The Christie Pathology Partnership LLP

The Christie Pathology Partnership

Inspection report

The Christie Hospital
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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 inspected but did not rate this service

The service did not deal directly with people who use services. In the context of this report service user refers to the clinicians' requesting tests and results.

- There were systems and processes which had achieved the internationally recognised ISO 15189 accreditation for each discipline and test that was provided.
- Staff followed infection control principles including the use of personal protective equipment (PPE).
- Staff had completed and kept up to date with their mandatory training.
- Staff were experienced, qualified and had the right skills and knowledge to meet the needs of the service. The quality of the training programme and continuous professional development were of a high standard.
- Staffing levels and skill mix were planned and reviewed so that services could always be maintained.
- Staff had the information they needed to deliver safe care and treatment to people.
- The provider ensured that the requirement set out by the Health and Safety Executive (HSE) in relation to the provision of enough information on specimen request forms to staff in clinical diagnostic laboratories was being complied with.
- The provider managed safety incidents well. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised.
- Leaders, management and governance of the organisation had the skills, knowledge and experience to perform their roles, had a good understanding of the services and managed the priorities and issues the service faced. They were visible in the service and approachable for staff and service users. Staff felt respected, supported and valued.
- The service provided tests and reports based on national guidance. Managers checked to make sure staff followed guidance.
- Leaders, management and governance had the skills and abilities to assure the delivery of a quality service. They were visible to staff who said they felt supported and valued.
- The service had processes and procedures in place to support safe recruitment practice and ongoing checks

However:

- Equipment checks and cleaning undertaken by staff were not always recorded or carried out in line with service requirements.
- The provider had not submitted an updated and compliant statement of purpose to the CQC. Staff appraisals were not always carried out providing all staff at every level with the opportunity to discuss career and development they needed.
- Staff appraisals were not always carried out for all staff to provide them with the opportunity to discuss development needs and career progression.
- Safeguarding training for all staff who required it had not always been undertaken.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Medical laboratories	Inspected but not rated	See overall summary
Medical laboratories	Inspected but not rated	See main summary

Summary of findings

Contents

Summary of this inspection

Background to The Christie Pathology Partnership

The Christie Pathology Partnership (CPP) is a joint venture between a private and local NHS hospital. The Partnership operates out of the existing Christie pathology laboratories. The Christie is the largest single site specialist cancer centre in Europe. The laboratories also provide testing, screening and assay development to support The Christie's early phase clinical trials, with around 200 trials underway at any one time.

This service is regulated to provide Diagnostic and Screening procedures, Management of blood and blood delivered products to the regional population (3.2 million) and other healthcare providers regionally and nationally. There was a registered manager in post at the time of our inspection.

The location has not previously been inspected.

The main services provided were:

- Biochemistry
- Haematology
- Blood Transfusion
- Stem Cell Processing
- Histopathology
- Oncology Cytogenetics
- Molecular Diagnostics
- Breast Tumour Receptors
- Bereavement and Mortuary

The Bereavement and Mortuary service was not inspected under our new methodology for medical laboratories

What people who use the service say

The annual feedback survey by service users was positive.

How we carried out this inspection

Two inspectors and one specialist advisor carried out this inspection. We spoke to the quality, governance and health and safety manager, the registered manager (remotely), the senior leadership team including heads of departments, two team leaders and two laboratory scientists. We looked at three appraisal and training records, three new employee recruitment files, complaints and incidents reported in the last 12 months and actions taken from lessons learned. We also looked at the provider's quality manual, the latest United Kingdom Accreditation Service (UKAS) report with actions and internal and external quality assurance procedures. You can find information about how we carry out our inspections on our website:

https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Summary of this inspection

Areas for improvement

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

Action the service MUST take

- The service must ensure that the CQC is notified of any changes to their statement of purpose and ensure it is kept under review and notify CQC when there are any changes to the information listed in Schedule 3. (Registration) Regulations 2009: Regulation 12)
- The service must ensure that equipment maintenance and cleaning checks are always carried out by staff in line with local procedures. (Regulation 15)

Action the service SHOULD take to improve:

- The service should ensure that staff appraisals are carried out for all staff to provide them with the opportunity to discuss development needs and career progression.
- The service should consider improving compliance for safeguarding training for staff who must have it.
- The service should consider that information is recorded in recruitment files to demonstrate exemption to disclosure and barring service checks for the role appointed to.

