Nationwide Pathology Limited

Nationwide Pathology

Inspection report

Unit 1, Bitteswell Business Park
Ullesthorpe Road, Bitteswell
Lutterworth
LE17 4LR
Tel: 01858571322
www.nationwidepathology.co.uk

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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 have the legal power to rate independent laboratory services.

We looked at 4 key questions: is the service safe, effective, responsive and well led. We did not inspect caring as the service did not have direct contact or interaction with patients at the time of our inspection.

• There were systems and processes which had achieved the internationally recognised International Organization for Standardization (ISO) 15189:2012 accreditation. There were enough staff with the right qualifications, skills, training and experience. 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. The service had a system to monitor 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 ensured testing was 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 planned and provided a service in a way that met the needs of referring clinicians. Facilities and premises were appropriate for the services being delivered. Customers could access the service when they needed it and received the laboratory results promptly.

• Managers 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. They used systems to manage performance effectively. Managers ran services well using reliable information systems and supported staff to develop their skills. Information systems were integrated and secure. Managers and staff engaged well with each other and there were positive, collaborative relationships with external partners.

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 have inspected but have not rated this service. This is because the CQC does not apply a rating to independent laboratory services. See the summary above for details

Summary of findings

Contents

Summary of this inspection

Background to Nationwide Pathology

Nationwide Pathology is operated by Nationwide Pathology Limited. The service was registered with CQC in 2020.

Nationwide Pathology provides diagnostic pathology and screening procedures to the general population in the United Kingdom. This service is directed to clients by way of phlebotomy services. Most clients take the blood samples themselves and send them to the laboratory. On occasion phlebotomists collect samples if there is a batch of tests to be taken. This is the only contact that staff have with patients.

The main services provided are testing for Haematology; Biochemistry; Immunology; Serology; Toxicology; Microbiology; Molecular Pathology; Vitamin and Nutritional. The service undertakes 200 to 300 samples a day with 60 to 70 parameters analysed.

The service employs approximately 20 staff.

The service is registered to provide the following regulated activities:

• Diagnostic and screening procedures.

There has been a registered manager in post since 2020.

The location has not previously been inspected.

How we carried out this inspection

This was an unannounced inspection. We inspected this service using our comprehensive inspection methodology.

A CQC inspector and one specialist advisor carried out this inspection with off-site support from an inspection manager. We spoke with the leadership team, the quality and laboratory manager and 6 other members of staff including medical laboratory scientists, assistants and supply coordinator. We looked at 3 appraisal and training records, 3 employee recruitment files, complaints and incidents reported in the last 12 months and actions taken from lessons learned. We also looked at the service's quality manual, the latest United Kingdom Accreditation Service (UKAS) report with actions and internal and external quality assurance procedures. 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.

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 not complying with legal requirements in future, or to improve services.

Action the service SHOULD take to improve:

Summary of this inspection

- The service should ensure they complete a Disclosure and Barring Services (DBS) check for all staff members that have direct public contact when undergoing regulated activities in addition to their staff appointment risk assessments (Regulation 17, (2) (d), (i) Good Governance).

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 have inspected but have not rated 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 to all 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 data protection, fire health and safety and managing medical emergencies. The mandatory training was comprehensive and ensured staff were able to meet the needs of clinicians using the service.

Staff compliance for mandatory training in January 2023 was 100% for all the mandatory training modules.

Relevant staff were also required to read the service's quality manual and systems procedures. Staff had to sign that they had read and would adhere to the outlined processes. Compliance was 100%.

Managers monitored mandatory training, the electronic training matrix identified when a staff member's mandatory training was overdue or completed. Staff's understanding of training was also assessed through competencies, which made sure they knew their roles, responsibilities and how to fulfil these.

Staff working at other services 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 or how to apply it. However, not all staff who had patient facing activities had completed a Disclosure and Barring Services check.

Medical laboratories

The service had a comprehensive safeguarding policy with processes for reporting concerns. They had their own learning system through which all statutory and mandatory training was delivered. The service used their safeguarding policy as a reference point, supporting their safeguarding training which covered most aspects of the national level 1 and 2 safeguarding training for adults and children. Staff mandatory training compliance for safeguarding for January 2023 was 100%.

The service had a safeguarding lead who was the first point of contact should any safeguarding concerns be raised. The safeguarding lead had contacts from local authorities should further support be required.

