Hey Baby 4d Manchester East Limited

Hey Baby 4D Manchester East Ltd

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Good
Are services safe?	Good
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

This was our first inspection of this clinic.

We rated it as good because:

The clinic had suitable facilities and equipment to meet the needs of women. Staff had trained in key skills and understood how to protect women from abuse. Staff were aware of risks and knew what to do in an emergency. The service had enough staff to care for women and records were stored safely and were up to date.

Staff followed up to date policies and ensured their treatment was evidence based. Staff monitored the effectiveness of care. Staff were competent in their roles. The team worked well together and with other services. Women were provided with advice regarding health promotion. Staff had training in supporting women to make informed decisions about their care and understood consent and mental capacity.

Staff treated women with compassion. They respected their privacy and dignity and provided emotional support to women and their loved ones.

The clinic met the needs of the local people, took in to account the women's individual needs and made it easy for women to provide feedback. Women could access appointments easily and adaptations were made if necessary.

The registered manager ran the service well. Staff felt supported and valued. Staff were clear about their roles and responsibilities. The registered manager was clear about her vision for the clinic, which was supported by staff.

However,

The registered manager did not always have clear oversight of the competency of the sonographers who were employed by the clinic. Sonographers did not have annual appraisals and did not undergo regular peer reviews. The provider did not always have effective quality assurance measures in place.

The clinic could improve on infection control as one cleaning product was found to be out of date, hand hygiene audits were not completed and the weekly deep clean completed by the registered manager was not documented.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good 	

Summary of findings

Contents

Summary of this inspection

Background to Hey Baby 4D Manchester East Ltd

Hey Baby 4D Manchester East Ltd is operated by Hey Baby 4D Manchester East Limited. It is part of the Hey Baby 4D franchise. The clinic provides private, non-diagnostic ultrasound services for the community of Stalybridge and other surrounding areas.

The service provides ultrasound scans, for women over the age of 18, for gender determination and reassurance purposes. Non-invasive prenatal tests (NIPT's) are available from 10 weeks, this test identifies chromosomal conditions, such as Down's Syndrome, as well as the probable sex of the baby. A "Sneak Peek Gender Test" is also offered that confirms the sex of the baby from as early as six weeks gestation.

Appointments include scan findings and images for keepsake purposes. When an anomaly is detected, women were referred to their local NHS early pregnancy assessment unit or maternity service.

The service registered with CQC in 2019. It is registered to carry on the regulated activity of diagnostic and screening procedures. The same registered manager has been in post since the service was registered.

This is the service's first inspection since they registered with the CQC.

How we carried out this inspection

We carried out this short notice announced inspection using our comprehensive methodology on 8 July 2022. The inspection team consisted of two CQC inspectors and an offsite inspection manager.

During the inspection visit, the inspection team:

Spoke with the registered manager, an administrative staff and a sonographer.

Spoke with three women and a woman's partner who used the service.

Observed three scans and a blood test.

Reviewed a range of policies, procedures, audit reports and other documents relating to 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.

Outstanding practice

We found the following outstanding practice:

Summary of this inspection

The clinic provided information packs to women when abnormal findings were discovered. The packs included leaflets for additional support services, useful websites, information about their referral to the hospital and a leaflet from a charity called Cradle who support women with early pregnancy loss. The clinic also provided overnight bags for women who were likely to be required to stay at the hospital.

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 registered manager must have a clear oversight of the sonographer's competency in their role. The sonographer's scan images must undergo regular clinical peer review. The sonographers must also have annual appraisals. (Regulation 17)

Action the service SHOULD take to improve:

The clinic should strengthen their Infection Prevention Control (IPC) practices and audits of this practice. Hand hygiene audits and deep cleans should be documented. Audits to monitor the expiry dates of products should be improved.

The clinic should consider having regular staff meetings with minuted outcomes to ensure that staff are kept up to date of any updates including shared learning.

Our findings

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Good

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

Mandatory training

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

The mandatory training was comprehensive and met the needs of women and staff.

Staff completed mandatory training such as infection control and fire safety, as well as other training which included LGBTQ+ and Preventing Radicalisation. Staff had training on recognising and responding to women who may not have capacity to consent to scans.

The registered manager monitored training compliance and updated staff when they needed to complete their training.

Records showed compliance with mandatory training was 100% and staff had protected time to complete this.

Safeguarding

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

The clinic had a safeguarding policy. Information about safeguarding adults and children, how to report a safeguarding incident, female genital mutilation (FGM) and mental health crisis were included within the policy.

Staff received training for their role on how to recognise and report abuse. All staff were trained to safeguard vulnerable adults and children. The registered manager and the sonographers had completed level three training and the administrative staff had received level two training.

