London Medical Laboratory Limited

London Medical 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 caring?	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 and interaction with patients.

- The service had enough staff with the right qualifications, skills, training and experience. Areas and equipment within the laboratory were clean and well maintained and the service-controlled infection risks well. The design, maintenance and use of facilities, premises and equipment kept people safe. There was a good system to report safety incidents and staff knew how to report and act on incidents and near misses.
- Managers monitored the effectiveness of the service and staff completed risk assessments for each test performed. The service ensured quality was monitored through participating in external and internal quality assurance programmes. Services provided were based on national guidance and evidence-based practice.
- Managers monitored and made sure staff were competent for their role and staff worked well together for the benefit of people. The laboratory was available seven days a week, twenty-four hours a day.
- The service planned and provided a service that met the needs of the people using the service and those who referred people there. People could access the service when they needed it and received laboratory results quickly. People could provide feedback to the service to be used for quality improvements.
- Leaders had the skills and abilities to perform their roles and a good understanding of the services they ran. Staff felt respected, valued and supported.
- The leaders used reliable systems to manage performance and quality and used systems to support staff to develop. There was a vision and set of values which staff understood and applied to their work. All staff were committed to continuously learning and improving the service.

However:

- Some of the paper training records were incomplete. Although the service was able to provide evidence of training, the service recognised better systems of streamlining training were needed and were in the process of developing these.

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 London Medical Laboratory Limited

The London Medical Laboratory Ltd was founded in November 2016 and is an independent clinical testing specialist and provider of pathology diagnostics services to people across the healthcare sector. They offer pathology testing solutions across many disciplines including clinical biochemistry, immunology, haematology, sexual health screening and molecular biology. Such tests include, health and wellness checks, thyroid function, liver and kidney, cholesterol and heart tests, as well as hormone, fertility, and sexual health tests.The London Medical Laboratory Ltd has several branches around greater London. However, these branches do not fall within CQC's scope of registration and therefore these aspects of the service were not inspected. The service also conducts Covid 19 testing, such as, PCR swab tests and antibody tests. On 15 December 2020, the law changed. Coronavirus testing has been exempted as a regulated activity under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This means that any testing activity in relation to coronavirus has been taken out of scope of CQC registration. The new Coronavirus, Testing Requirements and Standards (England) Regulations 2020 require all private coronavirus test providers to become accredited by the United Kingdom Accreditation Service (UKAS).

At the time of inspection, the service was working towards the United Kingdom Accreditation Service (UKAS) standards ISO 15189 for all of their blood tests. They had recently received UKAS accreditation ISO for all of their Covid 19 sampling. The United Kingdom Accreditation Service (UKAS) is recognised by the Government as the sole national accreditation body.

The service is regulated to provide Diagnostic and Screening procedures and there is a registered manager in post.

How we carried out this inspection

The inspection team consisted of two inspectors 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 seven staff, including senior management and laboratory staff, who conducted the sample testing, as well as the registered manager. We reviewed a range of policies and procedures and audits as well as other documentation such as 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	Inspected but not rated	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 to all staff and made sure everyone completed it.

All staff received and kept up to date with their mandatory training. Training topics were tailored to the individual roles within the service, but core subjects included: information governance, general data protection regulation (GDPR), health and safety, infection prevention and control, and fire safety. Laboratory staff completed additional training which included infection control of substances hazardous to health (COSHH), waste management and moving and handling. The management team also completed equality and diversity, performance management, bullying and harassment and mental health awareness.

Training was provided via an external training company with e-module sessions and some sessions required interactive face to face training such as level 3 training in Safeguarding.

Managers monitored mandatory training and alerted staff when they needed to update their training. At the time of inspection laboratory staff had completed the modules required for their role and were up to date with their mandatory training.

A new human resources manager had just been recruited and was in the process of ensuring there was a more streamlined process in the recording and management of training records.

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, the consultants and GP's who read the laboratory findings had received Safeguarding training to level 3 and were aware if findings indicated a risk or safeguarding concern. The registered manager acted as the safeguarding lead for the laboratory and there was a safeguarding policy for staff to follow.

There had not been any safeguarding incidents reported in the last year.

