:2012.

Reviews

First edition – 23rd January 2017.

Various revisions in between.

Recent revision

October 2024
Formatting of figure on page 14 adjusted and new figure inserted to remove Scientific director.
Updated communication section to remove reference to quality indicators / audit meeting and update general laboratory quality meeting title.
Remove references to Scientific Director throughout the text.
Updated reference to documents and titles throughout the text.
Updated company representative role as there are two representative and neither are HCPC registered.
Remove reference to IBMS training laboratory as the company is no longer one.
Remove reference to health institution exemption.
Updated Quality policy
Remove all reference to any project work.
Update job descriptions and organisational chart.

Table of Contents

GENERAL INFORMATION

Title of Laboratory

The laboratory is a part of Micropathology Limited, an independent research and diagnostic service provider.

Information on the services provided is available on the company's website (http://www.micropathology.com/) from where the Laboratory User Handbook (also held on iPassport for internal use) can be downloaded.

The routine diagnostic work of the company comprises of the molecular diagnosis of infectious diseases, genetic disorders, identification of human remains and familial relationship testing. In addition to these services the laboratory also undertakes a variety of research and contract testing activities and supports post-graduate research with other institutions. The research-based activities do not fall under the requirements of ISO15189:2012.

The Quality Manual

This Quality Manual describes the Quality Management System (QMS) of Micropathology Limited for the benefit of the management and staff of the company and provides information for inspection or accreditation bodies. It contains references to the ISO15189:2012 standard and to procedures written in fulfilment of these standards.

The sections of this Quality Manual are arranged to equate with the ISO15189:2012 standard. The title of each clause / subclause is accompanied by a brief description of how Micropathology Limited seeks to comply.

The Quality Policy of Micropathology Limited

Scope of the service:-
Micropathology Limited specialises in using the latest molecular techniques to provide a clinically supported service for rapid diagnosis and management of infectious and genetic disease. We also provide a human genetic profiling for relationship testing and human identification genetics service. Our staff undertakes biomedical research covering human and veterinary pathology. This includes contract research and clinical trials for external organisations, in concert with continuous in-house assay development.

The directors and staff of the company strive to provide the highest possible standards in all aspects of the company's activities. We welcome a continuing dialogue with our clients in any aspect of clinical diagnostic testing.

In order to provide these services, which meet or exceed the needs and requirements of its users and patients, the laboratory management team is fully committed to:

Providing the highest quality analytical pathology service by:-

- Upholding professional values and continuing commitment to good professional practice and conduct.
- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users.
- Ensuring the use of examination procedures used is the highest achievable quality and they are fit for intended use.
- Procuring and maintaining the most appropriate equipment and resources to enable the provision of quality examinations of specimens.
- Giving advice on the collection and handling of all diagnostic samples, (to minimise uncertainty of results), allowing the production of quality assured results in a timely, confidential and clinically useful manner.
- Ensuring laboratory staff are familiar with the contents of this Policy, the Quality Manual and all procedures relevant to their work.
- Ensuring samples are treated in the strictest of confidence and with due care and respect
- Regular assessments of the satisfaction of users and staff. (E.g. by feedback from meetings, service updates, Christmas letters and user information sheets).
- Participation in internal audit schemes.
- Participation in National and European standards of excellence relevant to our clinical diagnostic work.
- *Compliance with all relevant local and national legislation, including environmental legislation.*

Achieving continual quality improvement in all areas of the laboratory by:-

- Continually developing the Quality Management System to allow improvements to all elements of the diagnostic Service.
- Annually reviewing the performance of company over the previous year and subsequently setting quality indicators, objectives and plans for the future, which will be implemented to comply with this Quality Policy. These Quality Objectives are set at the Annual Management Review and are reviewed monthly at Laboratory meetings for progress.
- Following Caldicott principles and complying with the standards set by external organisations, e.g. ISO15189:2012, ISO15189:2022, Health and Safety Executive, Human Tissue Authority.
- Regularly reviewing the effectiveness of the Quality Management System through regular internal auditing.

The health, safety, welfare and development of all Micropathology Ltd staff by:-

- Ensuring a friendly working environment to encourage the retention and recruitment of highly professional staff, committed to excellent professional practice.
- Regularly reviewing, by audit and inspection, compliance with the Department's health & safety procedures.
- Analysing incidents, complaints and accident reports, applying remedial, corrective and/or preventative actions as appropriate and reviewing these actions for effectiveness.
- Providing resources for training, education and development for all staff.

Treating all visitors and callers to the Department with courtesy and respect by:-

- Being helpful and polite and giving consideration to their health, safety and welfare whilst in the laboratory and office facilities.

4 MANAGEMENT REQUIREMENTS

4.1 Organisation and Management Responsibility

4.1.1 Organisation

4.1.1.1 General

Micropathology Ltd shall meet the requirements of ISO15189:2012 and strive to maintain this accreditation when performing work at the laboratory and office facilities.

4.1.1.2 Legal Entity

Micropathology Ltd (Company registration number 3022426) is the sole entity legally responsible for the diagnostic activities performed on site.

4.1.1.3 Ethical conduct

All permanent staff enter into a formal employment contract S-2257 and S-2258. Activities not permitted at Micropathology Ltd, which could lead to a diminish in laboratory competence, impartiality, judgement or operational integrity are documented in the following sections: General terms of employment, Whistle blowers, Rights of Search, Confidentiality and Non-solicitation of the employee handbook. This forms part of the employee contract.

Employees behaviour and activities is also detailed in Anti-slavery and human trafficking S-1942-n, Anti-bribery and corruption S-1930-n, Equal opportunities S-1943-n, Gifts and hospitality S-1931-n and Code of conduct S-1932-n.

Upon commencement of employment, staff are also expected to complete an ethical conduct form S-1693-n. Ethical conduct also forms part of the performance review process S-2368-n.

All staff are bound by the terms of a confidentiality agreement, S-483-n.

All samples are treated in accordance with documentation: Guidance on the Use of Clinical Samples Retained in the Pathology Laboratory, M-176-n, The retention and storage of pathological specimens and records (5th edition) M-175-n and Procedure for the Control of Clinical Material S-178-n.

4.1.1.4 Laboratory director

Prof. Colin Fink, the Laboratory Medical director, and Dr Mark Atkins, Consultant Medical Virologist Microbiologist are Fellows of the Royal College of Pathologists. Prof. Fink maintains ultimate responsibility for the overall operation and administration of the laboratory. Prof. Fink and Dr Atkins are both responsible for directing the clinical diagnostic work and act in the manner of a Caldicott guardians. The duties and responsibilities are detailed in the relevant job descriptions as detailed in M-479-n and M-1607-n.

4.1.2 Management responsibility

4.1.2.1 Management commitment

Micropathology Limited will operate a Quality Management System (QMS), which will integrate the organisation procedures, processes and resources of the laboratory. The Quality Manager (M-482-n) is responsible for establishing, implementing and maintaining the QMS under the direction of the Medical (M-479-n). All members of staff are expected to continually improve the effectiveness of the Quality Management System under the direction of the Quality Manager. The Quality assistants (M-791-n, M – 2409-n) assist in these areas.

