Viapath Group LLP

Princess Royal University Hospital

Inspection report

Farnborough Common
Orpington
BR6 8ND
Tel: 01689863000
www.viapath.co.uk

Date of inspection visit: 26 - 27 October 2021
Date of publication: 30/12/2021

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, as we do not have the legal power to rate independent laboratories.

Our inspection looked at four key aspects: was the service safe, effective, responsive and well led? We did not include caring as the service had no interaction with patients:

- The service had staff with the right qualifications, skills, training and experience. The service controlled infection risks well. Areas and equipment within the laboratory were clean and well-maintained. The design, maintenance and use of facilities, premises and equipment kept people safe. There was a system to report safety incidents and staff knew how to report near misses.
- Staff completed risk assessments for each test carried out. Managers monitored the effectiveness of the service and made sure staff were competent. The laboratory 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 seven days a week.
- The laboratory planned and provided a service in a way that met the needs of referring clinicians. These clinicians could access the service when they needed it and received laboratory results promptly. User feedback was gathered and monitored at monthly engagement meetings with clinicians and external partners.
- Leaders had the skills and abilities to run the service and were visible and approachable. 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. Staff understood the service's vision and values, and how to apply them in their work.
- Staff were focused on the quality and reliability of testing to help meet patients' needs.

However:

- We found boxed consumables stored directly on floors in storage and laboratory areas. This degraded the effectiveness of environmental cleaning. We accept the issue had already been identified and logged on the corporate risk register for monitoring and action.

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 the CQC does not apply a rating to independent laboratory services.

Summary of findings

Contents

Summary of this inspection

Background to Princess Royal University Hospital

Located within the premises of an NHS hospital, the medical laboratory is operated by Viapath LLP and provides microbiology, clinical biochemistry, blood transfusion, cytology, haematology and histology services under contract with the trust.

The service had a registered manager in post since establishment in 2016 and is registered with the CQC to provide the regulated activity:

- Diagnostic and screening procedures, which includes the use of equipment to examine cells, tissues and other body fluids for the purpose of obtaining information on the causes and extent of a disease, disorder or injury.

The service had not been inspected by the CQC previously.

Some aspects of medical laboratory work is either out of the scope of our regulations or governed by other organisations. These activities included the blood bank, Covid-19 testing for hospital staff and testing for research programmes. These aspects were not inspected.

Laboratory tests funded by the NHS must be accredited against a set of standards called ISO 15189. The United Kingdom Accreditation Service (UKAS) is recognised by the Government as the sole national accreditation body and once tests are accredited, there are annual surveillance activities and full re-assessment every4th year. The service is currently undergoing assessment and these aspects were not inspected.

In addition, all laboratories must participate in an external quality assurance (EQA) scheme that advises providers of their quality assurance results and how their results compare with other laboratories. Quality checks are completed monthly by an external source and the Royal College of Pathologists (RCPath) maintains oversight of EQA schemes in the UK. This aspect of the service was not inspected.

How we carried out this inspection

This was an unannounced inspection using our comprehensive methodology.

During the inspection visit, we visited all areas of the laboratory complex and looked at the quality of the clinical environment; spoke with four members of the senior management team, including an executive with a regional role and spoke with seven other members of staff including scientific, technical and administrative workers.

In addition, we looked at a range of policies, procedures, audit reports and other documents relating to the running of the service.

We also spoke with an executive from the hospital.

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.

Summary of this inspection

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service SHOULD take to improve:

We told the service that it should take action because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall.

- The service should ensure that boxed consumables are stored on suitable mobile racking units.

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 the CQC does not apply a rating to independent laboratory services.

Mandatory training

The service provided mandatory training in key skills and made sure everyone completed it. Staff received and kept up-to-date with their mandatory training.

We saw training management records which indicated overall mandatory training compliance was 90%, which met targets set by the company and hospital leadership. Training was delivered in cooperation with the hospital and included classroom work as well as online learning packages accessed via the internet.

