Medical Diagnosis Limited

Medical Diagnosis Ltd

Inspection report

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Date of inspection visit: 27 September 2022
Date of publication: 28/11/2022

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 service had enough staff to provide the right level of service. Staff had training in key skills and managed safety well. The service controlled infection risks well. Staff assessed risks, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them.
- Staff provided good care in the collection of taking patient's samples and specimens. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients and fulfilled contract obligations with clinics. They supported patients to make decisions about their care and had access to good information. Key services were available seven days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs. They provided emotional support to patients, families and carers. It was easy for people to give feedback on the service.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Medical laboratories	Inspected but not rated	• The service had enough staff to provide the right level of service. Staff had training in key skills and managed safety well. The service controlled infection risks well. Staff assessed risks, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them. • Staff provided good care in the collection of taking patient's samples and specimens. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients and fulfilled contract obligations with clinics. They supported patients to make decisions about their care and had access to good information. Key services were available seven days a week. • Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs. They provided emotional support to patients, families and carers. It was easy for people to give feedback on the service. • Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service were committed to improving services continually.

Summary of findings

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Summary of this inspection

Background to Medical Diagnosis Ltd

Medical Diagnosis Limited is a professional diagnostic laboratory performing specialist and routine medical tests. They carried out examinations on behalf of individual patients, clinics and doctors from all over the country. Their diagnostic services included: allergy, biochemistry and hormonal blood tests.

This service was established in 2006. The service has had a registered manager in post since it was first registered under the Health and Social Care Act 2008 in October 2011 and is registered to provide the regulated activity:

- Diagnostic and screening procedures.

Medical Diagnosis is ISO 15189 is United Kingdom Accreditation Service (UKAS) Standard accredited, which is the internationally recognised accreditation for medical laboratories.

The most recent UKAS inspection took place August 2021, which resulted in the provider being accredited. The service were processing 1000 samples per week.

Patients visiting the service had a very short episode of care at Medical Diagnosis Limited.

The laboratory was open from 9am to 6pm from Monday to Friday. The service did not have a 24 hour on-call service.

We carried out an unannounced inspection on 27 September 2022 using our comprehensive inspection methodology.

How we carried out this inspection

- The service had enough staff to provide the right level of service. Staff had training in key skills and managed safety well. The service controlled infection risks well. Staff assessed risks, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them.
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Our findings

Overview of ratings

Our ratings for this location are:

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

Inspected but not rated

Medical laboratories

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

Are Medical laboratories safe?

Inspected but not rated

Mandatory training

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

We were shown mandatory training logs by the laboratory manager. The service had a matrix of job roles, showing the required training for each staff group. Staff had accounts with an external company to complete online mandatory training, and the Laboratory manager had oversight of staff training, including being able to see the status of all their training.

An overview of staffs completed mandatory training showed their training was up to date. There was 100% completion of training amongst all staff groups (phlebotomists, administration staff, medical laboratory assistants, and biomedical scientists), showing a 90% average pass rate of all training that had been undertaken.

Training for most staff covered subjects such as: basic life support; control of substances hazardous to health (COSHH); fire safety; infection control, health and safety; first aid; recording information; safeguarding and protection; (CYP) children and young person's safeguarding; reporting of injuries, diseases and dangerous occurrences regulations (RIDDOR); dignity in care; and GDPR Stage One.

Safeguarding

Staff knew how to recognise potential signs of abuse and who to report it to.

Staff working in the service had the appropriate level of safeguarding training relevant to their roles. The service also had a safeguarding policy.

Staff were able to list the different types of abuse that fell under the category of safeguarding.

Staff knew who to report a safeguarding to if they had concerns about the results of a sample collection.

There had been no safeguarding referrals made to the Local Authority within the last five years.

Inspected but not rated

Medical laboratories

Cleanliness, infection control and hygiene

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

The service had a dedicated cleaner employed by the company to carry out cleaning of the premises. The cleaning checklist listed the different types of cleaning which needed to be carried out, including: the cleaning and sanitisation of sinks; cleaning of windows; the cleaning and sanitisation of toilets and toilet boards; vacuuming and mopping.

