Advance Histopathology Laboratory Ltd

# Advance Histopathology Laboratory Limited

**Inspection report**

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

## Ratings

| | |
|---|---|
| Overall rating for this location | Inspected but not rated |
| Are services safe? | Inspected but not rated |
| Are services effective? | Inspected but not rated |
| Are services responsive to people's needs? | Inspected but not rated |
| Are services well-led? | Inspected but not rated |

# Summary of findings

## Overall summary

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

We looked at four key questions: is the service safe, effective, responsive and well led. We did not inspect caring as the service does not have direct contact or interaction with patients.

- The service had enough staff with the right qualifications, skills, training and experience. Staff had training on how to recognise and report abuse and they knew how to apply it. The service-controlled infection risk well. All areas and equipment within the laboratory were clean and well-maintained. The design, maintenance and use of facilities, premises and equipment kept people safe. Staff completed risk assessments for each test carried out, and for equipment used and the environment. There was a system to report safety incidents and staff knew how to report incidents and near misses.
- Managers monitored the effectiveness of the service and made sure staff were competent. The service provided services based on national guidance and evidence-based practice. Staff worked well together and with their partners for the benefit of patients and the service. The service was available six days a week with urgent cover available out of working hours and during busy times to support the requirement of the service.
- The laboratory planned and provided a service in a way that met the needs of referring clinicians using the service. Facilities and premises were appropriate for the services being delivered. Referring clinicians could access the service when they needed it and received the laboratory results promptly. There was an annual user feedback survey which referring clinicians and external partners were invited to complete.
- Leaders had the skills and abilities to run the service and were visible and approachable. Staff felt respected, supported and valued. Staff were clear about their roles and accountabilities. Leaders and teams used systems to manage performance effectively. Leaders ran services well using reliable information systems and supported staff to develop their skills. The information systems were integrated and secure. Leaders and staff engaged well with colleagues and there were positive, collaborative relationships with external partners.

However:

- At the time of inspection, the safeguarding lead for the service had not completed the required level of training for this role.

# Summary of findings

## Our judgements about each of the main services

| Service | Rating | Summary of each main service |
|---|---|---|
| **Medical laboratories** | Inspected but not rated | We did not rate this service. This is because CQC does not apply a rating to independent laboratory services. |

# Summary of findings

## Contents

# Summary of this inspection

## Background to Advance Histopathology Laboratory Limited

Advance Histopathology Laboratory Ltd (AHLab) provides histopathology diagnostic analysis utilising a range of cellular pathology techniques such as special stains, frozen section and electron microscopy. The service also provides a cytology management handling service and a specialist second opinion for doctors and patients on their pathology and cancer diagnosis.

This service was established in 2016. The service has had a registered manager in post since 2016 and is registered to provide the regulated activity:

- Diagnostic and screening procedures.

The laboratory is registered with the United Kingdom Accreditation Service (UKAS) (9997), which is the internationally recognised accreditation for medical laboratories. The most recent UKAS inspection took place June 2021, which resulted in the provider being requested to take one action, this had been completed.

The service processes around 18 samples per day and 390 cases per month. For the period of September 2020 to September 2021, the number of specimen samples processed by the service was 5,077. It is a small independent laboratory with an open office, a closed office, staff changing room and toilets.

The laboratory does not have any direct contact with patients.

The laboratory is open from 9am to 9pm from Monday to Friday and from 10am to 1pm on Saturdays. There is a 24 hour on call system in place for more urgent requests.

We carried out an unannounced inspection on 05 October 2021 using our comprehensive inspection methodology.

## How we carried out this inspection

The inspection team consisted of an inspector and a specialist adviser and was overseen by Nicola Wise, a head of hospital inspection.