4.1.2.2 Needs of users

Micropathology Limited keep in touch with users by i) informal/formal telephone conversations between staff members and clients, ii) visits and telephone calls made by the company representatives, iii) emails to info@micropathology.com and iv) company website. The information gathered may be discussed at Laboratory / section meetings. The company representatives write informative notes detailing all communication held with the users via email, telephone or formal visits. These are available on iPassport.

User feedback is collated as detailed in the procedure Management of complaints and user / personnel feedback and suggestions (S-1078-n) and logged in a customer spreadsheet. Complaints are also recorded directly onto the Non-compliance iPassport Database as detailed in S-1078-n. These maybe discussed at Laboratory meetings.

Micropathology Limited ensures it provides the necessary equipment; environment and staff resources to ensure the needs and requirements of users are met. Requirements for

additional equipment and resources are subject to discussion amongst staff and subsequently with the company directors or in a laboratory meeting.

Micropathology Ltd has a Business Contingency plan (S- 259-n) to ensure in the event of unforeseen circumstances, the needs and requirements of users are still met. Individual laboratory sections also have contingency plans: Microbiology S-1635-n, Virology S-1634-n and Sequencing S-1633-n, Serology S-1662-n.

Micropathology Limited provides routine diagnostic work on an ad-hoc basis. When necessary, Micropathology Limited may enter into a formal Service level agreement as detailed in the 'Procedure for the establishment and review of service level agreements- SOP S-633-n.

Documents pertaining to testing of patient samples and all related equipment maintenance records and calibrations are kept in accordance with the procedure S-177-n.

4.1.2.3 Quality policy

Laboratory management have defined their intent of the QMS in a Quality policy. This is detailed on page 6/7 of this Quality Manual. This policy is reviewed annually to ensure it is appropriate to Micropathology Ltd. A signed copy is displayed in the company kitchen all staff to review. It is also available on the electronic Quality Management System S-1115-n. Quality objectives set at the Annual Management review are determined in line with the Quality policy.

4.1.2.4 Quality objectives and planning

The laboratory management team defines quality objectives at the Annual Management Review. The quality objectives are communicated to the laboratory through the annual management review report (S- 1929-n) and laboratory meetings. Staff are responsible for ensuring that plans are made to meet these objectives. Quality objective progress is subject to discussion in laboratory meetings, and may if required, be subject to amendment. The annual management review determines whether the preceding years objectives have been successfully completed and provides an opportunity for revising them or creating new ones.

The laboratory management have a document ‘Quality indicators’ (S-640-n), which details methods used to monitor quality improvement processes in the pre-examination, examination and post-examination areas of the laboratory.

The laboratory management have a procedure Change Control (S-1099-n) to ensure appropriate change management to enable the integrity of the Quality Management System to be maintained during periods of change.

The change control request form (S-1098-n) serves to monitor change within the company premises.

4.1.2.5 Responsibility, authority and interrelationships

Job descriptions are retained in everyone’s training record folder or, in the case of the directors, the personnel file. Individual staff member’s terms and conditions of service (contracts of employment) are retained by Management in the personnel file. Staff may have more than one role. Details of these roles are also held within staffs individual training folder.

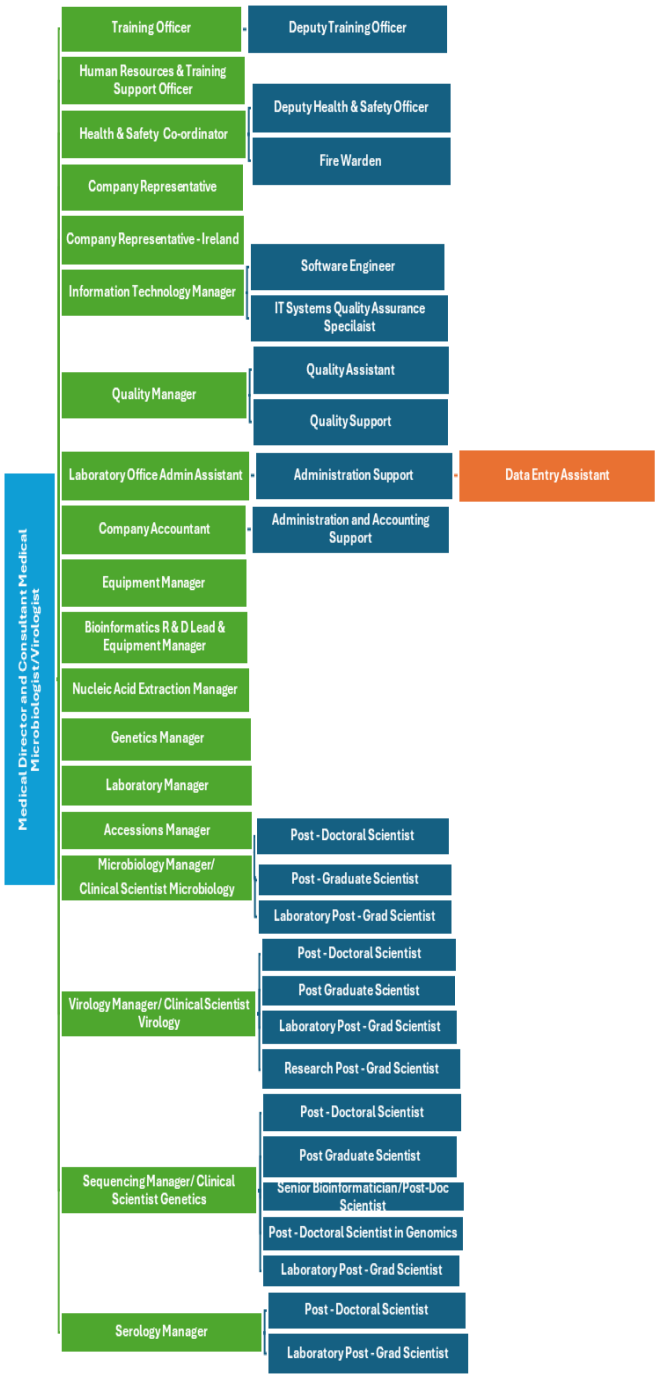
The laboratory have documented defined training programmes to ensure all staff are competent to perform their assigned duties.