The laboratory provided appropriate protective clothing: laboratory coats, gloves, eyewear and masks, that were worn by laboratory staff during all production procedures. The laboratory environment was visibly clean and well maintained. The service's infection and control policy stated that, "protective clothing worn in the laboratory must not be worn outside the laboratory premises." During staff lunch breaks, we did not observe any staff member to be wearing any protective clothing. Staff working in the laboratory were bare below the elbows.

The flooring and benching were all visibly clean and the laboratories had hand washing sinks and soap dispensers. There was also eye wash available in the main laboratory on the ground floor.

The patient toilet was clean and well maintained. There was a second sink directly outside of the toilet and adjacent was a small table affixed to a wall furnished with hand gel, and paper towels.

The main reception and patient areas were visibly clean.

PCR (polymerase chain reaction) based tests were completed separately in clean preparation areas to prevent PCR contamination.

The infection control policy we looked at stated that "laboratory staff should be immunised against blood-borne viruses as identified by infection control risk assessment and in accordance with available industry guidance." We saw evidence included in staff's human resources file, where there was documented consent for the service to perform regular testing and examinations to ascertain virology status and general health for the following as a condition of their employment: Hepatitis C; Hepatitis B; HIV Coronavirus; Varicella zoster virus (VCV); Measles; Mumps; and Rubella.

Environment and equipment

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

The laboratories at Medical Diagnosis was spread across two floors. The two senior staff had a separate office away from the laboratory. There were separate facilities for biochemistry, immunology, and microbiology. Lino flooring featured throughout the clinic rooms, reception area and laboratories, and there was a locked frosted glass door to access the laboratory suites from the main reception. The laboratories were small, but for the number of tests performed and the numbers of laboratory staff, it was adequate. The laboratory environment did not appear to be too cramped. A separate area was available for staff to relax in and have breaks and lunch.

There were fire extinguishers in labs and emergency exits were clearly signposted. We saw an up-to-date fire safety maintenance checklist located on the stairwell between the ground floor and first floor laboratories.

Medical laboratories

The patient waiting area was set on the ground floor of the premises. Entrance into the service was level with the car park directly outside of the premises, making it disabled friendly.

The patient waiting area was furnished with 6 standalone chairs and a leather sofa. There was a water dispenser stationed within very close proximity of the seating area.

There was one patient toilet facility at the exterior of the premises, designed with a wide door and equipped with a disabled grab rail.

Clinic rooms were glass panelled from floor to ceiling, and patient privacy was maintained through the use of pictured window film. We looked in one of the clinic rooms used for phlebotomy sample collection. The room was ambient, and a thermometer in the room recorded the day's temperature. There was an air conditioning device attached to the wall, and handwashing facilities within the room. Within the room, it had results from the service's legacy CQC inspection framed, and a framed accreditation certificate from UKAS (United Kingdom Accreditation Service).

The service had 15 analysers, of which they had capabilities to analyse different specimens. The analysers we were shown were capable of analysing hormones, analytes, enzymes, antibodies, vitamins and antigens covering categories, such as Haematology, Biochemistry (liver function tests, kidney function tests, thyroid, lipids and other metabolic parameters), Serology, Virology, Microbiology. Specialists' tests are run in batches, for example twice a week. In some cases, there was more than one of the same analyser of different manufacturers, which meant that in the event of machine failure, there was always access to a back-up analyser. Another analyser we were shown was used only for analysing Covid-19 antibodies. Internal quality control samples were run on the analysers daily before testing patient samples. All results are logged in the Laboratory Information Management System (LIMS).

We looked at the service and maintenance schedule of seven of the service's analysers, which were carried out by the manufacturer. Medical Diagnosis Limited had devised 'Technical Passport' booklets which logged dates, descriptions of work performed, spare parts needed, and signatures for where maintenance, services and repairs had been carried out by the manufacturer. A further quality control procedure was then undertaken after servicing, which the service also documented and showed whether the analyser was approved to be used or whether it had failed in its quality control. The Technical Passports for the analysers that we looked at showed historical service, repair, and maintenance schedules for the life duration of each machine. Where there was little to no service information, this was because the analyser had recently been purchased. One of the entries we saw in a Technical Passport under the 'Out of Service log' category showed there had been an error with the gripper and that a service would be undertaken the following day after maintenance had been completed.

