Biolab Limited

Biolab

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. We found:

- Staff had not undertaken mandatory training including safeguarding training.
- Infection prevention and control audits, such as hand hygiene and the environment, had not been undertaken. Staff did not dispose of clinical and hazardous waste safely.
- Equipment had not been serviced and maintained in line with the manufacturer's instructions. The laboratory did not have suitable facilities and it was not well maintained.
- Policies did not refer to the most up-to-date professional guidance and the versions used. Policies were not regularly reviewed in line with current guidance.
- The service did not have an effective leadership structure, including managers with the right skills and abilities to provide high-quality sustainable care. Leaders did not understand the challenges of maintaining and improving quality.
- The service did not have an effective system to improve service quality and safeguard high standards of care. The service did not have effective systems to identify and mitigate risks. The service held no staff meetings and there was no evidence of staff involvement in running the service.

However:

- Staff treated patients with compassion and kindness and respected their privacy and dignity.
- The service planned care to meet the needs of people who use the service.
- People could access the service when they needed.

We took enforcement action to urgently suspend the registration of Biolab Limited, who are now no longer legally allowed to carry out regulated activities at their services at Biolab, until 6 May 2022 and only after we have assessed them as fit do so.

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. See the summary above for what we found.

Summary of findings

Contents

Summary of this inspection

Background to Biolab

Biolab is operated by Biolab Limited and is based in Marylebone, London. Biolab is a laboratory providing blood sample collection (phlebotomy) and other sample analysis. They test for nutritional and environmental elements such as vitamin and mineral levels, toxic metals and other biochemical levels. It is a private outpatient service and does not provide services to NHS-funded patients.

The service is registered to provide the following regulated activity:

- Diagnostic and screening procedures.

The service had a registered manager, laboratory manager, three laboratory technicians, three phlebotomists and four administrative staff.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced part of the inspection on the 2 February 2022. During the inspection, we visited the whole department, including the reception, waiting area, phlebotomy rooms and the laboratory.

During the inspection visit, the inspection team:

- Spoke with the registered manager and eight staff
- Observed three patient having phlebotomy
- Looked at a range of policies, procedures and other documents relating to the running of the service.

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

Action the service MUST take to improve:

- The service must use equipment and control measures to protect patients, themselves and others from infection. They must keep equipment and the premises visibly clean.
- The service must ensure infection prevention and control audits are undertaken.
- The service must ensure clinical and hazardous waste are disposed of safely. Regulation
- The service must ensure staff are up to date with their safeguarding training and know how to escalate safeguarding concerns.
- The service must ensure the facilities, premises and equipment are well maintained.
- The service must establish effective governance processes and compliance monitoring. Regulation

Summary of this inspection

- The service must ensure the most up-to-date professional guidance is used in policies and procedures and they are reviewed regularly.
- The service must improve oversight of all risks and performance issues.
- The service must ensure the action plan for health and safety, fire and Legionella risk assessments are completed.
- The service must ensure recruitment checks such as a full Disclosure and Barring Service (DBS) check and immunity to Hepatitis B are obtained before staff commence employment.
- The service must ensure staff are up to date with their mandatory training.
- The service must ensure all staff are trained in basic life support.
- The service must appraise staff's work performance regularly.
- The service must have regular staff meetings.
- The service must improve the visibility of the company's leaders and executive members.
- The service must improve staff engagement and staff feedback mechanisms.

Action the service SHOULD take to improve:

- The service should consider displaying information regarding needle stick injury (NSI), so staff know what to do in the event of an NSI.
- The service should consider introducing annual training updates related to venepuncture and Aseptic Non-Touch Technique (ANTT).

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	Inspected but not rated	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
Caring	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.