Good

Diagnostic and screening services

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff provided us with appropriate examples of when they had identified safeguarding concerns and had made appropriate referrals to the local authority and the police.

Staff could give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act.

Staff understood their responsibilities if they identified women who had undergone FGM. Staff were familiar with the policy for FGM and had completed training on it.

Staff reported safeguarding incidents on to a safeguarding report log which were then reviewed by the registered manager.

The registered manager was the safeguarding lead. She had received additional training in relation to her role, for example she had recently completed a course in Honour Based Violence.

The registered manager and the administrative staff were chaperone trained. Chaperones were available for every scan and were a requirement for women having transvaginal scans.

The clinic displayed information regarding safeguarding from domestic abuse in the toilet. If women needed support, they could tear a tab off the poster and give it to a member of staff, this would indicate they needed help and staff would ensure that they were seen on a one-to-one basis. This reflected good practice as it meant women could discretely access important information and sensitive information could be obtained by staff in a safe way.

The clinic required all staff to have a Disclosure and Barring Service (DBS) check as part of their recruitment process. Seven files were reviewed, and all staff had their DBS check.

Cleanliness, infection control and hygiene

The service kept equipment and the premises visibly clean, however deep cleans of the clinic were not documented and hand hygiene audits were not completed.

Clinical areas were visibly clean and had suitable furnishings which were well-maintained.

There was an infection control policy in place and the registered manager was the infection control lead for the clinic. Records showed all staff had completed mandatory training in infection and prevention control.

The clinic had not reported any incidents of a healthcare acquired infection in the past 12 months.

The clinic had some COVID-19 measures in place. They had hand sanitising stations and gel throughout the clinic and safe wrap antiviral door handle stickers, which prevent bacterial transmission and are resistant to COVID-19. The clinic had continued to only book three women in one hour to avoid the clinic being too busy. Staff said that they would wear masks if women had a preference to do so. Posters which provided information to pregnant women who may contract COVID-19 were also visible in the waiting area.

There were adequate supplies of personal protective equipment (PPE) at the clinic such as masks and gloves.

Good

Diagnostic and screening services

Staff followed infection control principles including the use of PPE. All staff were bare below the elbow and the sonographer wore gloves and an apron when scanning women.

The clinic had hand washing facilities in the scan room, the kitchen and the toilet. World Health Organisation (WHO) hand hygiene guidance was posted above each sink to provide a visual guide to hand washing.

Reception staff cleaned the reception, waiting room, toilet and the kitchen on an hourly basis and recorded this.

Cleaning records for all rooms were up-to-date and demonstrated that all areas were cleaned regularly.

The sonographers were responsible for cleaning and decontaminating the ultrasound equipment. We observed staff using detergent wipes and chlorine-based disinfectant to clean and decontaminate surfaces and equipment that had come in to contact with the woman. The sonographer cleaned the transvaginal probes in line with British Medical Ultrasound Society (BMUS) and manufacturer guidelines. Sonographers completed a checklist when they cleaned a probe that had been used for a transvaginal scan.

The clinic only used non latex protectors for the internal probes to ensure that women with allergies to latex were safe.

A spill kit for cleaning up spills from bodily fluids was situated close to the treatment room.

There was a non-invasive prenatal test (NIPT) procedure in place outlining the steps to take when obtaining blood samples. The guidance cross referred to the service's IPC policy, outlining hand hygiene steps and the safe disposal of sharps and clinical waste to prevent and control the spread of infection.

Records showed all staff had completed mandatory training in hand hygiene and infection prevention and control training.

Although all staff had received hand hygiene training, hand hygiene audits were not completed. These audits ensure that high levels of infection control are maintained.

The clinic did not have a contract with an external company to carry out deep cleans of the clinic. The registered manager said that she carried out a deep clean every week, but this was not documented.

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 clinic had suitable facilities to meet the needs of women and their families. It was located across from a car park and was on the ground floor which assisted people with accessibility requirements. There was a reception area where women and families were greeted, a large waiting area with three wipeable couches, a scanning suite, toilet, storeroom and a staff kitchen. The kitchen was also used as a quiet room which women could access if they needed support from staff.

Good

Diagnostic and screening services

The clinic had enough suitable equipment to help them to safely care for women. The scanning suite was large and spacious. It contained an adjustable couch, the ultrasound machine, two seating areas for those accompanying the woman and two large television screens which had the scan images on them so that others could see the scan. Lighting around the scanning suite could be changed to blue or pink to reveal the gender of the baby for certain scans.

