Poundbury Cancer Centre Ltd

Poundbury Cancer Centre Ltd

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

The Poundbury Cancer Centre opened in 2015 to provide quality analytical, interpretive, advisory and consultancy clinical cellular pathology.

The company provided a diagnostic service for histopathology specimens that included both surgically excised specimens and diagnostic biopsies. It provided standalone laboratory support for cellular pathology. This included a routine paraffin service, a comprehensive array of immunocytochemical and molecular tests with same day processing for

diagnostic tests and facilities for both onsite, and off-site reporting using digital pathology platforms.

The Centre focused particularly on the provision of tests for personalised oncology treatment, including companion diagnostics, to match a patient to a specific drug or therapy.

At the time of inspection, the service had achieved accreditation with the United Kingdom Accreditation Service and IS015189 for histopathological examination of human tissue for the purposes of clinical diagnosis.

The service employed one laboratory director, five in house pathologists and five pathologists who are contracted for remote working. One business development manager, reported as being externally contracted, one operations manager, two senior bio-medical scientist (BMS), six associated pathologists training for Institute of Biomedical Science (IBMS) registration portfolio, ten medical laboratory assistants and one administrator.

The service consists of two laboratory rooms and one administration room on a single floor. It did not offer a seven-day week service.

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

Following our inspection on 5 August 2022 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.

We found that:

- The risk register of the service did not reflect the current risk to the service.
- Not all employment checks were carried out prior to the staff commencing employment.
- Damage had been caused to the fabric of the building and no remedial work had been completed.
- No infection control audit had been undertaken and no infection control policy is in place.
- No fire risk assessment had been completed following the damage to the building.
- No risk assessment had been carried out for those staff employed as a remote worker.
- Information was not readily available or accessible for staff in the absence of the quality manager.

However

- The service had enough staff to provide the right level of service.
- Staff had training in key skills and showed evidence of continuing professional development.

Summary of findings

- The service was planned to meet the needs of local people, took account of people's individual needs, and made it easy for people to give feedback.
- Managers monitored the effectiveness of the service, including the safe management of patient tissue samples staff completed risk assessments for each test performed to ensure these were in line with best practice standards. The service ensured quality was monitored through participating in external and internal quality assurance programs. Services provided were based on national guidance and evidence-based practice. Managers were visible and supportive of staff.

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. **Systems, processes and standard operating procedures are not always reliable or appropriate to keep people safe.** We found that the service did not have adequate systems and processes in places to identify, monitor escalate and mitigate risk in the areas of fire prevention, recruitment, environmental safety for remote workers, and infection control. Governance processes did not reflect the risks of the service and in the absence of the quality manager information was difficult to obtain.

Summary of findings

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Summary of this inspection

Background to Poundbury Cancer Centre Ltd

This was the first inspection of the service and was a routine, announced, inspection.

How we carried out this inspection

The inspection team consisted of one inspector, an inspection manager and one specialist advisor with experience in medical pathology. The inspection was overseen by Catherine Campbell, Head of Hospital Inspection.

During the inspection, we inspected the pathology laboratory using our comprehensive inspection methodology. We reviewed documents and records kept by the service, including four staff files. We spoke with six staff, four members of the management team and two members of staff to gain their views.

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 to improve:

