

Gerexa Limited

# Ashton Lollipop

## 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

Requires Improvement



Are services safe?

Requires Improvement



Are services effective?

Inspected but not rated



Are services caring?

Good



Are services responsive to people's needs?

Good



Are services well-led?

Requires Improvement



# Summary of findings

## Overall summary

We rated it as requires improvement because:

- The service did not always control infection risk well.
- The provider did not monitor or have oversight of when ultrasound machines had last been serviced. The service did not always ensure specialist equipment was maintained.
- The service did not always check to make sure policies were regularly reviewed.
- The service did not always have access to women's and staff records. Records were often stored off site. There was not a robust process for the safe storage, retention, and disposal of records.
- The complaints policy did not reference any external independent complaints service body for customers to access should they be unhappy with the providers response.

However:

- Leaders supported staff to develop their skills. Managers monitored the effectiveness of the service and made sure staff were competent.
- The service assessed risks to women and acted on them. Staff provided adequate care and treatment. Staff treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs. They provided emotional support to women, families and carers.
- The service planned care to meet the needs of local people, took account of women's individual needs. The service engaged well with women and the community. Staff were committed to improving services.

# Summary of findings

## Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires Improvement	

# Summary of findings

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# Summary of this inspection

## Background to Ashton Lollipop

Ashton Lollipop is operated by Gerexa Limited. The location has been registered since March 2021 to provide diagnostic and screening services. The clinic provides a range of pregnancy scans to self-referred, privately funded women who are 18 years or older. Scans were available in 2D, 3D and 4D, including early reassurance scans which were available from 7 weeks, genders scans available from 14 weeks and baby bonding scans available from 24 weeks. The service provides keepsake pictures to people who used the service as well as keepsakes such as heartbeat bears, gender reveal balloons and cannons. The clinic is based in Ashton-under-Lyne town centre. The clinic employs a registered manager who acts as the governance lead, a clinical manager who is also an ultrasound technician, another ultrasound technician and two receptionists.

We have not previously inspected this location.

## How we carried out this inspection

We carried out a comprehensive inspection to assess the provider's compliance with fundamental standards of safety and quality. We looked at key questions of the safe, effective, caring, responsive and well-led domains.

Two inspectors carried out the inspection, with support from an off-site inspection manager, carried out the inspection on 14 February 2023.

During the inspection visit, the inspection team:

- Inspected the premises.
- Spoke with the manager/lead technician.
- Looked at a range of policies, procedures and other documents relating to the running of the service.
- Spoke with 3 patients about their experience of treatment and care as a service user.

We have not previously inspected the service.

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

## Areas for improvement

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

### Action the service **MUST** take to improve:

- The provider must ensure that equipment is maintained and serviced in accordance with manufacturer's guidelines. Regulation 12 (1)(2)(d)
- The provider must ensure that their audit and governance systems are effective. Regulation 17.

# Summary of this inspection

- The service must review their policies for relevance to the service context and ensure review dates are appropriately identified. Regulation 17(1)(a)
- The service must have a robust process for the safe storage, retention and disposal of records. Regulation 17(2)(d)
- The provider must have processes in place to ensure that staff are suitably qualified, competent, skilled and experienced to provide a safe service. Regulation 17 (1)

## **Action the service SHOULD take to improve:**

- The service should consider improving handwashing facilities for clinical staff.
- The service's complaints policy should provide service users with information to escalate their complaint should they be unhappy with the internal response.






# Our findings

## Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement

# Diagnostic imaging

Safe	Requires Improvement 
Effective	Inspected but not rated 
Caring	Good 
Responsive	Good 
Well-led	Requires Improvement 

## Is the service safe?

Requires Improvement 

We have not previously inspected this service. We rated it as requires improvement.

## Mandatory training

**Staff did not always have up to date mandatory training in key skills.**

Three out of the four staff were up to date with their mandatory training modules. We noticed some gaps in training modules such as autism awareness, disability awareness and equality & diversity for a newer member of staff, but noted they had training courses scheduled.

The mandatory training was comprehensive and met the needs of women and staff. Modules included infection prevention control (IPC), mental capacity, GDPR awareness, moving and handling, preventing radicalisation, equality and diversity, fire safety and health and safety in health care.

The managers had a mandatory matrix training table, but this did not record when mandatory training expired, this meant the provider could not be assured staff training was up to date.