Medical Diagnosis Limited performed its own daily, weekly and monthly checking of its analysers and equipment. There was a rota for Biomedical scientists to perform general quality control checks on analysers, which included reviewing them for trends monitoring; checking the correct date and time on analysers and performing cleaning of analyser surfaces and worktops. More stringent and targeted maintenance performed by staff, specific to the type of analyser. Checking for planned calibrations and maintenance; and archiving results.

We were shown the service's water purification system, which was in place to create distilled water for the reconstitution of calibrators and controls of the analysers. We were shown a maintenance schedule dating back to 2014, of where prefilters and resin for the water purification system were replaced annually. The service also kept a signed and dated water purity maintenance schedule, which detailed water quality readings during filtration and deionization. We looked at the readings from this schedule for the month of February.

The service undertook fridge and freezer temperature monitoring. Temperatures were monitored either by electronic monitors which alert users by email if the temperature went out of acceptable range. System software plotted the temperatures for each equipment daily and records could be visualised graphically in computer software. Some of the fridges and freezers were monitored manually, with results recorded daily in an Excel spreadsheet.

Waste was managed safely and included the disposal of sharps in appropriate sharps bins, dated and signed when usage started.

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.

Results for tests outside of PCR testing, would generally be provided to patients within four hours or sooner and we saw evidence of this.

Patients with non-specific symptoms, would be encouraged to complete a comprehensive profile test, which was a test to see the general measure of what was happening in a patient's body.

The provider had escalation protocols for unexpected or abnormal results which required immediate or urgent medical intervention. Abnormal or unexpected results were highlighted to patients and referring clinicians verbally and through the pathology report.

We were shown an example of a patient's report highlighting critical results. The critical reading was highlighted in the Laboratory Information Management System (LIMS) with a yellow background. Critical result readings would be phoned through to the patient or the clinician – and if applicable, informed clinicians – and the phone call would be logged in the LIMS.

The service's policy on 'Reporting Results', stated that the laboratory were obligated to provide immediate notification, within 60 minutes outside of the usual normal results reporting process. The laboratory would continue to telephone or use other available contact channels if they had been unable to contact the clinic/clinician or patient until the result would be published.

The service could prioritise self-referring patients or clinicians needing results to be sent back urgently. Phlebotomists managed the expectations of self-referring patients, by first having a conversation with one of the biomedical scientists, and confirming with them that they could actually prioritise giving urgent results back, before the phlebotomist would go back to the patient and inform them they could receive their results back quickly.

We were given examples of what would constitute results being sent back urgently, such as a clinician who suspected their patient might be pregnant and wanted to see that growth tests were normal, or for a child who may be suspected to have anaemia. We were shown examples of where results were sent back to patients and clinicians quicker than four hours, sometimes in one hour. We were told this was not possible for every test, and this was dependent on whether the analyser was up and running for the day.

Patient reports did not include clinical advice, as clinical advice and interpretation was to be given by the patient's clinician. Since the laboratory did not receive clinical information about patients, it was not appropriate to include clinical advice on the reports. Self-referring patient's wanting advice and interpretation of their results, would need to go to their GP or doctor for this.

The service had a list of tests where critical values would warrant immediate follow up with the patient, clinic or clinician, some of these were: platelets; leukocytes; haemoglobin; CK; amylase; glucose; urea, potassium, sodium, creatinine.

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 bank and agency staff a full induction.

The service had a chief executive officer (CEO), who had a clinical background as a consultant cardiologist, who oversaw the business. There was a laboratory manager and deputy laboratory manager. Some roles within the organisation were interchangeable. The CEO oversaw the laboratory manager whose role was also the quality manager. The laboratory manager oversaw the deputy laboratory manager whose role was also the deputy quality manager. Direct reports to this level of senior oversight were: biomedical scientists; medical laboratory assistants; phlebotomists; reception/ administration staff and couriers.