The service had phlebotomy trained staff who interacted directly with patients. However, 1 staff member who was undertaking this activity did not have an up to date Disclosure and Barring Services (DBS) check. We were told by senior staff that recruitment processes were comprehensive with evidence of previous employment and reference checks, appropriate qualifications and registration, where applicable. However, exemption from DBS checks were not evidenced for the roles undertaken. We were assured by the service that this would be reviewed, and a DBS check would be completed for the member of staff who had not done it yet.

Cleanliness, infection control and hygiene

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

The service had infection prevention and control measures, and staff wore appropriate personal protective equipment. Staff we spoke with were familiar with the protocols and guidance and how to access them.

The service was accredited to International Organization for Standardization (ISO) 15189:2012 which is an international accreditation which specifies requirements for quality and competence in medical laboratories. Staff adhered to measures to prevent the spread of infectious diseases. Hand sanitising and hand washing was available at all stations. Staff and visitors were required to wear white coats on entering testing areas.

All areas and equipment was visibly clean. The checklists we viewed for some equipment were signed to indicate the equipment was cleaned after last use. All staff were responsible for cleaning the equipment they used. Information provided showed that the service had scheduled staff maintenance which included specific cleaning checks. We saw these were carried out according to the schedule.

The service had working protocols to make sure the risk of cross infection and contamination was prevented or minimised so far as was reasonably practicable. This included prevention of the spread of micro-organisms and contamination between specimens.

Environment and equipment

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

The environment and equipment were compliant with ISO 15189:2012 accreditation. The entrance to the facility was safe and secure with an electronic control access system for authorised personnel only.

Inspected but not rated

Medical laboratories

The design of the environment and facilities followed national guidance, such as the Department of Health, Health Building Note 15: Facilities for pathology services guidance. This included the laboratory size, clinical hand washing facilitation, eye wash station, first aid box, laboratory coat peg area, kitchen facilities, staff changing areas, standardised information technology system and availability of a car park area. The office area was located outside of the laboratory zone and there was a boundary between the laboratory areas and non-laboratory space. The storage room and test pack preparation area was located in a separate building to the laboratory and offices.

However, on the day of the inspection, the storage room and test pack preparation area was left unattended and unlocked. This room also contained fridges were samples were stored. We were told there was usually one member of staff permanently in the storage room and it was shut with a key out of work hours. After raising concerns with senior managers about the risk of tampering, we were informed and saw evidence to assure us that if the storage room was unoccupied at any time the room would be locked. We also saw evidence following the inspection that signage was clearly visible to make people aware of access restrictions to this area.

Staff had enough supplies of suitable equipment to undertake laboratory tests safely and spare equipment was also available for back up to ensure no disruption in the service provided.

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 staff completed daily laboratory equipment checks. Each sample analyser was registered with an external quality assurance company and serviced by an accredited company. All equipment had been serviced and portable appliance tested to ensure it was safe for staff to use.

The service had a contingency plan for each piece of equipment in the event of a system failure and arrangements for frequent and secure back-up of data. There was a protocol for manual processing of urgent specimens if there was a system failure for analysers, as well as agreements with external laboratories for the processing of samples should disruption occur.

All equipment, reagents and chemicals seen were in date and stored safely in the appropriate cupboards. The service had electronic stock lists which flagged expiry or near expiry dates. These lists also supported the management of stock when it was received.

Fridge temperatures were checked, and logs of calibration recorded. We found the fridge temperatures were within range.

Staff stored and disposed of specimens and clinical waste safely. 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. The service had a service level contract arrangement to safely manage waste and clinical specimens which were collected by a waste company regularly.

Assessing and responding to service user and staff risk

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

Medical laboratories

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. Further risk reviews included emergency door release, eye wash kit, first aid kit and temperature checks.

Laboratory results were available in a timely manner for clinical decision-making and the turnaround time for results was met in accordance with agreed procedures. The main method for reporting results was via the electronic recording system. For more urgent results there was a phone call criterion as to what results and which members of staff could report them and to whom they could be reported to. For complex cases where further test investigations, or a second opinion was needed, the turnaround times were agreed with the referrer.

The service was responsive when finding risks. The service had 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.

The service had a system to respond to requests for clinical advice in a timely manner, which was provided by consultant pathologists. This was in line with the Key Assurance Indicators (KAI) (Royal College of Pathologists 2019) for pathology services. Written reports were provided where requested. This duty was also undertaken by the speciality consultants.