The health and safety policy stated that “staff mandatory training must be done by every staff member”. The registered manager was not included on the training matrix however post inspection we were provided with evidence that the registered manager had been included in mandatory training.

## Safeguarding

**Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Most staff had training on how to recognise and report abuse and they knew how to apply it.**

The clinical manager was the safeguarding lead and had completed safeguarding children and adults training up to level three meeting intercollegiate guidance.

At the time of inspection all 4 staff had completed safeguarding adults’ level three. Three out of the four staff also had training in female genital mutilation awareness.



## Diagnostic imaging

The clinical manager knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. They verbally described situations where they would need to make a referral and could give examples of how to protect children from harm.

The service provided safeguarding children training to all staff. However, this training was dated from 2019 for 2 of the staff members.

The staff members knew how to protect a service user from abuse and knew the clinical manager was the safeguarding lead.

The safeguarding policy was up to date and was reviewed on an annual basis. The safeguarding policy included all aspects of potential abuse such as female genital mutilation, forced marriage and sexual exploitation. The policy included contact details for the local authority safeguarding team. However, the policy stated that all staff required level three safeguarding children training, we did not see evidence that the service was providing this for all staff.

The service required all staff to have a Disclosure and Barring Service (DBS) check as part of their recruitment. We were provided with evidence of DBS certificates for all staff.

The service had an up to date chaperone policy. The service clearly displayed and signposted the option for women to use chaperones. We saw evidence that staff had up to date chaperone training.

The service also signposted the local authority safeguarding contact details in waiting areas.

### Cleanliness, infection control and hygiene

**The service did not always control infection risk well. However, staff used equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean.**

The design of some chairs in the scanning room and waiting room did not enable them to be effectively cleaned. This is because the chairs were fabric covered and not impermeable to dirt and liquid.

The service did not complete audits for IPC or the cleanliness of the environment.

There were no handwashing facilities in the scanning room and the hand gel provided had no expiry date. The manager told us they would wash their hands using alcohol hand gel before and after every client, they could access the sink in the toilets if needed.

The service had a specific cleaning policy that was in line with British Medical Ultrasound Society (BMUS) guidance.

We did not see a cleaning schedule for the whole of the premises at the time of inspection, however the overall environment and equipment throughout the clinic were also visibly clean and well-maintained. Staff were responsible for cleaning the premises. There was a cleaning schedule for the toilet that was up to date. There was a up to date cleaning schedule for the ultrasound equipment and the service followed BMUS best guidance for the cleaning of the transducers. On post-inspection we were provided with cleaning logs for the site.

The manager told us blue roll was used on the ultrasound couch and was disposed of between clients. The manager told us all equipment would be wiped and cleaned between each customer.

# Diagnostic imaging

We observed that the lead technician cleaned the ultrasound bed, equipment and transducers in between appointments using low alcohol NHS approved anti-bacterial wipes.

The ultrasound bed was covered in disposable paper towel roll. We found the clinical manager used and replaced this for all the service users we observed.

The clinical manager followed infection control principles including the use of PPE. They wore gloves and were 'bare below the elbows' in line with IPC best practice guidelines.

## Environment and equipment

**The service ensured specialist equipment was maintained. The service had suitable facilities to meet the needs of women and their families.**

The service premises were situated on the ground floor and first floor of the building. The entrance had a small step and first floor was only accessible via stairs, therefore the premises were not wheelchair accessible.

The premises consisted of a reception/waiting area on the ground floor, a storage and kitchen area. The scanning room was located on the first floor and there were two toilet facilities available for both staff and service users.

There was a staff kitchen and storage area where water bottles were stored for customers if needed. In the storage area the service stored confetti balloons and cannons, cleaning equipment, and a spare printer.

There was a first aid kit held in the staff kitchen area, items that we checked were in date. All cleaning and PPE resources were checked and within date. The service also stocked latex free gloves for patients with latex allergies.

The waiting area was large enough to accommodate those waiting for their scans.

The scan room contained an ultrasound bed which was wipe clean and well maintained, however it was not adjustable in height. The design of some chairs and cushions in the waiting room, lobby and clinic room meant they could not be cleaned effectively. This is because the chairs and cushions were fabric covered and not impermeable to dirt and liquid.