- The service must ensure systems or processes are established and operated effectively to assess, monitor and mitigate risks. The risk register did not accurately detail the risks of the organisation and the actions to mitigate risks (Regulation,17(1)).
- The service must ensure information about candidates set out in schedule three of the regulations is confirmed and recorded before commencing employment. The service must ensure that it has ongoing systems and processes, including regular audits, to identify, monitor, escalate and mitigate risk from individuals who have not received the mandatory checks. (Regulation 19(2)) (Regulation 17(2)(a)).
- The service must ensure that repairs are carried out to the ceiling of the administration and laboratory area. (Regulation 15(1)(e)).
- The service must undertake an infection control audit with guidance from Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infections and related guidance. The service must ensure that it has ongoing systems and processes, including regular audits, to identify, monitor, escalate and mitigate infection control risk. (Regulation 15(2)) (Regulation 17(2)(a))
- The service must undertake a regulatory reform (fire safety) order 2005 Fire Risk assessment, to include an assessment of the damage to the ceiling and the breech in the compartmentalisation of the building. The service must ensure that it has ongoing systems and processes, including regular audits, to identify, monitor, escalate and mitigate risk, of smoke and fire breaching the wall between the two rooms. (Regulation 15(2)) (Regulation 17(2)(a)).
- The service must undertake a risk assessment of those staff who work remotely using national guidance, (Regulation17(2)(b).
- The service must have processes and systems in place to ensure that in the absence of the quality manager information is accessible to authorised people as necessary. (Regulation 17(2)(c)).

Action the service should take to improve:

Summary of this inspection

- The provider should ensure that the full date is recorded for Portable Appliance Testing and that it follows national guidance in relation to portable electrical appliances.
- The provider should ensure that the complaints policy includes detail of arrangements for the complainant to take their complaint to an independent review once the internal process had been exhausted.
- The provider should ensure that it has a whistleblowing policy and arrangements for staff advocacy through the appointment of a speak up guardian or similar framework
- The provider should ensure that the storage cupboard containing control of substances hazardous to health is closed when not being accessed and that it has appropriate signage. The provider should ensure there is a designated person responsible for managing training in the service

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.

Mandatory training

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

Staff received and kept up to date with their mandatory training. Mandatory training topics included Equality and Diversity, Fire Safety, Health and Safety, Infection Control Level 1, this list was not exhaustive. We were informed that manual handling was covered as part of the Health and Safety module.

Managers monitored mandatory training and alerted staff when they needed to update their training. Records showed 81% of staff had completed the Equality and Diversity module, 92% of staff had completed the fire safety training record, 92% of staff had completed the Health and Safety training and 81% of staff had completed the Infection Control level 1 training. We were informed there was no designated training manager and the bio medical scientist (BMS), pathologists oversaw the training of the trainee biomedical scientists.

Cleanliness, infection control and hygiene

The service did not control infection risk well. There were no systems or processes to ensure that infection control risks were identified and addressed. The service did not follow national guidance.

The company did not have an infection control policy and had not undertaken an infection control audit. We were informed the laboratory did not have a policy as they believed this was not required as they did not handle infectious material.

Cleaning records were seen for May, June, July and August 2022. Cleaning audits were undertaken as part of the health and safety audit. The health and safety audit of April 2022 reports that all areas were clean. The environment audit of July 2022 makes reference to conforming to ISO 15189 standards in cleanliness of environment and machinery and daily / weekly maintenance sheets record the checking of the environment and carrying out cleaning tasks.

On inspection the Laboratory's had a good visible level of cleanliness, inspectors were provided with laboratory coats to wear. Waste bins were uncovered.

Inspected but not rated

Medical laboratories

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, evidence of confirmation of appropriate waste removal and disposal was seen

The service had a waste handling and storage policy, reviewed in November 2021which refers to the company contracted to remove the waste. Waste management is included in the service's health and safety audit.

A health and safety audit had been carried out on 19 April 2022, which included fire exits, fire extinguishers, correct wearing of personal protective equipment (PPE), housekeeping throughout the location, health and safety risks, the control of substances hazardous to health (COSHH), and laboratory ventilation.

There were equipment registers. We were shown evidence of portable appliance testing dated 2022, the date of testing was not recorded. The laboratory used multi socket extension leads but there was no evidence of power breakers on the lead.

On inspection the steel Control of Substances Hazardous to Health (COSHH) cupboard in the laboratory was found to be open and there was no noticeable COSHH signage.

On inspection it was found that ceiling tiles from the suspended ceiling above the administration office and a laboratory had been removed above the adjoining wall of approximately two feet by four feet, creating a gap of approximately 18 inches between the adjoining wall and the ceiling above, allowing air to flow freely between the two rooms. We were informed by staff that this had been due to a flood from the flat above in November 2021 and that the service was awaiting a response from the building owners and the insurance company, and evidence was seen of ongoing discussions with insurers. No remedial work had been undertaken.