The service assessed and managed risks effectively. Participation in external quality assurance schemes was undertaken to monitor the process which were ISO 15189:2012 accredited. Where the United Kingdom Accreditation Service (UKAS) had identified that there were areas for improvement in formalised and documented reviews of risk assessments, action had been taken.

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 staff a full induction.

Staffing levels and skill mix were planned and reviewed so that services could always be maintained. The service had arrangements to cover for staff absences.

Staff were directly employed by the service. The laboratory was staffed by a laboratory/quality manager, 2 registered biomedical scientists who had further senior roles, 1 medical laboratory scientist / bioinformatician, 2 trainee biomedical scientists and 3 medical laboratory assistants. The laboratory manager and biomedical scientists were registered with the Health and Care Professions Council (HCPC).

The service also had office staff to support service delivery and manging the pathology pathways, as well as a courier and supply coordinator.

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 for pathology services (2019) guidance. The senior clinical staffing consisted of the laboratory / managing director who was also the registered manager, 3 consultants with individual specialisms (chemical pathologist, haematologist and microbiologist), a quality / laboratory manager and a laboratory supervisor who was a biomedical scientist. These staff were responsible for the analysis of samples and providing clinical interpretation or advice in accordance with their job specifications.

Medical laboratories

We heard how it was easy for any referrer or staff member to contact any of the senior staff at any time. Staff also had access to the consultants who worked remotely for analysis of samples. The service always had access to a consultant on call during evenings and weekends and there were arrangements for out-of-hours and emergency requests.

The service had a system for the support and supervision of HCPC and General Medical Council staff in the service. This was carried out through induction, appraisals, training, observation of practice and competency assessments.

There were arrangements for senior staff cover 24 hours a day with a reduced service out of hours when only urgent analysis was undertaken. Whilst a formal rota for senior staff cover was not provided staff knew who to contact for support and advice out of hours. Senior members of staff with the right skills were always contactable.

Records

Staff had the information they needed to deliver safe care and treatment to people. The service ensured that the requirement set out by the Health and Safety Executive in relation to the provision of sufficient information on specimen request forms to staff in clinical diagnostic laboratories was being complied with. Records were stored securely and easily available to all staff providing the service.

There were processes and procedures to ensure the safe labelling, reception and transportation of specimens. There were standard operating procedures (SOP) for labelling specimens, for samples received directly, specimen acceptance and specimen reporting. These SOPs contained comprehensive information for staff on specimen collection, storage, handling and packing, including safety considerations. In addition, information was available on the service website to ensure the correct labelling of specimens by those requesting tests.

Most clients took samples themselves and sent them to the laboratory via postal services. This followed UN3373 transport packaging guidance for the transportation of infectious and potentially infectious biological substances. Packaging and transport requirements for patient samples – UN3373, sets guidance on elements such as the quality, number of components, security and standards of the packaging containing patient samples to ensure safe transport and minimise cross infection risk.

Referring clinicians were required to inform staff of any urgent specimens via email or telephone. Once these samples were received, they were monitored by senior staff throughout the process to ensure this was completed in the required timescale.

The service had systems to ensure the specimen requests forms included enough information before tests were carried out. This included patient identification and other additional requirements such as type of sample, date and time of specimen collection. This was in line with the Health and Safety Executive's requirement in relation to the provision of enough information on specimen request forms in clinical diagnostic laboratories. Non-compliant specimens were not accepted by the service and the clinician contacted the referrer to rectify and resubmit the sample.

Staff ensured that patient samples were not mixed up by not accepting specimens that were not compliant with the labelling SOP. Clear sample labelling was observed and multiple samples from the same patient were grouped together. There were appropriate internal quality controls to minimise risk to patient safety from non-conforming specimens and labelling. Clear guidance was available on the service's website for end users to ensure compliance for taking and labelling specimens. Clear labelling was seen on a sample of specimens.

Medical laboratories

Laboratory results were recorded electronically, and staff could access them easily. The service had a system to ensure specimens and records were not mixed up. This was through a second check process by staff. This ensured the information assessed and recorded was accurate. Staff had access to an electronic records system that they could update, ensuring information was available on the system in a timely manner.