The service had a good recruitment system to enable relevant recruitment checks had been completed for staff. Disclosure and barring service (DBS) checks prior to staff starting had been completed, photographic ID and references along with qualification verification.

Cleanliness, infection control and hygiene

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

There were strict working protocols in place to make sure the risk of cross infection and contamination was prevented as reasonably practicable. The service had a cross infection policy which provided clear guidance to staff on measures to take to avoid cross contamination. The policy provided operating procedures for staff to follow, for example, sharps injury, specimen handling, spillage, manual cleaning and Covid-19 precautions.

The laboratory area was clean and had suitable furnishings which were clean and well-maintained. Staff followed infection control principles including the use of personal protective equipment (PPE) and we observed good practice by staff during the inspection.

There was a good supply of cleaning equipment such as sterile wipes, wall mounted hand gel and wall mounted paper towels throughout the service. Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Cleaning audits were conducted on a routine basis.

Infection prevention control (IPC) audits were completed such as hand hygiene and an IPC tool was used to check on laboratory, housekeeping and PPE. There was a good compliance with audits and for those areas which were non-complaint, for example for one period we saw follow up actions and further monitoring for housekeeping cleaning records which had not been logged or signed,

Staff were routinely tested for Covid-19. There had been no local outbreaks of Covid-19 at the service.

There were spillage kits used to clean up spills of any liquid in the laboratory area.

At the time of our inspection there had been no reported infection control incidents.

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 pathology department was contained in a two storey converted building in an industrial area ideally suited to the purpose of being a laboratory. The design of the environment followed national guidance such as the Department of Health; HBN15:Facilities for pathology services and this included aspects such as, such as the size, layout, flooring, sinks, clinical hand wash basins, staff changing and laboratory coat pegs. We saw clear boundary zones between the laboratory and the non-laboratory areas.

Entry into the service was card operated and key coded and CCTV cameras monitored the entrance of the service.

The service was rapidly expanding and we saw plans for the expansion, which included an extension of the building. The service was following recommended guidelines and seeking professional external support for the expansion.

There was an inventory of equipment, including analysers that included the name of the manufacturer, serial number, date of purchase, location, record of contracted maintenance and record of equipment breakdown. The service had a backup generator and mitigating actions in the event of equipment failure. Equipment had recently been assessed and passed by The United Kingdom Accreditation Service (UKAS). UKAS is the national accreditation body for the United Kingdom. Each sample analyser was calibrated with external assurance.

There was a safe system for the storage and disposal of specimens. Clinical waste was stored in lidded containers prior to it being transported to a safe secure locked container. Waste was collected twice weekly from a designated specialist waste collector.

Those reagents and consumables that required temperature control were stored in fridges and freezers in the laboratory. All temperature controlled storage was monitored electronically and recorded on the laboratory computer. Reagents and consumables at room temperature were stored appropriately in the stock room or near the analysers.

Tests were registered and system connected. Tests had a QR barcode so information on the tests were registered beforehand, so for example, expiry dates could be detected. As the majority of the machines used, could detect expiry dates this meant the batch would not work within the machine if the date had expired.

Fire safety equipment and checks were completed and up to date. There was a weekly fire test and we reviewed the fire safety logbook which showed all fire equipment and safety fire checks had been tested regularly.

At the time of the inspection the door to the laboratory was broken and could not be closed properly. Since the inspection we have been told the door has now been repaired.

Assessing and responding to patient risk

Senior staff completed and updated risk assessments and removed or minimised risks.

Apart from Covid-19 tests, which did not fall within our remit, the majority of other tests were wellness checks and therefore did not require an urgent response. This meant the tests were self-referrals from people purchasing the tests through the service or through wellness test referrals from independent GP's. The laboratory had protocols to deal with test results that required a further follow up, for example, if tests came back with a high level of white blood cells a request for an immediate repeat test would be made and the patient would be contacted by telephone.

The GP's who worked for the service could call 111 and get access to an out of hours GP if required, but due to the non-urgent nature of the tests this rarely happened. A biomedical scientist was present on every shift.

Senior registered HCPC biomedical consultants oversaw the whole testing process and would authorise test results before being shared with the resident GP's who would then contact the patient. If an abnormal result was flagged, it would be retested, and the GP would contact the patient. This was in line with Key Assurance Indicators (KAI, 2019) for pathology service guidelines.