Fire records showed that a regulatory reform (fire safety) order 2005 Fire Risk Assessment had been completed on 6 February 2018. The assessment stated that it should be reviewed annually or at such earlier time as there was reason to suspect that it was no longer valid or there had been a significant change in matters to which it related. No further regulatory reform (fire safety) order 2005 Fire Risk Assessment had been completed to address the breach in the building's compartmentalisation and no evidence that this assessment had been reviewed annually.

The laboratory adjacent to the administration office used formalin, which contained formaldehyde, in its slide preparation. To manage the risk of exposure an extraction system was used to reduce the contaminants levels in the air. Staff monitored the concentration of formaldehyde in the air daily using and we saw records of tests being completed for April, May, June and July 2022.

Further testing was carried out through the year by using airflow badges. Selected staff members wore an airflow badge which measured levels of formaldehyde for periods, ranging from 40 minutes to ten hours. According to records seen, three staff wore testing badges in November 2018, five staff in May and November 2019, five staff in May June and December 2020, two staff in July 2021 and two staff in July 2022.

An internal risk assessment had been completed on 25 September 2018. This referred to the risk of personal injury through inhalation, which was scored five, low likelihood and high consequence. This had not been updated to include the barrier breach between the laboratory and the administration ceilings.

The company used remote workers and an 'assessment of display requirements and adjustments for remote reporting using digital pathology' was seen however there was no evidence that these workers premises had been assessed using the guidance, 'managing home workers health and safety', published by the Health and Safety Executive. This was also identified in the external accreditation report which referred to the lack of risk assessment. In response the service provided an action plan which referred to sending out questionnaires on remote reporting. Questionnaire returns seen by us referred to quality of display only and did not refer to the Health and Safety Executive recommendations of risk assessment.

The external accreditation report referred to the space constraints 'for the archiving of their blocks and slides and laboratory space for any future expansion of service'. We were shown the developmental plans for the service which would be moved to a new, larger location with bespoke areas for the laboratories, consultation rooms for future planned services, and administration areas.

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.

We were told that all reports were scrutinised by a consultant pathologist and any abnormal test results were immediately communicated by phone with the physician that had sent the sample.

The services quality manual did detail the quality assurance process for each sample. Senior registered consultants oversaw the whole testing process and would authorise test results. If an abnormal result was flagged, it would be retested, and this was in line with Key Assurance Indicators (KAI, 2019) for Royal College of Pathology service guidelines.

Reports were routinely sent electronically through a secure portal.

There was a reporting process which outlined the process for addressing unexpected findings. Audits were undertaken to establish if there were any trends, and these were reported back at the monthly business meetings. Minutes from these meetings showed that audit did identify shortfalls and actions had been taken to address these. The service held regular meetings with the service users to discuss performance.

Laboratory staffing

The service had enough laboratory staff with the right qualifications, skills, training and experience to provide the right level of service. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave agency staff a full induction.

The service had enough staff with the right skills to run the laboratory safely. Staffing levels met The Royal Society of Pathologist, (RCPath), Key Assurance Indicators, (KAI 2019 guidance) on provision of senior staff. We were informed that the service was fully staffed and did not use bank staff. There were contingency plans should there be a staff shortfall when they would employ a locum.

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

The service had a development plan which would see the expansion of the service and a change of location. The service was in the process of recruiting staff.

Inspected but not rated

Medical laboratories

Senior clinical staffing

The service had enough medically qualified consultants and consultant-level scientists with the right qualifications, skills, training and experience to provide clinical advice. Managers regularly reviewed and adjusted senior staffing levels and skill mix.

The service holds records of staff who provide diagnostic and interpretative services, together with their qualifications and details of training and supervision. However, please see comments below regarding recruitment processes.