Staff responsibilities and line managers are detailed in individual staff job descriptions, which are based below or associated templates:

Scientist - M-129-n
Company Representative - M-191-n
Company Accountant - M-298-n
Medical Director M-479-n
Laboratory Office Admin Assistant - M-480-n
Clinical Scientist Genetics M-2520
Clinical Scientist Microbiology M-2506
Clinical Scientist Virology M-2501
Quality Manager M-482-n
Quality Assistant M – 2409-n and M – 791-n
Quality support M- 2728-n
Health and Safety Co-ordinator - M-622-n
Training Officer - M-623-n
Post-doctoral Scientist – M-666-n
Administration support M-1390-n
Consultant Medical Virologist Microbiologist M-1607-n
Information Technology Manager M-1100-n

ROLES
Equipment Manager M-928 –n
Accessions Manager M-1053-n
Virology Manager M –1054-n
Sequencing Manager M-1055-n
Genetics Manager M 2507-n
Microbiology Manager M-1056-n
Serology Manager M-1061-n
Laboratory Manager M-1518-n
Deputy training officer M-1930-n
Deputy health and safety officer M-1935-n.
Fire warden – M-263-n

Software developer M-1841-n
Human resources and training officer support M-1934
IT systems quality systems specialist M-2007
Administration and accounting support M-1689-n
Data entry assistant - M-2199
Laboratory Post - Graduate Scientist - M – 2260.
Laboratory Assistant - TEMPORARY M – 2267 and M – 2268
Bioinformatics R & D Lead and Equipment Manager M – 2513-n
Post-Doctoral Scientist, Equipment and Nucleic Acid Extraction Manager M – 2422-n
Senior Bioinformatician/ Post-Doctoral Scientist M – 2642-n



Line management inter-relationships are defined above.

Key roles of Medical laboratory director, Quality Manager, IT, Health and Safety, Training Officer are assigned along with relevant deputies or assistants. Additional roles of responsibility are defined within individual staff job descriptions.

There is currently one Medical laboratory company director and a Consultant microbiologist / virologist who are aided by three HealthCare Professions Council state-registered Clinical Scientists (Molecular geneticist, Microbiology and Virology). They in turn are aided by a number of post-doctoral or post-graduate scientists, one of whom is

registered with the IBMS as a Biomedical Scientist and one as an FRCPAth registered Immunologist. The company also employ two Company Representatives, an accountant and several workers who provide administrative assistance.

4.1.2.6 Communication

Communication processes within Micropathology Ltd are documented in S-1939-n Communication. Main general laboratory quality meetings are held on a regular basis to allow a formal exchange of information. These are chaired by the Quality Manager. These meetings follow an agenda and are minuted.

Issues regarding planning and laboratory moves are discussed in ad-hoc Strategic planning meetings chaired and minuted by the Quality Manager. Laboratory staff also hold mini-meetings on an ad-hoc basis within defined laboratory sections (Microbiology, Virology, Serology and Sequencing). These meetings are chaired by the section head and follow an agenda. All meetings are minuted.

Signed copies of the minutes of meetings are held on iPassport under Laboratory Management > meetings for all members of staff, including those not present at the laboratory meeting itself.

4.1.2.7 Quality Manager

The laboratory management has appointed a Quality Manager (M-482-n). The Quality Manager reports directly to the management team and fulfils the role by; ensuring that the quality management system (QMS) is implemented and maintained, reporting to the laboratory management on the functioning and effectiveness of the QMS, educating the staff in quality principles and practice, and coordinating the needs and requirements of users.

4.2 Quality management system

4.2.1 General requirement

The laboratory management have established a Quality Management System, the details of which are outlined in this Quality Manual. All documentation required of this quality management system is held within the electronic QMS iPassport which is hosted by Genial Genetics. Each document may reference other related documents within the document text by referencing each documents iPassport unique identification number. All staff are

involved in continually monitoring its effectiveness in accordance with the ISO15189:2012 standard and to meet the needs and requirements of users.

To ensure compliance with ISO15189:2012 the laboratory shall determine and implement throughout the laboratory, all processes required of the QMS. The laboratory ensures these processes are documented and effective through regular auditing S- 168-n. Non-compliance reporting and monitoring of quality objectives allows continual improvement of these processes.

4.2.2 Documentation requirements

4.2.2.1 General

The Micropathology Ltd QMS documentation includes:

- A Quality Policy (page 6/7) S-1115-n
- Quality objectives, which are updated in on annual basis during the annual management review and are detailed in the Annual Management review report (S-1929-n) and Quality indicators SOP (S-640-n).
- The production of this Quality Manual (S-1089-n) and included within it references to written procedures and records as required by this International Standard.
- Documents and records determined by Micropathology Ltd staff essential in ensuring the effective planning, operation and control of the processes are held on iPassport, the electronic QMS. Related documents are referenced within each document using the specific documents unique iPassport reference number.
- Copies of all external regulations and standards which staff should be considerate of in their work are held on iPassport, the electronic QMS.

4.2.2.2 Quality Manual

This Quality Manual describes the Quality Management System (QMS) of Micropathology Limited for the benefit of the management and staff of the company and provides information for inspection or accreditation bodies. It contains references to ISO15189:2012 standard and to procedures written in fulfilment of these standards.

This Quality manual contains the Quality Policy (S-1115-n).

The sections of this Quality Manual are arranged to equate with the ISO15189:2012 standard and provide information on the scope of the Quality Management System. The

title of each standard is accompanied by a brief description of how Micropathology Limited seeks to comply.

New editions are circulated amongst the staff to keep them informed and up-to-date**.**

4.3 Document Control

The laboratory management have established a procedure, Document control, (S-1-n), which controls all internally and externally generated documents relevant to the establishment, maintenance and improvement of the Quality Management System.

4.4 Service level agreements

4.4.1 Establishment of service level agreements

The laboratory has established a document for the establishment and review of service level agreements (SLAs) for the provision of medical laboratory services (S-633-n)**.** Every request received by Micropathology Ltd is an agreement to perform a diagnostic service, where relevant and appropriate.

The laboratory has a service level agreement template which may be used (S-632-n). In this the requirements of the user and provider of the laboratory service are defined. The laboratory will also consider user defined service level agreements.
Please also refer to the section Selection, verification and validation of examination procedures (page 29 of this Quality Manual) for details of the selection of appropriate processes.

4.4.2 Review of service level agreements

SLAs are reviewed as detailed in S-633-n. Micropathology Ltd communicate with users three months inside the anniversary of the review date of the SLA to determine whether the SLA is to continue. Notes of these communications are held on iPassport.

4.5 Examination by referral laboratories

Micropathology do not routinely refer specimens to other laboratories. If necessary samples can be sent for referral according to the procedure are handled using the

procedure ‘Examination by referral laboratories and sending samples to other laboratories’ (S-11-n). Accreditation status, EQA performance and general laboratory performance may also be requested by way of a letter (Accreditation status letter S-564-n). Results are transcribed into the Micropathology Ltd LIMS for indefinite retention of data. Results are forwarded to the user along with details of where the testing was performed and any clinical reference values / biological interval information.

4.6 External services and supplies

The laboratory have established procedures for the selection and purchasing of external services, supplies, equipment, reagents, consumables that may affect the quality of its service. This is detailed in the procedure ‘Procurement and Management of equipment, S-186-n and Reagents and consumables S-192-n. Monitoring of suppliers is detailed in S – 2283-n.