Mandatory training

The service did not provide mandatory training in key skills to all staff

Staff did not receive and keep up-to-date with their mandatory training. The service did not have a mandatory training policy with information on the training that needed to be completed and the frequency. We checked six staff files and found staff had not completed mandatory training. One staff member had an appraisal which stated they should complete mandatory training in coronavirus awareness, health and safety, hazardous substances, infection control, manual handling, risk assessments and fire safety. However, this training had not been completed. We spoke with five staff who said they had not completed mandatory training. The manager also told us staff had not completed mandatory training.

Managers did not monitor mandatory training and did not alert staff when they needed to update their training. The service did not have a system to monitor mandatory training. One staff member was employed at the service for five years. We checked the staff members file and found no mandatory training had been completed over the five-year period. When asked, the registered manager said mandatory training was not monitored. This meant the service could not be assured that staff had up to date knowledge.

Safeguarding

Staff did not understand how to protect patients from abuse. Staff did not have training on how to recognise and report abuse.

The service did not have an up-to-date safeguarding policy including guidance on modern day slavery and female genital mutilation. The policy which was updated in July 2019 and did not refer to the specific professional guidance and version used to inform it. This would ensure a clear audit process for any changes in safeguarding requirements.

Staff did not receive training specific for their role on how to recognise and report abuse. The six staff files we checked did not have evidence of safeguarding training in line with the national safeguarding intercollegiate guidance 2019. When asked, the manager could not provide evidence of training for any of the staff.

Staff did not know how to identify adults and children at risk of or suffering significant harm. We spoke with eight staff members including three laboratory technicians, two phlebotomists and three administrative staff. All staff we spoke with did not demonstrate an awareness of potential safeguarding issues. Staff did not know what safeguarding children and vulnerable adults concerns should be reported.

Staff did not how to make a safeguarding referral and who to inform if they had concerns. The service did not have a trained safeguarding lead. Staff did not know how to refer safeguarding concerns to external agencies. This meant vulnerable patients or patients who were being abused by others may not be identified, supported or referred to appropriate agencies by staff.

Cleanliness, infection control and hygiene

The service did not control infection risks well.

The service did not perform well for cleanliness. The service did not have an up-to-date infection control policy. The policy referenced infection control guidance from 2010 and an aide-memoire from 2006 which were both superseded by current guidelines.

Staff did not use records to identify how well the service prevented infections. The service did not have a cleaning schedule. Infection prevention and control audits, such as hand hygiene and the environment, had not been undertaken. These audits would check compliance with recognised guidance and standards and identify areas of improvement.

We observed staff did not always follow the Aseptic Non-Touch Technique (ANTT) when doing venepuncture (a procedure to withdraw a blood sample). On two occasions, staff re-palpated the puncture site after disinfecting. There were no posters displayed regarding needle stick injury (NSI), so staff would know what to do in the event of an NSI.

The cupboards and drawers in main phlebotomy room were visibly unclean. When asked, staff said the cupboards and drawers were cleaned on an ad hoc basis.

There was no zoning in the laboratory. In the main phlebotomy room, a sharps bin was located on the counter with the telephone, paper tray and pens. Zoning minimises the risk of infection by creating designated clean and dirty zones. Specimens, sharps bins, paper and pens were stored in the same area. The computer keyboard was visibly unclean and was not covered by a plastic cover to prevent contamination in line with Health and Safety Executive (HSE) Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities 2003.

The laboratory environment was not clean and was visibly cluttered. The countertops, cupboards, sinks, mini fridges and floor were visibly unclean. There was equipment, empty bottles, garbage bags and boxes stored on the floor of the laboratory, which meant the floor was not easily cleaned. The countertop was lined with a white paper sheet which meant it was not easily cleaned. Staff said the white paper sheet was changed weekly and the floor was cleaned weekly. Counter tops and other work surfaces, including those in the specimen reception area, should be cleaned with a suitable disinfectant as required and routinely at the end of each working day. There were two bottles of high-level surface disinfectants used to clean the laboratory counter tops and both had expired in February 2021.