The service had enough medically qualified consultants and consultant-level scientists to provide a safe service. The medical staff matched the planned number. The service had a good skill mix of staff on each shift and reviewed this regularly. Managers accurately calculated and reviewed the number of medical and staff did not work excessive hours.

Records

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

We review the documentation on samples that arrived that day. They 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 (5TH edition). Electronic records were password protected and only accessed by authorised staff.

Results were reported electronically and were usually available immediately upon validation and authorisation.

We observed the receipt of several samples. A minimum of three identifiers were used.; the patients name, date of birth, hospital or NHS number, the referral form was then checked against the identification number on the sample and the paperwork was then scanned into the system and flagged urgent when the referral indicated it needed to be. Pathologist was then asked what tests would be required; the samples were logged into the system with the originating specimen number being the patient's hospital number. A laboratory reference number was then assigned, sequentially, starting with the year. The scanned paperwork was then linked to the specimen on the system and labels were printed which were placed on paperwork, slides, specimen blocks as appropriate.

On receipt of the sample an electronic tracking system informed the client that the sample had been received by the laboratory.

The service had an information management policy which included details on storage, retention and disposal of records. The Data Protection Policy V3 provided the name, duties and responsibilities of the Data Controller.

Incidents

Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave honest information and suitable support. Managers ensured that actions from safety alerts were implemented and monitored.

Inspected but not rated

Medical laboratories

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.

We saw evidence of incident investigation and a root cause analysis having been carried out. The service had carried out a specific audit on the request of an external provider.

Reports from investigations showed managers investigated incidents thoroughly. There was evidence that changes had been made as a result of identified learning. Staff received feedback from investigation of incidents, both internal and external to the service.

Since October 2021 there have been five incidences reported, none of which required a Duty of Candour notification. There were no identifiable themes. The service also keeps a Corrective and preventive action log (CAPA) which logs clinical laboratory incidents and actions to monitor defects, deficiencies and non-conformities, internally and externally to the service. Both are discussed at the monthly business meetings. Other the same period there were 123 of these recorded.

Incidents are risk rated, utilizing a risk matrix that was set out in the services Risk Management Policy and the policy states that it had been adopted from the National Patient Safety (NPSA) 2008 guidance. This scoring was used in determining level of risk for the purposes of the risk register.

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. Managers made sure staff followed quality control procedures.

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 referred to expert professional bodies. And were accessible by staff.

The service had received United Kingdom Accreditation Service (external accreditation body) ISO 15189 and was last inspected in May and June 2022. A current schedule of accreditation was seen.

There were internal and external quality control systems for ensuring intended quality was achieved. The service provided an audit schedule, the results of these audits were presented at the monthly business meetings. A review of the July 2022 Business Meeting reported on the percentage of defects which was recorded as 15.85% in June, within the accepted range of 8.1 to 18.2%, The minutes did not contain a narrative explaining the results and the actions taken to address. The service used an external quality assessment for quality assurance on tests for each analysis taken. The certificate was dated April 2022 to March 2023.

Medical laboratories

There was a program of regular audits and a program of calibration of measuring systems and verification, so that results were traceable.

The service participates in External Quality Assurance Schemes (EMQN) which are accredited to ISO 17043. The service provides data on molecular testing in lung cancer, melanoma, and colorectal cancer. Results were shared with the team and discussed at the business meetings. All staff attend these business meetings and staff spoken to confirmed that they received copies of minutes of the meetings.

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. The service invested in new equipment and technology if they knew this would improve the quality and effectiveness of the service.

The minutes from the business management meeting in June 2022 referred to a document acknowledgement audit that reported 68.4% acknowledged documents with a service target being 85%. Staff were made aware by attendance at the business meeting and the minutes of the need to engage.

Patient outcomes

Staff monitored the effectiveness of their service. They used the findings to make improvements and achieved good outcomes. The service used quality assurance schemes to monitor and check their results. The service had ISO15189 accreditation.

Managers monitored the effectiveness of the service, including the safe management of patient tissue samples, staff completed risk assessments for each test performed, to ensure work undertaken was in line with best practice guidance. The provider ensured quality was monitored through participating in external and internal quality assurance programs. Services provided were based on national guidance and evidence-based practice.