4.7 Advisory services

The laboratory has established methods for communication with users as detailed in complaints and user / personnel feedback / suggestions S – 1078-n and Communication SOP S – 1939-n.

Information is available on the company’s website (http://www.micropathology.com/) from where the Laboratory User Handbook (S-748-n), sample request forms and information sheets can also be downloaded.

Details for contacting the laboratory are available on the company website and in the laboratory user handbook. The company also employs a company representative, who, continues to visit and telephone clients regularly and provides feedback, via written report, on their satisfaction with the service, any suggestions for improvement, any complaints and any requests they might have.

The laboratory management have established a procedure for the provision of clinical advice and interpretive comments. See S-13-n, Clinical Advice, Authorising and out of hours service.

Medical and scientific staff consult on the effective provision of services at laboratory meetings (see section 4.1.2.6 or further details).

Staff may alert users to scientific and logistic issues with samples by telephone or email communication. Staff may also indicate any issues by way of a caveat or interpretative comments on reports**.** Medical and scientific staff consult on the effective provision of services at laboratory meetings.

4.8 Resolution of complaints

The laboratory Management have established a procedure for the management of complaints and other feedback / suggestions received from clinicians, laboratory staff, personnel and other parties (S-1078-n). Records of such communications are kept and are acted upon if required.

4.9 – 4.11 Identification and control of non-conformities, corrective action and preventative action

The laboratory management has established procedure for the identification and control of non-conformities and the implementation of corrective and preventative action (Identification and control of non-conformities, S-572-n). Risk management and opportunities for improvement is detailed in S – 2722-n.

4.12 Continual improvement

The laboratory management has established procedures; Procedures for evaluation and improvement processes (S-187-n) and Quality Indicators (S-640-n) for continual improvement. Through the Annual Management Review and associated report (S – 1929-n) the laboratories performance on an annual basis is assessed.

4.13 Control of Records

The laboratory management have established a procedure, S-177-n, for the Control of Records. Documents amendments are in accordance with the procedure 'Document control' S-1-n.

The company is registered as a data controller with the Information Commissioner's Office. Prof. Colin Fink and Dr Mark Atkins act in the manner of Caldicott guardians.

4.14 Evaluation and audits

The laboratory management have established procedures Quality Indicators (S-640-n), Procedure for evaluation and improvement (S-187-n), Identification and control of non-

conformities (S-572-n), Risk management and opportunities for improvement S – 2722-n, Inter laboratory comparisons (EQA) (S-531-n) and Auditing (S-168-n)) for:

a) Periodic review of requests, suitability of procedure and sample requirements (4.14.2) as detailed in the annual management review S-1929-n.
b) Assessment of user satisfaction and complaints (4.14.3) S- 1078-n
c) Staff suggestions (4.14.4) S – 640-n
d) Internal audit (4.14.5) -S- 168-n
e) Risk Management (4.14.6) S-2722-n
f) Quality Indicators (4.14.7) S – 640-n
g) Reports from external assessments bodies (4.14.8) S – 531-n

To demonstrate that:

- The Quality Management System is being conducted in a manner that meets the need and requirements of users;
- There is conformity to the QMS;
- Continual improvement of the QMS and improved effectiveness.

Additionally, all items may be subject to discussion in various types of laboratory meetings. All meetings are minuted and minutes distributed to all staff.

The results of the evaluation and improvement processes are included in the input of the annual management review (4.15.4).

4.15 Management review

The laboratory management review the QMS at yearly intervals (4.15.1). The following items of information are considered (4.15.2);

a. Periodic review of requests, suitability of procedure and sample requirements
b. Assessment of user satisfaction and complaints
c. Staff suggestions
d. Internal audit
e. Risk Management
f. Use of Quality indicators
g. Reports of assessments by external organisations

h. Interlaboratory comparison programme reports
i. Monitoring and resolution of complaints
j. Performance of suppliers
k. Identification and control of non-conformities
l. Results of continual improvement
m. Follow up of previous management reviews.
n. Major changes in organisation and management, resource (including staffing) or process
o. Recommendations for improvement, including technical requirements.

The review also includes information regarding the causes for non-compliances within these sections and details any noticeable trends / patterns that may indicate a process problem (4.15.3).

Key objectives for the subsequent year are defined and plans formulated for their implementation. Records are kept and a summary (S- 1929-n S – 2487-n) is communicated to staff and sent to the UKAS assessment manager ahead of yearly inspections (4.15.4).

5 TECHNICAL REQUIREMENTS

5.1 Personnel

5.1.1 General

The laboratory management have established a procedure, S-182-n (Procedure for personnel management), which allows staff to contribute fully and effectively to the service and receive fair and consistent treatment from laboratory management.

5.1.2 Personnel qualifications

Details of staff personal qualifications (CVs and copies of relevant degree certificates) are kept in the confidential personnel folder. Copies of IBMS / RCPath registration certificates are kept in the individuals training record folder. Staff registered by the HCPC can be checked on the HCPC website https://www.hcpc-uk.org

5.1.3 Job descriptions

Job descriptions are based on the templates as detailed in section Responsibility, authority

and inter-relationships (Page 12 and 13 of this Quality Manual). Copies are retained in each individual's training record folder or, in the case of the directors, the personnel file.

Individual staff member's terms and conditions of service (contracts of employment) are retained by Directors in the confidential personnel folder. The confidential personnel folder also contains sickness and absence records, and occupational health records.

5.1.4 and 5.1.5 Staff induction and training

New personnel go through a staff orientation and induction process (S-30-n Induction and S-598-n, Induction record) which includes an assessment of ethical conduct (S-1693-n) and confidentiality of patient information S-483-n.

Following completion of this, staff follow a supervised SOP-based training in all relevant aspects of their routine diagnostic work (see Training policy and competency assessment M-54-n, Training record form S-587-n and Personal Training Programme M-199-n). The training officer oversees this process. Records of the induction process and training are retained in each individual's personnel file and training record folder respectively.

Following the period of SOP-based training, other training resources are available: Micropathology Limited subscribes to a variety of journals and is a corporate member of the University of Warwick Library. All members of staff have access to the Internet. Micropathology Ltd. also hold in-house Journal Clubs; internal staff and external speakers may be invited to present and all staff are encouraged to participate. Personnel are encouraged to attend relevant meetings and conferences. Funding (to cover society membership, travel, conference fees and expenses) is provided by arrangement with the directors.

Training and competency, copies of registration certificates and Continuing Professional Development are kept in the individual's training folder.

The Health & Safety Co-ordinator keeps records of attendance at fire safety training, manual handling training sessions. Confidential records of accidents are retained in staff personnel files.

The training programme is tailored to each member of staff based on their intended role. Records of these are held on iPassport and in staff training folders.

5.1.6 Competence

Competency is individually tailored for each staff member as detailed in M-54-n Training policy and competency assessment.

Staff are also subject to witness audits as detailed in the procedure 'Auditing' S-168 and are involved in participation in EQA (Inter laboratory comparison S-531-n) and IQA (IQA list S-273-n) schemes to demonstrate competence and inter-operator comparability schemes (S-1256-n, S-1270-n, S-1356-n, S-1924-n).