Medical laboratories

The service did not have an adequate number of handwashing sinks. The laboratory and the second consulting room, used as an overflow phlebotomy room, did not have a handwash sink. The service did not comply with published guidance as all laboratories should have dedicated handwashing sinks. The poor access to a handwash sink decreases compliance with hand hygiene. The sink in the main phlebotomy room was a stainless-steel sink which had an overflow, and both sinks in the laboratory had an overflow. This was not in line with good infection prevention and control (IPC) practice.

Staff use of personal protective equipment (PPE). Staff used PPE such as a mask, apron and gloves during phlebotomy. The laboratory did not have a designated area for storing PPE, putting on or removing it. It is good IPC to perform hand hygiene before putting on PPE in line with guidance from the UK Health Security Agency. When asked, staff said they would wash their hands in the staff toilet, before proceeding to the laboratory to put on PPE.

The main phlebotomy room had a disposable privacy curtain. Staff did not mark the curtain with its first date of use and the planned date of change. When asked, staff did not know when the curtains needed to be changed. This was an infection risk.

The laboratory had a body fluid spill kit which expired in March 2021. This meant staff could not be assured the kit would still be useful if there was a hazardous spill and meant there was no stock checking or rotation process in place.

The general cleaning of the premises was provided by an external company. The domestic cupboard contained three mop buckets and two mops. We found there was no colour coding for the mops and there was no national colour coding poster displayed. Staff showed limited understanding of the cleanliness colour coding system and were not aware of the 2021 National Standards of Healthcare Cleanliness guidance.

Patients could order test kits for urine, saliva and stool tests. Specimen were returned to the laboratory in a small sample container, which were then placed in a larger plastic container, before it was posted to the laboratory. On arrival, staff removed the samples from the larger plastic container, which were then recycled without being cleaned or disinfected. This meant there was a risk of cross contamination.

We checked six staff files and found the service did not have evidence to show two clinical staff had been vaccinated against Hepatitis B. The manager said these records were available but when asked, these records could not be provided.

The service had COVID-19 safety measures to ensure transmission was minimised. For example, social distancing, hand sanitisers and seating separation. Information related to COVID-19 precautions were available on the service's website. However, upon arrival, the reception staff did not ask patients if they were experiencing any COVID-19 symptoms or if they had been in close contact with someone who was experiencing symptoms of COVID-19.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe. Staff did not manage clinical and hazardous waste well.

The laboratory did not have suitable facilities and it was not well maintained. The laboratory had not been maintained. For example, the floor was damaged and not cleansable. Cupboards were in a state of disrepair, damaged and did not have doors. The sinks and counter tops were not adequately sealed.

Inspected but not rated

Medical laboratories

The design of the environment and equipment did follow national guidance. The laboratory did not have adequate ventilation. There was a fume cupboard that did not have an exhaust system. Fume cupboards are used to capture and remove air-borne hazardous substances generated during use. Records showed the fume cupboard had not been serviced since November 2017.

Staff did not carry out daily safety checks of specialist equipment. The equipment in the laboratory was visibly unclean.

The service did not have enough suitable equipment to keep patients safe. The service did not have a planned preventive maintenance programme for the equipment. Records showed the equipment had not been maintained in line with the manufacturer's instructions. For example, the spectrophotometer was due to be serviced in March 2021 and it had not been serviced. Spectrophotometers are used to measure the concentration of a known substance in a solution. There were no servicing records available for other specialist equipment such as the roller mixers, centrifuges or the CLA-1 Luminometer (which is used in the allergy testing process). When asked, staff could not provide records to show this equipment had been serviced.

The service did not have an effective system to ensure that repairs to broken equipment were carried out quickly, so patients did not experience delays. Staff said some of the equipment was not in working order and could not be used. This included the spectrometer and an Afinion, both used in analysis and the small roller mixer. When asked, staff said the equipment had not been scheduled for repair and consequently, tests were being undertaken by other laboratories.