The clinic had appropriate facilities and equipment for taking blood samples for NIPTs and the "sneak a peek" procedures. There were clear instructions on the labelling and packaging of the blood sample kits. We observed that blood samples were securely kept in the storeroom in individual kits. The clinic had a sharps bin which they stored in the secure stock room when it was not in use.

The clinic had two privacy screens. One was in the scanning suite which provided women with privacy and dignity when they were required to change. The second was in the staff kitchen and quiet room to provide a space for women if they received bad news.

Staff carried out and recorded daily safety checks of specialist equipment, including the ultrasound machine. We observed records confirming that daily checks had been consistently completed.

The ultrasound machine was visibly well maintained and had been serviced in the last year.

All electrical equipment had been PAT tested. We saw evidence of PAT testing stickers on all the equipment.

The clinic had a contract in place for the removal of clinical waste. Staff disposed of clinical waste safely. Clinical waste was stored securely in locked clinical waste bins at the rear of the location which was collected by an external company twice a month.

Staff followed Control of Substances Hazardous to Health (COSHH) guidelines and COSHH substances were stored in the storeroom or locked cabinets. COSHH audits had been completed.

There were fire extinguishers, which had been serviced in the last 12 months, and there was a fire evacuation policy which the staff understood.

The clinic had a first aid kit which had medical equipment that was in date. Some of the staff were trained in first aid and knew how to use the first aid kit.

The registered manager had a property file which contained key documentation such as insurance and contracts with external companies.

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.

Women who booked their appointments online were encouraged to provide details of their pregnancy via an additional note section.

Women were asked to bring their pregnancy notes to the scan. The woman's medical notes enabled the sonographer access to her medical and obstetric history. We saw the sonographer asking for these to review when women attended their appointments.

The service did not have an exclusion or inclusion policy. However, all staff were aware that they did not offer scans to women under 18 years of age or those who had been scanned in the previous two weeks. Staff checked the age of women by checking their pregnancy notes or by asking for proof of identification.

Staff clearly explained to women the importance of attending all NHS scans and appointments. This was also clear on the informed consent form which asked women to tick if they understood that the scans carried out were supplementary to the NHS maternity pathway.

Staff knew how to deal with medical emergencies. Staff would alert the first aiders within the team and would make the appropriate referrals. Staff provided us with two examples in which they had made referrals to the early pregnancy unit (EPU) upon discovering abnormalities.

The clinic had a policy and clear guidance for sonographers to follow if they identified an abnormality or anomaly during the scan. Sonographers were able to tell us how they would inform the woman and how they would make a referral to the local EPU. The staff would contact the woman the week following their appointment with the EPU as part of after care.

Sonographers made referrals to NHS services on dedicated referral forms. We reviewed the clinics referral records and there had been 60 referrals to NHS services since January 2022.

Staff shared key information to keep women safe when handing over care to other services. Women were given a copy of their scan report to take to the appropriate health professional when referred due to a complication or abnormality.

Staff ensured that women who were having their blood taken had access to dressings and plasters. The blood was sealed in a plastic container and a bag which was then stored in a cardboard pack. This immediate action taken by the sonographer, trained in phlebotomy, prevented the risk of cross contamination.

Staffing

The clinic had enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care.

The clinic had enough staff to keep women safe. The registered manager employed four reception staff and five self-employed sonographers. The registered manager had comprehensive staff files with all appropriate checks completed. Such checks include professional indemnity insurance, evidence of qualifications and registration checks.

We observed that there were staff available to support women who required a chaperone.

The registered manager told us that the clinic was fully staffed but that she had advertisements out for sonographers to enhance staffing levels further.

The registered manager told us that the clinic had low sickness levels. She had ensured that staff continued to work in separate groups to reduce the risk of illness spreading.

Good

Diagnostic and screening services

The registered manager reviewed staffing daily. Staff were flexible to cover absences within the service.

The clinic had not had to cancel any appointments due to staffing shortages in the last 12 months preceding the inspection.

The clinic did not employ any agency or locum staff.

Reception staff had multiple roles such as working on reception, assisting in the ultrasound suite, booking appointments, supporting women who had received bad new and helping families choose and print scan images.

Records

Staff kept detailed records of women's care and diagnostic procedures. Records were clear, up to date, stored securely and easily available to staff.

Women's notes were comprehensive, and all staff could access them easily.

Sonographers gave every woman a report of their findings from the scan. We observed a woman having an early pregnancy scan, in which the sonographer completed a wellbeing report of the baby's position, as well as checks of the heart, brain and limbs.

Women's records such as consent and scan reports were stored on an electronic system which could be accessed by all staff. Consent forms were sent to women electronically prior to their scan. The clinic provided paper copies for women who did not have access to electronic copies. Paper copies of consent forms were stored in locked cabinets.