Staff completed training modules tailored to their roles, including information governance; occupational health and safety, control of substances hazardous to health (COSHH) and infection prevention and control (IPC). Staff we spoke with were up to date with their mandatory training and said they had been given time at work to complete the topics. We saw staff using computer terminals in an open plan office, who showed us they were undertaking online learning and professional development activities.

Managers monitored individual and departmental training status using 'dashboard' reports generated by the electronic learning package. They were notified by an automated email once a staff member's mandatory training was completed or became overdue. Staff also received an automated email alert when they needed to update their training.

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.

Safeguarding policy and processes were governed by the NHS trust and Viapath staff accessed NHS statutory and mandatory training for safeguarding using the trust's online learning service.

Although staff working in the laboratory did not come into direct contact with patients, they were aware of circumstances that might indicate there was a safeguarding risk or concern.

Staff we spoke with knew to raise any concerns initially with their team or shift supervisor, who escalated it to the senior manager on duty who then contacted the safeguarding team from the hospital.

In addition, any concern was reported using the trust's electronic incident reporting system, which automatically alerted the safeguarding team and managers responsible. All staff were trained to level one and two for safeguarding adults and children in accordance with hospital policy.

None of the staff could recall the need to raise a safeguarding concern in the last year.

The general manager acted as the safeguarding lead for the laboratory and reported into the trust's safeguarding panel.

The company had a well-defined recruitment pathway and procedures to help ensure that the relevant recruitment checks had been completed for all staff. These included a disclosure and barring service (DBS) check prior to appointment, photographic ID and references along with qualification verification.

Cleanliness, infection control and hygiene

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

The laboratory complex was located on the first floor of the main hospital building. We inspected the service during Covid-19pandemic restrictions and saw that access was controlled in ways to help reduce the risk of viral transmission.

We reviewed risk assessments and protocols introduced as part of the service's response to the pandemic. These were compiled in cooperation with the hospital trust and measures introduced included the fitting of clear plastic screens into the sample reception desk, provision of masks and gloves for staff and enhanced environmental cleaning.

In addition, the risk of transmission was mitigated within the service through social distancing, the use of personal protective equipment and the establishment of a two-shift system which reduced the number of staff working in the laboratory at any one time.

Managers explained that individual risk assessments been completed for all staff at the outset of the pandemic and where appropriate alternative working arrangements, such as working from home, had been made for staff.

Staff confirmed they were undertaking weekly Covid-19 testing in line with trust policy and we saw staff processing these tests during our inspection.

Hand sanitiser was provided throughout the hospital, including the laboratories, along with explanatory signs to help people maintain social distancing. We saw staff using the sanitiser as they moved around the laboratory.

We observed staff wearing personal protective equipment (PPE) in line with current guidance.

All areas we visited appeared clean and had suitable furnishings which were clean and well-maintained. Seamless easy-clean floor covering was used throughout the laboratory areas, staff room and toilets. Cleaning records were up-to-date and demonstrated that areas were cleaned regularly.

Medical laboratories

Store areas were tidy and generally free from clutter. We observed boxed laboratory consumables stacked on floors in two laboratory spaces and storerooms. We noted the issue had already been identified and logged on the corporate risk register for monitoring and action. Managers stated that the boxes would be removed and clinical grade mobile racking ordered to lift stock deliveries off the floors.

All laboratory areas we visited had spill kits, which were designed is assist staff safely clean any fluids from floors or work tops.

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 built environment, including air-conditioning, fire protection and water services, fixtures and fittings were controlled and maintained by the hospital trust under service level agreements. Managers told us this presented occasional challenges, for example if a change of layout was required, but spoke in positive terms about the level of support and speed of response from hospital engineering and environmental services.

Fire safety equipment and evacuation signs were sited at strategic points throughout the complex. Managers explained that alarm tests were conducted weekly and we saw that external contractors had completed fire equipment safety checks, which were all in date.

Entry to the laboratory complex and zones within were restricted by card-operated and key-code security locks, which we saw being operated by staff as they moved through the building. Office and administrative areas were separated from laboratory and storage rooms.

The design of the environment and facilities followed national guidance, such as laboratory size and facilities for hand washing.

