Spire Healthcare Limited

The Montefiore Hospital

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 responsive to people's needs?	Inspected but not rated
Are services well-led?	Inspected but not rated

Summary of findings

Overall summary

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

We looked at four key questions: is the service safe, effective, responsive and well led. We did not inspect caring. This is because the service does not interact with patients.

- The service provided training in key skills to all staff and made sure everyone completed it. Staff had training on how to recognise and report abuse and they knew how to apply it. All areas within the laboratory were clean and had suitable furnishings. The design, maintenance and use of facilities, premises and equipment kept people safe. Staff completed and updated risk assessments to remove or minimise risks. The service had enough staff with the right qualifications, skills, training and experience. There was a system to report safety incidents and staff knew how to report incidents and near misses.
- The service provided care and treatment based on national guidance and evidence-based practice. The service made sure staff were competent for their roles. Staff worked together with the wider hospital team to benefit patients. The service was available six days a week with urgent cover available outside of normal hours and during busy times.
- The service was delivered in a way that met the needs of the hospital. Facilities and premises were appropriate for the services being delivered. There was an annual user feedback survey which staff at the hospital were invited to complete. Staff were encouraged to suggest improvements.
- Leaders had the skills and abilities to run the service and were visible and approachable. There was a clear leadership structure from service level to senior management level. Staff were aware of the overall vision and strategy and felt part of the vision for the hospital. Staff felt respected, supported and valued. The service had an open culture where staff could raise concerns. Leaders operated effective governance processes. Leaders and teams used systems to manage performance effectively. The service collected reliable data and analysed it. The information systems were integrated and secure. Leaders and staff engaged well with colleagues from the hospital and there were positive and collaborative relationships with external partners. Staff were committed to continually learning and improving services.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Medical laboratories	**Inspected but not rated**	We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

Summary of findings

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Summary of this inspection

Background to The Montefiore Hospital

The Montefiore Hospital provides a laboratory service to Montefiore House Limited, a private hospital, where the laboratory is co-located. They specialise in analysing blood samples (biochemistry and haematology). The laboratory was established in 2013 and is operated by Spire Healthcare Limited.

The service has had a registered manager in post since 2013 and is registered to provide the following regulated activities:

- Diagnostic and screening procedures.
- Management of supply of blood and blood derived products.

The service was last inspected in 2014 under a different methodology and met the standards of quality and safety with no breaches in regulation.

The laboratory is registered with the United Kingdom Accreditation Service (UKAS), which is the internationally recognised accreditation for medical laboratories. The most recent UKAS inspection took place on 15 October 2020. There were four actions which had all been completed.

The service processes a number of blood samples each day as well as triaging other samples, such as tissue, urine and sputum, to other hospitals for analysis. It is a small independent laboratory in one room within a private hospital. There is a biomedical scientist manager, two biomedical scientists, and one assistant biomedical scientist. Staff have the use of the facilities within the hospital such as the staff changing rooms, restaurant and toilets.

The laboratory does not have any direct contact with patients.

The laboratory is open from 8am to 6pm from Monday to Friday and from 9am to 1pm on Saturdays. There is a 24 hour on call system in place for more urgent requests.

We carried out an unannounced inspection on 25 May 2021 using our comprehensive inspection methodology.

How we carried out this inspection

The inspection team consisted of an inspector and a specialist adviser and was overseen by Amanda Williams, a head of hospital inspection.

During the inspection, we inspected the pathology laboratory using our comprehensive inspection methodology. We spoke with five staff, including three biomedical scientists, who conducted the sample testing and the pathology operations manager.

We reviewed the centralised patient record system and saw people's records on the system including the audit trail of samples. We reviewed three staff records. Following the inspection, we spoke with one further member of staff who was the head of pathology and the registered manager of the location.