We reviewed five records. Scan reports were all complete, accurate and stored securely. The sonographer had documented the time, date, report and findings. Informed consent forms had been completed in all records.

Records were stored securely. Staff told us that customer files were stored for nine years.

Scan images were printed for the woman to take away. For some of the scans, images were emailed via a secure transfer.

The computer systems used by the clinic were password protected and changed when a member of staff left the clinic.

The ultrasound machine was not password protected. However, the scanning suite was locked when not in use and reception staff had continuous oversight of access to the room.

Medicines

The clinic did not store or administer any medicines to women.

Incidents

The clinic had systems and processes in place to manage safety incidents well. Staff recognised and reported incidents and near misses.

Good

Diagnostic and screening services

The clinic's "clinical governance policy" and "emergency and significant events policy" provided guidance for staff of the actions to take in the event of incidents occurring.

The policies stated all incidents, errors or issues must be logged on to the Clinical Governance and Quality Assurance Audit Form and provided examples of potential incidents that may occur. We reviewed the audit form on the day of the inspection and found that the registered manager had reported incidents appropriately and had included lessons learned.

Staff were aware of the incidents that had occurred in the last six months and the actions that had been taken. Staff told us that they would complete an incident log which would then be passed on to the registered manager. This process was in line with the clinical governance policy and emergency and significant events policy.

Staff learned of incidents via the staff communication log, the monthly updates that were provided by the registered manager and through discussions when working together.

The clinic had no never events recorded.

The clinic had a duty of candour policy in place. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify women of safety incidents and provide support to that person. The staff we spoke to were aware of the duty of candour.

The registered manager told us that if any further investigations were required, incident investigations would be referred to the director within the Hey Baby 4D franchise.

Are Diagnostic and screening services effective?

Inspected but not rated

We do not currently rate effective.

Evidence-based care and treatment

The clinic provided care and procedures based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of women subject to the Mental Health Act 1983.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance.

We reviewed all the clinics policies. Each policy had been produced in line with national guidance and had a renewal date.

The policies were all version controlled. The registered manager had introduced a document which provided the policy updates which staff were encouraged to read.

Staff told us that they could easily access the policies.

The Franchise updated the registered manager about updates to policies and procedures which she would then communicate with her staff.

Staff protected the rights of women subject to the Mental Health Act and followed the Code of Practice.

Sonographers employed by the clinic followed national guidance from the National Institute for Health Care and Excellence (NICE), The Foetal Anomaly Screening Programme (FASP) and the British Medical Ultrasound Society (BMUS). The registered manager received updates from these institutions and then shared with staff.

Sonographers ensured the lowest possible output of power was used when scanning, this is in line with the "as low as reasonably achievable" (ALARA) principle as recommended by BMUS. The clinic would not scan a woman longer than 10 minutes. Sonographer's who could not obtain a clear image encouraged women to go for a walk and return for a further scan to see if this adjusted the position of the foetus.

Sonographers used the "Paused and checked" practitioner checklist as issued by the Society of Radiographers and BMUS.

Patient outcomes

There were some systems and processes in place to monitor patient outcomes.

The registered manager and reception staff completed non-clinical audits in relation to five per cent of scans completed by the sonographer. We saw evidence of these audits which reviewed whether the sonographer followed certain procedures such as providing the woman with information about her right to stop the scan at any time.

The clinic did not participate in national audits due to the size of the service.

The clinic completed a rescan audit which documented the month and the amount of rescans completed.

The clinic had referred 60 women to NHS care providers since January due to potential concerns. We observed staff completing courtesy calls with women who had been referred to the hospital the week prior to check on their wellbeing.

The clinic obtained feedback through a variety of methods, mainly social media platforms and Google reviews.

Nutrition and Hydration

Staff provided information on hydration and healthy eating during pregnancy to women.

Due to the nature of the service provided, food and drink were not required or provided in the clinic. However, posters were displayed in the waiting room regarding hydration and health eating during pregnancy.

Pain Relief

Staff assessed and monitored women regularly to see if they were in pain during scans.

We observed the sonographer checking the woman's comfort during an examination.

Posters were displayed in the scanning suite which provided information regarding pain and the right to stop the scan at any time if the woman had discomfort.

Due to the nature of the service provided, pain relief was not required.

Competent staff

The clinic made sure that staff were qualified but did not always make sure staff remained competent in their roles. The manager completed appraisals for the administrative staff but not for the clinical staff.

Staff were experienced and qualified to meet the needs of women. The sonographers had the relevant qualifications and were all members of appropriate professional bodies.