At least four biomedical scientists were on site during laboratory working hours, with two biomedical scientists working within each department laboratory. The service did not use bank or agency staff. We were told that the service could be run without the CEO being present, and we saw the efficient running of the service without the input from the CEO.

We were provided with a staff rota for the month of September, which showed that the service had adequate staffing numbers to be able to carry out its service safely and efficiently. Rotas showed staff generally worked an eight-hour shift. Several phlebotomists were on the rota to work ten-hour shifts. Start times for staff varied from 8am to 10am. There were no specific start times for couriers.

Biomedical staff were responsible for authorising reports in the Laboratory Information Systems (LIMS) before reports were issued to patients or clinicians. Roles and responsibilities of biomedical scientists included: preparation, the storing and use of reagents required for laboratory investigations; undertaking preliminary fault finding and corrective action when the quality control procedures indicated loss of performance; informing the requester of clinically significant results; reporting to the Laboratory manager any instance or event which may cause a service failure.

Roles and responsibilities for medical laboratory assistants included but were not limited to: sorting and identifying specimens received; registering patient details and tests required on the Laboratory Information System; cleaning and sterilising of laboratory equipment, shelves, bench tops, sinks, toilets and floors.

Records

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

We looked at a set of 27 referral forms. The referral forms were a combination of self-referrals and referrals from clinicians. Referrals made by a doctor were signed and dated by them, with some of those referrals also being stamped with their general medical council (GMC) number.

The records we looked at were legible and referral forms captured patient's personal information, the specific test they were looking to have from a list of fifty-two pre-defined tests. Overleaf of the referral form, it asked the patient to record any clinical details from a pre-defined list of symptoms, as well as travel history, and the option to tick for a chaperone to be present or for one to be refused. A patient signature was required for permission to send results.

Inspected but not rated

Medical laboratories

Completion of self-referring patient's referral forms were checked against a form of identification from the patient. This was to ensure that accurate information was being captured on the referral form and on sample collection receptables.

Reports were issued from the Laboratory Information Management System (LIMS). The LIMS documented the full audit trail of activity on patient samples, from receipt to result issue. Results on a patient sample could be seen alongside the quality control validations run that same day the tests were performed, giving the scientist a good picture of the results.

All reports would be sent to the referring clinician with a few exceptions, of which were documented in the standard operating procedures (SOP) for reporting results. Clinicians were sent reports electronically. Clinicians also had access to a portal to view reports securely.

Referral forms were scanned to an electronic system. An external company collected hard copies of referral forms, which was stored and destroyed as per retention requirements stated in a standard operating procedure.

Incidents

The service managed safety incidents well. 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.

Incidents and errors were logged centrally and included for example; sample affected; a root cause analysis; a risk rating, and corrective and preventative action.

Errors were summarised in a monthly report, which was presented at staff meetings. Any patient reports with errors were amended and sent to patients. We were shown an example of where an amended report clearly stated on it that it was an amended report. Patients were contacted by phone to notify them they were being sent an amended report, to ensure they were aware of it. Telephone calls were logged on the Laboratory Information Management System (LIMS), along with any notes about the conversation.

There had been no serious incidents or never events in the service.

The service did keep an error log and we viewed examples of these. We saw action was taken to investigate and minimise recurrence. We saw on the log an issue with staff being unable to read handwriting on referral forms received from clinics. To resolve this, an email had been sent to all clinics asking them to ensure that clear information was entered onto referral forms.

The laboratory manager had a good understanding of duty of candour and they explained the actions they would take to make sure they fulfilled their duty. They confirmed there had been no incidents which met the criteria for duty of candour. Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. This means providers must be open and honest with service users and other 'relevant persons' (people acting lawfully on behalf of service users) when things go wrong with care and treatment, giving them reasonable support, truthful information and a written apology.

Are Medical laboratories effective?

Inspected but not rated

Medical laboratories

Inspected but not rated

Evidence-based care and treatment

The service followed national guidance when presenting and interpreting results. Managers made sure staff followed quality control procedures.