Summary of this inspection

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Medical laboratories	Inspected but not rated	Inspected but not rated	Not inspected	Inspected but not rated	Inspected but not rated	Inspected but not rated
Overall	Inspected but not rated	Inspected but not rated	Not inspected	Inspected but not rated	Inspected but not rated	Inspected but not rated

Inspected but not rated

Medical laboratories

Safe	Inspected but not rated
Effective	Inspected but not rated
Responsive	Inspected but not rated
Well-led	Inspected but not rated

Are Medical laboratories safe?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

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

All staff received and kept up to date with their mandatory training. Staff completed online modules tailored to their role including health and safety, manual handling, infection prevention and control and some face to face training such as basic life support. Staff felt training was comprehensive and met the needs of their role.

A dashboard showed when individuals' training was due to be completed and an alert notified the staff member and their manager. Three staff files we reviewed had completion certificates for mandatory training and all were up to date.

Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff working in the laboratory did not come into contact with patients. However, staff were aware of how certain laboratory findings might suggest there is a safeguarding risk or concern. For example, a pattern of low sodium levels could indicate a patient is not receiving sufficient hydration. All staff were trained to level two in safeguarding for adults and children. The nominated safeguarding lead was the lead nurse at The Montefiore Hospital and staff told us they would refer any safeguarding concerns to their manager in the first instance, which followed the safeguarding policy for the service.

All areas within the laboratory were clean and had suitable furnishings. The laboratory had completed a comprehensive risk assessment which considered the additional impact of the COVID-19 pandemic. This was reviewed and updated in line with new government advice and guidance.

There was guidance in place to help prevent the risk of cross contamination of samples and for reducing the risk of handling samples for staff.

Staff followed infection control principles including the use of personal protective equipment (PPE) during our observations and audits showed 100% compliance. All staff members undertook an online course about the correct use of PPE. Additionally, staff had to sign to show they had read and understood the COVID-19 risk assessment.

There was a handwashing sink in the laboratory along with hand gel and instructions for use.

Inspected but not rated

Medical laboratories

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them.

The provider had a national system for procuring laboratory equipment which ensured it was fit for purpose. The provider used the same equipment in all its laboratories which ensured there was consistency and that staff were familiar with the machinery used at all the provider's locations. There were service records, which were up to date along with contracts for repair.

The design of the environment followed national guidance. We saw posters on the door of the laboratory, the staff changing rooms, and on the staff restaurant promoting the rules on social distancing and we observed staff adhered to the guidance.

There was an inventory of clinical equipment including the sample analysers as well as a policy for the safe storage and disposal of specimens. Staff recorded specimen results on the pathology system which transferred onto the hospital's electronic patient record. There was a clear electronic audit trail detailing the specimen process and we saw evidence that completed samples were disposed of in accordance with requirements set out by the Health and Safety Executive (HSE).

We saw there were systems to check that equipment was calibrated at the beginning of each day, and tests to check accuracy of results obtained were carried out. We saw there were 'start up' protocols for each of the machines which ensured they would run properly and that chemicals used in the analysis of specimens had not passed their use-by date and would not run out. There were records to show these checks were completed as required. We also saw that a variety of quality control tests were performed at the beginning of each day to show that the machines were producing accurate results.

Staff completed and updated risk assessments to remove or minimise risks.

There were comprehensive risk assessments and risk management plans which were reviewed regularly.

The service processed samples within 24 hours of receipt. Abnormal results were printed in bold to highlight these to clinicians, and reports detailed normal ranges adjusted for age, sex and where relevant ethnicity. We saw examples of records which showed that clinicians had been advised of abnormal results by telephone. This meant that clinicians were advised promptly of any abnormal results, which indicated a risk to patients' health. Staff told us they were able to process some samples, such as full blood count, within minutes of receipt.

There was an on-call system outside of normal hours. However, staff told us they often had to work outside of hours on Saturdays and Sundays to meet the needs of additional outpatient clinics set up by the hospital during the past year.