The service had a contingency plan in the event of a system failure or continuing 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 the Royal College of Pathologists (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. Results were also available to referrers and patients via the service's website. Each person had an individualised password protected access to view only their results online.

Incidents

The service managed safety incidents well. Managers investigated incidents and shared lessons learned with the whole team and the wider service.

Staff knew what incidents to report and how to report them. The service had an up to date and reviewed incident policy covering the reporting and investigation of incidents.

In the 12 months before this inspection, the service identified the top 5 trends in incidents with: 66 procedural incidents, 10 report format incidents, 8 validation incidents and 6 calibration and 6 external quality assurance incidents. We saw that all incidents were reviewed by managers and included an incident classification, immediate action plan, root cause analysis, corrective action plan, preventative action plan, a sign off and a review of the effectiveness of the corrective actions applicable.

The service was ISO 15189 accredited for the identification and control of non-conformity work, corrective and preventative actions. Where gaps in processes were identified by the UKAS assessment the service took actions to address them.

The method for reviewing non-conformity work was the 'corrective action and preventative action model (CAPA). This was a process that organisations take to identify the causes of non-conformities and to take corrective actions to prevent them from happening again.

Staff completing reviews for incidents were competent. Incidents identified were reported internally using the CAPA module and externally if applicable. We saw evidence of learning from incidents which was shared with staff in daily safety huddles and recorded on the electronic quality management system.

No serious incidents were reported on the internal incident reporting system in the last 12 months. The registered manager had a good understanding of duty of candour and explained the actions they would take to make sure they fulfilled their duty. Duty of candour is a regulatory duty that relates to openness and transparency and requires

Inspected but not rated

Medical laboratories

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.

Are Medical laboratories effective?

Inspected but not rated

We have inspected but have not rated this service. This is because the CQC does not apply a rating to independent laboratory services.

Evidence-based care and treatment

The service provided tests and reports based on national guidance. 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 procedures (SOP) to support the delivery of the service. They reviewed these regularly and included references to national guidance and best practice documents, from organisations such as the Royal College of Pathologists (RCPath).

Managers and staff carried out a programme of regular audits. The service had internal and external quality assurance systems and was accredited to ISO 15189:2012 for the standard of presentation and interpretation of results.

The service used external quality assurance (EQA) for tests being offered. The service had bi-monthly quality management meetings to review and share information and actions with minutes for reference.

The service's internal quality assurance (IQA) had a programme of calibration for measuring systems and verification so that all results were traceable, where possible, to a stated reference material. Calibration certifications were provided for externally calibrated equipment checks and internal calibration was carried out by staff.

Patient outcomes

Staff monitored the effectiveness of tests and samples. The service had been accredited under relevant clinical accreditation schemes. The service participated in relevant national clinical audits.

The service participated in nationally and internationally recognised internal and external quality assurance processes and systems such as the United Kingdom Accreditation Scheme (UKAS) (ISO15189), United Kingdom National External Quality Assurance Scheme (UK NEQAS) for microbiology operated by Public Health England, UK NEQAS for immunology, immunochemistry and allergy and the Randox International Quality Assessment Scheme (RIQAS).

Medical laboratories

The service monitored the quality of service provision, including health and safety requirements and guidance set out by the relevant professional bodies. Where risks were identified these were addressed in the quality management meetings and annual management review meeting and added and amended into the service's SOPs when this was applicable.

The service had key assurance indicators (KAIs) for timeliness of reports and clinical advice. Key performance indicators were recorded and monitored to ensure contractual obligations were met. The service demonstrated they were consistently meeting their targets.

There were systems and checks to make sure the results being offered were accurate and that reference ranges being used were appropriate. Staff checked results and equipment calibrations for each test carried out and any deviations were addressed. The service produced reports and shared data at daily staff huddles and senior staff meetings for IQA and EQA compliance. IQA and EQA compliance is used to ensure day-to-day consistency of analytical processes so that the results of laboratory instruments or point-of-care tests were correct and true.

If EQA was not showing satisfactory results there were policies, practices and procedures for dealing with this. Non-conformities were acted on and results of internal audit were discussed at senior management meetings and actions were reviewed at each meeting.

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 staff had appropriate education, training and we saw evidence of continuous practice development. Managers provided all new staff with an induction tailored to their role before they started work.

Staff were supported to undertake further professional and personal development. We saw appraisals had provided opportunities for staff to reflect and request further training and development which were accommodated where possible.