The service had its own laboratory guide which was kept in each of the sample collection rooms and outlined pre-analytical guidance for users of laboratory services, with the different step by step instructions to take when collecting a sample from a patient.

The service used quality assurance schemes to monitor and check their results. The service had ISO151819 accreditation. The most recent UKAS inspection took place August 2021, which resulted in the provider being accredited.

Staff followed up-to-date policies to plan and deliver a high-quality service in line with best practice and national guidance. The provider had a range of policies, and standard operating procedures (SOPs) to support the delivery of the service. Policies looked at included: Reagents and Consumables; Collection and Handling of Primary Samples; Reporting Results; and Internal Audits. We were shown 19 policies which included policies on: Intimate Examinations; Phlebotomy; Infection Control; Pre-examination; and Evaluation and Continual Improvement. The SOPs and policies were reviewed periodically. The 'Internal Audits' SOP referenced (International Organisation for Standardisation) ISO 15189, an international standard which requires laboratories to comply with quality and competence.

The SOP for reporting results clearly outlined what was to be checked and what should be on the reports, urgent requests, amended reports and critical values for measurements. We were shown all the obsolete SOPs that were moved to an obsolete folder on the computer. Current SOPs were kept in a current SOP folder.

Nutrition and hydration

Staff made sure patients who were fasting before tests were given food and drink or knew where they could get some.

Patients had access to water. Patients were recommended to fast in the morning for glucose tolerance test checks at least eight to ten hours in advance. If a patient attended as a walk-in, it would be communicated to them that fasting would be recommend for their test. If they hadn't been fasting, and the service undertook their test and their glucose results were high, the service would recommend for the patient's test to be repeated once they had been fasting.

Patients who were fasting were recommended to have their tests taken in the morning.

Patient outcomes

Staff monitored the effectiveness of their service. They used the findings to make improvements and achieved good outcomes.

The service participated in many External Quality Assessments (EQA) schemes covering all accredited tests. Each Biomedical scientist had responsibility for EQAs, so all scientists were involved. Test results and EQA returns were all

logged centrally, along with the outcome – satisfactory or unsatisfactory – so the laboratory could monitor performance. Any test results out of expected ranges were investigated and the outcomes and corrective actions were logged. If any results were seriously out of range, additional testing would be performed on potentially affected patient samples to see if they could also have been impacted. The service had not had such occurrences.

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.

The CEO had an annual appraisal done by the Independent Doctors Federation, which included a personal development plan. The Independent Doctors Federation submitted reports to the GMC on a five-yearly cycle. We saw an example of the registered manager's most recent appraisal report from 5 January 2022.

The laboratory manager and deputy laboratory manager were appraised by the CEO. A standard template was used for reporting appraisals, which included sections on: evidence of DBS check (Disclosure and Barring Service); what has been done well; what has given most pleasure; what has given the least pleasure; suggestions and improvements; career development plans; training completed. We saw evidence of the deputy laboratory manager having completed a course in quality management.

We saw the nurses had a list of training certificates for phlebotomy, which included venepuncture, and neonatal and paediatric phlebotomy (Level 3).

Staff could undertake Institute of Biomedical Science Training (IBMS) and portfolio development to become registered as a biomedical scientist. In-house training was offered to ensure there were enough numbers of biomedical scientist staff, as it was not easy to recruit qualified staff. The laboratory was supportive of training needs.

New staff were given a support colleague, for both work and social needs, to help the employee get to know other staff and provide advice and guidance as necessary. An induction checklist was used.

Multidisciplinary working

Staff did not work with other providers' teams.

The service did not give clinical advice or provide interpretation of results; therefore, they were not engaging in multidisciplinary working beyond the immediate team. The service followed up with the GPs of self-referring patients who exhibited test results outside of normal parameters.

Seven-day services

Key services were available seven days a week to support timely patient care.

The service was open Monday to Friday between the hours of 8am– 6pm. Opening hours on Saturday and Sunday were 9am – 3pm and 9am – 12pm respectively. The processing of samples by biomedical staff usually took place between the hours of 9am to 5pm. The service did not offer a service to process urgent samples outside of the normal processing hours.