During the inspection, we inspected the pathology laboratory using our comprehensive inspection methodology. We spoke with four staff, including laboratory staff, who conducted the sample testing, office manager, laboratory/quality manager and registered manager. We reviewed 11 patient records and eight staff records.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

# Our findings

## Overview of ratings

Our ratings for this location are:

| | Safe | Effective | Caring | Responsive | Well-led | Overall |
|---|---|---|---|---|---|---|
| Medical laboratories | Inspected but not rated | Inspected but not rated | Not inspected | Inspected but not rated | Inspected but not rated | Inspected but not rated |
| Overall | Inspected but not rated | Inspected but not rated | Not inspected | Inspected but not rated | Inspected but not rated | Inspected but not rated |

Inspected but not rated

# Medical laboratories

| | |
|---|---|
| Safe | Inspected but not rated |
| Effective | Inspected but not rated |
| Responsive | Inspected but not rated |
| Well-led | Inspected but not rated |

## Are Medical laboratories safe?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

**Mandatory training**

**The service provided mandatory training in key skills to staff and made sure everyone completed it.**

All staff received and kept up to date with their mandatory training. Staff completed training modules tailored to their role including health and safety, Control of Substances Hazardous to Health (COSHH), risk assessments, manual handling, basic life support and infection prevention and control. The mandatory training was comprehensive and met the needs of service users, patients and staff. A dashboard reviewed showed that staff completed 26 mandatory training modules.

Managers monitored mandatory training, they were notified via email once a staff member's mandatory training was overdue or completed. Staff were alerted via email and during staff meetings when they needed to update their training.

Staff working under practice privileges were required to provide evidence of mandatory training and certificates of other training they had completed which were specific to their roles. The service kept copies of these and professional certificates on the individual's staff electronic record.

**Safeguarding**

**Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.**

Staff knew how to make a safeguarding referral and who to inform if they had concerns. Staff working in the laboratory did not come into contact with patients. However, they were aware of how certain laboratory findings might indicate there was a safeguarding risk or concern.

Staff received training specific for their role on how to recognise and report abuse. The laboratory and office staff were trained to level three in safeguarding adults and children. The consultants working under practising privileges were trained up to level three or four in safeguarding adults and children. Managers told us they added the safeguarding level 3 adult and children to the training modules this year. Staff were also trained on countering bribery and corruption. The

clinical director was the safeguarding lead for the service and had completed his level two safeguarding trainings and due to complete the level three safeguarding training by December 2021. Following our inspection, the clinical director provided evidence that they had completed this training. Staff have not had to escalate any safeguarding concerns in the last 12 months.

**Cleanliness, infection control and hygiene**

**The service controlled infection risk well. Staff used equipment and control measures to protect themselves and others from infection. They kept equipment and the premises visibly clean.**

The laboratory areas and equipment were visibly clean and well-maintained. The laboratory was cleaned daily by a cleaner and staff were responsible for cleaning the equipment at the start and end of the day.

Staff followed infection control principles, they took action to prevent cross contamination including the use of personal protective equipment (PPE). Staff we spoke with were familiar with the protocols and guidance and how to access them. There was also a standard operating procedure (SOP) in place to minimise or prevent the risk of Hepatitis, HIV, COVID and accidental needlestick injury.

The service had completed a risk assessment of their prevention of infection processes, which considered the impact of the COVID-19 pandemic. This was reviewed and updated regularly in line with national and professional guidance.

**Environment and equipment**

**The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.**

The design of the environment and facilities followed national guidance, such as the Department of Health; HBN 15 Facilities for pathology services guidance. This included the laboratory size, clinical hand washing facilitation, eye was station, first aid box, laboratory coat peg area, kitchen facilities, staff changing and shower areas, standardized information technology system and availability of a car park area. The office area was sited outside the laboratory zone and there was a boundary between the laboratory areas and non-laboratory space.

The service had enough suitable equipment which facilitated undertaking laboratory tests safely. There was spare equipment which was used for back up when needed to ensure no disruption in the service provided.

We observed the management of equipment including regular checks of equipment were systematic and staff knew who to go to if they encountered any problems. Staff carried out daily safety checks of specialist laboratory equipment. We saw that daily laboratory equipment checks had been completed between January 2021 to October 2021 .