The scan room contained an ultrasound bed which was clean and well maintained, however it was not adjustable in height, therefore it may not be accessible for service user with additional needs. The clinical manager told this they had not experienced any customers that were not able to safely manoeuvre on to the bed and had a small step available for those who required it.

We noticed there was damage to the ceiling in the scan room caused by heavy rainfall, post inspection we were provided with evidence that this had been reported and was awaiting repair.

Ultrasound machine maintenance records were not held on site. The provider did not have a service schedule or timetable in place to monitor when the ultrasound machine services were due. Following our inspection, the registered manager provided evidence to show the machine had been serviced in September 2022.

The manager told us that they had access to a replacement machine if the main machine broke down, this was kept on site, but we did not see any recent service records for this machine. The service had access to a backup photo printer and projector.

# Diagnostic imaging

Electrical equipment, including the ultrasound scanning machine did not have portable appliance testing (PAT) stickers on, and we saw no evidence that PAT testing had taken place.

The provider had an accident book to record any incidents and accidents.

Clinical waste bags were not in use in the service, but the clinical manager told us that they did not produce any clinical waste.

## Assessing and responding to patient risk

**Staff completed and updated risk assessments for each woman and removed or minimised risks. Staff knew what to do and acted quickly when there was an emergency.**

Staff had first aid training and when asked knew how to act to any sudden deterioration in a service user's health, we were told that staff would call for an ambulance if needed however this was not referenced in any of the documents we were provided. The service had a first aid kit on site.

The manager told us that they did not perform scans on women under the age of 18 years, this was included as part of the consent policy. The manager told us the receptionist would always confirm the patient's age before booking, the women were also asked again at the appointment. However, we did not see any evidence of a specific exclusion criteria policy

Women were asked to bring their medical notes to their scan so that their identity could be checked and the number of weeks they were pregnant.

The consent form referred to the British Medical Ultrasound guidelines on souvenir scans and told service users they should not treat their scan as an alternative to their NHS scans. Service users signed to say they understood this as part of the consent process. The consent form also required the women to confirm their date of birth and give permission for the provider to contact hospitals and GP surgeries if adverse findings were found.

The clinic had an adverse findings policy in the event of a foetal abnormality. In such an event, the service would call the early pregnancy unit and arrange an appointment directly for the woman. The service provided women with a "referral letter" detailing the findings of the ultrasound scan. The service told us in the past six months, 5 women had been referred to the early pregnancy unit. Staff received specific training in delivering bad news.

The service also carried out a risk assessment for each woman which was completed on arrival. Previous medical history and allergies were part of a tick sheet criteria which was completed prior to the scan. This was reviewed by the technician before the scan, the clinical manager told us if there were any issues they would rearrange or discuss cancelling the appointment if required.

We saw evidence of environment risk assessment completed, this included spillages, uneven floors, lifting, contact with hazardous materials, fire and electrical faults. However, there was no date to indicate when this was last reviewed or updated.

The service had a specific lone working policy that up to date, lone working was also included as part of the general risk assessments.

# Diagnostic imaging

## Staffing

**The service had enough staff to keep patients safe from avoidable harm and to provide the right care and treatment.**

At the time of inspection, the service comprised of a registered manager, 2 ultrasound technicians, 1 of which also acted as the clinical manager and 2 receptionists. All staff were employed on a flexible basis dependent on the service need.

The clinical manager told us they were looking to hire a sonographer to work weekends.

The service did not employ any agency staff.

We saw evidence that the ultrasound technicians had undergone specific training courses conducted by a third party. The certificates included training in conducting second and third trimesters scans, advanced 3D application training and best practice ultrasound.

The service had a recruitment policy that was up to date which included a list of requirements prior to recruitment. This included evidence of CV, right to work in the UK, Disclosure and Barring Service (DBS) checks, work health assessments, references, evidence of qualifications, and confirmation of registration with a professional body where this applied.

## Records

**Staff kept detailed records of women's care and diagnostic procedures. Records were stored securely and but not easily available to all staff providing care. The service did not always store data in line with regulations.**

No records of appointment details were kept on computer. Appointments made by people who used the service were recorded on a daily sheet in an appointment file. Details recorded included the customer's name, how many weeks pregnant, their telephone number and whether a deposit had been paid. Staff managed confidential waste themselves and the service had a shredder on site.