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
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

Mandatory training

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

Information showed the provider was 87% compliant for all areas of mandatory training. There were 28 mandatory training topics required for example, the control of substances hazardous to health, (COSHH), fire safety, safeguarding adults, health and safety, harassment, and bullying, modern slavery, infection prevention and control, and equality and diversity. For Cytogenetics staff it was 85.3%, histology 90% and blood sciences 86.4% of mandatory training completed by staff.

Time was allocated in rotas when mandatory training was required.

Safeguarding

Staff did not always have training on how to recognise and report abuse or how to apply it.

The provider had a safeguarding policy with processes for reporting concerns. They had their own learning management system through which all statutory and mandatory training was delivered. There was a single safeguarding adults' course which did not correlate directly to the national level 1 and 2 safeguarding training, however, it did cover most aspects from both levels. The provider stated that they do not have any staff who work with patients or children. However, mandatory training for safeguarding adult's current compliance rate was 79%. The provider's overall compliance target was 95%. Compliance for each department was Blood sciences 77.40%, Cytogenetics 75% Histology 87% Finance 100%, Bereavement 75%, and Quality 100%. These compliance figures were below the provider's compliance targets for safeguarding training. It was not clear from the information provided in percentages what number of staff had undertaken safeguarding training.

Processes were in place to support safe recruitment practice and ongoing checks.

We looked at five staff files of different grades including the registered manager and found that recruitment processes were comprehensive with evidence of previous employment and reference checks, appropriate qualifications and registration where applicable. However, exemption from disclosure and barring checks were not evidenced in

recruitment records for roles undertaken. We were told that there was no formally documented process or risk assessment when the decision was taken to not undertake disclosure and barring checks. The recruitment policy did show that where roles were identified that may require a disclosure and barring check that this should be undertaken. We were told that no current roles required a disclosure and barring check.
Following additional information provided at the factual accuracy report stage, the commission were satisfied that the provider had processes in place to identify at recruitment stage what roles required a disclosure and barring service check and demonstrated how they verified this using the online NHS disclosure and barring service. This was flexible enough to be put into practice should roles change. However, the provider should consider that information is recorded in recruitment files to demonstrate exemption to disclosure and barring service checks for the role appointed to.

Cleanliness, infection control and hygiene

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

The service had infection prevention and control measures, and staff wore appropriate personal protective equipment. The provider was accredited to ISO 15189:2012 which is an international accreditation which specifies requirements for quality and competence in medical laboratories. Staff adhered to measures to prevent the spread of COVID-19 with routine weekly staff testing, wearing of face masks and a one route in and one route out system in the laboratory to reduce the risk of cross infection. Hand sanitising and hand washing was available at all stations. Staff and visitors were required to wear white coats on entering testing areas.

All areas and equipment looked clean. The check lists we viewed for some equipment were signed to indicate the equipment was cleaned after last use. All staff were responsible for cleaning the equipment they used. However information provided showed that scheduled staff maintenance including specific cleaning checks were not always carried out according to the schedule.

Environment and equipment

The design, maintenance and use of facilities, premises kept people safe and staff were trained to use them. However, equipment checks were not always kept or carried out.

The environment and equipment were compliant with ISO 15189:2012 accreditation. The entrance to the facility was safe and secure with a swipe card access system for authorised personal only. Specimen and requests could be deposited through a window without external visitors entering the laboratory.

Equipment maintenance was managed by the hospital estates through external service contracts. Information shared by the provider from the internal recording system showed that maintenance checks were carried out.