All sonographers had received the correct training on how to use the ultrasound scanner and how to disinfect it.

All staff had completed an induction. Staff told us this included becoming familiar with the clinics policies and procedures through reading, electronic learning and shadowing other employees.

The registered manager made sure that staff had specialist training if their role required it. For example, we saw evidence that one of the sonographers was trained in phlebotomy (blood taking). This enabled the sonographer to take blood samples for NIPT's and "Sneak Peek" which provided women with the gender of the baby at an early stage in their pregnancy.

The registered manager identified any training needs their administrative staff had and gave them time and opportunities to develop their skills and knowledge. Staff told us that they had access to an additional electronic learning package that allowed them to do this.

The NIPT's procedural guidance provided staff with knowledge that they shared with women, including the benefits and limitations of this screening method.

Staff attended team meetings when they were held. We were provided with access to two team meeting minutes and all staff were documented as being in attendance.

The registered manager completed annual appraisals with the administrative staff. This provided an opportunity for staff to reflect on their strengths, weaknesses and consider goals for the coming year.

The registered manager did not complete annual appraisals with the sonographers. The manager told us that sonographers receive appraisals in their NHS roles.

Multidisciplinary working

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

We observed good teamwork between all colleagues during our inspection.

Good

Diagnostic and screening services

The clinic had established links with the local NHS trusts early pregnancy units to refer women when concerns were identified. Between January 2022 and the July 2022, 60 referrals had been made to a local NHS trust following abnormal results.

The staff provided recent examples of when they had successfully communicated with the local authority and the police when they had safeguarding concerns about women. This led to positive outcomes.

The clinic had a good working relationship with "Future Health" who provide the results from the blood tests for NIPTs. The registered manager had ensured that the process to track the NIPT's blood tests was in place, this included accurate labelling, tracking samples and results being emailed via an encrypted email.

Staff worked across some of the different franchises when required to care for women.

The registered managers across the franchises held monthly teleconference calls to share learning and ideas with each other.

Staff meetings were sometimes held with another franchise which allowed staff to interact with others and share learning and ideas.

Seven-day services

Services were available to support timely care to women.

Staff knew how to request support from local NHS services in the evening and at weekends. They explained having a good working relationship with some of the 24-hour services including the local NHS Hospital.

The clinic provided ultrasound scans every day. Evening appointments were available from Monday to Friday and daytime appointments were available at the weekend.

Health promotion

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

The clinic had relevant information promoting healthy lifestyles and support in the waiting room, the scanning suite and the toilet.

Staff assessed each patient's health at every appointment and provided support for any individual needs to live a healthier lifestyle.

The clinic had posters displayed which provided advice on physical activity, a healthy diet, sleep and the harms of smoking.

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.

Good

Diagnostic and screening services

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

Staff gained consent from women for their care and treatment in line with legislation and guidance. Women told us they had provided consent online when booking their appointment. Women who did not book online, were asked to provide their consent when they attended their appointment by signing a paper form provided by staff. Women who had transvaginal scans were required to provide consent again on a separate form.

Staff made sure women consented to treatment based on all the information available.

Staff clearly recorded consent in women's records. We reviewed five consent forms on the electronic system and found these were completed.

The phlebotomy trained sonographer ensured women understood the procedure for NIPT's and what the results could mean before they asked for the woman's consent.

Are Diagnostic and screening services caring?

Good

This was the first inspection for this service. We rated it as good.

Compassionate care

There was a strong, visible, person – centred culture. Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. These relationships were highly valued by staff and women who used the service.

We spoke to three women and a woman's partner who had used the service between May and June 2022. All the women were positive about the way that staff had treated them. One woman said that she did not feel like a customer but "more of a friend" whilst another woman said that the staff were "very welcoming" and made her feel as though she was the priority.

We observed staff welcoming women and loved ones with warmth and compassion.

The clinic had a wall dedicated to images of the scans and images of the child later in their development which parents/guardians had consented to. This showed that following using the service, women and their families were in contact with the staff due to their positive experiences of care.

We observed three scans and a blood test. The sonographer was discreet and responsive when caring for women. She took time to interact with women and those close to her in a respectful and considerate way.

During the scans we heard the sonographer and chaperone introduce themselves and explain the processes at each step. Staff asked the women and their loved ones if they had any questions and told the woman that she could stop at any time if she experienced any discomfort.

Good

Diagnostic and screening services

All staff had completed chaperone training. Chaperones were available on request and attended every transvaginal scan.

Staff followed policy to keep women's care and treatment confidential.

Staff understood and respected the individual needs of each patient and showed understanding and a non-judgmental attitude when caring for or discussing women with mental health needs.