On arrival service users were asked to confirm their name and date of birth and asked to complete a consent form. The consent form required service users to supply their name, date of birth, contact details, GP details and signature. The clinical manager told us consent forms were kept in a locked cabinet on site and then later at the manager's home before being shredded. As part of our inspection, we asked to review patient consent forms, but we were told there were no recent records stored on site, they were managed from the manager's home. The service's website advised customers that records were kept at the location, however we found this was not always the case.

During each scan, the technician would store the scan images on the ultrasound scanning machine. At the end of the scan, they would copy the images report to a blank memory stick. The receptionist would use the computer to upload the images and print the relevant images. The memory stick would then be wiped ready for the next patient.

The images and records held on the ultrasound scanning machine were destroyed after approximately 12 weeks.

It was not clear from the records management and handling policy how long the service would retain patient records for.

Policies were paper based and kept in a folder on site.

# Diagnostic imaging

## Incidents

**The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service.**

The service had an incident reporting policy in date, and which referenced duty of candour and how lessons would be learned from incidents. The policy stated, “All staff will also receive an annual update on incident reporting through mandatory training.”, however we did not see any evidence of this taking place.

Staff knew what incidents to report and how to report them.

The clinical manager gave examples of what incidents to report and knew how to report them. We saw evidence of completed incident notification forms relating to the environment. They told us that no accidents had occurred since the clinic opened. The service also had an accident book, the manager had told us that they had needed to report any accidents.

The service also had a specific duty of candour policy. The clinical manager understood the duty of candour, the importance of being open and transparent, and to provide full explanation to women or relatives if things went wrong. The service also had a duty of candour policy detailing their commitments to openness and transparency.

Managers shared learning about discrepancies with their staff at regular meetings.

## Is the service effective?

Inspected but not rated 

We have not previously inspected this service. We inspected but do not rate the domain for effective.

## Evidence-based care and treatment

**The service referred customers to read national guidance on souvenir scanning, however, did not always check to make sure policies were regularly reviewed.**

The clinical manager told us their service followed British Medical Ultrasound Society (Guidelines for Professional Ultrasound Practice) for information on ultrasound. These guidelines state that scans in pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs. We saw evidence that BMUS was referenced as part of the consent processes and for the cleaning of transducer probes. The service also kept a paper copy of this guidance on site.

The 2 ultrasound technicians carried out all scans that the service offered including early pregnancy scans which were performed from 7 weeks. The Society for Radiographers does not recommend that early pregnancy scans are performed before 12 weeks of gestation, therefore the service was not adhering to relevant guidelines.

We saw evidence of audits on waiting times, rescan rates and image quality. The clinical manager told us they used peer review to undertake imaging audits, in terms of image quality and positioning.

Policies were paper based and kept in a folder on site.

# Diagnostic imaging

Most of the service policies were up to date. However, the consent and COVID policy did not include any review date. The chaperone policy was not specific to the service, it referenced a member of staff that did not work for the company and cited a different company name.

We did not see any evidence on infection control audits.

The clinic did not always follow nationally recognised best practice, which recommends a two-week time gap between scans. We overheard one patient who had come for a rescan just under a week ago.

## Patient outcomes

**Staff monitored the effectiveness of care. They used the findings to make improvements and achieved good outcomes for women.**

Managers monitored the effectiveness of care and used the findings to improve them. The clinic sent an email to each customer who used the service as possible to receive feedback on their experience. The clinical manager was proud of her 5-star reviews and was always keen to improve the service provided.

We saw evidence that the service collated feedback which was predominately positive.

We saw evidence that the service regularly conducted audits that included waiting times; image quality satisfaction and feedback. The clinical manager used the data to maintain their high standards of image quality and to monitor workflow in the service.

The service was not auditing gender accuracy at the time of this inspection.

## Competent staff

**Managers appraised staff's performance and held supervision meetings with them to provide support and development. However, the service did not always ensure staff were up to date with relevant skills needed for their roles.**

The clinical manager supported staff to develop through yearly appraisals of their work, identified any training needs for staff to develop their skills and knowledge. All staff had received an annual appraisal.

Managers gave all new staff a full induction tailored to their role before they started work. Leaders told us new staff would undergo a shadowing period where they were classed as supernumerary, however it did not specify in any policy how long this shadowing period would be for and how staff were assessed as competent.