However, we reviewed maintenance and equipment logs from December 2020 to August 2021 undertaken by staff which showed that weekly, bi-monthly and four monthly maintenance records were not always carried out. For example, between December 2020 to June 2021 weekly checks had not been logged for periods of up to four weeks at a time. For bi-monthly checks one piece of equipment had been checked once in a 10-month period. The documentation showed that four monthly checks of specific equipment had not been carried out at all. A daily equipment check list for the 9th August was provided from a data request and showed inconsistencies in checks between day and night staff. On the 11/08/21 no weekend checks were made of equipment by day or night shift. On the 16/08/21 to 21/08/21 there was no evidence of daily checks completed by the night shift.

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

The environment was limited for space. This was recognised by the senior leadership team including an equipment review for sustainability. This was on the risk register and a business case was presented to the NHS trust partnership for approval.

There were arrangements for managing waste and clinical specimens to keep people safe.

Samples were labelled and stored appropriately. Procedures for disposal of waste followed the partnership NHS trust's procedures and waste collection service.

Assessing and responding to service user and staff risk

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

The provider had procedures to respond to requests for clinical advice and for reporting biochemistry results. For example, the main method for reporting results was from the electronic recording system. For more urgent results there was a phone call criterion as to what results and which members of staff could report them and to whom they could be reported to. Written reports were provided where requested. This duty was undertaken by the Consultant Clinical Scientist or designated Clinical Scientist (with support as required from the Consultant Clinical Scientist) who was duty liaison officer in the laboratory.

Participation in external quality assurance schemes was undertaken to monitor the process which were ISO 15189:2012 accredited. Where UKAS had identified that there were areas for improvement in formalised and documented reviews of risk assessments, action had been taken.

Anticipated turnaround times for the reporting of specimen results was monitored monthly using performance indicators through balance score cards. The turnaround times were agreed with local partners. Information provided between April and September 2021 showed the provider was achieving above its own targets for most of the turnaround times including urgent reporting cases.

However, overall profile turnaround times of within a 60-minute range was running less than the expected figure of 95% between April to September 2021. Figures for August and September were 75% and 79%. We were told one of the key issues affecting turnaround times was due to 'down time' of some equipment that caused delays in processing test samples. Down time means that a piece of equipment was not working effectively and needed to be fixed by the manufacturer. An equipment and estate review have been undertaken to address and improve the service with a business case presented to the NHS Trust for approval. The need for more space and replacement of equipment was on the risk register. A memorandum of understanding was in place with other laboratories should the need arise to transfer tests out if equipment downtime was more than 24hours. Staff worked overtime to address any back log to minimise the impact on service users.

Control of substances hazardous to health assessments (COSHH) and risk assessments were carried out to protect staff in performing their duties. In addition, there were instruction manuals and standard operating procedures to keep staff, and service users safe (where applicable) when tests were requested and carried out.

Laboratory staffing

Medical laboratories

Staffing levels and skill mix were planned and reviewed so that services could always be maintained. Staffing levels and skill mix planned and where possible cover was provided for staff absences.

Blood sciences and the blood transfusion service ran a seven-day service and had a day and night shift staffing rota to cover demand. Two staff were being trained to support night shift cover.

Data provided for September 2021 showed there were 4.72% permanent vacancies of the current substantive workforce which was a reduction in vacancies from the previous month at 5.25%.

Blood Sciences were recruiting to replace two staff leaving and an additional band 6 and band 3 post was being advertised in response to increasing demand post COVID-19 recovery.

There were staffing pressures due to sickness rates as a result of COVID-19 which had increased by 2% from July to September but shortfalls were managed through internal requests for staff cover which was offered as overtime and locum cover if required. Hand over and shift changes were managed safely through safety huddles at the beginning of each shift and a shift handover document was completed.

Senior Clinical staffing

Senior Clinical staffing levels and skill mix were planned and reviewed so that services could always be maintained, and cover provided where possible.
Most staff were directly employed by the partnership. Senior staff told us that there had been difficulty in recruiting to a gastrointestinal and urological consultant post within the service. It was recognised that there was a national pathology staffing shortage. This was on the risk register and reviewed at board level. Measures had been taken to address this by advertising for a locum post to provide cover, but this was unsuccessful for the gastrointestinal consultant. Interim arrangements were in place to cover two vacant consultant posts whilst recruitment processes were ongoing.