Each sample analyser was registered with an external quality assurance company and serviced annually by an accredited company. All equipment seen had been serviced and PAT (portable appliance testing) tested to ensure it was safe to use. The service carried out an internal annual equipment audit, the November 2020 equipment audit showed 100% compliance with the standards audited.

All equipment, reagents and chemicals seen were in date and stored safely in the appropriate cupboards.

# Medical laboratories

Staff stored and disposed of specimens and clinical waste safely. There were contract arrangements in place to safely manage waste and clinical specimens. Clinical waste and sharps bins were collected by the waste company once a week. We saw clinical and domestic waste bins were available and waste was handled appropriately with separate colour-coded arrangements for general waste, clinical waste and sharps. Staff used sharps bins appropriately and complied with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. We observed that sharps containers were dated, signed when brought into use and not over filled.

**Assessing and responding to patient risk**

**Staff completed risk assessments for each test carried out, and for equipment used and the environment. They removed or minimised risks and updated the assessments.**

Staff completed and updated risk assessments to remove or minimise risks. There were up to date risk assessments and risk management plans for various sample testing, equipment and chemicals used in the service which were reviewed regularly.

There were escalation protocols for unexpected or abnormal results that required immediate or urgent medical intervention. Abnormal or unexpected results that required attention were highlighted to the referring clinicians verbally and through the pathology report. Staff told us and we saw examples of records which showed that referring clinicians had been advised of abnormal results, which may indicate a risk to patients' health, in a timely way by telephone.

The service had a system in place to respond to requests for clinical advice in a timely manner, this advice was provided by consultant pathologists who were appropriately trained to deal with these requests. This was in line with the Key Assurance Indicators (KAI, 2019) for pathology service.

Laboratory results were available in a timely manner for clinical decision-making and the turnaround time for results was better than the national average. For complex cases where further test investigations, or a second opinion was needed, the turnaround times were agreed with the referrer. An interim report was provided to the referrer, this reduced risks by shortening the waiting time for clinical decisions to be made or treatment to be commenced.

**Staffing**

**The service had enough office, laboratory and senior clinical staff with the right qualifications, skills, training and experience to run the service. Managers gave locum staff a full induction.**

The service was staffed by a laboratory/quality manager, one registered biomedical scientist, one associated practitioner, one laboratory support worker and three medical secretaries. The laboratory manager and biomedical scientists were registered with the Health and Care Professions Council (HCPC).

The service had enough senior clinical staff, to provide out of hours cover and advice and run the service safely. Staffing levels were in line with the KAI (2019) guidance. The senior clinical staffing consisted of a clinical director who was a consultant pathologist and 14 consultants working under practising privileges in the service. These staff were responsible for the analysis of samples and providing clinical interpretation or advice. The granting of practising privileges is an established process whereby a medical practitioner is granted permission to work within an independent healthcare service.

The clinical director was available on site every day to analyse samples and provide clinical advice. Staff also had access to consultants who worked remotely for analysis of samples.

There were arrangements in place for out of hours and emergency requests. The service always had a consultant on call during evenings and weekends.

There was a system in place for the support and supervision of HCPC and General Medical Council (GMC) staff in the service. For example, through induction, appraisals, training, observation of practice and competency assessments.

We saw that consultants attended regular multi-disciplinary team meetings at which clinical advice was provided, and interpretation of results were discussed.

The service had low vacancy rates. At the time of our inspection there was one vacancy post for a band 7 biomedical laboratory scientist, which the service were recruiting to.

The service had low turnover rates. Between October 2020 and September 2021 the service had no turnover

The service had low sickness rates. The overall sickness rate for the period of October 2020 to September 2021 was 1.9%.

Managers limited their use of agency and locum staff and when these staff were used, they requested staff familiar with the service. Managers could access locums when they needed additional medical staff, ensuring agreed staffing levels were maintained.

**Records**

**Staff kept detailed records of patients' results. Records were clear, up-to-date, stored securely and easily available to all staff providing care.**

The patients' laboratory results we reviewed during inspection were legible, accurate and staff could access them easily.