We saw evidence of monthly team meetings where staff were given updates to changes to practice.

Staff were experienced, qualified, and had the right skills and knowledge to meet the needs of patients. However, we did see a new staff had not undergone some mandatory training modules.

## Multidisciplinary working

**Staff worked together as a team to benefit women. They supported each other to provide good care.**

# Diagnostic imaging

There clinical manager told us that they would be contact GPs and early pregnancy units if there were possible anomalies or concerns.

## Seven-day services

**Services were available to support timely care.**

The clinical manager told us the service was usually open a couple of days a week, days were not fixed and were flexible according to customer demand.

## Health promotion

**Staff gave women practical support and advice to lead healthier lives.**

The service had relevant information promoting healthy lifestyles and support in patient areas.

## Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

**Staff supported women to make informed decisions about their care. They followed national guidance to gain women's consent. They knew how to support women who lacked capacity to make their own decisions.**

Staff understood how and when to assess whether a service user had the capacity to make decisions about their care. Staff gained consent from women for their care and treatment in line with national legislation and guidance. The form referenced BMUS and the importance of attending NHS scans. The consent form was also available in other languages. The service also had access to a translation service.

Most staff (three out of four staff) had received training in the Mental Capacity Act to deal with people who lacked mental capacity. Staff were aware of women who may need support to make informed decisions and consent.

The service had a consent policy in place however it did not contain a review date. The policy made reference to a consent form but did not include it as part of the policy. The policy referenced the Mental Capacity Act and outlined a flowchart for assessing and gaining consent.

The service did not treat anyone under 18 years old and we saw the clinical manager check identification before carrying out scans.

## Is the service caring?

Good 

We have not previously inspected this service. We rated it as good.

## Compassionate care

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

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way.

## Diagnostic imaging

All 3 of the patients we spoke with said staff treated them well and with kindness. We witnessed staff members introduced themselves to customers and taking the time to explain what the scan would involve.

Staff understood and respected the personal, cultural and social needs of patients and how they may relate to care needs.

### Emotional support

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

Staff were able to provide service users with help, emotional support and advice when they needed it. Women felt staff were approachable and answered any questions they had.

Staff supported patients to maintain their privacy and dignity. Staff followed policy to keep patient care and treatment confidential. Women felt staff were very understanding and professional.

The service signposted a local charity that provided counselling and bereavement support.

### Understanding and involvement of women and those close to them

**Staff supported women, families and carers to understand their condition and make decisions about their care and treatment.**

Staff took the time to explain what the scan involved. Staff made sure women and those close to them understood what the scan involved.

Patients felt staff talked in a way that they could understand. Staff told us they had specialist support for patients who required communication aids; they told us they had access to translation services and a hearing loop.

All the patients we spoke to were positive about the service, they felt staff were friendly and appreciated the timeliness of booking appointments.

Women and their families could give feedback on the service.

## Is the service responsive?

Good 

We have not previously inspected this service. We rated it as good.

### Service delivery to meet the needs of local people

**The service planned and provided care in a way that met the needs of local people and the communities served.**

The service planned and provided services in a way that met the needs of local people. The service offered a choice of appointments to service users and could adapt the clinic opening times to meet demand.



# Diagnostic imaging

The clinic was located in Ashton-under-Lyne town centre and was easily accessible by public transport and by car. There were free parking facilities outside the premises.

The waiting area had comfortable and there was sufficient seating for women and their families and friends. There was a toilet available for customer and staff use that was regularly cleaned.

Managers ensured that women who did not attend appointments were contacted.

The service provided information about the different types of scans (2D,3D or 4D) on their clinic website.

The service only accepted telephone bookings and deposits were taken over the phone.

## Meeting people's individual needs

**Staff made reasonable adjustments to help women access services, however the service was not always inclusive of women's individual needs.**

The clinic was situated on two floors and was not wheelchair accessible. The clinical manager told us that any service users that had mobility issues could be referred to another service location situated in Manchester city centre but expressed they had not experienced this issue.

As part of the customer risk assessment the clinic routinely asked women whether they had any disabilities or additional needs that may affect their ability to receive an ultrasound scan.

The service signposted that chaperones were available for customers if needed.