5.1.7 Review of staff performance

Staff annual joint reviews are carried out according to the procedure Performance review S – 2368-n).

These are performed by staff line managers. The Human Resources manager keeps records in the staff personnel folder.

5.1.8 Continuing professional development

All personnel are encouraged undergo continual professional development (M-54-n) and to keep records electronically or in personal or training record files for each individual.

5.1.9 Personnel records

Personnel records are kept as detailed in the procedure for personnel management S-182-n. Job descriptions, training and competency, copies of registration certificates and Continuing Professional Development are kept in the individual's training folder.

The confidential personnel folder contains records of induction, CV's, copies of degree certificates, terms and conditions of employment, sickness and absence records, ethical records and occupational health records / records of accidents.

The Health & Safety Co-ordinator keeps records of attendance at fire safety training, manual handling training sessions and visual display equipment assessments.

.

5.2 Accommodation and environmental conditions

5.2.1 General

Micropathology Limited occupies several combined units within The Venture Centre on the University of Warwick Science Park. A floor plan of Micropathology Limited is provided in Appendix 1.

Risk assessments (R – 1945-n, R – 1946, R – 1947-n, R – 1948-n , R – 1949-n, R – 1950-n) are performed for each area to assess the health and safety of laboratory personnel and sufficiency and adequacy of laboratory space to ensure the continued quality, safety and efficacy of the service provided to the users .

5.2.2 Laboratory and office facilities

The Venture Centre provides a secure working environment. All visitors must first sign in at the reception desk and there is a security presence at night, during weekends and Bank Holidays. Micropathology Limited has its own security system, including electronic door locks and an intruder alarm. Key coded electronic locks protect all entry and exit doors.
Medical information, patient samples and laboratory resources are safeguarded from unauthorised access in accordance with the procedures ‘Control of records (S-177-n) and Control of clinical material (S-178-n) and the confidentiality agreement S-483-n.

Communication within the company is defined in the document ‘Communication’ S-1939-n.

Facilities within the office and laboratory space are controlled as detailed within the procedure S- 1952-n, Health and Safety and Welfare at Micropathology Ltd.

5.2.3 Storage facilities

Records:

The laboratory management have established a procedure, S-177-n, for the Control of Records. Current process and quality records are stored electronically in the QMS iPassport. There is adequate storage space for the retention of paper records, as appropriate. Archived paper copies may be scanned to the Company server and stored for reference. Experimental data results are stored electronically on the server and are backed up in accordance with above procedure (S-177-n). Patient records are stored electronically on the LIMS.

Clinical material:

Fridges and freezers are available for the storage of clinical material. Clinical samples are archived in numbered boxes kept at -20ºC. The laboratory management have established a procedure, S-178-n, for the Control of Clinical Material detailing the storage of these samples. Monitoring of the fridge freezer temperatures is detailed in S – 36-n, Temperature and humidity data logging.

Extracted nucleic acids

Specimen extracts are available for repeat testing or additional testing. Extracts are stored at 4ºC. The laboratory management have established a procedure, S-178-n, for the Control of Clinical Material detailing the storage of these samples. Monitoring of the fridge freezer temperatures is detailed in S – 36-n, Temperature and humidity data logging.

Hazardous substances:

There are separate cabinets for the storage of duty-free spirits, other flammable liquids, acids, alkalis and toxic chemicals. Non-toxic chemicals are stored in the appropriately labelled cupboard in the laboratory.

Reagents and consumables:

Reagents and controls are stored at 4ºC, -20ºC or -70ºC as required in fridges and freezers in the laboratory or storerooms. Monitoring of the fridge freezer and room temperatures and humidity, as applicable, is detailed in S – 36-n, Temperature and humidity data logging.

Some reagents may be stored at room temperature. Consumables are stored in various locations within the laboratory and store rooms.

Waste material for disposal:

This is stored in the laboratory in large, rigid, lidded containers prior to autoclaving. Autoclaved waste is transported to the clinical waste skip at the rear of the laboratory to be removed by authorised agents. The laboratory have established a procedure 'Waste disposal and disinfection' S-51-n for the disposal of clinical waste.

5.2.4 Staff facilities

Toilets, which are cleaned and maintained by the Venture Centre, can be found in the corridor next to the units. Shower facilities and additional toilets are available further along the corridor. Basic catering and dining facilities are provided within the unit. Members of staff are provided with locking desk drawers for the storage of personal effects and protective clothing is stored in various locations within the laboratory. There are no requirements for overnight accommodation.

5.2.5 Patients

Patient samples are not taken at Micropathology Limited. Micropathology Ltd. may sometimes take samples from staff for occupational reasons as defined in S-1981-n.

5.2.6 Facility maintenance and environmental conditions

Micropathology Ltd have a procedure 1952-n, Health and Safety and Welfare at Micropathology Ltd. that details Facility maintenance and environmental conditions. There is a designated Health & Safety Co-ordinator, and Deputy Health & Safety Officer and Fire Warden and Fire Marshalls. They are responsible for defining, implementing and maintaining the Health and Safety and Fire procedures and relevant standards within the company to ensure it is maintained in a functional and reliable condition.

Fire risk assessments are carried out according to the protocol provided in Fire risk assessment procedure (S-31-n).

Copies of the Laboratory Safety Manual (R-589-n) and Waste Disposal procedure (S-51-n) are available on iPassport and displayed in the laboratory respectively.

Personal protective equipment (gloves, lab coats, eye protection) is available for each employee and visitors.

The laboratory containment facilities conform to the requirements of the Advisory Committee on Dangerous Pathogens guidelines.

Room temperature and humidity are monitored on a daily basis in accordance with S-36-n and results recorded on the forms S – 1269-n andS-1569-n.

The laboratory is divided into specific areas allowing effective separation between the pre-amplification (clean) and post-amplification (sequencing) rooms to prevent sample contamination. Please refer to the laboratory floor plan as detailed in Appendix 1.

5.3 Laboratory equipment reagents and consumables

5.3.1 Equipment

5.3.1.1 General

The laboratory management have established a procedure, for the proper procurement and management of equipment required to fulfil the needs and requirements of users and the provision of the service. See S-186-n Procurement and management of equipment. Details of preventative maintenance, incident reporting and equipment records are detailed within this SOP.

5.3.1.2 Equipment acceptance testing

The laboratory management have established a procedure, for the acceptance testing and verification of equipment (See S-804-n) to demonstrate acceptability of equipment performance and 'fitness for purpose' upon installation or software upgrade.

Equipment acceptance testing post repair, post service ,on loan or removed from storage is detailed in S-1058-n and equipment move validation S – 868-n

5.3.1.3 Equipment instructions for use

All relevant instruction manuals are either uploaded to the electronic Quality Management System software, iPassport, or are stored near to the relevant equipment as detailed in S-186 Procurement and management of equipment. In both instances, manuals are subject to document control as detailed in the procedure 'Document control' S-1-n.