Staff did not dispose of clinical and hazardous waste safely. The service did not have a contract for the safe disposal of hazardous waste such as chemicals. When asked, staff said chemicals were poured down the sink. The manager said chemical waste was collected by an external company on an ad hoc basis and there was no contract in place. When asked, the registered manager could not provide evidence of when ad hoc collection had taken place. This was not in line with Hazardous Waste Regulations (2005) for the correct disposal of hazardous chemicals. Under the Regulations, the movement of wastes is controlled by a documentation system which must be completed whenever waste is removed from premises. These records should be retained for a minimum of three years.

The service had a contract for the removal of clinical waste; however, this waste was not disposed of correctly onsite before it was collected. The laboratory had four sharps bins on the counter tops containing biological waste, which were not labelled and were filled above the fill line. There was one sharps bin with biological samples that did not have a lid. There was one clinical waste bin in the premises, located in the laboratory, which did not have a lid. Waste was not segregated in line with current guidance for example; empty boxes were disposed in the clinical waste bin. There were no clinical waste bins in the main and overflow phlebotomy rooms. Waste bins within the phlebotomy room did not have signage indicating the type of waste to be disposed of in them and staff did not use correct colour-coded waste bags as per national IPC guidelines.

Flammable substances and acid were stored in unlocked cabinets. Chemicals were stored in cupboards that did not have doors. The service had not undertaken Control of Substances Hazardous to Health (COSHH) risk assessments since 2009, meaning there were insufficient control measures to prevent or reduce staff exposure to these hazardous substances.

Fire extinguishers in the laboratory had not been serviced since September 2017 and should have a basic service each year

Portable appliance testing had been completed in May 2021. The service's oxygen supply and portable oxygen cylinder had been checked in March 2021.

Inspected but not rated

Medical laboratories

Assessing and responding to patient risk

Staff prioritised results where patients needed urgent medical attention and made sure they informed the person who requested the test as soon as possible. However, staff did not assess the risk for each patient and removed or minimised them.

The service did not have a policy for identifying deteriorating patients and escalating them appropriately. The managers said staff could alert a doctor if one was available onsite or call the emergency services.

The service did not have a policy for training staff in basic life support (BLS), setting out the level of training staff should complete and how often training should be refreshed. Records showed that nine staff had not completed training in BLS. One staff member completed BLS training in December 2019, and this had not been refreshed, which should be annually. The service saw children, but staff had not completed training in paediatric BLS.

Due to the nature of the service, there was no resuscitation trolley. Instead, the service had first aid kits, a portable oxygen cylinder and oxygen masks. The service did not have an automatic external defibrillator (AED). Oxygen masks were not in its packaging and they were dusty. Both first aid kits had sterile wound cleaning wipes which had expired in June 2021 and October 2021. There was atropine sulphate stored with the oxygen, which had expired in January 2014. Atrophine sulphate is not an emergency medicine and when asked, staff did not know what it was used for. Staff did not check the equipment and first aid kit regularly.

Staff shared key information when handing over test samples to the external laboratory or liaising with the referring doctor.

Laboratory staffing

The service had enough laboratory staff with the right qualifications to provide the right level of service. Managers regularly reviewed and adjusted staffing levels and skill mix.

The service had enough laboratory technicians, phlebotomist and support staff. Staff levels were planned and reflected demand on the service.

Managers accurately calculated and reviewed the number and grade of staff needed for each shift in accordance with national guidance. The service did not use bank staff.

Senior clinical staffing

The service did not have enough medically qualified consultants and consultant-level scientists with the skills to provide clinical advice.

The lab director was based at another location and made sporadic visits to the service. Staff said the lab director visited the service five times in the previous year.

Records

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

Due to the nature of the service, limited but relevant patient information was kept electronically, and all staff could access this easily.

Inspected but not rated

Medical laboratories

Patients attended the service with a test request form or a referral letter, which was scanned and added to the patients record. The paper forms were then shredded.

Medicines

The service did not store and used medical reagents safely.