The clinic had access to an interpreter service for those people who used the service that did not speak English as a first language. Information was available in different languages that were most prevalent in the local area and were available in an easy-read format.

Three out of four staff had undergone disability awareness training, as well as ADHD awareness and autism training.

The service made appointments sufficiently long enough for women and their families to ask any questions and to complete the consent form before their scan. They were advised to turn up 15 minutes before their appointment time to avoid any delays.

The service was aware of the needs of service users with hearing impairment, and they had a hearing loop on site.

Customers were given a choice of sweets and biscuits to eat while they waited and provided water if needed.

The ultrasound couch was not adjustable in height to support service users with mobility issues.

## Access and flow

**People could access the service when they needed it.**

The service was very flexible and offered an arrange of appointment times to meet the customer's demand. The service provided a choice of keepsakes to service users such as gender reveal balloons, cannons or teddy bears.

## Diagnostic imaging

Managers monitored waiting times, the service frequently monitored them, and we saw evidence of monthly audits. The results showed minimal delays to appointments, the clinical manager told us this is something they were constantly monitoring to maintain their high standards.

The service also offered rescan appointments for customers whose images could not be obtained at the first attempt. The service provided audits on the number of customers requiring rescans and tried to keep this at a minimum.

### Learning from complaints and concerns

**It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included customers in the investigation of their complaint.**

The service clearly displayed information about how to raise a concern or feedback in the waiting and reception areas.

The provider's website also included a section on how to make a complaint, the website also signposted the Information Commissioner's Office if customers wished to complain about the handling of data.

The service had a recent complaint regarding the temperature of the rooms. In response to this feedback the service introduced two heaters. The clinical manager told us feedback would be discussed at team meetings and managers closely monitored any feedback for themes and ways to improve.

The clinical manager told us that customers would receive an email after the scan asking them to provide feedback.

The complaints policy referenced steps management would take should they receive a complaint. Staff understood the policy on complaints and knew how to handle feedback.

The clinical manager shared with us a complaint they had received regarding the clinics temperature and how they introduced heaters based on that feedback.

The complaints policy was on display in the clinic, and we saw staff encouraging women to leave reviews. Women and their families could give feedback on the service and staff encouraged and supported them to do this.

However, complaints policy and information provided on the services website did not inform customers on how they could raise their concerns with the Independent Sector Complaints Adjudication Service (ISCAS) if they were not happy with the response they received from the service.

### Is the service well-led?

We have not previously inspected this service. We rated it as requires improvement.

# Diagnostic imaging

## Leadership

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

The clinical manager was supportive, visible, and approachable. Throughout the inspection, we saw them speaking with and supporting women.

Reception staff told us that they were happy to approach either manager with any concerns and that it was a good place to work.

The clinical manager was the lead technician and was appropriately skilled to perform the ultrasound scans. The clinical manager told us they were responsible for governance, monitoring customer feedback and conducting audits. The clinical manager also worked as the safeguarding lead and held a level 3 in safeguarding for adults.

The CQC registered manager acted as the information governance lead. The registered manager was also responsible for submitting statutory notifications, reviewing policies, stock management and providing the strategy for business growth. We saw evidence that he participated in monthly team and director team meetings. The registered manager told us he was looking to step back from the business but remain a director and that plans for the company involved the clinical manager to become a registered manager.

After the inspection we saw evidence that the clinical manager had put in an application to become the registered manager.

Staff told us they felt management were approachable and easily accessible and we saw evidence of regular staff appraisals.

## Vision and Strategy

**The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with relevant stakeholders. Leaders and staff understood and knew how to apply them and monitor progress.**

The clinical manager told us they wanted to increase the number of scans they were doing on a monthly basis.

The provider had an annual scan strategy that including aims for business sustainability and improvement. The strategy referenced monitoring and reviewing customer feedback to retain its position as a popular place in Manchester for customers to come to have their souvenir scans. The strategy laid out various business goals and set how they would achieve these targets. Goals included staying above 250 scans a month, putting the customer first and increasing the amount of positive feedback.

## Culture

**Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service had an open culture where women, their families and staff could raise concerns without fear.**

Staff enjoyed working for the company and felt comfortable to raise concerns if needed. Staff felt that both the clinical and registered manager were approachable. Managers promoted a positive culture that supported and valued staff.