Ambient (room) temperature and sample storage refrigerators were monitored using a purpose-built recording system that automatically alerted key staff if a fault developed. It had helped identify issues with ambient room temperatures during summer that resulted from the way the air conditioning was zoned within the building. Managers stated this was being addressed with the trust.

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

Managers showed us a specially designed computerised management system used for recording equipment checks, calibration and maintenance. We saw that external contractors and equipment suppliers completed regular servicing and maintenance as needed. Staff carried out daily safety checks of laboratory equipment and we saw records supporting this. Staff knew who to go to if they encountered any problems.

We checked a selection of non-clinical electrical devices and saw they were labelled with the dates of the most recent electrical safety test. Managers explained that the NHS trust performed these inspection tests under a service level agreement.

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

Inspected but not rated

Medical laboratories

Clinical or laboratory waste was handled, stored and removed in a safe way. Staff segregated and handled laboratory and general waste in line with national guidance. There were arrangements with the NHS trust to manage the disposal of waste and clinical specimens.

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.

Although the service had not worked directly with patients in the past, we met members of a new phlebotomy team undergoing induction training in preparation for a new blood sample collection service for the trust.

Managers explained that the service was due to 'go live' next month and staff would be fully compliant with the hospital's statutory and mandatory training programme, including basic life support (BLS).

As part of the new contract, the service was also taking over ward-based blood glucose monitoring. Managers told us the equipment used was being brought under the control of the laboratory and glucose testing subjected to the same quality audit controls (EQA) as the other tests.

Laboratory staff said they also had access to the EPR system. This offered advantages such as when test requests were incomplete or illegible, they could be reprinted. Results were easily communicated back to the consultants and doctors responsible for the patients' care.

Managers described how results beyond critical limits were communicated through the EPR and stated there was a protocol for when results were significantly abnormal. In this case, the results were phoned through to the doctor responsible.

Results beyond critical limits for patients outside the hospital were communicated directly to the source of the request during normal working hours. Abnormal results obtained after hours and on weekends were communicated to the NHS 111 service, who then contacted the patient and where necessary, arranged for the patient to be brought back to hospital.

We saw that laboratory staff had been appointed as workplace first aiders and were trained in BLS as part of their first aid qualification. The trust provided resuscitation and security teams that could be called to an emergency. Staff we spoke with knew the telephone number to call for assistance.

In regard to testing, 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.

The service had a system to respond to requests for clinical advice, which was provided by 'on call' consultant scientists who were trained to deal with these requests. This was in line with national guidance called key assurance Indicators (KAI) for pathology services.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to run the service.

Inspected but not rated

Medical laboratories

With a total headcount of 120, the service had enough scientific staff to provide out of hours cover and run the service safely. Staffing levels were in line with the KAI (2019) guidance.

The consultants and their clinical and scientific colleagues are always available, on site or in some cases remotely, to provide clinical and interpretive advice to both the service users and the laboratory staff.

There was a system to ensure the support and supervision of professionally registered (HCPC) staff in the service through induction, appraisals, training, observation of practice and competency assessments.

Managers stated that the service had vacancy, turnover and sickness rates within safe limits, although they acknowledged the pandemic had presented challenges.

Managers could access locums when they needed additional laboratory staff, ensuring agreed staffing levels were maintained

Records

The service kept records of patients' transport. Records were stored securely and easily available to all staff providing the service.

The patients' laboratory results we saw were legible, accurate and easily accessible yet secure.

There were systems to ensure patient's samples and records were not mixed up. 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 to ensure the specimen requests forms included enough information before tests were carried out, which complied with national guidance.

Referring clinicians were required to inform staff of any urgent specimen via telephone, which were then triaged and labelled by staff.

There was a contingency plan for the event of a system failure or service disruption and staff were aware of this.

Records were stored securely in line with the Data Protection Act 2018, General Data Protection Regulation policy and RCPath guidance on storage and retention of records and specimens.

Medicines

The service did not prescribe, administer or store any medications.