The service had enough staff with the right qualifications, skills, training and experience. The staff turnover rates were low.

There was a risk assessment in place to establish the maximum number of staff permitted to use the laboratory and observe COVID-19 social distancing. The maximum number of people permitted inside the laboratory at one time was four.

There was a minimum of two staff required to run the laboratory safely and to enable staff to check results before uploading them onto the system.

Inspected but not rated

Medical laboratories

Staff were registered with the Health and Care Professions Council (HCPC), which is a register of health and care professions in the United Kingdom.

The laboratory had access to a bank of roaming biomedical scientists, who were employed by the provider, and who travelled to laboratories provided by Spire Healthcare Limited, according to clinical need. There was one roaming biomedical scientist on site on the day of our inspection who told us all laboratories provided by Spire Healthcare Limited used the same policies and procedures which made it easier to work across sites.

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

There were clear processes to make sure results were uploaded correctly. A second staff member checked each sample result on completion. Results were loaded onto the electronic pathology system, which was linked directly to the individual patient records.

There were regular audits carried out to make sure 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 complied with.

Records were stored securely in line with the Data Protection Act 2018 and General Data Protection Regulation policy. The electronic records were only accessible through a password protected system to authorised staff.

We reviewed three sets of samples and found that all three were processed in line with protocol, accurately recorded and shared with the appropriate clinicians on completion. If the electronic system was not working staff told us they would request urgent repair. There was a plan in place for this event and some samples could still be processed on site while others would be triaged to other laboratories. There was a formal process for issuing amended reports, if required.

There was a system to report safety incidents and staff knew how to report incidents and near misses. Lessons were shared with the whole team and with other laboratories provided by Spire Healthcare Limited.

Staff knew what incidents to report and how to report them. There was a policy covering the reporting and investigation of incidents.

If a sample was compromised or contaminated staff told us they would use the hospital electronic incident reporting system to report it and contact the requesting clinician. Staff told us the most common cause of this was wrong sample type.

There had been no recorded serious incidents or never events in the previous two years. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event. Incidents across all sites provided by Spire Healthcare Limited were discussed at the monthly team meeting. We saw a record of a recent incident at another site discussed and documented in the minutes we reviewed.

There was evidence that changes had been made as a result of feedback. Recently there had been delays in turnaround time for samples that were processed off site. An additional overnight courier service was added which resolved the issue.

Inspected but not rated

Medical laboratories

Are Medical laboratories effective?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Managers and staff carried out a programme of repeated audits to check improvement over time. These included a quarterly health and safety quality checklist and an audit of the accuracy of recording samples received and checked at pathology reception. A senior management review of audits carried out in 2020 found that all scheduled audits had been completed.

Managers used information from the audits to improve processes. This was discussed in monthly staff meetings.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. The service had a range of policies to support the delivery of services. We reviewed a sample of these. All those we reviewed were version controlled, reviewed by the provider in a reasonable timeframe and contained references to national guidance and best practice documents such as Royal College Pathologists (RCP) and National Institute for Health and Care Excellence (NICE).

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients.

Managers gave all new staff a full induction tailored to their role before they started work. We spoke with a recently employed staff member who confirmed they had a good induction with a period of shadowing. The induction included information specific to the service, such as fire safety and emergency procedures as well as corporate information relating to the provider.

Managers supported staff to develop through six monthly, development appraisals of their work as well as one to one monthly meetings. However, not all staff felt there was clear career progression available within the organisation.

Staff reported concerns about sample results to the manager.

Managers made sure staff attended team meetings or had access to meeting notes when they could not attend.

Staff had additional roles such as quality management, training and education and health and safety.

Staff worked together with the wider hospital team to benefit patients.

Inspected but not rated

Medical laboratories

There was a daily 'ten at ten' meeting led by the hospital, which laboratory staff attended. This meeting was held by video link for ten minutes at 10am daily and attended by leads and other staff from throughout the hospital. Staff told us attending this meeting gave them operational information such as numbers of patients attending for surgery, which helped them to plan for the day as well as reminding them how their work directly impacts on patient outcomes.