There was a system in place to ensure patient's samples and records were not mixed up this was through a second check process by staff. This ensured the information assessed and recorded was accurate. All staff had access to an electronic records system that they could update, ensuring information was available on the system in a timely manner.

There was a system in place to ensure the specimen requests forms included enough information before tests were carried out. This included three patient identifiers and other additional requirements such as type of sample, clinical history and date and time of specimen collection. This was in line with the Health and Safety Executive's (HSE) requirement in relation to the provision of enough information on specimen request forms in clinical diagnostic laboratories.

Referring clinicians were required to inform staff of any urgent specimen via email or telephone. Once these samples were received, they were triaged by staff and an urgent label was used to label the specimen sample and record.

There was a contingency plan in place in the event of a system failure or continuing service disruption, staff were aware of this.

Inspected but not rated

# Medical laboratories

Records were stored securely in line with the Data Protection Act 2018, General Data Protection Regulation policy and RCPath (2015) guidance on storage and retention of pathological records and specimens. The electronic records were only accessible via a password protected system to authorised staff.

**Incidents**

**The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learnt with the whole team and the wider service.**

Staff knew what incidents to report and how to report them. The service had a policy covering the reporting and investigation of incidents.

For the period of January 2020 to September 2021, the service reported there had been 13 incidents, which were related to equipment malfunction, specimens not labelled or lacking missing patient information. We saw that all incidents were reviewed by managers and included a root cause and action plan. If a sample was compromised, contaminated or had missing information, staff told us they would complete an incident form to report it and contact the referring clinician. Staff told us the most common cause of this was missing or incorrect information on specimen samples received and equipment malfunction.

Staff demonstrated an understanding of duty of candour and its impact on their practice. Staff were able to give examples of incidents when duty of candour would apply. Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. This means providers must be open and honest with service users and other 'relevant persons' (people acting lawfully on behalf of service users) when things go wrong with care and treatment, giving them reasonable support, truthful information and a written apology.

Managers investigated and kept a record of all reported incidents. Staff and referring clinicians were involved in and notified of these investigations. Staff received feedback following the investigation of incidents, for both internal and external investigations.

## Are Medical laboratories effective?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

**Evidence-based care and treatment**

**The service provided services based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.**

Staff followed up-to-date policies to plan and deliver a high-quality service in line with best practice and national guidance. The service had a range of policies, protocols and a standard operating procedure (SOP) to support the delivery of services. The sample of policies and protocols reviewed were all version controlled, reviewed by the provider in a reasonable timeframe and contained references to national guidance and best practice documents such as Royal College Pathologists (RCP) and National Institute for Health and Care Excellence (NICE).

# Medical laboratories

The service used the United Kingdom National External Quality Assessment Service (UKNEQAS) guidelines for scoring stains. This approach ensured scoring was in line with best practice and national guidance.

Managers and staff carried out a programme of regular audits which included external quality assurance (EQA) of tests offered and quality assurance of presentation and interpretation of laboratory results. The programme also included the calibration of measuring systems and verification which ensured results were traceable. The results of these audits were used to identify areas for improvement and compliance with national guidance and best practice.

**Patient outcomes**

**Staff monitored the effectiveness of services provided. They used the findings to make improvements and achieved good outcomes for patients. The service had been accredited under relevant clinical accreditation schemes.**

The service participated in relevant clinical and external audits, including repeated audits. Outcomes of audits seen were positive, consistent and met expectations, such as national standards. Managers and staff used the results to improve service delivery.

The service had key assurance indicators for timeliness of reports and clinical advice, these were monitored regularly at governance meetings and through regular audits.

The service participated in the United Kingdom National External Quality Assessment Service (UKNEQAS) schemes for cellular pathology technique (CPT). The 2020-2021 UKASNEQAS audit results showed that the service was meeting the standards audited.

All consultants working in the service participated in External Quality Assessment (EQA) and where results were not satisfactory the consultants would develop an action plan which was monitored during their appraisal and by professional bodies. The service reported there has been no unsatisfactory external quality assurance results.