There was an action plan to appoint two clinical fellows to help support the consultants to address any backlogs as part of the post COVID-19 recovery plan.
There were arrangements for senior staff cover 24 hours a day with a reduced service out of hours when only urgent analysis was undertaken. Whilst a formal rota for senior staff cover was not provided staff knew who to contact for support and advice out of hours. Three senior members of staff with the right skills were contactable. In the event they could not be contacted staff knew to escalate the major incident policy. Staff went through to the main hospital switch board who released names and numbers for senior staff who could be contacted.

Staff had the information they needed to deliver safe care and treatment to people

There were processes and procedures in place to ensure the safe labelling, reception and transportation of specimens. There were standard operating procedures for labelling specimens, for samples received directly, specimen acceptance and specimen reporting. The web-based 'User Handbooks' contained comprehensive information for users on specimen collection, storage, handling and packing, including safety considerations. In addition, information was available on the provider website to ensure the correct labelling of specimens by those requesting tests. The transport of specimens both within the hospital and externally conformed to ISO 15189 (5.4.5) accreditation.

Records

Inspected but not rated

Medical laboratories

The provider ensured that the requirement set out by the Health and Safety Executive (HSE) in relation to the provision of sufficient information on specimen request forms to staff in clinical diagnostic laboratories was being complied with.

The provider had standard operating procedures which gave clear guidance for service users to follow. This gave enough information on specimen request forms. Non-compliant specimens were not accepted by the provider and the clinician contacted the referrer to rectify and resubmit the sample.

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

Incidents

The service managed safety incidents well. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave service users honest information.

The service was ISO 15189 accredited for the identification and control of non-conformities, corrective and preventative actions. Where gaps in processes were identified by the UKAS assessment the provider took actions to address them. For example, not all incidents were acted on in a timely manner. The actions taken was that all incidents were assigned to individuals with target dates and included in the monthly incident review meetings.

The method for reviewing nonconformities was the 'corrective action and preventative action model (CAPA). This was a process that organisations take to identify the causes of non-conformities and to take corrective actions to prevent them from happening again. Staff completing reviews for incidents had received training to ensure they were competent. Incidents identified were reported internally using the CAPA module and externally if applicable. We saw evidence of learning from incidents which was shared with staff in daily safety huddles and recorded on the electronic quality management system. This included the document master list, the library of departmental documents and the audit calendar.

No serious incidents were reported on the internal incident reporting system in the last 12 months. Mechanisms for reporting them was in place and reviewed at the monthly meetings under health and safety incidents.

Are Medical laboratories effective?

Inspected but not rated

Evidence-based care and treatment

The service provided tests and reports based on national guidance. Managers checked to make sure staff followed guidance.

Medical laboratories

The provider had internal and external quality assurance systems and was accredited to ISO 15189:2012 for the standard of presentation/interpretation of results and their procedures for internal quality control (IQC) of all examinations. This verified that the intended quality was achieved. The provider's internal quality assurance (IQA) had a programme of calibration for measuring systems and verification so that all results were traceable, where possible, to a stated reference material. Calibration certifications were provided for externally calibrated equipment checks and internal calibration was carried out by staff.
The provider used external quality assurance (EQA) for all tests being offered. The provider had monthly EQA senior oversight meetings to review and share information and actions with minutes for reference.