Managers supported staff to develop through their yearly appraisals, peer review of results and cases and constructive evaluations of their work and training needs. Staff told us they had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. It was reported 100% of eligible staff had received an appraisal up to January 2023.

Staff including senior staff said that they were well supported and had access to training and continuous professional development.

Staff could explain how to handle and prepare samples for testing and what they do to report concerns about results and EQA compliance.

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.

Inspected but not rated

Medical laboratories

The service worked together as a team to benefit patients and their customers. Pathology consultants and biomedical scientists provided support to other clinicians, through advice and interpretation of diagnostic reports, to make clinical decisions about patients care and treatment and also by supporting the analysis processes.

The service held daily staff huddles to identify and improve practice as well as prioritising work for the day. The service also held multidisciplinary meetings to inform of areas of non-conformance work and identify actions to address these.

The laboratory director and senior leadership team held regular and effective multidisciplinary team meetings with partner organisations. These were used to discuss pathology results, provide clinical advice and gain additional clinical information with the aim of improving patient care.

Seven-day services

Key services were available six days a week to support timely patient care. The service was flexible to manage emergency requests.

The laboratory was open from 8:30am to 6pm, Monday to Friday and from 9am to 2pm on Saturdays. We were told that should any urgent requests or referrers request any urgent pathology tests the service had the flexibility to make arrangements to support out-of-hours requests or expand their opening hours.

There was a 24 hour on call system in operation outside of normal hours for more urgent requests as well as senior staff to support the safe management of this.

Are Medical laboratories responsive?

Inspected but not rated

We have inspected but have not rated 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 planned and provided a service in a way that met the needs of local people and the customers served. It also worked with others in the wider health system and local organisations to meet testing and reporting requirements.

Managers planned and organised services, so they met the needs of their customers.

Facilities and premises were appropriate for the services being delivered. The service provided information for health and social care providers to set out the service provided. Service specifications were contained within contracts and service level agreements to make sure the needs of clients were met.

Relevant information was provided on the service's website, including the types of tests for people using the service. This set out the services provided, sample requirements and how the service could be accessed. The website also included contacts to enquire about the tests and services being provided.

Inspected but not rated

Medical laboratories

The service reviewed user feedback from professionals and providers who used the service to obtain information about how to plan and improve service delivery. The 2022 user survey results were positive and showed that respondents stated the service mostly met their needs. The very few comments for improvement were in majority of activities that are not regulated by the commission. We did however review comments and action points identified by the service and saw they addressed the concerns raised.

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 customers.

The service had a dedicated courier service to collect specimens, which reduced risks of loss or damage in transit.

Customers could arrange special requests and turnaround times. As an example, GP's were able to communicate directly with the laboratory manager to make such arrangements. Additionally, clients had a client liaison manager to support special or out of hours requests.

Staff ensured clients received test reports in a timely manner and they were advised of any delays as soon as possible. This ensured the clinician could explain to the patient the diagnostic results and treatment options in timely way.

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.

The service had a system to ensure urgent specimens were prioritised during the day. As an example, sample collection kits were sent out to clients with bespoke request forms. These forms allowed priority tests to be identified on receipt by the service and acted upon in line with defined standard operating procedure (SOP) timeline priorities for each test. This ensured patients were able to receive results in a timely manner.

Learning from complaints and concerns

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

An annual user satisfaction was used to gather feedback on the service. This included areas of improvement and compliments from service users accessing and using the service. The service responded to areas of improvement setting out an explanation for their actions and where possible commenting on steps they would take to improve processes. Actions from learning were communicated with the appropriate staff teams, service leads for dissemination and shared in daily staff huddles.

Inspected but not rated

Medical laboratories

Staff understood the complaints policy and knew how to handle and respond to complaints. No formal complaints had been received with the service in last 12 months, therefore the service did not need to refer any complaints to the Independent Parliamentary and Health Service Ombudsman. The registered manager said any complaints would be looked at using the corrective and preventative action process.

The service did not receive any compliments in the last 12 months.

Are Medical laboratories well-led?

Inspected but not rated

We have inspected but have not rated this service. This is because the 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 staff. They supported staff to develop their skills and take on more senior roles.

The leadership, management and governance of the organisation assured delivery of a high-quality service with leadership capacity and capability to deliver high-quality and sustainable care.