The laboratory was open from 8am to 6pm from Monday to Friday and from 9am to 1pm on Saturdays. There was a 24 hour on call system in operation for more urgent requests.

Staff told us they often had to work outside of hours on Saturdays and Sundays to meet the needs of additional outpatient clinics set up by the hospital during the past year. Leaders told us the out of hours system was being reviewed.

Are Medical laboratories responsive?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

The service delivered in a way that met the needs of the hospital.

During the COVID-19 pandemic the service had facilitated in sending hospital staff's weekly COVID-19 polymerase chain reaction (PCR) test to another laboratory for processing. A PCR test is performed to detect genetic material from a specific organism, such as a virus. The test detects the presence of a virus if you are infected at the time of the test. Regular PCR testing for staff had recently been discontinued in favour of twice weekly lateral flow testing. The PCR tests for patients continued to be received by the laboratory and sent to another laboratory for processing.

There was an annual user feedback survey which staff at the hospital were invited to complete. The service was complemented on the quick turnaround time as well as staff helpfulness and hard work. Less favourable comments included delays in receiving results due off-site processing. There was a review of the feedback along with action plans.

Staff were encouraged to suggest improvements and we saw evidence of six suggestions being discussed at team meetings. For example, a staff member suggested that a detailed list of samples that could only be processed on weekdays, due to reduced staff numbers at weekends, was displayed in the hospital's outpatients' department to remind staff. We saw that this had been actioned and the list was in place.

Are Medical laboratories well-led?

Inspected but not rated

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

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.

Inspected but not rated

Medical laboratories

The manager biomedical scientist had responsibilities for overall management of the laboratory. There was a management structure with clear lines of responsibility and accountability. All laboratory staff identified the laboratory manager as the person they reported to. Staff told us they supported each other.

There was a clear leadership structure from service level to senior management level. Senior managers worked at provider level with responsibility for a portfolio of Spire Healthcare Limited laboratories. The pathology operations manager and the head of pathology visited the location regularly. The head of pathology was the registered manager for the service.

Staff told us that the managers were all approachable and that the manager biomedical scientist was visible. There was also support from the hospital leadership team including the daily 'ten at ten' meeting led by the hospital, which laboratory staff attended. Staff told us they had received good support form leaders from the provider and from the hospital during the COVID-19 pandemic.

We observed positive working relationships between staff. Due to the small size of the laboratory, everyone knew each other, and we observed friendly interactions between staff. There was an informal buddy system, which staff told us worked well.

Staff told us they also felt part of the wider hospital team and were comfortable speaking with staff members.

The strategic vision and strategy and set of values were determined at a provider level.

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

For the past year the focus had been on maintaining the service during a very busy time when the hospital had increasing numbers of patients attending for surgery, due to contracts with local NHS providers during the COVID-19 pandemic. Staff told us the laboratory had become much busier and they had worked extra hours in order to meet the need for additional sample analysis.

The business objectives for 2021 included the acquisition of new equipment to improve processing times as well as a focus on staffing needs to continue to meet the growing number of samples submitted for processing.

Staff felt respected, supported and valued. The service had an open culture where staff could raise concerns.

All the staff we spoke with during inspection were open and friendly and spoke positively about working in the laboratory. They gave examples of feeling supported and offering support to colleagues. Staff told us they felt part of the hospital team as well as part of the small laboratory team. They were invited to hospital celebrations such as Christmas parties.

Managers supported staff to develop through six monthly, development appraisals of their work. However, not all staff felt there was clear career progression available within the organisation.

Staff were recognised and praised for their commitment to the role during meetings. The service had received compliments from the hospital staff in the user feedback survey. For example, staff from one hospital team had commented that laboratory staff were fantastic, hard-working, helpful and responsive.