Staff understood and respected the personal, cultural, social and religious needs of women 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 gave women and those close to them emotional support and advice when they needed it. We saw how staff provided reassurance and offered useful information to a woman who was experiencing anxiety in relation to her pregnancy.

We observed the sonographer providing reassurance during the scans.

One woman we contacted told us that she had attended for an early scan and had some anxiety about what would happen. When the scan revealed that the baby was fine, she became upset and said that the sonographer became emotional herself which she found to be caring.

The registered manager told us that they would offer women who were anxious the last appointment of the day if they felt that would help them.

Staff were able to talk us through the procedure when abnormal results or concerns were detected. The sonographer would inform the woman that they had concerns and explain that they would refer them to an NHS early pregnancy unit. The sonographer would inform the registered manager and make the referral.

Staff understood how to support women who became distressed in an open environment and helped them maintain their privacy and dignity.

Staff told us that when an abnormal finding had been detected during a scan or from a blood test, they would always contact the woman following their referral to additional services, to check how they were and to make sure that they had been followed up.

Women who have the NIPT's are contacted by the sonographer with their results and can be referred to a genetic counsellor.

Understanding and involvement of women and those close to them

Good

Diagnostic and screening services

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

Staff made sure women and those close to them understood their care and procedures. Staff talked with women and their loved ones in a way they could understand. We saw staff explaining the process and the images that had been taken to relatives, including children.

The sonographer talked throughout the scan about the position of the baby and the images from the scan in a way that was easy to understand for women and their families. Women, that we spoke with, said that they felt involved in their treatment and had their questions answered clearly.

Staff recognised that women and their loved ones needed to have access to, and links with, support networks and advocacy within their community and supported people to do this.

The clinic had a coloured light system around the room for gender reveals. During one scan, we saw staff engaging the woman and her family and encouraging the child to participate in the gender reveal.

Women having NIPTs had the tests explained to them, including what the results would mean. Women that received bad news were referred to other services for support.

Women and their families were encouraged to provide feedback about the clinic. Staff encouraged feedback during clinic visits, as well as phone call, email and social media posts. The website had a section which provided links to review sites. A feedback box was also situated in the waiting room.

We contacted three women and a woman's partner following their appointments by telephone and reviewed feedback that was provided online. From the previous 10 online reviews, nine scored five stars and from the previous 10 social media reviews, 10 were five stars. Comments included: "The clinic and staff are highly organised, clear and very confident in their roles. They felt trustworthy and reassuring" and "I felt really comfortable and relaxed throughout the scan, she really took the time to show me everything."

Are Diagnostic and screening services responsive?

Good

This was the first inspection for this service. We rated responsive 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.

Staff planned and organised services, so they met the changing needs of the local population. Opening hours were flexible to meet the needs of women's working patterns and hours.

Facilities and premises were appropriate for the services being delivered.

Good

Diagnostic and screening services

The clinic had a large waiting area, a scanning suite, a quiet room and a toilet. The clinic was close to a train station and had two large car parks opposite.

The clinic provided a range of scans to meet the stage of pregnancy.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women access services. They directed women to other services where necessary.

The clinic was located on the ground floor providing ease of access for all service users.

Women could book their appointment by using the website, contacting the service by telephone or via social media.

The website for the clinic, which was the main source of bookings, was available in different languages.

The examination couch was fully adjustable and able to accommodate bariatric women.

The toilet had a baby changing table which had free nappies and deodorants for women, family and friends.

Staff used an online interpretation programme for women whose first language was not English. The registered manager would like a more comprehensive and recognised interpretation service to be used and had raised this with the Franchise.

Staff made adaptations to their service to meet the needs of women and their loved ones. Staff provided an example, in which a woman with hearing loss had a scan. Staff used a text function on the scanning machine to explain the findings of the scan. The staff member also, with the woman's permission, placed her hands on the speaker of the scanning machine to feel the baby's heartbeat.

There was a small seating area in the staff room with a privacy screen where women could sit if they became distressed. Advice leaflets for Antenatal Results and Choices (ARC) and Cradle (A national pregnancy loss charity) were available in this area. Stress balls were provided to help lessen tension after receiving bad news.

The clinic provided packs to women when abnormal findings were discovered. The packs included leaflets for additional support services, useful websites, information about their referral to the hospital and a leaflet from a charity called Cradle who support women with early pregnancy loss. Overnight bags were also provided to women who were considered likely to be inpatients at the hospital.

Gender reveals were based on individual preference and discussed with women and their families prior to their appointment.

The clinic offered a range of baby keepsake and souvenir options which could be purchased at the time of booking or at the time of their scan. These included photographs and videos of their scans and heartbeat bears (the sound of a woman's unborn babies heartbeat placed inside the teddy bear).