There was a management structure with clear lines of responsibility and accountability. The operations director, laboratory co-ordinator and quality / laboratory manager reported to the laboratory / managing director and the finance and compliance director who were founders of the service. The quality / laboratory manager was responsible for the overall management of the laboratory and laboratory staff. While the office supervisor had responsibilities for the management of the office staff and administrative tasks.

There was good oversight of staffing which was reviewed at each senior leadership and quality meeting. Where risks were identified in staffing and sustainability these were identified as non-conforming work and acted on with an action plan.

Leaders were visible in the service. Some senior leaders were also biomedical scientists including the laboratory / managing director who also acted as the registered manager.

Vision and Strategy

The service had a clear quality and sustainability plan for what it wanted to achieve and a strategy to turn it into action, developed with relevant stakeholders. The strategy was focused on sustainability of services and aligned to local plans within the wider health economy.

There was a clear quality and sustainability strategy documented in the quality meetings with the top priorities evidenced and communicated to staff through various methods including e-mail, team meetings, communication forums and daily team huddles.

The service had clear values on what it wanted to achieve. It stated that "it recognises that our clients expect us to be at the forefront of the pathology industry. Therefore, significant investment is consistently made to ensure that our laboratory utilises the most up to date science and technology". There was also an emphasis on a tailor-made, accessible approach to healthcare and a commitment to assisting clinicians in the diagnosis, treatment and management of patients. The service also stated they worked alongside their clients to provide the best possible service to their patients.

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

There was evidence that the leader planned for the future training needs of staff, (see training and competent staff). A staff member told us that they had been promoted to more senior roles during the time they had worked at the service. They said this was because managers supported staff to improve.

Culture

Staff felt supported. The service had an open culture where staff and service users could raise concerns without fear. The service provided opportunities for career development.

Staff we spoke to including leaders said that they felt supported by the senior leadership team and had regular one to ones with their line manager. There was an open culture whereby staff could approach any senior or line manager for help and support.

Wellbeing of all staff was prioritised by senior leaders. Where it was identified that there were pressures placed on staff to cover sickness, staff turnover and increased workload post COVID-19 recovery these were reviewed, monitored and risk assessed.

There were mechanisms for providing all staff at every level with the development they needed, including high-quality appraisal and career development conversations. These were seen in the staff appraisals we reviewed. The service also prided itself on bringing in new tests to expand staff interest and knowledge.

There was a clear policy and process for dealing with incidents and complaints. Incidents raised on the internal incident reporting system with the potential to impact on the patient were always considered as a joint process and managed by the whole team.

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 were effective and efficient structures, processes and systems of accountability to support the delivery of the strategy and good quality, sustainable services. These were regularly reviewed and improved. Levels of governance and management functioned effectively and interacted well with each other. There was a clear performance management reporting structure with regular governance meetings looking at operational performance.

Staff at all levels were clear about their roles and understood what they were accountable for, and to whom.

Governance meetings also addressed and reviewed evidence-based practice such as National Institute for Health and Care Excellence guidelines and outcomes. Governance meetings included a bi-monthly quality management meeting and a yearly annual review meeting to look at areas such as risk, performance, finances and strategy. Communication and dissemination of these meetings were made available to all staff and impactful changes addressed in the daily staff huddle.

Arrangements with partners and third-party providers were governed and managed effectively to encourage appropriate interaction and promote coordinated care.

The service ensured there was effective interface with providers using the services that included the assessment of user satisfaction and areas for improvement through an annual service user satisfaction survey.

The service reviewed performance effectively. There was evidence of audits for external quality assessment and identification and control of poor performance or results from external quality assurance schemes that were compliant with United Kingdom Accreditation Services (UKAS) accreditation.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

The service had assurance systems and performance issues were escalated through clear structures and processes. There were processes to manage current and future performance which were reviewed and improved through a programme of clinical and internal audit. Leaders monitored quality, operational and financial processes and had systems to identify where action should be taken. The service was able to demonstrate that the actions required or recommended as a result of the service's governance meetings were being monitored, checked and reviewed.

The service had UKAS accreditation ISO 15189 for most tests being carried out. Customers were made aware of which tests had not completed UKAS accreditation.

The service was able to share the latest UKAS compliance report from June 2022 and any subsequent action plans together with progress against these. It had acted to comply with the UKAS mandatory actions required and this was acknowledged in the UKAS action plan.