**Competent staff**

**The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.**

Staff were experienced, qualified and had the right skills and knowledge. The laboratory director was a specialist medical consultant and a member of the Royal College of Pathologists. The laboratory staff had appropriate education, training and we saw evidence of continuous practice development in the staff records reviewed.

Managers provided all new staff with an induction tailored to their role before they started work. We noted this taking place for a new member of staff during our inspection.

Managers supported staff to develop through yearly appraisal, peer review of results and cases and constructive appraisals of their work and training needs. From October 2020 to September 2021, the service reported 100% of staff had received an appraisal. Managers identified any training needs their staff had during appraisals and gave them the

time and opportunity to develop their skills and knowledge. Staff told us they had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. For example, the laboratory manager, office manager and biomedical scientist had completed external audit training following their last appraisals to help develop their competency and regulatory knowledge on undertaking the required audits effectively.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. The team meetings were planned in advance, which enabled staff to be able to attend these meetings. Staff were able to give feedback about the service or share their ideas at the meeting or privately. We saw that staff had given feedback and requested changes to some of the service's policies and standard operating procedures, this resulted in the amendment of these documents.

**Multidisciplinary working**

**Consultants, biomedical scientist, laboratory support and office staff worked together as a team to benefit patients. They supported each other to provide good care.**

The clinical director and consultants held regular and effective multidisciplinary meetings with partner organisations to discuss patients, provide clinical advice and gain additional clinical information with the aim of improving patient care.

The clinical directors told us they attended weekly MDT meetings for different specialities at different NHS and independent health care hospitals. These meetings included other professionals such as medical consultants, nurses, doctors, radiologists and occupational therapists.

We noted in some patient records that consultants had sought external second opinions for some complex cases.

**Seven-day services**

**The service was available six days a week to support timely service delivery.**

The laboratory was open between 9am and 9pm, Monday to Friday and from 10am to 1pm on Saturdays. There was a 24 hour on call system in operation outside of normal hours for more urgent requests.

## Are Medical laboratories responsive?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

**Service delivery to meet the needs of local people**

**The laboratory planned and provided a service in a way that met the needs of external services using the service.**

The service operated during the COVID-19 pandemic and provided histology and cytology management services for various specialities including oncology, which reflected the essential needs of the population being served.

Inspected but not rated

# Medical laboratories

Relevant information was provided on the service's website including a user guide for health and social care providers, which set out the services provided, sample requirements and request forms. The website also included information such as pricing, feedback survey results and COVID-19 information.

The service carried out an annual user survey from professionals and providers using the service to obtain information about the service to plan and improve service delivery. The December 2020 user survey result showed that 71.4% of respondents stated the user guide met their needs, 91% of users considered the arrangements for specimen transport met their needs and 96% of users were happy with the range of investigations available in the service.

**Meeting people's individual needs**

**The service was inclusive and coordinated care with other services and providers.**

Staff ensured the service delivered met the individual needs of patients and referring clinicians. The service's staff were trained and able to collect samples from external partners at short notice if the medical facility the sample being collected from was within 15 minutes walking distance.

The December 2020 user survey results showed that 100% of respondents strongly agree or agree that the service met their needs. In the same survey, most users felt both the consultant pathologists and laboratory staff were easy to contact.

The service ensured the referring clinician received test reports in a timely manner and where the test was complex and required a second opinion or a further layer of testing the consultants would advise the referrer of this and provide verbal test result feedback before sending the formal report.

The laboratory reports were sent directly to the referring clinician in charge of the patient's care and staff also liaised with them to ensure all aspects of the procedure and results were clear. This ensured the patient's clinician could explain to the patient and their carers their diagnostic results and treatment options in a way they understood.

The December 2020 user survey result showed that 96% of users were satisfied with the advice and assistance provided by the laboratory consultant pathologists and 82% were positive that the laboratory reports were clear, understandable and comprehensive.

**Access and flow**

**Referring clinicians could access the service when they needed it and received the laboratory test and results promptly. Turnaround reporting times were in line with national standards.**

Managers monitored turnaround times and made sure referring clinicians could access services when needed and received their laboratory results within agreed timeframes and national targets. There was a system in place to ensure urgent samples were prioritised during the day to ensure patients received appropriate treatment in a timely manner. Staff told us they were able to process some samples, such as a small biopsy, within 24 hours which reduced the risk of treatment delays.