Inspected but not rated

Medical laboratories

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They knew how to support children and patients who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff gained written consent from patients to have their samples taken, as well as written consent to have their results sent to them or their clinician (if specified to do so). Staff could describe gaining written consent from parents of paediatric patients.

Are Medical laboratories caring?

Inspected but not rated

Compassionate care

Staff treated patients with compassion and kindness and took account of their individual needs.

Staff were discreet and responsive when attending to patients. Staff followed local policy to keep patient care and treatment confidential. Staff were friendly, approachable and introduced themselves to patients. Privacy and dignity were maintained in the areas we visited by ensuring doors were closed as required.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress.

Staff were able to describe how they would provide reassurance and support for nervous and anxious patients.

Understanding and involvement of patients and those close to them

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

Staff made sure patients understood the tests that they were taking. Staff talked with patients, families and carers in a way they could understand.

Information was provided to patients about the fee structure for tests.

Are Medical laboratories responsive?

Inspected but not rated

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 service's workload was about fifty per cent walk-ins and 50% referrals from clinics. Patients generally arrived to request specific tests, as they usually knew what they wanted. If a patient arrived without a specific request, the CEO or

the biomedical scientists could advise as to the appropriate test to take. If the patient had non-specific symptoms, a comprehensive profile test could be offered. Advice was aimed at minimising the number of tests that patients took. The CEO referred to an example where a patient wanted thousands of pounds worth of tests, however the CEO advised they were not all relevant or useful, and halved the number and cost of tests. The CEO's approach was that patients felt they were getting a better service if they had fewer tests, because the tests were more specific and more relevant.

The laboratory reports did not include clinical advice. The reports showed the results and the normal ranges. Any result outside the normal range was highlighted in red text. Any result significantly outside the normal range was additionally highlighted with a yellow background. Such results were phoned through to the patients as well as emailing the reports.

We saw four 'agreements for service', where Medical Diagnosis Limited had contracts with providers to provide sample testing. There was a total number of 30 clinics which the service had a contract with, although we were told some of those contracts were not currently active. Examples of contracts included those with GPs and nutritional clinics, some of which were based in London and outside of London.

The service had its own couriers to transport specimens from clinics to the laboratory. There were four couriers working in the services. The postal service was also used to receive specimen samples.

Meeting people's individual needs

The service was inclusive and took account of people's individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated with other services and providers.

Staff ensured the service delivered met the individual needs of patients and referring clinicians. They were trained and able to collect specimens from external partners at short notice. The provider had its own in-house dedicated courier service to collect specimens, which reduced risks of loss or damage in transit. The provider also made sure they obtained copies of consent forms and patient wishes when they completed testing of sensitive samples.

Staff ensured patients and referring clinicians received test reports in a timely manner and they were advised of any delays as soon as possible. Staff sent laboratory reports directly to the referring clinician. This ensured the clinician could explain to the patient the diagnostic results and treatment options in a way they understood.

Access and flow

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

Managers monitored turnaround times and made sure referring clinicians could access services when needed and received their laboratory results within agreed timeframes and national targets. There was a system in place to ensure urgent samples were prioritised during the day to ensure patients received appropriate treatment in a timely manner.

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.

Staff understood the policy on complaints and knew how to handle them including how to acknowledge complaints.

Inspected but not rated

Medical laboratories

Complaints were managed and resolved by the Laboratory manager. We were shown a complaints log for the preceding eighteen months, which was presented in a tabulated format. It captured: the date; order number of the test linked to the patient; a description of the complaint and any corrective action taken.

In the last eighteen months, there had been ten complaints made to the service which related mainly to Covid-19 results not being sent on time. These complaints were made in the early part of 2021. A more recent complaint made by a patient on 16 October 2021, was that they were not served at their appointment time and walk-in patients were served first. In the description of corrective action for this complaint, it stated that: the "laboratory offers pre-booked appointments as well as walk-ins, staff advise patients to pre-book appointments when possible. Following this complaint, patients waiting in the queue were being asked about their appointment time and being served according to their appointment time and laboratory management often prioritised front-line staff."