Staff explained some reagents (a substance used in chemical analysis) needed to be mixed and had an expiry date. There was one reagent which had been mixed and had a six-month expiry date of November 2020 and staff said it was still being used. One of the mini fridges had two bottles of reagents which had expired in July 2019 and December 2020. There were several bottles of chemicals with instructions that they must be used within five years of opening. None of these bottles had the recorded date of opening and we observed the manufacturing date was September 2006.

Incidents

The service did not manage patient safety incidents well. Staff recognised but did not report all incidents and near misses. Managers did not investigate incidents and share lessons learned with the whole team and the wider service.

Staff did not have a clear understanding of what incidents to report and how to report them. Staff gave conflicting information on how incidents should be reported. One staff member showed us an accident book while the manager showed an online form. The manager said there was one incident in the previous 12 months. Following our inspection, the service provided a log with 40 events from January 2021 to December 2021, including missing tests kits and missing request forms. Incidents were not discussed with the whole team with the aim to prevent recurrence.

Staff said a form was completed for incorrect, mislabelled, expired or damaged samples and the form was sent to the referring practitioner. The service did not record and monitor these events in the different categories. The service reported 237 incorrect, mislabelled, expired or damaged sample forms from January 2021 to December 2021.

Staff understood the duty of candour. They were open and transparent, and gave patients and families a full explanation if and when things went wrong. There was one incident where an incorrect test was completed. Records show a full explanation was given to the patient and the patient was offered the correct test free of charge.

Are Medical laboratories effective?

Inspected but not rated

We did not rate this service.

Evidence-based care and treatment

The service followed national guidance when presenting and interpreting results. The service did not provide care based on national guidance and evidence-based practice. Managers did not check to make sure staff followed guidance.

Inspected but not rated

Medical laboratories

Staff did not follow up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Policies did not refer to the most up-to-date professional guidance and the versions used. Policies were not regularly reviewed in line with current guidance. For example, the infection control policy referred out of date guidance and the safeguarding policy did not refer to published guidance. Policies and procedures should include the name of the current guidance and the version used in its development to ensure a clear audit process for any changes.

The service had a standard operating procedure (SOP) for phlebotomy and for different tests performed in the laboratory. Staff followed guidance when presenting and interpreting results.

Nutrition and hydration

Staff made sure patients had access to drinks.

Water dispensers were available throughout the department.

Competent staff

The service did not make sure staff were competent for their roles. Managers did not appraise staff's work performance regularly and hold supervision meetings with them to provide support and development.

Managers did not identify training needs and give staff the time and opportunity to develop their skills and knowledge. Staff did not have regular appraisals. We found one member of staff had been employed with the service for eight years and completed one appraisal during this period. Similarly, two other staff members who had been employed for five years had completed one appraisal during this period. When asked, staff said appraisals were completed for the first time in 2021.

Staff were experienced and qualified, but not all had the right skills to meet the needs of patients. The service kept records of the staff qualification and experience. However, the manager did not ensure staff maintained competency standards. The service had no recognised annual training update identified for venepuncture. Aseptic Non-Touch Technique (ANTT) training was not an annual mandated training module for clinical staff. Only one of the phlebotomists had completed training on paediatric phlebotomy.

Managers gave new staff a full induction tailored to their role before they started work. The service completed induction checklists for all new staff. Staff who had recently completed the induction spoke positively about the experience. Managers said staff had a probationary review of performance after three months.

Managers did not make sure staff attended team meetings. The service did not have staff meetings. The laboratory technicians and phlebotomists said there were no staff meetings where improvements to the service, incidents or concerns could be discussed. The administrative staff said the manager had informal discussions about the appointment diary.

Multidisciplinary working

Staff worked with other providers' teams to benefit patients. Clinical and non-clinical staff within the service worked together as a team to benefit patients.

Inspected but not rated

Medical laboratories

Staff described the positive working relationship between the laboratory technicians and phlebotomists as well as the administrative staff. Staff said they had a good working relationship with the referrers.

Seven-day services

Services were available to support timely care.