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.

There were standard protocols for any external quality assessment that did not show a satisfactory result. Returned results were viewed by the biomedical scientist and then escalated to the senior management team for sign off. The returned results were also reviewed at consultant level. We reviewed a sample of external quality assessment results and saw the summary report with steps taken for those results that required further action.

Audits included a range of clinical, administrative and environmental audits based on national guidance and utilising the laboratory information management system. These were reported to the monthly business meetings.

The service assured itself by the means of an external accreditation body inspection conducted four yearly intervals. The report of July 2022 had summarised that the service had a ‘good clinical audit processes and quality evidence and provided effective reports, especially molecular reports. The service has produced an action plan to address the shortfalls identified in the external accreditation report.

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. Not all staff had received an annual appraisal.

Inspected but not rated

Medical laboratories

Staff spoken with confirmed that they had received regular supervision and a review of the appraisal record showed that from 22 staff three staff were recorded as being overdue for an appraisal.

The laboratory director was a specialist medical consultant and fellow of The Royal College of Pathologists.

We checked a total of four staff personnel records. We saw references had only been obtained for two of the four records seen. A review of the service's Disclosure and Barring (DBS) checks found that six staff had started work with the service without their checks being completed. One reason given for the omission was they were employed as a 'maintenance person and a DBS was not required and two had been requested but not obtained due to non-specified visa issues.

Business meeting minutes for June noted five staff whose competencies had not been completed. From the staff competencies spreadsheet, we saw of 22 staff included on the database five staff had not had their competences, four of which were marked as being in progress. reviewed.

Managers identified any training needs their staff had and, when possible, gave them the time and opportunity to develop their skills and knowledge.

Multidisciplinary working

Staff worked with other providers' teams to benefit prompt reporting. They supported each other to provide a good service.

We were told that staff would attend multi-disciplinary team meetings with external stakeholders as required. We were shown minutes of meeting with an external provider when key performance indicators were discussed.

The service was delivered and reviewed in a coordinated way when different teams, services or organisations were involved.

Seven-day services

The service does not operate a seven-day service. We were informed that the service is open Monday to Friday.

Are Medical laboratories responsive?

Inspected but not rated

We did not rate this service.

Service planning and delivery to meet the needs of the local people

Managers planned and provided services in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

The annual quality report referred to the workload of the service, and the activity of the service. It provided information on the number and types of requests which had seen an increase in past years. This has been used in the planning of the new development and staff were being recruited and a new premise identified.

Inspected but not rated

Medical laboratories

Managers planned and organised services, so they met the needs of the local population. Facilities and premises were noted in the external accreditation report as having space constraints. This was discussed with the service, and we were informed that the new development planned for the service would address this and the planned growth in the service.

We were shown plans for the development of the service which included relocation to a new premise and an increase in the registered services offered.

Access and flow

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

In cases where the service required the assistance of an outside facility or facilities to undertake services that it does not offer, the service had a referral laboratories policy which detailed the procedures to be adopted.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included the person who made the complaint in the investigation.

The service had a complaints policy which stated that all complaints should be acknowledged within two working days from the date of receipt by the laboratory director or quality manager. All complaints were given a time frame of 14 days to be finalised from date of receiving the complaint. If longer, then an interim report was expected to be completed. Complaints were to be reviewed in an internal audit as per the service complaints policy

The policy did not detail arrangements for the complainant to take their complaint to an independent review once the internal process had been exhausted.

A review of complaints over the past year found three complaints. We saw evidence of investigation taking place and disseminated. Managers investigated complaints and identified themes.

Managers shared feedback from complaints with staff and learning was used to improve the service. Staff could give examples of how they used stakeholders feedback to improve daily practice. This was discussed and minutes recorded at the monthly business meetings and emailed to the staff.

Are Medical laboratories well-led?

Inspected but not rated

We did not rate this service.

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.