Compliance with current national legislation and regulations in relation to General Data Protection Regulation was followed.

Where risks were identified, they were added to the non-conforming work list and risk reduction plans implemented. Non-conforming work was reviewed bi-monthly within the quality management meetings. We saw evidence the service regularly reviewed and actioned non-conforming work issues including actions recommended by UKAS. Information was shared with all staff by the managers and senior team leaders.

The service was looking to migrate some non-conforming list risks and implement a risk register to support an improved oversight of their risks. This was being implemented as part of further UKAS accreditation programmes.

The service had a business continuity plan which set out clinical proposals to respond and reduce the risks from events such as machine failure to lack of electric supply.

Information Management

The service collected reliable data and analysed it. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The service was compliant with data protection and had secure systems to protect personal data both internally and externally including a cybersecurity certificate.

Staff had access to the information they needed via the electronic system with individual log in details which were password protected. The service was still using both paper and electronic means of keeping records.

The service compiled a quality manual which described the quality management system to meet the requirements of ISO15189 and appropriate national and international standards. ISO 15189 is an international accreditation standard for medical laboratories. Laboratory accreditation helps laboratories develop quality management systems, assesses their competence and ensure they are functioning in line with industry and legal standards.

Management reviews took account of analysis, records and the interpretation of audits and external quality assurance schemes. Metrics were recorded and reported to the national organisation. Issues identified were discussed with senior clinicians. Any quality issues were escalated up through the pathology leadership structure.

The service was able to share the latest UKAS compliance report and any subsequent action plans together with progress against them.

During inspection, it was noted that confidential waste which had passed its retention period was removed offsite for incineration by a director who transported the confidential waste to the location of incineration. We highlighted concerns regarding tracking and assurance that information was not lost as there were no checks to guarantee confidential waste was disposed of correctly. The service provided us with assurances that confidential waste would now be destroyed onsite and the risk of losing confidential waste minimised. We also received assurance this action was now included in the instructions for the disposal of waste and sample storage policy and that article 5 - Principles relating to processing of personal data of the General Data Protection Regulation (GDPR) were followed.

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 and staff actively and openly engaged with service users, they collaborated with partner organisations to help improve services.

The service worked closely with clients such as private GPs, sporting clubs and private occupational health companies to ensure that there were agreed mechanisms to ensure results were available, shared and communicated in a timely fashion.

Inspected but not rated

Medical laboratories

The service was responsive to the needs of the clients. The service had dedicated direct relationship contacts with major providers to support the management of queries and specific requests.

The main feedback mechanism to gather user satisfaction was through an annual survey, although trust pilot and internet browser scores were also reviewed. Results from the survey were discussed at board level. Other mechanisms included feedback from clinical leads within established partnerships and service level agreements.

The service shared information and outcomes with external agencies. We saw evidence of this with the Medicines and Healthcare products Regulatory Agency and with the United Kingdom Health Security Agency.

The service had good relationships with suppliers. This ensured they were aware of new tests and equipment.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

Leaders and staff strived for continuous learning and improvement and participated in recognised accreditation schemes such as the internationally recognised ISO 15189 accreditation. ISO 15189 is an international accreditation standard for medical laboratories. Laboratory accreditation helps laboratories develop quality management systems, assesses their competence and ensure they are functioning in line with industry and legal standards.

The service also participated in external quality assurance schemes which are accredited to ISO17043. ISO17043 specifies general competence requirements for providers to undertake a test and gain increased confidence that the programmes they rely on are being operated competently and in accordance with specified technical and management system requirements. Schemes under this accreditation included:

- United Kingdom National External Quality Assurance Scheme (UK NEQAS) for microbiology - Operated by Public Health England
- UK NEQAS for immunology, immunochemistry and allergy
- Randox International Quality Assessment Scheme

Leaders and staff audited quality assurance and any poor performance was investigated with a response to the external quality assurance provider with an action plan to mitigating risks and improvements being made.

The service was a leader in innovation. They were the first service in the country to use a specific system designed to address common clinical laboratory challenges to deliver better outcomes.

The service was leading in other aspects of analysis such as quantitative fit testing for customers regarding stool samples. They were also on the forefront of a blood checking system used for performance testing in professional athletes that implemented a trending system for monitoring individual results.