The clinical manager spoke passionately about the service and the care they provided for women.

# Diagnostic imaging

The service had a whistleblowing policy in place and had a disability policy which included equality and diversity.

## Governance

**Leaders did not always operate effective and governance processes, throughout the service. However, staff had regular opportunities to meet, discuss and learn from the service.**

The registered manager was responsible for updating and reviewing the service policies. Most policies that we looked at during the inspection were up to date and have evidence of review dates. There were a few exceptions such as the COVID policy and consent policy.

The complaints policy referenced a different company name, this was corrected by the provider on post inspection, but we did notice the policy review date had not been updated. The chaperone policy referenced a staff member that did not work for the business, the provider made appropriate changes at post inspection to the policy but did not update the review date.

Ultrasound machine maintenance records were not held on site. The provider did not have a schedule or timetable system in place to monitor when the ultrasound machine services were due.

The service held monthly staff minutes and followed a formal structure. Minutes of meetings demonstrated topics such as, waiting times, BMUS updates, complaints and seasonal customer offers.

Performance was monitored through clinical audit and results were reviewed monthly by the clinical and registered manager during director meetings. The meetings were held monthly and included a range of topics; lease agreements, audit results, opening hours and any identified issues or risks.

Staff were clear about their roles and accountabilities and were keen to work together to continue to improve how they governed the service.

## Management of risk, issues and performance

**Leaders had systems in place to manage performance. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.**

The service provided an employer liability insurance certificate that was up to date.

The service had a lone workers policy in place at the time of this inspection, and we also saw evidence that lone working had been risk assessed.

The clinical manager told us the main risk for the business was competitors and remaining affordably competitive. These risks were documented on the provider risk register. Other risks included industry changed and technology improvements. All risks were scored according and included ways the provider could minimise the risks. The risk register did not include a review date for each individual risk however, the register was reviewed on an annual basis.

The clinical manager also told us they were prepared for any equipment breakdown and had a backup ultrasound machine along with other equipment such as scanners, projectors and printers.

## Information Management

**The service collected reliable data and analysed it to make decisions and improvements.**

# Diagnostic imaging

The clinic had an information records management and handling policy, but this made no mention of retention timescales and disposal of paper records and patient sensitive information. This presented a risk that patient information was being kept for longer than is necessary.

We were told that the images stored on the ultrasound scanner were wiped off after around 12 weeks, the clinical manager could not give exact timescales. The clinical manager told us customer consent forms and risk assessments were kept around six months. Customer records were stored in a secure box or at the registered manager's home address before being destroyed. This process or timeframes were not referenced in their information records management and handling policy.

The manager ensured paper and electronic records were destroyed safely when no longer required, however shredded confidential waste was not disposed of by a confidential waste contractor.

Full terms and conditions of the services and price packages were clearly defined on the company website.

The clinical manager told us no customer information was stored on any computers but assured us they had security back up provided by a third party, yet we saw no evidence of this.

The service conducted routine monthly audits to review waiting times. The clinical manager told us they would regularly review this data along with any customer feedback to improve client experience.

## Engagement

**Leaders and staff actively and openly engaged with women and staff to plan and manage services.**

The service had a public website which provided the public with information about what the service offered. The service used social media platforms to engage with new, existing and potential service users.

Customers were encouraged to provide feedback on their experience via social media, this was overly positive.

Staff meetings were held every month to discuss review, improve and share updates about the service.

## Learning, continuous improvement and innovation

**Staff were committed to continually improving services.**

The service was continually looking to stay competitive and ahead of the field. The service carried out regular audits and constantly monitored customer feedback to drive service improvements.

Staff engaged in regular meetings to discuss discrepancies and any recent complaints or feedback.

The clinical manager told us they were involved in an innovative technique which they called "6D scanning". A third-party company provided the software which enabled the service process and enhance scan images in terms of colouring and quality.

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	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The provider did not ensure equipment was maintained and serviced in accordance with manufacturer's guidelines.</p>

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>The provider did not ensure that their audit and governance systems were effective.</p> <p>The service did not review their policies for relevance to the service context and ensure review dates are appropriately identified.</p> <p>The service did not have a robust process for the safe storage, retention and disposal of records.</p> <p>The provider did not have processes in place to ensure that staff are suitably qualified, competent, skilled and experienced to provide a safe service</p>