Good

Diagnostic and screening services

Access and flow

People could access the service when they needed it. They received the right care and their results promptly.

Women were able to book their appointment by telephone or on the website at a time and date to suit them.

The registered manager told us that prior to the COVID-19 pandemic they booked four scans an hour. Since the pandemic, they have offered three scans an hour which has provided women with more time with the sonographer.

Women received 20 minutes per appointment. We observed three scans and in all of them the sonographer took the time to provide the women and families with information and time to ask any relevant questions.

Women that cancelled their appointments were offered the chance to re book for another day or time.

Women that did not receive a clear image of their unborn child were offered a rescan.

The registered manager did not routinely audit waiting times. The clinic that we observed did not have any women and families waiting. Women that we spoke to said that their appointments were timely.

The appointment structure meant that a rescan could take place quickly. If this was unachievable, the woman would be booked in at the earliest opportunity for a rescan.

Women that required an appointment at a busier time, such as a Saturday afternoon, could request to be placed on a waiting list if there were no appointments available at their desired time. The registered manager would ensure the next available appointment for their desired time and day would be offered to them. There was not a waiting list for appointments on the day that we attended.

Staff facilitated fast access to scan images and made these available to women immediately.

Staff supported women when they were referred or transferred between services. The sonographer completed the referral form and either them or the registered manager would contact the EPU to refer the woman.

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 women in the investigation of their complaint.

Women, relatives and carers knew how to complain or raise concerns. We spoke to three women and one family member who all knew how to complain or raise concerns if they needed to. They said that they would speak with the registered manager by telephone or in person.

The clinic clearly displayed information about how to raise a concern in patient areas.

Good

Diagnostic and screening services

The clinic had a policy for complaints. Staff understood the policy and knew how to handle them. If a complaint was raised, this was discussed with the registered manager who would update the clinical governance log sheet and look to resolve the complaint quickly.

The clinic is a member of "The Centre for Effective Dispute Resolution (CEDR) which is an independent non-profit organisation and a registered charity that provides expertise in relation to conflict resolution.

The registered manager and staff that we spoke to were aware of the last three complaints that had been raised and what actions had been taken to resolve the complaints. The registered manager reviewed the complaints and looked for themes which she would then address.

Are Diagnostic and screening services well-led?

Requires Improvement

We rated it as requires improvement.

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 women and staff. They supported staff to develop their skills and take on more senior roles.

The registered manager had been in the role since the clinic was registered in October 2019.

The registered manager and her husband were directors for the clinic. They reported to the franchise director and their account manager.

The registered manager demonstrated an awareness of the clinic's performance, limitations and the challenges it faced. They were also aware of actions needed to address such challenges. The registered manager said that the clinic's main operational challenge was the kitchen and quiet room being in the same room. They had plans to have a wall built in this room and were in consultation with the landlord of the property to do so.

Staff told us that the registered manager was approachable, supportive and effective in their role. Staff felt confident to raise their own ideas and concerns with the registered manager.

The clinic had a reception supervisor who would take the lead if the registered manager was not available.

The registered manager attended monthly teleconference calls with other registered managers from the Hey Baby 4D franchise to share ideas and challenges to feedback to their individual teams.

The Franchisor provided marketing and operational support, such as templates for documents and digital marketing services. The Franchisor had completed two audits to prepare them for a CQC visit. The audits covered the key lines of enquiry that the CQC review. The results were shared with the registered manager.

Good

Diagnostic and screening services

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. Leaders and staff understood and knew how to apply them and monitor progress.

The vision, strategy and values for the clinic were displayed on posters throughout the location. The staff, including the registered manager, wanted the clinic to be "fair," "family orientated", "fun" and "friendly."

The registered manager told us that the vision was to continue to provide excellent customer care, as well as trying to integrate further into the local community by 2024. She wanted to make links with local community parenting groups.

Culture

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

Throughout the inspection we saw a positive culture of teamwork and compassion. Staff told us that they were proud to work for the clinic and spoke positively about their registered manager.

We observed the staff, including the registered manager welcoming the women and their families as they arrived. Staff provided warmth and reassurance to women who needed it.

The clinic had an open culture in which women could share their fears and concerns. Staff told us how they supported women in situations like this.

Staff that we spoke with felt respected, supported and valued. They were confident that they could raise any concerns they had with their registered manager.

Staff felt their work was acknowledged by the registered manager. They told us that if a compliment was received this would be shared with them.

Staff felt they had opportunities to develop and grow in their roles. One member of staff told us that the registered manager was keen on providing the team with additional learning in line with their passions and experience.