5.3.1.4 Equipment calibration and metological traceability

The laboratory management has a procedure for the calibration of equipment S-223-n (Equipment Calibration and traceability) and for determination of traceability, where required, of any equipment involved in the diagnostic process.

5.3.1.5 Equipment maintenance and repair

The laboratory management have established a programme of preventative maintenance in accordance with the procedure S-186-n, Procurement and management of equipment. Where equipment has to be removed from the direct control of the laboratory for servicing, or repair, its performance is verified upon return before routine use, as detailed in the procedure Equipment verification – post service / repair / on loan or removed from storage S-1058-n.

All equipment, where required, should be decontaminated, prior to repair or preventative maintenance. A decontamination certificate should be completed by laboratory staff (Decontamination certificate for contractors R-1557-n).

5.3.1.6 Equipment adverse incident reporting

Adverse incidents and accidents are reported in accordance with the procedure S-186-n, Procurement and management of equipment.

5.3.1.7 Equipment records

Equipment records are kept as detailed in the procedure S-186-n, Procurement and management of equipment.

The inventory of laboratory equipment is kept in the iPassport database. The inventory of pipettes is kept in a database F:\UKAS ISO15189 2012\Equipment\Pipettes. The pipette calibration records can be found in the ‘Pipette Calibration Records’ file in the laboratory and the relevant year folders within F:\UKAS ISO15189 2012\Equipment\Pipettes. Use of this database is detailed in S – 2723-n. IT related equipment is held in Spiceworks, an IT network monitoring tool.

Thermal cycler calibrations certificates are located in the F:\UKAS ISO15189 2012\Equipment\Thermocycler Validations folder. Additionally, all certificates are also attached to the corresponding equipment on iPassport.

Equipment preventative maintenance visits are recorded on the QMS iPassport and in three equipment folders "Equipment - Service contracts", "Equipment - Calibration certificates" and "Equipment - Service reports" stored in the Quality Management System cupboard.

To ensure all equipment post calibration or service is fit for purpose, service reports and calibration certificates are reviewed and signed and dated as a statement of acceptability (As defined in the Procurement of Management of Equipment procedure S-186-n).

5.3.2 Reagents and consumables.

The laboratory management have established a procedure, for the proper management of all materials used in the provision of the service. See S-192-n Reagents and consumables (Management of materials) for details on reception and storage, acceptance testing, inventory management, instructions for use, adverse incident reporting and records. In-house databases are used to record primer and control batches and acceptance testing in accordance with the procedure S- 1696-n Online controls register user guide and S-1790-n Primer eregister user guide.

5.4 Pre-examination processes

5.4.2 Information for users

Details of the laboratory services including examinations, laboratory location and hours of operation, completion of the request form, transportation of samples, requirements for consent, sample rejection criteria and factors affecting the performance of examination or interpretation of results are detailed in the Laboratory User Handbook (S-748-n).

The laboratory produces a series of educational information sheets covering several tests offered by Micropathology Ltd. These are readily available on the company website www.micropathology.com for reference.

Micropathology Limited prefers to deal with healthcare providers and diagnostic laboratories, however some special interest groups of patients approach Prof. Fink directly. Investigative tests on samples from these patients will only be considered if Prof. Fink or a GP referral (to Prof. Colin Fink) are received.

Additionally, the laboratory receives requests from HM Coroners for identification of human remains. The company will NOT undertake receipt of specimens for testing directly from members of the public, for reasons of medical safety.

5.4.3 Request form information

The company accepts requests for diagnostic testing on any locally sourced pathology request form. The company will only carry out testing from *bona fide* laboratory, hospital or medical practitioner sources.

Users are able to source standard request forms and request forms for the identification of human remains via our website (http://www.micropathology.com/) . Alternatively users may contact the company directly. Requests for additional testing on a sample already received may be made by telephone or email as detailed in the Laboratory User Handbook (S-748-n) and the procedure S-2246 Telephone message and additional test request SOP.
.

Details for the completion of the request form are included in the Laboratory User Handbook (S-748-n).

5.4.4 Primary Sample Collection and Handling

5.4.4.1 General

Micropathology Limited mainly handles specimens that have been collected by our clients who are themselves familiar with the safety requirements necessary for their transportation. Specimens received by the laboratory are subject to handling conditions laid out in the Laboratory Safety Manual (R-589-n) and in the SOP S-10-n: (Specimen receipt (Accessions)). Sample volume requirements are stated in the User Handbook.

Details ensuring unequivocal link between the patient sample and the request form are provided in the Laboratory User handbook (S-748-n).

For the identification of human remains service, tissue samples are generally provided by hospital mortuary services. Personal items from the deceased or mouth swab specimens from close relatives are usually collected by police officers or coroner's assistants. Information on secure specimen collection is available from the laboratory.

Micropathology Ltd. may sometimes take samples from staff for occupational reasons as defined in S-1981-n.

5.4.4.2 Instructions for pre-collection activities

The laboratory provides instructions for the proper completion of request forms in the Laboratory user handbook S-748-n. Micropathology Limited are not involved in the collection of primary samples from patients, however on occasion staff samples may be taken for occupational health reasons; S – 1981-n defines the procedure for pre-collection activities in relation to staff sampling. Samples requiring further preparation upon receipt into the laboratory are handled in accordance with the Specimen receipt procedure, S-10-n.

5.4.4.3 Instructions for collection acitivities

The laboratory are not involved in the collection of primary samples from patients. S-1981-n defines the process for collection of samples from staff when required.

5.4.5 Specimen Transportation

Transport of specimens to other diagnostic laboratories at the client's request, or return the sample to the sender, is performed according to the SOP 'Specimen transportation' (S-779-n). The correct packaging of samples for transportation is detailed in the Laboratory Safety Manual (R-589-n).

5.4.6 Specimen Reception

Specimen receipt is performed according to the SOP S-10-n, 'Specimen receipt (Accessions)'. Rejection of specimens is also covered in this SOP.

The date and time of receipt of samples into the laboratory is captured both in the LIMS system and additionally on an accessions sample labelling form (S-859-n). The identity of the persons receiving the sample into the laboratory is captured on the accessions sample labelling form (S-859-n).

Urgent samples are handled in accordance with the procedure S-10-n, 'Specimen receipt (Accessions)'.

5.4.7 Pre-examination handling, preparation and storage

Details of patient sample security, protection from deterioration, loss and damage are included in the procedure, S-178-n, for the Procedure for the Control of Clinical Material.

Time limits for requesting additional examinations are detailed in the Laboratory User Handbook (S-748-n).