The service is opened Monday to Friday from 9am – 5:30pm.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care. They followed national guidance to gain patients' consent.

Staff gained verbal consent from patients for their care in line with legislation and guidance. Staff made sure patients consented to venepuncture and this was based on all the information available. We observed patients giving verbal consent before staff obtained blood samples from them.

The service did not have a consent policy. There was no reference guide for staff on the Mental Capacity Act 2005 (MCA) and Gillick competence. Staff had not received training on the MCA and staff we spoke with were not aware of their responsibilities.

Are Medical laboratories caring?

Inspected but not rated

We did not rate this service.

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. Patients said staff treated them well, with kindness and were very helpful and reassuring. Staff answered patient enquiries and interacted with them in a friendly and sensitive manner.

We observed staff interacting with a patient with learning difficulties and their parents and saw staff were friendly, kind and compassionate.

Staff followed policy to keep patient care and treatment confidential. All tests were carried out in individual rooms ensuring privacy for all patients. The service had a privacy and dignity policy to ensure patient's privacy and dignity was maintained.

Emotional support

Inspected but not rated

Medical laboratories

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

Staff gave patients and those close to them help, emotional support and advice when they needed it. Staff were able to describe how they would provide reassurance and support for nervous and anxious patients. We observed three patients during venepuncture and patients said they received a good service.

Understanding and involvement of patients and those close to them

Staff supported and involved patients, families and carers to understand their condition and laboratory results.

Staff made sure patients understood their tests. Staff talked with patients, families and carers in a way they could understand.

Patients gave positive feedback about the service. Staff said there was a low uptake for the patient satisfaction survey in 2021. However, the service received email feedback from patients. Records showed patients had a positive experience. The emails we reviewed showed patients were involved and understood what they were attending the service for and when the referring practitioner would be expected to receive their results.

Are Medical laboratories responsive?

Inspected but not rated

We did not rate this service.

Service delivery to meet the needs of local people

The service planned and provided tests in a way that met the needs of service users. However, the premises and equipment had not been maintained.

Managers planned and organised services so they met the needs of the service users. Managers described the way they planned and managed services across the department. Phlebotomists worked with the laboratory technicians and referring practitioners to meet the needs of people using the service. Capacity and demand were managed by the department's leadership team.

Facilities and premises were not appropriate for the services being delivered. The premises and equipment had not been maintained.

Meeting people's individual needs

Staff made reasonable adjustments to help patients access services. However, the service did not have access to interpreters or signers if needed.

The service had a ramp enabling disabled access.

Inspected but not rated

Medical laboratories

Managers did not ensure staff, and patients, loved ones and carers could get help from interpreters or signers if needed. The service did not have a procedure for accessing interpreters or signers if needed.

The service had various sample collection information on its website including glucose tolerance and red cell magnesium tests.

Access and flow

People could access the service when they needed it and received appointments promptly.

Patients were offered a range of appointments and patients could also return samples by post. The services' website had a list of samples that could be returned by post and instructions on how this should be carried out. There were patient instructions prior to the tests and test request forms on the website.

Managers monitored appointment times and made sure patients could access services when needed. Patient feedback we reviewed showed patients received an appointment at a time that suited them. Patients had a 15-minute appointment for phlebotomy. Appointments were made in advance with time between them for cleaning in line with COVID-19 guidance.

Managers and staff worked to make sure patients did not stay longer than they needed to. Patients were attended to promptly when they arrived for their appointments.

Managers monitored and took action to minimise missed appointments. Staff said it was very rare for patients to miss an appointment and patients would usually call to reschedule if they could not attend. The service had three phlebotomists, so staff absences were covered, and the service did not cancel patients' appointments.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received.

Patients, relatives and carers knew how to complain or raise concerns. Information on how to make a complaint was available on the patient's noticeboard.