Inspected but not rated

Medical laboratories

There was an emphasis on the safety and wellbeing of staff. During the COVID-19 staff had completed a risk assessment to establish whether they were at increased risk of the virus. None of the laboratory staff needed to shield as a result. Staff who tested positive for COVID-19 were asked to isolate and not to attend work.

Leaders operated effective governance processes. Staff were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

All levels of governance and management functioned effectively and interacted with each other appropriately. There was a structured approach to the running and safety of the laboratory.

There were clear lines of accountability and staff knew who to report to. We saw management of equipment was systematic and staff knew who to go to if they encountered any problems. We saw records of equipment checks which took place at the beginning of each day.

There were governance structures that included: assessment of user satisfaction and complaints; internal audit of quality management systems; internal audit of examination processes; reports from external assessment bodies; quality improvement, including corrective and preventive action and the monitoring of quality indicators; external quality assessment and identification and control of poor or results from external quality assurance schemes.

There was a clear protocol to ensure the retention of pathological specimens was in accordance with requirements of the Human Tissue Act (2004).

There were monthly team meetings and minutes were circulated to staff who could not attend. Managers attended a weekly meeting which took place by video call. There was a monthly governance meeting with a fixed agenda. We reviewed the minutes of the most recent meeting. Senior managers sent weekly communications to all laboratories managed by the provider. There was an annual management review of the service, the details of which were shared with the team.

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact.

The laboratory was registered with the United Kingdom Accreditation Service (UKAS), which is the internationally recognised accreditation for medical laboratories. The most recent UKAS inspection took place on 15 October 2020. There were four actions which had all been completed.

The laboratory had a formal risk register and used an electronic incident reporting system to record new risks. We saw evidence that changes had been made based on risk. For example, one risk assessment related to the regular breakdown of blood analysis equipment which meant results were delayed. This was addressed and replacement equipment installed.

There was a systematic programme of clinical and internal audit to monitor quality and operational processes, and systems to identify where action should be taken. We saw audits were a regular discussion point on the staff meeting minutes and several audits had more than one cycle and showed improvements.

There was a policy to ensure compliance to Data Protection Act 2018 and General Data Protection Regulation policy.

Actions from governance meetings were checked and reviewed for completion.

Inspected but not rated

Medical laboratories

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

The laboratory had very clear and simple to use systems that all staff could access.

Staff demonstrated how easy it was to pull data from the system and could present this in several formats to help with understanding and analysis of the laboratory's day to day running.

The service had established electronic information systems and were able to prove that all their systems were password protected.

The service had a range of policies including general data protection and information security. The service used a pathology system which recorded results and this system fed through to the hospital's patient record system. Arrangements were in place to ensure the confidentiality of electronic patient information. Staff had access to an in date General Data Protection Regulation policy. We found computer terminals were locked when not in use to prevent unauthorised persons from accessing confidential information.

Leaders and staff engaged well with colleagues from the hospital and there positive and collaborative relationships with external partners, such as other hospitals and laboratories, to build a shared understanding of challenges within the system.

The service asked user feedback through an annual survey which staff at the hospital were invited to complete. The service was complimented on the quick turnaround time as well as staff helpfulness and hard work. Less favourable comments included delays in receiving results due to off-site processing. There was a review of the feedback along with action plans.

We reviewed minutes from staff meetings and found they were inclusive. They followed a standard agenda and staff were able to contribute even if they were unable to attend by submitting emails or asking the manager to raise a topic.

Staff were part of the annual management review which included compliments to staff for their hard work and dedication.

Staff were committed to continually learning and improving services.

There was culture of progress embedded in the leadership team, they demonstrated a commitment to ensure the laboratory had up to date technology and systems to aid the staff and ensure safety.

The provider had achieved the internationally recognised UKAS accreditation for each category of test that was provided, including haematology and biochemistry.