The service used a statistical software to monitor the tests and any errors would be shown. This was monitored on a daily basis.

As the tests were sold by the laboratory, they were able to register patient details prior to the test being taken and this meant less mistakes were made with patient information.

There were contingency plans for system fail. In the first instance, the service had an additional analyser, but also had reciprocal arrangements with other laboratories.

There were risk assessments for sample testing and equipment, and these were reviewed regularly by the senior team. There was a standard operating procedure for each specimen and risk assessments with hazards, risk ratings and control measures were in place.

Staffing

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

The service had enough staff with the right skills to run the laboratory safely. Staffing levels met KAI 2019 guidance. The laboratory was managed by a laboratory manager and consisted of four senior biomedical scientists and four medical laboratory assistants. The laboratory manager and biomedical scientists were registered with the Health and Care Professions Council (HCPC).

The biomedical scientists were guided by consultant pathologists who were members of the Royal College of Pathologists and held substantive consultant level positions in the NHS. Cover was provided as part of their contractual agreement with the medical director, being able to step in if required. The four consultants were experts in their disciplines of haematology, biochemistry, microbiology and cellular pathology. They were able to provide clinical advice and interpretation. There was always a biomedical scientist for every shift.

The service had procedures to make sure there was support and supervision of professionally registered (HCPC) staff in the service and this was through induction, appraisal, training, and competency assessments.

The laboratory operated 24 hours seven days a week, so there was always a biomedical scientist on call for any urgent request.

The service did use agency medical laboratory assistant staff when needed. They used an agency where suitable employment background checks, which included training and qualifications were made available. Agency staff were given a full induction before starting work.

Due to the rapid expansion of the service they were in the process of recruiting a further five biomedical scientists.

Records

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

Records we reviewed were clear, contained detailed information and were accessible to staff. Information on specimen request forms were detailed and 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.

Records were stored electronically and securely in line with Data Protection Act 2018 and RCPath (2015) guidance on the storage and retention of pathological records and specimens. Electronic records were password protected and only accessed by authorised staff.

There were good systems to make sure patient samples and records were not mixed up, through a second check by staff.

Results were reported electronically and were usually available immediately upon validation and authorisation. Electronic reports with detailed information was sent securely to the patient or independent GP.

Contingency plans were in place in the event of system failure.

Medicines

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

Medical reagents were stored safely, and batch numbers and expiry dates were monitored.

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. Staff raised concerns and reported incidents and near misses in line with the services policy. There was an incident reporting log for staff to complete and this was sent to the senior management team.

There had been no serious incidents reported in the past year. Incidents were discussed in the monthly clinical governance and quality meetings as a set agenda item. Trends were analysed by the senior team every six months, for example incidents on incorrect results, delayed kits, test appointment, lost sample and payment issue. The latest report we reviewed showed 14 incidents had been raised in relation to incorrect patient information and 12 incidents of delayed specimen kits were the top incidents reported.

We reviewed a selection of reported incidents and saw though investigations had been made which included root cause analysis, remedial action, corrective action, preventative action taken, and effectiveness follow up had been completed. Incidents were reviewed and closed by the Quality Manager.

Preanalytical logs were kept where incidents were recorded for example for incorrect results sent out and samples leaked. We saw results for 10 October 2021 to 31 October 2021, where very few incidents had been logged. The majority of preanalytical incidents logged had been due to postal errors or delays.

Findings of reviews were used to support quality improvements, for example we reviewed a reported incident and saw follow up actions of updating a standard operating procedure training for staff and competency assessments had been put in place.

If external quality assurance results were not in line with acceptable results, they would use an alternative referral laboratory while investigating the problems. The service gave a previous example of when they had to use a referral laboratory for one week for their thyroid tests, due to the reagents having warmed during the journey to the laboratory. This was due in part to a time when there were delays with deliveries in the UK.

Inspected but not rated

Medical laboratories

The clinical and product assurance (CAPA) model was used for incidents of non-conformity. This model was used to identify the causes of non-conformity so the corrective and preventative actions could be taken.

Learning from incidents was shared through regular team meetings within the service.