There was a culture of promoting equality and diversity. The clinic staff had completed equality and diversity training and were familiar with the equality and diversity policy. Staff explained their awareness of diversity and how reasonable adjustments have been made to ensure they treat women with protected characteristics equally.

Governance

Leaders did not always operate effective governance processes. Staff did not always have regular opportunities to meet in a formal capacity to discuss and learn from the performance of the service. Staff at all levels were clear about their roles and accountabilities.

The policies and procedures were easily accessible to staff as they were available on the clinic intranet and the registered manager had created a folder with paper copies of them. Staff told us that the registered manager quizzes them on their knowledge of the policies and will focus on specific policies with additional training, for example recently staff have been encouraged to watch a video on FGM that the registered manager had sent them.

The clinic had a clinical governance log that was regularly updated which highlighted key issues and actions taken.

Staff were updated via a communication log which was accessed on their internal computer system. The log provided staff with the opportunity to share key updates with each other.

Staff job descriptions were clearly displayed in the policy folder. Staff were clear about their roles and responsibilities.

The registered manager told us that they had monthly bulletins that she emailed to her staff and discussed with them. The bulletins included an update on complaints and feedback, rescans, policy updates, health and safety updates, staff training and bookings for the previous month.

The franchise had completed two audits of the clinic in 2021 and 2022 in preparation for a CQC inspection.

The clinic completed their own audits such as maintenance audits and cleaning audits.

The clinic completed audits of rescans completed.

The Hey Baby 4D franchise had medical liability and indemnity insurance which covered all staff who worked for the organisation.

The team meetings were held infrequently with the last two being in January 2022 and October 2021. Although the team saw each other regularly and had other ways of sharing updates, regular team meetings would have provided a formal space to discuss the key issues faced and allow staff to share ideas in a professional environment.

The clinic did not have regular clinical peer reviews for image quality. The clinic could not be assured of the quality of images produced.

The registered manager and administrative staff completed nonclinical reviews of the sonographer's work which was documented. The reviews had not always been signed by the sonographer or registered manager. We did not see evidence of the information from these reviews being collated and lessons being learned from them.

Sonographers did not have supervision or annual appraisals within the clinic. We were told that the sonographers were supervised and appraised by the NHS, but we did not see anything on inspection that assured us that the clinic had oversight of this.

The clinic had a protocol for checking expiry dates; however, we found a cleaning product for the use of transvaginal ultrasound probes to be out of date by two months. When products pass their expiry date, their effectiveness may be reduced. The clinic requires a more robust system to ensure products do not reach their expiration date.

Management of risk, issues and performance

Good

Diagnostic and screening services

Leaders and teams identified and escalated risks and issues and identified actions to reduce their impact. They did not always use systems to manage performance effectively.

There was a lone working policy. The registered manager ensured that there is no lone working.

The registered manager had ensured that all administrative staff were trained to be a chaperone to ensure the safety of the woman and the sonographer.

The clinic had a business continuity and contingency plan in place, which outlined actions that staff would take if a major incident occurred. The clinic had valid insurance in place, including employer's liability insurance.

Referrals to other services, such as the NHS early pregnancy units, were also recorded.

The clinic did not have a risk register. Despite this, the service did carry out risk assessments such as fire and safety, COVID 19, Control of Substances Hazardous to Health (COSHH) and fit and proper persons. All the risk assessments we saw were in date and had been completed in the last 12 months.

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.

The clinic had policies for the storage of online records and images which the staff followed. Reports and scan images could be accessed from the computers in the clinic via a secure server.

All staff had completed mandatory training on information governance and were able to tell us how this applied in their work.

There were sufficient computer terminals in the clinic that all staff were able to access data and women's records.

Women were encouraged to bring their pregnancy notes to the appointment which meant that staff had access to relevant information about the pregnancy when completing a scan.

The registered manager was aware of how to notify the CQC when required and knew what situations required statutory notifications to be submitted.

The clinic had not experienced any security breaches since they had been registered.

Engagement

Leaders and staff actively and openly engaged with women, staff, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women.

Staff told us that the registered manager was available and involved in the day to day running of the clinic. Staff had regular engagement with the registered manager.

Good

Diagnostic and screening services

The clinic encouraged women and their family/friends to provide feedback about the clinic. The clinic also used their website and social media to review feedback from women.

The website provided various ways for women to contact staff to get information.

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.

The registered manager was interested in her staff developing professionally. Online training for personal and professional growth was offered.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider must ensure that they have systems in place to ensure all staff have annual appraisals and that clinical work is regularly peer reviewed to ensure staff are competent in their roles.