Patient outcomes
Staff monitored the effectiveness of tests and samples. The service had been accredited under relevant clinical accreditation schemes.
The service participated in relevant national clinical audits.
The provider participated in nationally and internationally recognised internal and external quality assurance processes and systems where these were available such as the United Kingdom Accreditation Scheme (UKAS) (ISO15189), Human Tissue Authority (HTA), Medicines and Healthcare Products Regulatory Agency (MHRA) and Joint Accreditation Committee ISCT-Europe & EBMT (JACIE) which is Europe's only official accreditation body in the field of haematopoietic stem cell transplantation (JACIE). It was compliant with the Human Tissue Act (2005) Human Tissue Authority Post Mortem sector Standards (HTA) and Blood Safety and Quality Regulations 2005 (SI 2005 No 50) NHS Operational.
The provider monitored the quality of service provision, including health and safety requirements and guidance set out by the relevant professional bodies and royal colleges. Where risks were identified, they were added to the risk register and risk reduction plans implemented and reviewed quarterly at senior leadership level. However, some risks had remained on the risk register for extended periods of time. This included the need for a new facility and more storage space to prevent business interruption in stem cell and blood sciences since 2010 and 2015, respectively. Approval for action to these specific risks were under the control of the NHS partnership provider side.
The provider had key assurance indicators (KAIs) for timeliness of reports and clinical advice. Key performance indicators, determined by service users, were recorded on the pathology balanced scorecard and monitored at Pathology Board meetings to ensure contractual obligations were met.
There were systems and checks to make sure the results being offered were accurate and that reference ranges being used were appropriate. Staff checked results and equipment calibrations for each test carried out and any deviations were addressed, reported and shared at daily staff huddles and senior staff meetings for IQA and EQA compliance.
If EQA was not showing satisfactory results there were policies, practices and procedures for dealing with this. For example, findings from audits were raised as non-conformities, where a standard had not been met the service completed a root cause analysis investigation to respond to the EQA provider. Non-conformities were acted on and results of internal audit were discussed at the Quality Committee and actions were reviewed at each meeting.

Competent staff
The service made sure staff were competent for their roles. Managers appraised staff's work performance but had not always held supervision meetings with them to provide support and development.

The provider had appointed a training lead in July 2021 who was dedicated to coordinating training needs. This had just been implemented in blood sciences and was to be rolled out across the service. The training lead demonstrated a comprehensive training programme to ensure staff were inducted, appropriately trained and had access to continuous development to support them in their roles. There was evidence of this in the range of modules provided in the training package being implemented for staff in blood sciences. For example, at induction the employees' training analysis was based on their experience. There were twice weekly meetings with new employees to provide support. Continuous professional development sessions were held monthly where lunch time topics were provided. There was a training

committee chair with oversight of monthly competencies.
Staff were supported to undertake further professional and personal development for example, all training leads had a budget for professional training and to implement training where gaps in learning had been identified. There were opportunities for apprentices to develop to diploma level and register for the health and care professions council (HCPC) which is the statutory regulator for several health and care professions, including biomedical scientists. We looked at five appraisal records which were detailed and reflected on achievements, performance and challenges to achieving objectives. Appraisals had provided opportunities to reflect and request further training and development which were accommodated where possible by heads of departments. However, staff appraisals which were completed by line managers or clinical heads had not always been completed. Staff appraisals for 2020 showed 100% completion. This had reduced to 40% in 2021. The provider said that the pandemic had impacted on opportunities to carry out appraisal which would normally be at around 70% for the same time frame. We were told this was being addressed by mandating appraisals. Managers were required to schedule time in weekly activities for appraisal with time allocated in staff rotas to complete.
Following the inspection, we were told that appraisal meetings had improved to between 60-70% in departments that were lagging.
The service had a quality, health and safety training lead to ensure that staff had the right support to deliver their roles effectively. There was a learning pool software providing staff with good access to training and professional development. Staff including senior staff said that they were well supported and had access to training and continuous professional development. There was evidence of post graduate training.
Staff could explain how to handle and prepare samples for testing and what they do to report concerns about results and EQA compliance.
Staff had received appropriate training and information regarding COVID-19and were adhering to safety measures in line with the NHS hospital protocols.