The service understood their responsibilities under the duty of candour (DoC) and that this meant being open and transparent with patients when things went wrong. There was a policy to guide staff and staff gave examples of when they followed DoC, such as when the incorrect results may have been given by mistake.

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

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 high quality care according to best practice and national guidance. Their policies were supported by standard operating procedures to provide up to date effective guidance for staff. The policies we reviewed were ratified and version controlled by the senior leadership team and made reference to expert professional bodies.

The service had received United Kingdom Accreditation Service (UKAS) ISO 15189 for all of their Covid-19 sampling and were working towards UKAS accreditation for all other tests. The service had risk assessments for all of their specimen tests.

There were internal and external quality control systems for ensuring intended quality was achieved. The service used the United Kingdom National External Quality Assessment (UKNEQAS) service for quality assurance on tests for each analysis taken. There was a programme of regular audits and a programme of calibration of measuring systems and verification, so that results were traceable. Results of audits were used as part of their continued quality assurance of the service. We reviewed a selection of internal quality audits and saw when errors occurred actions were taken, and summary reports were run for overview from the leadership team. Internal quality controls were run daily at intervals throughout the day.

There was good oversight of technology and equipment used and the service invested in new equipment and technology if they knew this would improve the quality and effectiveness of the service.

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 audits both internal and external. Outcomes for patients were positive, consistent and met expectations, such as national standards. They monitored the quality of service provision including health and safety requirements and guidance set out by the relevant professional bodies.

Managers and staff carried out a varied programme of repeated audits to check improvement over time. An external quality assurance (EQA) check was completed on at least one system once a week.

There were standard protocols for any EQA that did not show a satisfactory result. Returned results were viewed by the BMS of the section and then given to the quality manager and pathology manager for sign off. The returned results were also reviewed at consultant level. We reviewed a sample of EQA results and saw the summary report with steps taken for those results that required further action.

Uncertainty of measurement (UOM) for susceptibility testing had been estimated for each test during the verification process and these were reviewed at regular intervals to ensure the UOM values did not exceed pre-defined maximum uncertainty.

In certain cases, the laboratory rejected samples if the sample fell short of quality, volume or other criteria. This could be rectified by the sample being taken again. A summary list for sample rejection was available to staff in their laboratory handbook.

Once every few weeks the laboratory were sent samples from other laboratories for benchmarking purposes.

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 to meet the needs of patients. The laboratory director was a specialist medical consultant and fellow of The Royal College of Pathologist. There were specific management roles for quality, training and education and health and safety.

GP's were registered with the General Medical Council (GMC) and oversight of their competency and continued professional development was provided by the medical director. We saw evidence of the GP's appraisal, continued professional development and involvement in interpretive EQA schemes including evidence of acknowledging EQA reports and giving advice when necessary.

Managers supported staff to develop through yearly, constructive appraisals of their work. The majority of these were due to take place in December 2021. During these meetings staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Staff had received one to one meetings with their manager since they had been appointed.

Managers gave new staff an induction tailored for their role before they started. There was a user manual issued specific for laboratory staff.

Staff were aware of and competent in handling samples in line with professional guidance published by the RCPath. There was a full check for competency every two years and staff were assessed at six and 12 monthly intervals for those parts of the role they did not complete routinely. Laboratory staff training included four levels, trained to perform under supervision, can perform procedure under minimal supervision, competent to perform procedure and able to train.

Inspected but not rated

Medical laboratories

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Staff were able to complete external courses for their personal development as well as training for their specific role.

We checked a total of five staff personal records. Disclosure and barring (DBS) checks had been completed for all the records we reviewed; references sought before employment as well as checks to ensure staff were legally able to work. Some of the paper based training records we reviewed had not been updated but the service was able to provide evidence that the necessary training and competency checks had been completed.

Pathology staff had received appropriate and updated training and information regarding Covid-19 from the professional bodies.

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.

The medical director and laboratory manager held regular and effective multidisciplinary meetings with the biomedical scientists, GP's, quality team and health and safety manager.

The service held regular two weekly meetings with pharmacist organisations to discuss quality improvements with the service. There were handover meetings for staff at each shift where any updates or concern were discussed.