Staff understood the policy on complaints and knew how to handle them. The service had a complaints policy and staff knew how to handle complaints. The complaints policy listed the Care Quality Commission (CQC) as an adjudicator for patients' complaints rather than an independent second line complaints service. The CQC does not mediate complaints.

Are Medical laboratories well-led?

Inspected but not rated

We did not rate this service.

Leadership

Inspected but not rated

Medical laboratories

Leaders did not have the skills and abilities to run the service. They did not understand and manage the priorities and issues the service faced. They did not support staff to develop their skills.

The service did not have an effective leadership structure including managers with the right skills and abilities to provide high-quality sustainable care. The service had three directors including the registered manager, a lab director, and a director who was not involved in the running of the service. The registered manager was responsible for the day to day running of the service. The lab director was based at another location and made sporadic visits to the service. Staff said the lab director visited the service five times in the previous year.

The managers did not have oversight on quality and effectiveness or how the service was managed. Staff did not understand the priorities and issues the service faced. Following our inspection, the manager told us further operational support would be provided to the service to improve its function.

Vision and Strategy

The service had a vision for what it wanted to achieve. However, it did not have a strategy to turn it into action.

Managers said the services vision and strategy were being reviewed and there were plans to improve the service. However, the service did not have a documented strategy with completion dates or plans on how to monitor any improvements made. Staff did not know the service's vision and strategy.

Managers said the vision was to continually strive for excellence and to always provide the best possible care and attention to patient's needs and always take the necessary steps to ensure the highest possible accuracy of every test result.

Culture

Staff focused on the needs of patients receiving tests. However, the service did not have an open culture where staff could raise concerns without fear.

Staff at all levels were not actively encouraged to speak up and raise concerns about the service. Staff said concerns were raised with the manager. However, there was no follow up actions. Staff did not feel empowered to make any improvements within the service.

There was insufficient collaboration, team-working and support between the managers and staff.

The service did not have a system which fostered career development.

Governance

Leaders did not operate an effective governance process. Staff were not clear about their roles and accountabilities and they did not meet to discuss and learn from the performance of the service.

Inspected but not rated

Medical laboratories

The service did not have an effective system to improve service quality and safeguard high standards of care. Although the service recognised the lab needed to be refurbished and had plans drawn up in 2017, it had yet to be refurbished to date.

The service did not have an effective governance structure or framework. There were no clinical governance systems such as governance or risk meetings. Following our inspection, the service provided records of one meeting to discuss the COVID-19 pandemic in June 2021. An item on the agenda was the discussion of control substances that are hazardous to health (COSHH). However, at inspection, the service did not have up-to-date COSHH risk assessments, and hazardous substances were not disposed of appropriately.

Policies and procedures were not reviewed in line with current guidance. For example, the safeguarding policy did not refer to the national safeguarding intercollegiate guidance 2019 and the infection control policy referred to out of date guidance.

The service did not have staff meetings where improvements to the service, incidents or concerns could be discussed.

An audit programme had not been implemented to monitor the quality of services being provided. The service had not completed audits such as for the environment, infection control and hand hygiene.

Managers did not provide appropriate support, training, professional development, supervision and appraisal. Where appraisals had been completed, the actions were not followed up, for example, mandatory training.

The service did not have a recruitment policy that set out the standards it followed when recruiting staff. The manager said, as part of the staff recruitment process, they carried out appropriate background checks. This included a full Disclosure and Barring Service (DBS), proof of identification, references check as well as immunity to Hepatitis B, where appropriate.

We reviewed the staff files and found that these checks were not always completed. For example, the service did not carry out DBS checks and have complete immunisation records showing immunity to Hepatitis B for two clinical staff. Following our inspection, the manager said staff had been sent for Hepatitis B checks and applications for DBS had been completed.

Managers said staff received information and relevant updates through a monthly newsletter. We saw examples of newsletter with updates on tests provided by the service.

Management of risk, issues and performance

Leaders and teams did not use systems to manage performance effectively. They did not identify and escalate relevant risks and issues or identify actions to reduce their impact.