Are Medical laboratories well-led?

Inspected but not rated

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.

The CEO of Medical Diagnosis, who was also the registered manager, had been running the service since 2006. The CEO had oversight of the business. They coordinated staff and helped to answer day-to-day questions that the laboratory manager may have. The registered manager was primarily involved with finding new business, talking to clinics and costings.

There was strong visibility amongst the laboratory manager and the deputy laboratory manager within the laboratories.

In the CEO's absence, the laboratory manager or the deputy laboratory manager were available to give advice to biomedical scientists and medical laboratory assistants.

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 CEO gave a full explanation of succession planning for the service.

The laboratory manager told us the vision and strategy was to develop new methodologies and tests to keep the service's quality level that it was already achieving for its customers.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.

Inspected but not rated

Medical laboratories

Staff sentiments about the culture of working for Medical Diagnosis Limited were very positive. Several staff members were long serving employees of the business and described how much of a pleasure it was to work in the service.

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.

Face to face meetings had resumed from more informal means such as using a messenger app to keep staff informed of company matters during the Covid-19 pandemic.

We looked at the last set of meeting minutes. The minutes showed that turnaround times for tests, customer satisfaction results, and the results for the number of referral forms that had been appropriately completed by clinics over a six-month period had been discussed.

The service used feedback from patients as well as clinics to appraise how well it was performing but also improve the service it was providing.

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. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

Staff knew how to escalate risks to the managers. The service had a register of identified risks with clear mitigations. One of the risks was that of infection at the blood sampling site and the mitigation for this was identified. Another risk identified was a patient having pain at their blood sampling site. The mitigation for this was for a well-trained person to take the sample; and to use a needle of smaller gauge than the selected vein.

The service had a Disciplinary Policy, which the service would follow with the aims of improving individual conduct and performance. The disciplinary process was procedural but informal actions were considered, where appropriate, to resolve problems.

The service was accredited for each test carried out. The recent United Kingdom Accreditation Service (UKAS), inspection took place in August 2021.

The service had a SOP for non-conforming work, and the purpose of this procedure was to ensure that nonconforming work in any aspect of the quality management system was identified, and that immediate action was taken to control a situation, particularly with respect to examination results.

Information Management

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The laboratory had a comprehensive Laboratory Information Management System (LIMS) for recording all laboratory activity. It displayed all data in an appropriate way and appeared easy to use. The LIMS was supported by the manufacturer.

There was a system to ensure the security of confidential patient data. The electronic record systems were password protected and only certain staff had access to the various functions of the laboratory information system.

Paper copies of referral forms were collected by an external company and destroyed after appropriate retention dates.

There was a policy to ensure compliance with the Data Protection Act 2018 and a General Data Protection Regulation policy. Staff had completed training on information governance and data security which covered their roles and responsibilities in relation to handling data and patient information.

The Laboratory manager maintained original copies of quality manual systems on a flash drive kept in the management's office. These included the quality manual, standard operation procedures, forms and work instructions. All the internal documents were distributed by the Laboratory manager as controlled copies. Any document intended for distribution was assigned a controlled copy with the name of institution or person within the table of the first page, and then was printed or converted to pdf format so that it carried a watermark "CONTROLLED COPY".

Engagement

Leaders and staff actively did their best to actively receive back feedback from clinics they were in contract with.

User surveys were sent to clinics that used the service. No negative feedback had been received; however, the question on the survey receiving the lowest score related to prices of tests. The overall satisfaction level that the service received from user engagement was (4.63), which was above the threshold of 4.5, which was the threshold for an optimal score.

The survey had been sent to 187 recipients, including doctors, clinics, and healthcare workers. The service collected 27 responses (14.44%).

The laboratory did not advertise, so most of the work came in from repeat users, clinics that contracted with the laboratory, and from recommendations.

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.

Innovations for the service were the introduction of new tests, which analysed urine, blood and stools. The advent of these new tests meant that samples could be processed more quicly.

Staff were able to make suggestions about quality improvements and changes they would like to see in the service.