Medical alerts, changes to procedures or updates are sent out via email to staff and spoken about at the relevant meetings

Seven-day services

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

The laboratory operated on a twenty four hour, seven day a week basis, whereby staff worked on a shift basis. A senior biomedical scientist was present at each shift.

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

Managers planned and organised services, so they met the changing needs of the local population. The provider offered a wide range of blood and urine tests from routine core profiles to specialist analyses on a private basis. The majority of non Covid testing was for wellness blood checks. They performed approximately 500 blood tests per day.

Inspected but not rated

Medical laboratories

The provider had undergone rapid growth within the past year and had planned for future growth with the expansion of the premises to accommodate a larger laboratory and with plans to roll out more wellness tests kits within pharmacies. They also planned to work with more independent GP's again for blood wellness checks. The service also offered bespoke profile testing.

The process of testing was made simple from start to finish with postal, courier or at home testing options available. The service had eight 'shops' at different locations where people could attend to have their blood test taken. However, these shops did not fall within CQC scope of registration and did not form part of the inspection. The provider managed the whole process from producing the test to processing and summarising the results on site. This meant results could be delivered more quickly.

The service operated during the COVID-19 pandemic offering private swab testing and antigen tests which reflected the essential needs of the population being served.

A customer service telephone line was open Monday to Sunday from 9am to 6pm.

Access and flow

People 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 majority of tests were processed the day they arrived in the laboratory. There were turnaround times for each test which were displayed in the staff user handbook. Most tests turnaround times were the next day with the exception of infectious diseases, male/female STI screen, male/female advanced screen which took three days. The majority of tests completed were not of an urgent nature.

The turnaround times for results were closely monitored through the clinical governance and quality meetings. Trends of turnaround times were displayed on a weekly basis in the laboratory with a percentage of tests of turnaround times displayed. Information we reviewed showed from June 2021 to November 2021 on average 85% of tests had a turnaround time of six hours.

When the provider experienced difficulties with access and flow they made alternative arrangements to ensure tests were actioned quickly. For example, they use a courier service for tests when they have experienced difficulties with the postal system.

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 understood the policy on complaints and knew how to handle them. Managers investigated and responded to all complaints and routinely monitored them to identify themes and any emerging trends. Acknowledging receipt of a formal complaint was made within three working days with a completion of investigations and a response within 28 days.

Where the internal complaints process had been exhausted patients were advised and directed to the independent Parliamentary and Health Service Ombudsman.

Complaint trends we reviewed included customer service issues, late results, postal delays and kit issues.

Inspected but not rated

Medical laboratories

Managers shared feedback from complaints with staff and learning was used to improve the service.

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

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 patients and staff. They supported staff to develop their skills and take on more senior roles.

There was a management structure with clear roles and responsibilities to provide sustainable high quality care. Specific to the laboratory was a laboratory manager who had responsibility and management of the laboratory and laboratory staff. The laboratory manager reported to the medical director who was part of the senior leadership team.

There was good oversight of the challenges the service faced, particularly during the pandemic and due to the rapid growth of the service. Therefore, the management structure had been bolstered and the recent recruitment of a risk manager and quality manager meant there was stronger oversight and assurance in these areas.

Staff we spoke with were positive about the managers and how they were approachable and open to discussing new ideas and taking onboard any concerns raised. Staff said they received good support when needed and managers were very visible within the service.

We observed good team working and a supportive working relationships during the inspection.

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.

There was a clear vison underpinned by a set of values which prioritised quality and sustainability. This was supported by a set of policies to ensure the vision was delivered such as the quality policy. The service were building solid foundations, as in making sure systems and processes were embedded so they could make quick and agile changes when required.

The mission vision and values were called the ’10 commandments’ and posters were displayed throughout the service. The service strategy was aimed at expansion of the service and technology.

The values of the service such as ‘we are family’ ‘creatively agile’ were demonstrated through the inspection.

Culture

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

Staff felt supported, valued and respected. Staff told us they enjoyed working within the service and there was a good team spirit. The culture encouraged openness and honesty at all levels. Staff told us their opinions and ideas were well received and respected by the senior team

Staff development was recognised and encouraged. Training opportunities were available for all staff and we were told several staff from administrative roles with no clinical background, had decided to embark on the medical laboratory assistant training and were given full support from the senior leadership team.