Staff we spoke with were positive about the managers and how they were approachable and open to discussing new ideas and taking on board 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 relationship during the inspection.

Leaders understood the challenges to quality and sustainability and could identify the actions needed to address them.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them and monitor progress.

The service in its Annual Management Review October 2020 to September 2021 and in its quality, policy provided a mission statement. Staff spoken with told us that they were involved in discussion about the services values and culture and understood its aims and objectives.

Culture

Staff felt respected, supported and valued. The service promoted equality and diversity in daily work and provided opportunities for career development.

Staff development was recognised and encouraged. Training opportunities were available for all staff. Staff said they felt supported, and the management team was open and approachable. Staff gave examples of competency based training and post-graduation training opportunities.

Governance

Leaders were not always aware of the risks, issues and challenges in the service. Leaders were not always clear about their roles and their accountability for quality.

On the day of our inspection staff, in the absence of the quality manager, had difficulty in locating requested documents. We were informed that this this was being addressed with several staff being allocated roles for when the quality manager would be absent.

The company held monthly business meetings which included health and safety and integrated governance subjects. We saw minutes from the April, May, June, July 2022 meetings which evidenced discussion of incidents, device alerts, information governance, performance data discussion, discussion of policy documents and distribution, implementation of audits and accreditation compliance.

Management of risk, issues and performance.

Risks issues and safety concerns are not always dealt with appropriately or quickly enough. The risk management approach is applied inconsistently or is not linked effectively into planning processes.

The service's Business Impact and Continuity Plan was updated in April 2021. The company had a business risk register; we were shown a copy dated August 2022. There was no evidence in the minutes of the monthly business meeting that this risk register had been discussed and reviewed by the senior staff.

Medical laboratories

There was no evidence that the service had requested external advice on the breach in the laboratory ceiling and had made no remedial repairs to address the damage. The August risk register did not detail the person responsible, there was insufficient evidence of review and comprehensive identification and description of risks, with no evidence of external advice sought in relation to fire risks.

The risk register made reference to there being insufficient numbers of staff trained in workplace first aid. Training records did not include data on first aid training.

An effective audit process was not in place to demonstrate that the services provided were effective and safe for staff and visitors.

We found that leaders did not always complete regular audits of the laboratory environment and public areas. We saw Fire records that showed that a regulatory reform (fire safety) order 2005 Fire Risk Assessment had been completed on 6 February 2018. The assessment states that it should be reviewed annually or at such earlier time as there is reason to suspect that it is no longer valid or there has been a significant change in matters to which it relates. No further regulatory reform (fire safety) order 2005 Fire Risk Assessment has been completed to address the breach in the building's compartmentalization.

There was no evidence of an infection control audit having been carried out and we were informed by the quality manager that the service did not carry out infection control audits or have an infection control policy, as the service did not handle infectious materials.

The company employed remote workers and we were shown an 'assessment of display requirements and adjustments for remote reporting using digital pathology' assessment. The returns seen by us referred to quality of display only and did not refer to the Health and Safety Executive recommendations of risk assessment.

There was no evidence that the premises where these staff were working had been assessed using the guidance, 'managing home workers health and safety', published by the Health and Safety Executive'.

The company has not completed employment checks as set out in schedule 3 of the regulations. There was no evidence that the company had obtained references for medical staff or had carried out a risk assessment on those staff who do not have a DBS. We checked a total of four staff personal records. References were in place for two of the four records seen. A review of the services disclosure and barring (DBS) checks found that six staff had started work with the service without their checks being completed. One was given as a reason that they were employed as a 'maintenance person DBS not required', two had been requested and reason given for two was 'visa'.

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 and there was evidence of data audit.

The service had assurance from an external accreditation assessment of documentation reported that the service's management and control of records 'is seen to be effective and in accordance with the requirements of ISO 15189.'

There were arrangements to ensure data or notifications were submitted to external bodies as required. There were also arrangements (including internal and external validation) to ensure the availability, integrity and confidentiality of identifiable data, records and data management systems, in line with data security standards. Lessons were learned when there were data security breaches and as an example, we were shown a detailed root cause analysis which had been undertaken following the sending of incorrect material being sent to an incorrect address.