5.5 Examination processes

5.5.1 Selection, verification and validation of examination procedures

5.5.1.1 General

The laboratory selects examination procedures, which have been validated, or verified using the procedures detailed below (5.5.1.2 and 5.5.1.3) for diagnostic use. These are detailed in the laboratory user handbook S-748-n. The persons involved in testing diagnostic samples are recorded on laboratory worksheets (S-639-n, S-716-n, S-717-n, S-807-n, S-901-n, S-1137-n, S-1244-n, S-1245-n, S-1246-n, S-1247-n, S-1484-n, S-1881-n), which are subsequently electronically archived, or are recorded on the equipment used in the analysis of the patient samples.

5.5.1.2 Verification of examination procedures

The laboratory has a procedure for the validation of examination procedures used without modification. Diagnostic kits used without modification, and equipment, are verified using the procedure 'Equipment / method / software upgrade verification of examination procedures' S-804-n through the examination of objective evidence and comparison to the manufacturers performance characteristics.

Completed verifications are subject to document control (S-1-n) and are held electronically on the QMS, iPassport.

5.5.1.3 Validation of examination procedures

In-house diagnostic assays, non-standard methods, standard methods used outside the intended scope or validated methods subsequently modified are all validated for their intended use prior to their introduction according the SOP Assay validation - MASTER (S-508-n) and template (S-266-n). Validation procedures for each assay are recorded using this template and include the objective evidence in the form of performance characteristics, in support of the assay validation.

Completed validations are subject to document control (S-1-n) and are held electronically on the QMS, iPassport.

When examination procedures are changed so that results or their interpretation may be significantly different then Micropathology Limited informs all users of the service by letter or email in advance of the change and/or addition of a caveat to reported results informing clients of an impending or recent alteration.

5.5.1.4 Measurement uncertainty

The laboratory management have a document 'Uncertainty of measurement and Quality control monitoring' S-910-n which details the estimation of measurement uncertainty for assays and other 'imported uncertainties, which may influence the results of an assay.

5.5.2 Biological reference intervals or clinical decision values

Reference values for serology assays are detailed in the Laboratory User handbook, S-748-n.

The Laboratory management have two documents 'Master SOP' (S-5-n) and Assay validation –MASTER (S-508-n) that details the inclusion of biological reference intervals or clinical decision values where appropriate.

5.5.3 Documentation of examination procedures

Diagnostic assays are performed according to Standard Operating Procedures that are available on the QMS, iPassport. A template is provided for the guidance of those writing new procedures S-5-n (Master SOP).

Manufacturer's instructions are held electronically on iPassport as controlled (external) documents. Deviations from the instructions are validated, documented and reviewed separately.

All documents associated with the performance of the examinations are also subject to document control (S-1-n).

When examination procedures are changed so that results or their interpretation may be significantly different then Micropathology Limited informs all users of the service by letter or email in advance of the change and/or addition of a caveat to reported results informing clients of an impending alteration.

5.6 Ensuring quality of examination procedures

5.6.1 General

Micropathology Ltd have a document, Health and Safety and Welfare R-1952-n which details facility maintenance and details procedures undertaken to ensure that the quality of examination procedures is maintained.

In addition, the quality of examinations is ensured by the application of the following processes and procedures:

a) Internal Quality Control of ELISAs - S-158-n.
b) The inclusion of positive and negative controls in nucleic acid detection assays is detailed in the relevant SOPs and associated validation procedures.
c) Assay internal positive control is detailed in the SOP Ensuring the Quality of examination results – Repeat testing of samples S-796-n.
d) External Quality Assessment schemes – Participation in EQA schemes is detailed in the Inter-laboratory comparisons (EQA) S-531-n and Procedures for evaluation and improvement S-187-n SOPs.
e) Internal Quality Assurance - IQA S-183-n.

5.6.2 Quality Control

5.6.2.1 General

The laboratory uses quality control materials in all diagnostic assays in accordance with instructions detailed in assay specific assay validations (S-508-n) / SOPs (S – 5-n) or manufacturers specifications.

5.6.2.2 Quality Control materials

The laboratory use Quality controls of diagnostic kits in accordance with manufacturers specifications. All kit instructions are held on the electronic Quality Management system iPassport in accordance with the procedure, Document control S-1-n.

All controls used in in-house validated assays are used in accordance with the assay specific SOP. They are used in a manner to mimic patient samples at or near to the limit of detection of the assay (Assay validation – MASTER S-508-n and Master SOP S-5-n).

5.6.2.3 Quality control data

The laboratory management has a procedure ‘Ensuring the quality of examination procedures - repeat testing of samples’ S-796-n which prevent the release of patient results in the event of quality control failure.

The laboratory has designed several excel based programs which monitors the Quality controls of quantitative and qualitative assays to detect trends in examination performance that may indicate problems in the examination system (S-910-n Uncertainty of measurement and Quality Control Monitoring).

5.6.3 Inter-laboratory comparisons

5.6.3.1 Participation

The laboratory management have a document, Inter laboratory comparison (EQA) S-531-n, detailing the requirement for the laboratory to participate in suitable external quality assurance panels.

5.6.3.2 Alternative approaches

The procedure Inter laboratory comparison (EQA) S-531-n, also details , the requirement to arrange informal inter laboratory comparisons in the absence of a suitable formal external panel.

5.6.3.3 Analysis of interlaboratory comparison samples

The handling, processing and testing of inter-laboratory comparison samples is detailed in the Inter laboratory comparison (EQA) procedure S-531-n and the individual procedures for analysis of EQA panels from QCMD (S-1158-n), NEQAS (S-1558-n) and INSTAND (S-1534-n).

5.6.3.4 Evaluation of laboratory performance

The evaluation of laboratory performance in inter-laboratory comparison schemes is recorded on:

- EQA Analysis form (QCMD/NEQAS) S-1433-n
- NEQAS EQA review form S-570-n

in accordance with the procedure Inter laboratory comparison (EQA) procedure S-531-n and individual procedures for analysis of EQA panels from QCMD (S-1158-n), NEQAS (S-1558-n) and INSTAND (S-1534-n). Results are also discussed in various laboratory and /

or Quality meetings, all of which are minuted and the minutes available on iPassport, the electronic Quality Management system.

5.6.4 Comparability of results

Staff consider the comparability of patient sample results, using different equipment and procedures, during the validation processes (Assay validation – MASTER S-508-n).

5.7 Post-examination processes

5.7.1 Review of results

Staff review results prior to release in accordance with the procedure ‘Results release’ S-1063-n. Consideration is paid to the performance of the quality control material, the patient clinical history and any relevant patient testing history. S-2248-n Reporting results in StarLIMS SOP and S-5 Master SOP detail the process of result entering into LIMS.

5.7.2 Storage, retention and disposal of clinical samples

The laboratory management have a documented procedure S-178-n, for the control of clinical material, detailing the identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.

5.8 Reporting of results

5.8.1 General

All results are recorded and reported using StarLIMS in accordance with the SOP ‘S-2248-n Reporting results in StarLIMS . In accordance with the laboratory document, MASTER SOP template, each examination procedure should define the ‘Calculation of results’ and ‘Acceptance criteria’.

Reports are emailed to clients on the day that they are generated. This is detailed in the procedure ‘Results release’ S-1063-n.