Wellbeing and appreciation of staff efforts were recognised. There was a weekly 'staff of the week' and managers said they made a conscious effort to say thank you to staff especially during busy periods.

There was an emphasis on the safety and wellbeing of staff in the service. During the Covid-19 pandemic, the service completed risk assessments for staff and provided weekly testing. Staff also had access to, and all had received the Covid-19 vaccination.

Governance

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

There were effective structures, processes and systems of accountability to support the delivery of the service. There was a clinical governance committee whose primary objective was to provide assurance that the key critical systems and processes within the service were effective and robust.

The committee reviewed and monitored: incident and management reporting, health and safety, quality audits, risk management as well as reviewing internal and external assurance reports. The management of any serious incident action plans from assurance reports were reviewed through the committee. The committee was made up of the senior leadership team which included the medical director and laboratory manager.

Assurance was also gained through regular clinical and quality governance meetings, laboratory meetings, strategy meeting, staff meetings and the annual management review meetings. We reviewed a selection of clinical governance meetings and laboratory meeting minutes and found good representation from staff of all levels including the senior leadership team. Areas covered within the clinical governance meetings included incidents, risks and quality performance. Actions with time frames were set against an item that required follow up and we saw these were continually monitored and reviewed each month. The laboratory meeting minutes were specific to matters within the laboratory such as UKAS accreditation information, staffing and activity.

We saw evidence of external quality assessments and actions taken for poor performance with investigations and control measures put in place.

The provider ensured the retention of pathological specimens was in accordance with requirements of the Human Tissue Act through compliance with the Human Tissue Act (2005)

Management of risk, 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.

The service was working towards UKAS accreditation ISO 15189 for each of their blood tests. They had recently received full UKAS accreditation for all of their Covid 19 sampling and had received a good report. Due to the service expanding they had been advised by UKAS to wait until they had completed the extension of their laboratory and premises before completing the whole process for their blood tests.

The service had risk assessments in place for all tests. We reviewed a sample and found detailed assessments and identification of the hazards when performing the procedure had been made. The hazards included existing control measures in place, and these were red, amber and green (RAG) rated. Actions and recommendations were included in all the risk assessments and regular reviews conducted.

Staff knew how to escalate a risk to their line managers and there was a newly appointed risk manager who had oversight at a senior level. The service had a laboratory risk register which was regularly reviewed and discussed at a senior level with control measures and responsible person for mitigating the action.

Data risk was managed externally and had been penetration tested as they had a number of high profile clients.

Information Management

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

The laboratory manager ensured equipment was sufficient and appropriate for the service through calibration and certification of assurance through external quality assessments.

There were systems to ensure the information used to monitor, manage and report on quality and performance were accurate, valid, reliable and timely. The service used an external quality management system that supported the management of quality risk and safety. Clear and robust service performance measures were reported and monitored through the governance meetings.

The service continuously monitored their technical systems for improvement and were in the process of implementing a laboratory information management system software package, as they felt this would help improve and streamline quality standards with the expansion of the service.

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

Staff had received training on information governance and data security and were supported by policies in relation to confidentiality and information governance and data protection, which was in line with The Data Protection Act 2018.

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 used an external consumer review website to monitor patient satisfaction and gather their views and experiences. People were able to rate the service on performance and quality of service with five stars being the highest rating given. From August 2021 to December 2021 the service score was 4.4 and over 80% of people had rated the service with five stars. People could also provide direct feedback through their website.

Medical laboratories

The service worked closely with independent GP's and pharmacists and held regular meetings to discuss activity and service improvement.

The service engaged well with staff, through a variety of means, such as, staff meetings and e-mails and information displayed throughout the service. This included, providing the results of evaluation and improvement processes.

Learning, continuous improvement and innovation

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

The laboratory owned the end to end process for the majority of their tests. For example, they sold the wellness tests directly from pharmacists or by postal system which meant patients did not have to have a GP referral. This in turn meant the service were able to quality control the tests from the start and have better oversight of all tests.

The service planned to expand and work with pharmacists to offer their wellness tests in more pharmacies across the UK. This was in recognition of people being more aware and responsible of their wellbeing.