Engagement

The service collaborated with partner organisations to help improve services for patients.

The service provided a histopathology user survey form for external providers. We were provided with six of these feedback forms from external stakeholders. All the comments referred to the service as being very good with one provider reporting the service was 'a very well-run operation'.

Business management meetings referred to a 'staff suggestions initiative' to engage with staff. There was evidence that these suggestions were discussed at the meeting.

The Business meeting minutes for May 2022 referred to a staff satisfaction survey being distributed and awaiting returns.

The quality report for 2020-2021 reported on a user survey, with a response rate of 75%. It reported that of the respondents 78% strongly agreed that they were satisfied with the overall service.

There were positive and collaborative relationships with external partners to build a shared understanding of challenges within the system and the needs of the relevant population, and to deliver services to meet those needs. There was transparency and openness with all stakeholders about performance.

The service does not have a whistleblowing policy and does not have a speak up guardian or a similar role within the organisation.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

It was noted in the April business meeting minutes that root cause analysis training had been delivered on 24 May 2022. The service was an approved centre for biomedical scientist training. One of the staff showed a competency manual. All staff spoken to stated that they had opportunities for further training and had received an induction. The external accreditation report states that the training and competency requirements for ISO15189 have been met.

Leaders and staff aspired to continuous learning, improvement and innovation. This included participation in appropriate research projects and recognised accreditation schemes. There were standardised improvement tools and methods, and staff have the skills to use them. Learning from internal and external reviews was effective and included those related to mortality or death of a person using the service.

This section is primarily information for the provider

Requirement notices

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 17 HSCA (RA) Regulations 2014 Good governance • The provider should ensure that the full date is recorded for Portable Appliance Testing and that it follows national guidance in relation to portable electrical appliances. • The provider should ensure that the complaints policy includes detail of arrangements for the complainant to take their complaint to an independent review once the internal process had been exhausted. • The provider should ensure that it has a whistleblowing policy and arrangements for staff advocacy through the appointment of a speak up guardian or similar framework • The provider should ensure that the storage cupboard containing control of substances hazardous to health is closed when not being accessed and that it has appropriate signage. The provider should ensure there is a designated person responsible for managing training in the service

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 17 HSCA (RA) Regulations 2014 Good governance **Action the service MUST take to improve**: • The service must ensure systems or processes are established and operated effectively to assess, monitor and mitigate risks. The risk register did not accurately detail the risks of the organisation and the actions to mitigate risks (Regulation,17(1)). • The service must ensure information about candidates set out in schedule three of the regulations is confirmed and recorded before commencing employment. The service must ensure that it has ongoing systems and processes, including regular audits, to identify, monitor, escalate and mitigate risk from individuals who have not received the mandatory checks. (Regulation 19(2)) (Regulation 17(2)(a)). • The service must ensure that repairs are carried out to the ceiling of the administration and laboratory area. (Regulation 15(1)(e)). • The service must undertake an infection control audit with guidance from Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infections and related guidance. The service must ensure that it has ongoing systems and processes, including regular audits, to identify, monitor, escalate and mitigate infection control risk. (Regulation 15(2)) (Regulation 17(2)(a)) • The service must undertake a regulatory reform (fire safety) order 2005 Fire Risk assessment, to include an assessment of the damage to the ceiling and the breech in the compartmentalisation of the building. The service must ensure that it has ongoing systems and processes, including regular audits, to identify, monitor, escalate and mitigate risk, of smoke and fire breaching the wall between the two rooms. (Regulation 15(2)) (Regulation 17(2)(a)).

This section is primarily information for the provider

Enforcement actions

- The service must undertake a risk assessment of those staff who work remotely using national guidance, (Regulation17(2)(b).
- The service must have processes and systems in place to ensure that in the absence of the quality manager information is accessible to authorised people as necessary. (Regulation 17(2)(c)).