Multidisciplinary working
The provider worked together with other clinicians as a team to benefit patients. This was because pathology consultants provided support to other clinicians, through advice and interpretation of diagnostic reports, to make clinical decisions about patients care and treatment. They also attended multidisciplinary meetings in person if required.
Seven-day services
Key services were available seven days a week to support timely patient care.
A seven-day service in blood sciences was provided with shift staff and on call support from clinicians when required. However, there was not formally documented on call rotas for clinicians providing out of hours cover. The Royal College of Pathologist recommends that there should be published rotas identifying named individuals with appropriate skills to deliver the service with the means to be contacted in place. It states that 'appropriate level of cover must be available 24hrs a day every day and be agreed with service users and management'. The partnership had a process in place whereby the three clinical biochemists would be contacted first. If contact could not be made staff followed the major incident policy. This was a local agreement with the NHS partnership and contacts would be made through the main hospital switchboard. When we spoke to staff, they knew who to contact out of hours and what procedure was in place and staff understood it.

Are Medical laboratories responsive?

Inspected but not rated

Service delivery to meet the needs of local people

Inspected but not rated

Medical laboratories

The provider planned and provided a repertoire and service 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 meet testing and reporting requirements.

The provider provided a wide range of diagnostic services for cancer patients referred to the NHS partner organisation as well as across the region. They provided a consultation service concerning difficult tumours for other hospitals both within and occasionally outside the region. The department was the nominated service for haematological malignancy cytogenetic testing regionally.

The central lymphoma review and cytogenetics services were delivered by the provider to the local cancer diagnostic partnership. The provider undertook genetic testing to aid diagnosis of leukaemia and other tumours, to some hospitals in the North West of England. It was one of the largest specialist cancer genetics units in the UK.

The Stem Cell Laboratory provided a processing, cryopreservation storage and distribution service for bone marrow, peripheral blood stem cells and lymphocytes for the Haematology and Transplant Unit.

The provider was accredited by JACIE as part of the transplant program and was licensed by the HTA. It was included in the Christie Stem Cell Transplant Program Quality System and details were given in the Christie Stem Cell Transplant Program Quality Manual.

Learning from complaints and concerns

It was easy for the service user to give feedback and raise concerns about the service received. The provider treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. An annual user satisfaction was used to gather feedback on the service. This included complaints and compliments from service users accessing and using the service. The provider responded to complaints within a set timeframe. Complaints were monitored and reviewed at the pathology operations group (POG). Where failings were identified from investigations face to face apologies were made and actions from learning communicated with the appropriate staff teams, service leads for dissemination and shared in daily staff huddles.

The provider acted on complaints within their control, for example, a complaint about a delayed result due to equipment being unavailable had resulted in putting forward a business case for more space and an equipment refresh to improve turnaround times where possible.

User satisfaction was monitored through an annual satisfaction survey. The data provided for 2020 was positive about the service provided Service users rated their experience of the joint venture as 72.7% good to excellent combined. 27.3% rated it as fair. The service was rated 84.8% satisfied with the requesting process for pathology investigations and 87.1% for the helpfulness of staff with comments made that staff are “amazing people to work with.” Turnaround times for test results from requesting was rated as 87.1%. Overall, 90% of respondents said the existing blood sciences met their requirements for what tests were offered by the partnership.

Are Medical laboratories well-led?

Inspected but not rated

Inspected but not rated

Medical laboratories

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for staff. They supported staff to develop their skills and take on more senior roles.

The leadership, management and governance of the organisation assured delivery of a high-quality service with the leadership capacity and capability to deliver high-quality and sustainable care. There were currently two consultant vacancies in the leadership team which we were told were going through a recruitment process and when filled there would be a full leadership establishment.
There was good oversight of staffing which was reviewed at each senior leadership and board level meetings. Where risks were identified in staffing and sustainability these were put on the organisation's risk register with an action plan including presenting business cases to the NHS partnership and reviewed until resolved or mitigated. Initiatives were being undertaken with a training programme and developing staff from within the organisation to progress and outside the organisation by supporting local university placements.

There were plans to appoint two clinical fellows to support the consultants to address any backlogs as part of the post COVID-19 recovery plan.

Leaders were visible in the service. Some senior leaders were also clinical consultant leads including the clinical director and registered manager.

Leaders considered new and emerging guidance and ensured its effective implementation. This was evident with reference to COVID-19 guidance and was also aligned to the NHS trust policy to keep patients, visitors, and staff safe.