Turnaround times are set by measurement of the median time between sample receipt and result availability. Weekends are not included in test turnaround time calculations. Batching is rarely applied to samples and when this happens the client’s needs and requirements are always considered. Users are informed by email or telephone if results will be delayed by assay or equipment failure as detailed in ‘Results release’ S-1063-n.

5.8.2 Report attributes

Space is included on all Micropathology Ltd results reports produced by the LIMS for comments on sample quality, sample suitability, critical results and interpretative comments.

5.8.3 Report content

All reports transmitted from Micropathology Ltd include the examination performed, including those by a referral laboratory, the examination results, biological reference values / critical decision values, interpretation of results, any other comments particularly those concerning the points in report attributes.

The report issuing laboratory, patient identification, requesters identification, date of primary sample collection, type of primary sample, name of the person reviewing and authorising the results, date and time of report release and report pagination are also included.

5.9 Release of results

5.9.1 General

The laboratory management have established a procedure, S-1063-n Results release, detailing who may release results and to whom. This document also details the procedure to take when results fall within an ‘alert’ or ‘critical’ value and for those results given over the telephone. Records are maintained of any results given over the telephone, in particular with reference to a critical result on the telephone message logging form (S-808-n). These records are attached to the relevant patient entry in StarLIMS.

A final report always follows those results transmitted as an interim.

5.9.2 Automated selection and reporting of results

The laboratory does not automatically select and report results.

5.9.3 Revised reports

The laboratory management have established a procedure, S-1063-n Results release, for issuing an amended report. The original report remains with the relevant patient entry in StarLIMS.

5.10 Laboratory Information Management

5.10.1 General

The Employee contract (Employee handbook and statement of main terms and conditions), 'Safety and Confidentiality Agreement' S – 483-n and IT security policy (M-1936-n) ensure the confidentiality of patient information by all staff upon commencement of employment at Micropathology Ltd. The Control of Records procedure, S-177-n, details the security in place at Micropathology Limited to prevent unauthorised access to all confidential patient and company records.

The procedure, StarLIMS usage' (S-42-n) defines how users can access the patient LIMS for data and result entry.

The company is also registered with the Information Commissioners Office for Data Protection.

5.10.2 Authorities and responsibilities

The authorities and responsibilities for the management of the information system are detailed in the documented procedure 'StarLIMS Usage' S-42-n.

5.10.3 Information system management

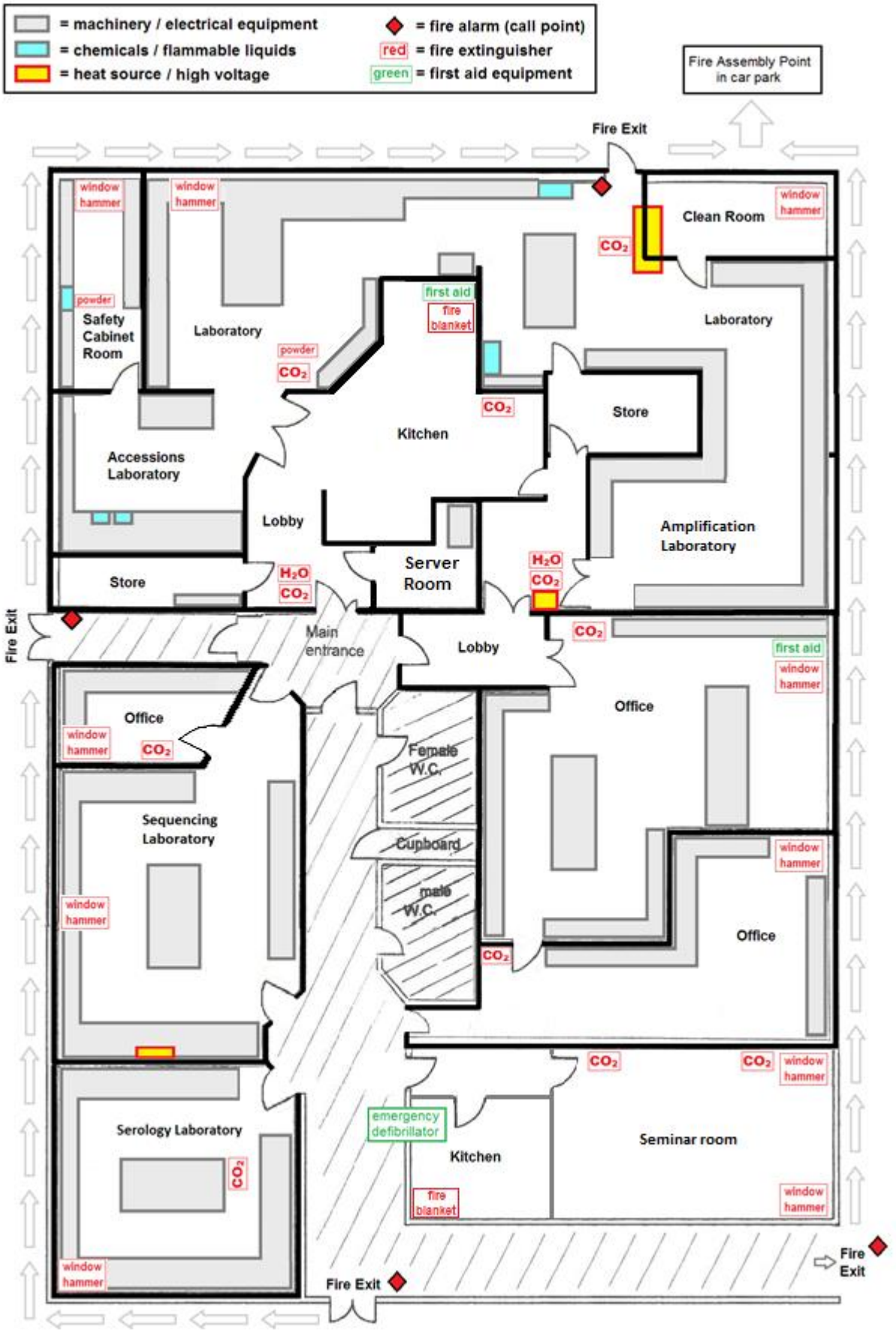
The laboratory management have a documented procedure 'Software systems change procedure S-1833-n for managing changes prior and post implementation to LIMS database. Micropathology Ltd. co-operate with clients to verify information systems, where appropriate.

The day to day functioning of the system is documented in the procedure 'StarLIMS Usage' S-42-n, S-2247-n Booking samples into StarLIMS and S-2248-n Reporting results in StarLIMS SOP.

The laboratory management have a documented procedure ‘Contingency plan’ S-259-n, to maintain services in the event of failure or downtime in the information systems which affect the laboratory service.

The Control of Records procedure, S-177-n, details the security in place at Micropathology Limited to prevent records deterioration.

Appendix 1 – Micropathology Ltd. Floorplan



Note: Shaded areas are not part of Micropathology Ltd.