Managers explained that the supply of laboratory testing reagents had "some teething issues" during the initial stages of the pandemic.

This had been resolved, although it resulted in the laboratory carrying more stock of consumables or reagents than previously and resulted in storage of some items on floors.

Inspected but not rated

Medical laboratories

Incidents

Staff knew how to report incidents. Managers investigated incidents and shared lessons learned with the whole team, the wider service and partner organisations

The laboratory used two electronic incident reporting and management systems: one patient safety recording system belonging to the trust, and a specialised laboratory system where any quality incidents involving test results or equipment were reported, investigated and managed.

The laboratory used the trust's patient safety reporting system for recording any adverse incidents, which were reviewed by the laboratory quality assurance group which reported to the Viapath board as well as the host trust. The top incident categories reported were delay or failure to perform tests (due to equipment malfunction) and test results or reports that were available but inaccurate.

We saw governance meeting minutes that indicted where there had been incidents, managers shared findings with staff and lessons had been learnt. We saw examples of safety bulletins displayed on staff noticeboards and staff confirmed they also received notices and alerts via email and at team briefings at change of shift (called huddles).

The senior management team understood their obligations under Duty of Candour (DoC). This statutory duty, under the Health and Social Care Act (Regulated Activities Regulations 2014) requires providers of health and social care services to notify patients (or other relevant persons) of certain safety incidents and provide them with reasonable support.

Are Medical laboratories effective?

Inspected but not rated

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

Evidence-based care and treatment

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

Managers and staff described how the service had a range of policies, protocols and standard operating procedures to support the delivery of services. Sources of national guidance included the host NHS trust; National Institute for Health and Care Excellence (NICE), NHS England (NHSE), British Standards, Health and Safety Executive (HSE), Serious Hazards of Transfusion reporting system (SHOT) and the Human Tissue Authority (HTA).

Senior managers told us the service received automatic alerts and notifications from bodies such as NICE, NHSE and SHOT. We saw quality review group meeting notes that showed the service routinely checked NICE and NHSE standards for best practice and to find resolutions to problems.

Medical laboratories

Managers added that the laboratory was also receiving advice from the company and benchmarking against other Viapath services in the region. The sample of policies and protocols we checked were version controlled and contained appropriate references to national guidance and best practice documents such as Royal College Pathologists (RCPath) and NICE.

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. Audit results were used to identify areas for improvement and compliance with best practice.

Patient outcomes

Staff monitored the accuracy and effectiveness of services provided. They used the findings to make improvements for patients.

The provider monitored the quality of service provision through benchmarking audits compared against guidance set out by the relevant professional bodies and royal colleges. These included key assurance indicators (KAIs) for timeliness of reports, clinical advice and appropriate reference ranges used for differing population groups. We saw that the service was preparing for assessment by the United Kingdom Accreditation Service (UKAS) and scientific staff described how the laboratory participated in an external quality assurance (EQA) programme, which involved monthly quality checks conducted by an independent laboratory.

Senior scientists explained there were 77 EQA schemes currently active across all the laboratories on the site. In addition, senior staff had quality and governance responsibilities that covered this site and another Viapath laboratory in London. Managers felt this added to the accuracy and effectiveness of services provided.

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. Registered staff had appropriate education, training and we saw evidence of continuous practice development in the staff records we reviewed.

The service used a competency-based training and approval system as well as buddy support from experienced laboratory technicians and scientists. Training and competencies were part of the evidence required for accreditation and assessments by other regulators such as BS and HTA.

Staff told us how they received induction training, had manuals issued that were specific to their skills stations and were trained by competent colleagues prior to examination by an assessor.

Managers explained that competencies were confirmed and monitored by observed practice and reassessment every two years.

Each staff member was appraised annually, with a half-yearly appraisal review along with 121s on a regular basis – usually weekly or fortnightly. Managers identified any training needs their staff had during appraisals and gave them the time and opportunity to develop their skills and knowledge.

Inspected but not rated

Medical laboratories

Staff told us they had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.

Senior managers told us that competency status, appraisal reviews and mandatory training were KPIs for the service and reported monthly at operational management meetings. Mandatory training status was also reported to the host trust as part of the contract.