Inspected but not rated

# Medical laboratories

The service's turnaround target times from specimen receipt to availability of authorised results was between seven to 10 calendar days. The target for small specimen results was 24 to 36 hours and 48 to 72 hours for large specimens. Complex specimen results had a target of up to seven days. This was in line with the Royal College of Pathologists (RCPath) histology turnaround times and reporting.

The RcPath national turnaround times guidelines are for 80% of diagnostic results to be available within seven days and 90% within 10 calendar days. For the period of September 2020 to August 2021, the average turnaround time for the service was 2.8 working days. This was better than the RcPath national guidelines of seven days.

**Learning from complaints and concerns**

**It was easy for referring clinicians to give feedback and raise concerns about the service received. The service treated concerns and complaints seriously, investigated them and shared lessons learnt with all staff.**

Staff had received training on managing complaints and conflict resolution. Staff we spoke with understood the policy on complaints and knew how to handle them including how to acknowledge complaints. No formal complaints had been received by the service in last 12 months, therefore they had not needed to refer any complaints to the Independent Parliamentary and health service Ombudsman.

The service had received three compliments between January and September 2021, which were related to the turnaround times and helpfulness of staff. Managers shared feedback such as compliments and negative feedback with staff at team and governance meetings to identify and share any learning or improvement.

## Are Medical laboratories well-led?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

**Leadership**

**Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for referring clinicians and staff. They supported staff to develop their skills and take on more senior roles.**

There was a management structure with clear lines of responsibility and accountability. The laboratory/quality manager was responsible for the overall management of the laboratory and laboratory staff. While the office manager had responsibilities for the management of the office staff and administrative tasks. The office manager and laboratory/quality manager reported to the clinical director who was a consultant pathologist and the registered manager for the service.

Staff we spoke with told us that the managers were all approachable and visible. Staff told us they had received good support from leaders when needed and during the COVID-19 pandemic. We observed positive working relationships between staff and they reported that they supported each other.

Inspected but not rated

# Medical laboratories

**Vision and strategy**

**The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders.**

The service's mission statement was, 'to be a centre of excellence providing superior, rapid, accurate services in both clinical diagnostics and research that clinicians, service providers and employees are proud of and investors seek for long-term returns.

The service's strategy focused on staff training and development, expansion of the service, technology and relocation of the office space to another building within the same area. The strategy and plans were discussed at the team and governance meetings.

Staff told us they were aware of the overall vision and strategy and felt part of the vision for the service.

**Culture**

**Staff felt respected, supported and valued. They were focused on the needs of patients and referring clinicians.**

The service's culture encouraged openness and honesty. Staff told us they could raise concerns without fear and felt proud to work in the service.

Managers supported staff to develop through regular appraisals of their work and external trainings such as audit training. Staff also had access to the employee assistance programme for advice and support, wellbeing support workshop and a platform for trauma management support.

There was an emphasis on the safety and wellbeing of staff in the service. During the COVID-19 pandemic, staff had completed a risk assessment to establish whether they were at increased risk of the virus. Staff also had access to COVID-19 testing and had all received the COVID-19 vaccination.

**Governance**

**Leaders operated effective governance processes, throughout the service and with partner organisations.**

Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service. There was a structured approach to the running and safety of the laboratory. There were clear lines of accountability and staff knew who to report to.

There were governance structures in place for example for the assessment of user satisfaction, internal audit of quality management systems; reports from external assessment bodies. These arrangements facilitated action being taken in response to external and internal audits and preventative action in response to the management of risks.

The service gained assurance through various governance meetings such as: the weekly strategy meeting, quarterly staff meetings and the annual management review meetings. The staff meetings and annual management review meetings

were attended by staff at all levels including the clinical director and consultants. We reviewed various governance meetings and noted they were well attended by staff and covered areas such as incidents, risks, training, audits, staff suggestions, service user feedback, quality management system, appraisal, staff recruitment, incidents and health and safety.