Were told by a senior leader that new and emerging guidance from The National Institute for Health and Care Excellence (NICE) was reviewed periodically at clinical research and effectiveness meetings However, we did not see any evidence or the cascading of this information in the senior leadership or staff meeting minutes that were provided.

Vison and Strategy

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

There was a clear quality and sustainability strategy documented in the quality manuals with the top priorities evidenced and communicated to staff through various methods including the intranet, e-mail, team meetings and daily team huddles. The quality manual was provided to all staff and there was a requirement that it was read. This was also available on the providers website for service users and external organisations to view. There was evidence that the provider had consideration for the future training needs of staff, (See training and competent staff) and undertook a wide repertoire range to meet the needs of the population nationally and locally. The provider was the reference centre for cancer and received results from other hospitals. It was also the regional hub for reporting which were collated and uploaded onto the central electronic reporting system.

Staff participated in the Greater Manchester Social Care Partnership and supported local universities taking placement students and apprenticeship schemes to help address shortages in the pathology profession.

Medical laboratories

Culture

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

Staff feedback was undertaken through the national staff engagement survey. The most recent survey in January 2021 achieved a 60% participation rate for the United Kingdom and Ireland overall. The final participation rate for The Christie Pathology Partnership was 66%. The previous staff survey (date not known) was 52% (57% UK wide) which was an improvement in staff engagement and feedback. The survey results were reviewed at senior team meetings.

From the bottom ten scoring areas in the survey five key themes were identified and focus groups were arranged to look at the key priorities. Staff from all bands were actively encouraged to get involved with the focus group by team leaders with dates and times of meetings posted publicly on the laboratory door.

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

Wellbeing of all staff was prioritised by senior leaders. Where it was identified that there were pressures placed on staff to cover sickness, staff turnover and increased workload post COVID-19 recovery these were reviewed, monitored and risk assessments generated on the organisational risk register for staff stress. There was support for staff which was accessible through an external employer assist programme which offered advice and counselling free of charge. There was also a mental health first aider and an equality, diversity & inclusivity champion, as well as access to a trust complimentary therapy team.

Risk assessments in the workplace were undertaken for COVID-19 and followed best practice guidelines including staff risk factors, modes of travel to work and work from home options when this could be accommodated.

There were mechanisms for providing all staff at every level with the development they needed, including high-quality appraisal and career development conversations were seen in the staff appraisals reviewed. However, from data provided appraisal rates for all staff for 2021 were at 40%.We were told that the pandemic had delayed appraisals. There was a specific focus on improving this. Appraisals have been mandated and managers were required to schedule time into weekly activities to account for appraisals, and time allocated in staff rotas.

We were told after the inspection that appraisal meetings have now been improved with an increase of between 60-70% undertaken in certain departments that were lagging.

There was a clear policy and process for dealing with incidents and complaints. Incidents raised on the internal incident reporting system with the potential to impact on the patient was always considered as a joint process and linked in with the trust governance team. For example, if it was an incident relating to a transfusion, the transfusion lead would speak to the patient with the hospital consultant.

Equality and diversity were promoted by the provider and equality and diversity training were mandatory for all staff. Black history month had been promoted with staff accessing webinars. There had been a higher than average uptake of vaccinations against COVID-19 for staff from a black and minority ethnic background. This was said to be because the provider had positively engaged with staff through support and one to one discussion to address any concerns.

Leaders had undergone an awareness session to support staff who may live with hidden disabilities to ensure they had the right approaches to support them.

One member of staff told us they were well supported, and reasonable adjustments made to enable them access in the workplace.

Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

There were clear governance structures between the NHS and laboratory partnership with partnership board meetings held bi-monthly and partnership operational group meetings held monthly. Quality assurance and governance meetings were also held bi-monthly. There were clear roles and responsibilities within the joint venture board with three directors from the NHS trust and three directors from the laboratory partner. The organisational, management and responsibility structure was clearly defined in the providers quality manual and was compliant with ISO 4.1, HTA GQS3.