Multidisciplinary working

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

Senior managers and scientists held regular multidisciplinary meetings (MDT) with partner organisations to discuss patients, provide clinical advice and gain additional clinical information with the aim of improving patient diagnosis and care.

For example, histopathology consultants participated in MDT meetings with host trust and the service had an MDT coordinator who help prepare presentations and data for MDT meetings.

Seven-day services

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

The laboratory was open 24 hours a day, utilising a two shift system. Senior managers and scientists were available out of normal hours on an 'on call' basis for enquiries.

Are Medical laboratories responsive?

Inspected but not rated

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

Service delivery to meet the needs of local people

The service operated during the Covid-19 pandemic and provided testing services for various specialities, which reflected the essential needs of the population being served.

Managers stated that services were provided in support of the trust and staff recognised the importance of screening for some groups in the community and gave the example of sickle cell testing.

Managers commented that patient ethnicity data was collected as part of the testing process. This was because some of standard reference ranges for tests were adjusted for ethnicity to ensure the results were interpreted as accurately as possible

Inspected but not rated

Medical laboratories

When we inspected, we saw that a new phlebotomy team had begun induction training and familiarisation. They were preparing to provide the blood sample collection service to the hospital and managers explained that the service was due to 'go live' next month.

Managers said that new phlebotomy service would include an annual user survey from professionals and providers using the service to help plan and improve service delivery.

Laboratory results were available in a timely manner for clinical decision-making and the turnaround times for results were closely monitored by the company. The service met RCPath national turnaround times guidelines.

We spoke with a senior executive of the hospital, who commented in positive terms about the overall service provided by the laboratory

Access and flow

Referring clinicians could access the service when they needed it and received the laboratory test 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 to ensure urgent samples were prioritised to ensure patients received appropriate treatment in a timely manner. For example, A&E blood gasses were reported within eight minutes.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service had processes in place to treat concerns and complaints seriously, investigate them and share 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.

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 the CQC does not apply a rating to independent laboratory services.

Leadership

Inspected but not rated

Medical laboratories

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 overall management of the laboratory was through a tripartite consisting of clinical director, scientific director and general manager. The general manager led a team of speciality-specific operational managers for each discipline. The CQC Registered Manager for the service is a Viapath director of operations.

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.

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 space and services to alternative sites. The strategy and plans were discussed at 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 and all had received the Covid-19 vaccination.

Lone working had been identified as an issue of concern for staff working on shifts and this was being addressed through the provision of personal alert devices.

Inspected but not rated

Medical laboratories

Managers made sure staff attended team meetings or had access to notes or recordings when they could not attend. Some meetings were held using video conferencing facilities but the most were team meetings or 'huddles'

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.

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 for the traceability of records and the retention and storage of pathological specimen such as stains and blocks, which ensured an audit trail was maintained. This was in line with national guidance.

The service operated an operational quality management system which was assessed by UKAS to the ISO 15189:2012 standard. 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 process which involved a multi-disciplinary team approach to determine what actions were needed to prevent failures and plan improvement. This was supported by specialised computer software that helped staff to manage and record the process and actions taken.

The risk register included risks such as the maintenance of business critical software, key equipment maintenance, ambient temperatures, storage and accreditation progress. We saw that the risk register was reviewed regularly and included a description of each risk, severity, controls and persons responsible for the mitigating actions.

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.

Inspected but not rated

Medical laboratories

Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure.

There were systems 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 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 relevant to their roles.

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.

Staff we spoke with felt engaged with their leaders and involved with service provision and improvement.

The service engaged with staff through various means such as emails and regular staff meetings.

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

Learning, continuous improvement and innovation

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

Managers and staff demonstrated an understanding of quality improvement and compliance systems and had the skills to use them.

During the pandemic restrictions, the laboratory had worked to reduce the requirement for visiting engineers and had introduced remote maintenance and engineering calls, where a senior member of staff and an engineer worked through the repair or issue using a video call. Managers and staff agreed this had been very successful.