The service had processes and systems in place for the traceability of records and the retention and storage of pathological specimen such as stains and blocks, which ensured a robust audit trail was maintained. This was in line with the RCPath (2015) guidance on retention and storage of pathological specimen (April 2015) and the Human Tissue Authority (2021) guidance on record retention.

The service operated an operational quality management system which was aligned to the UKAS ISO 15189. This included information management, equipment, record management, personnel management, facilities and safety management, audits and process control of specimen samples.

**Managing risks, issues and performance**

**Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and took action to reduce their impact.**

Staff knew how to escalate risks to the managers. The service used a bespoke risk assessment software package which used a multi-disciplinary team approach to assess risk and determine what actions were needed to prevent failures and plan improvement. Staff were trained in the use of the service's bespoke risk register. The risk register included risks such as security, specimen loss from transport, fire alarm, electricity, equipment, regulatory compliance and staffing. We saw that the risk register was reviewed regularly and included a description of each risk, severity, risk recurring, possible impact and mitigating actions.

The service was accredited for each test carried out. The recent United Kingdom Accreditation Service (UKAS), inspection took place in June 2021 and resulted in the service being requested to take one action, which had now been completed.

The service had adequate facilities equipment and reagents needed to deliver the service and cope with any viral outbreaks.

**Managing information**

**The service collected reliable data and analysed it. The information systems were integrated and secure.**

Staff could find data such as audits and user survey results, in easily accessible formats, to understand performance, make decisions and improvements.

Data and notifications were consistently submitted to external organisations as required.

There were systems in place to ensure the information used to monitor, manage and report on quality and performance were accurate, valid, reliable and timely. The governance management meeting took account of the analysis and audit results and external quality assurance schemes.

There was a system in place to ensure the security of confidential patient data. The electronic record systems were password protected. Referring clinicians could access authorised reports of patients on the service portal following the completion of the registration process. This ensured only an authorised person could access patient confidential data.

There was a policy to ensure compliance with the Data Protection Act 2018 and a General Data Protection Regulation policy. Staff had completed training on information governance and data security which covered their roles and responsibilities in relation to handling data and patient information.

The service was registered with the Information Commissioner's Office with a certification in place until May 2022.

**Engagement**

**Leaders actively and openly engaged with referring clinicians and staff to plan and manage services. They collaborated with partner organisations to help improve services for patients.**

The service engaged with staff through various means such as emails and regular staff meetings. We saw the staff feedback and change request dashboard, which contained staff feedback and suggested changes to the wordings of some of their policies and standard operating procedures (SOP), which resulted in amendments to these documents. Following staff suggestions at the March 2020 team meeting, the service had introduced a staff social media messaging group to facilitate timely staff updates, provide support and improve communication. Staff told us that no patient information was shared on this messaging group. Staff were able to give feedback about the service through the staff feedback book or share their ideas privately or during staff meetings. Staff told us as they were a small team, it was easy to resolve any issue on the spot and receive timely responses to their feedback.

Staff were part of the service's annual management review meetings which included feedback to staff on their hard work and behaviour.

The service sought user feedback through an annual survey sent to external partners such as: clinics, GP practices, hospitals, individual consultants and health care providers who were invited to complete the survey. The response rate for the December 2020 survey was 14.4% and the service received positive feedback on the range of available investigations, laboratory results, advice and support, the quick turnaround time as well as staff helpfulness.

**Learning, continuous improvement and innovation**

**All staff were committed to continually learning and improving services. Leaders encouraged innovation.**

The service acted on feedback to improve the service. For example, they had improved the process of logging control issues by developing a control tissue log which followed the UKNEQAS scoring criteria guideline. The log allowed staff to specify the block ID and complete information on the tissue type, source and specify the test been carried out. This had assisted staff to trace the source of tissues and allocated labels.

There was a culture of improvement and progress embedded in the service by the management team to meet the referring clinicians needs and to ensure the laboratory had up to date technology to aid staff and ensure their safety.