Performance data was not collected and analysed to ensure the delivery of a quality service that benefited patients and provided a positive patient experience.

Medical laboratories

The service did not have effective systems to identify risks and plan to eliminate or reduce them. The service did not have a risk management strategy, setting out a system for continuous risk management. The service did not have a risk register. The risk of poor infection control practices, a lack of mandatory training, appraisals, equipment that had not been serviced and the state of disrepair of the laboratory had not been mitigated. This indicated that managers had limited oversight of all the issues faced by the service.

Where risks had been identified, the service had not taken adequate steps to mitigate the risks. The service had undertaken an external health and safety risk assessment in April 2021 and a Legionella risk assessment in August 2020. Both risk assessments had action plans which had not been completed. The service completed its own fire risk assessment, which was undated, and did not identify the fire extinguishers in the laboratory had not been checked since September 2017. Additionally, the health and safety risk assessment stated the service did not have an adequate provision of extinguishers and fire blankets were not available. There were no clear lines of accountability and responsibility for actions to be taken.

The service did not complete risk assessments appropriately. Risk assessments for the laboratory and the phlebotomy overflow room stated handwashing facilities with soap and water were in place. The laboratory and the phlebotomy overflow room did not have handwashing sinks.

The service did not have a business continuity plan that could operate in the event of an unexpected disruption to the service.

Information Management

The service did not collect reliable data and analyse it. Staff could not find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements.

The service did not have a consistent system for recording incidents. There was no reliable data on mandatory training, appraisals, supervision, equipment maintenance and the disposal of hazardous waste. Records were not stored in a format that was easily accessible and managers were unsure of the information the service had in its possession.

We observed the staff noticeboard was on the floor behind a door in the laboratory. Staff said the wall had recently been decorated and the noticeboard had not been replaced.

Engagement

There was limited engagement from leaders with staff and patients.

The service did not actively engage with staff to plan and manage the services appropriately. Staff were not involved in the running of the service, being able to give feedback and suggestions. Staff meetings were not held.

There was a low return rate for the patient satisfaction survey completed in 2021. The service received positive feedback from patients through emails.

Learning, continuous improvement and innovation

Staff were not committed to continually learning and improving services. They did not have a good understanding of quality improvement methods and the skills to use them.

Inspected but not rated

Medical laboratories

The service did not have a strategy for learning, continuous improvement and innovation.

Staff did not have a good understanding of quality improvement. The service did not have an effective strategy for quality improvement.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed 1. The provider did not ensure recruitment checks such as a full Disclosure and Barring Service (DBS) check, references and immunity to Hepatitis B were obtained before staff commence employment.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment 1. The provider did not ensure staff were up-to-date with their safeguarding training and knew how to escalate safeguarding concerns. 2. The provider did not ensure that the service had an up-to-date safeguarding policy which reflected national guidance.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment 1. The provider did not ensure the facilities, premises and equipment were well maintained. 2. The provider did not ensure clinical and hazardous waste were disposed of safely.

Regulated activity	Regulation

This section is primarily information for the provider

Enforcement actions

Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance 1. The provider did not establish effective governance processes and compliance monitoring. 2. The provider did not ensure the most up-to-date professional guidance was used in policies and procedures and that they were reviewed regularly. 3. The provider did not have oversight of all risks and performance issues. 4. The provider did not ensure the action plan for health and safety, fire and Legionella risk assessments were completed. 5. The provider did not ensure staff were up to date with their mandatory training. 6. The provider did not ensure all staff were trained in basic life support. 7. The provider did not appraise staff's work performance regularly. 8. The provider did not have regular staff meetings. 9. The provider did not ensure the visibility of the company's leaders and executive members. 10. The provider did not have effective staff engagement and staff feedback mechanisms.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment 1. The provider did not have equipment and control measures to protect patients, themselves and others from infection. 2. The provider did ensure equipment and the premises were clean. 3. The provider did not ensure infection prevention and control audits were undertaken.