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

There was evidence of audits for external quality assessment and identification and control of poor performance or results from external quality assurance schemes that were compliant with UKAS accreditation.

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

Management of risk, issues and performance

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

The provider has UKAS accreditation ISO 15189 for each test being carried out.

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

Compliance with current national legislation and regulations in relation to general data protection regulation (GDPR) was a group policy and integrated with the partnership trust policy. Evidence of all data breaches were reviewed at the health and safety and quality assurance meetings. However, the data breaches identified in the information provided were not directly attributed to the provider. Where this occurred, actions were taken by the NHS partnership to investigate and address.

The provider was able to demonstrate that the actions required or recommended as a result of the provider clinical governance meetings were being checked and reviewed.

Where risks were identified, they were added to the risk register and risk reduction plans implemented. It was reviewed quarterly at senior leadership level and monthly at the partnership and oversight group. However, some risks had remained on the risk register for extended periods of time. This included the need for a new facility and more storage space to prevent business interruption in stem cell and blood sciences since 2010 and 2015 respectively. Approval for action to these specific risks were under the control of the NHS partnership provider side. The provider regularly reviewed and actioned the risk register including actions recommended by UKAS. Information was shared with heads of departments and managers and senior team leaders.

The provider had a business continuity plan which set out clinical proposals to respond and reduce the risks from COVID-19. The provider had worked collaboratively with the trust reviewing work priorities in order to safeguard core services retaining maximum capacity where possible. A recovery plan had been submitted to the clinical advisory group (CAG) and the service was running at 95% capacity pre pandemic levels.

There was evidence that bi-weekly reviews of COVID-19 and risks within the wider hospital partnership were discussed in POG meetings and actions taken from new and emerging evidence.

The provider was “very proud of all staff who had responded to the challenges created by the pandemic by working together and managing to maintain an excellent service”.

Information Management

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

The provider was compliant with data protection and had secure systems to protect personal data both internally and externally.

Staff had access to the information they needed via the Q-pulse system with individual log in details which were password protected. The provider was still using both paper and electronic means of keeping records. Any data breaches in the partnership including the trust, were investigated and acted on. No data breaches had been singularly identified for the provider. Results were uploaded onto the patient electronic records so that requesting service users could access them.

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

The provider was able to share the latest UKAS compliance report and any subsequent action plans together with progress against them. MHRA compliance report was requested but not received. (MHRA is the designated authority that administers and enforces the law on medical devices in the UK. It has a range of investigatory and enforcement powers to ensure their safety and quality.)

Engagement

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

Inspected but not rated

Medical laboratories

The provider worked closely with the NHS to ensure that there was agreed mechanisms to ensure results were available, shared and communicated in a timely fashion.

The main feedback mechanisms to gather user satisfaction was through an annual survey. The results from the survey were discussed at board level. Other mechanisms included feedback from clinical leads within the partnership and wider trust.

The partnership monthly board meetings also offered the opportunity for provider feedback about the service.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

Leaders and staff strived for continuous learning and improvement and participated in recognised accreditation schemes such as the internationally recognised ISO 15189 accreditation. The provider also participated in external quality assurance schemes which are accredited to ISO17043 such as:

- UK NEQAS CPT (General, frozen section, megablocks, BMT)
- UK NEQAS ICC (General pathology, breast Her2, breast hormone, cytology, alimentary tract pathology, lymphoma, ALK-1 and PDL1)

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

The provider has recovered to 95% capacity pre-pandemic levels after testing went down in the trust to 75% during the pandemic.

The provider had a dedicated trials coordinator, working with the trust and offering testing for clinical trials work.

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

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 Management of supply of blood and blood derived products	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose The service had not ensured that the CQC is notified of any changes to their statement of purpose and ensure it is kept under review and notify CQC when there are any changes to the information listed in Schedule 3. (Registration) Regulations 2009: Regulation 12)

Regulated activity	Regulation
Diagnostic and screening procedures Management of supply of blood and blood derived products	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment The service did not always ensure that equipment maintenance and cleaning checks were carried out by staff in line with local procedures. (Regulation 15 (1)(a) (e)