Hey Baby 4D Southend

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Good
Are services safe?	Good
Are services effective?	Not sufficient evidence to rate
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Overall summary

Hey Baby 4D Southend is operated by Hey Baby 4D South East Group Limited. The service provides diagnostic imaging for self-referring women through a range of ultrasound scan examinations during pregnancy. Ultrasound scan packages include early reassurance scans (from seven – 24 weeks), gender scans (from 16 weeks), growth and wellbeing scans (from 24 – 38 weeks) and 4D scan packages (from 24 -34 weeks). The service also offers non-invasive prenatal testing (NIPTS, a blood test taken during pregnancy to identify foetal chromosomal anomalies). Facilities include one ultrasound room, a waiting area, reception, staff area and a disabled toilet.

We inspected this service using our comprehensive inspection methodology. We carried an initial short notice announced inspection on 26 February 2019, along with an unannounced visit to the service on 7 March 2019.

Summary of findings

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

The main service provided was diagnostic and screening procedures.

Services we rate

This was the first time we have rated this service. We rated the service as **Good** overall.

We found good practice in relation to diagnostic imaging:

- The service used well maintained equipment and premises.
- Feedback was positive.
- Staff were seen to be kind, caring and compassionate.
- The service was located close to public transport and accessible to women and visitors.
- The service was responsive to the needs of the local population offering flexibility in choice for appointment times.

However, we also found areas of practice that require improvement in diagnostic imaging:

- The registered manager had a lack of oversight of mandatory training compliance and staff competencies for sonographers working at the service.
- Cleaning records for clinical and non-clinical areas had not been regularly completed.
- There was a lack of audit programme in place. Therefore, we could not gain assurances that the service was routinely monitored to ensure improvements were made.
- The safeguarding lead for the service had not completed level three safeguarding children training despite the service seeing women aged 16 to 17 years of age. There was no child safeguarding policy in place and the service was not registered to see women of this age.
- Patient confidential information was not always stored in a secure manner.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with four requirement notice(s) that affected diagnostic imaging. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good	Hey Baby 4D Southend is operated by Hey Baby 4D South East Group Limited. The service provides diagnostic imaging for self-referring women through a range of ultrasound scan examinations during pregnancy. Ultrasound scan packages include early reassurance scans (from seven – 24 weeks), gender scans (from 16 weeks), growth and wellbeing scans (from 24 – 38 weeks) and 4D scan packages (from 24 -34 weeks). The service also offers non-invasive prenatal testing (NIPTS, a blood test taken during pregnancy to identify foetal chromosomal anomalies). Facilities include one ultrasound room, a waiting area, reception, staff area and a disabled toilet. In diagnostic imaging, we found areas of good practice including: • The service had suitable premises and looked after them well. • The service had adequate staffing in place. • Staff understood how and when to assess whether a woman had capacity to make decisions about their care. • Staff cared for women with compassion. Feedback was positive. • The service mostly took account of individual women's need. • People could access the service when they needed it. However, we found the following areas for improvement: • There were no processes in place to ensure staff were up to date with mandatory training. • The safeguarding lead had not completed level three safeguarding adults and children training. There was no specific child safeguarding policy in place. • There were limited processes in place to ensure staff had the appropriate competencies to carry out their role. • The registered manager had not identified several risks the service faced.

Summary of findings

- There was a lack of managerial oversight in relation to infection prevention and control processes.
- There was a lack of effective processes in place to ensure that all staff had received a disclosure and barring service check.
- Confidential patient information was not always stored in a secure manner.

Summary of findings

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Good

Hey Baby 4d Southend

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Hey Baby 4D Southend

Hey Baby 4D Southend is operated by Hey Baby 4D South East Group Limited. The service was newly registered with the Care Quality Commission and opened in September 2018. It is a private ultrasound scanning service in Southend-on-Sea, Essex. The service primarily serves the communities of Southend-on-Sea and surrounding areas for women on a self-referral basis only.

The service offers:

- Early reassurance scanning (from seven – 24 weeks)
- Gender scan (from 16 weeks)
- Growth and wellbeing scan (from 24 – 28 weeks)
- Four-dimensional (4D) scan package (from 24 – 34 weeks)
- Non-invasive prenatal testing blood testing (a blood test to identify various conditions such as Down's Syndrome, Edward's and Patau's Syndromes and gender of the baby).

Appointments include scan findings and images for keepsake purposes. In the event of possible anomaly detection, women are referred to the local NHS early pregnancy assessment unit or maternity service, depending on the stage/gestation of pregnancy. The clinic was open between the hours of 9am to 2pm on Sundays, 4pm to 8pm on Tuesdays, 5pm to 8pm Thursdays and 9am to 2pm on Sundays.

The service has had a registered manager in post since September 2018.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a CQC assistant inspector. The inspection team was overseen by Fiona Allinson, Head of Hospital Inspection.

Information about Hey Baby 4D Southend

The service has one ultrasound scanning room and is registered to provide the following regulated activities:

• Diagnostic and screening procedures

During the inspection, we visited the service's location in Southend-on-Sea, Essex. We spoke with four members of staff including the registered manager, two sonographers and sonography assistant. We spoke with two women. During our inspection, we reviewed 23 sets of medical records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since registration with CQC.

Activity (22 September 2018 – 26 February 2019)

• In the reporting period 22 September 2018 to 26 February 2019, the service saw 518 women for ultrasounds examination and 15 women for non-invasive prenatal testing.

• All attendances at the service were on a private, self-funding basis.

Two sonographers, one sonography assistant and the registered manager worked at the service. There was no accountable officer for controlled drugs (CDs) in post as the service did not supply or administer medicines.

Track record on safety

- Zero Never events

- Zero clinical incidents

- No serious injuries

Summary of this inspection

- No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA),

- No incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)

- No incidences of hospital acquired Clostridium difficile (c.diff)

- No incidences of hospital acquired E-Coli

- Five complaints

Services provided at the hospital under service level agreement:

• Non-invasive prenatal testing (NIPTS).

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Good

We rated safe as **Good** because:

- The service had suitable premises and looked after them well.
- Staff completed and updated risk assessment for each woman. They kept clear records and referred anomalies to other NHS services where required.
- The service had adequate staffing in place.
- Staff kept detailed records of women's care and treatment. Records were clear, up-to-date and easily available to staff.

However:

- There were no systems or processes in place to ensure that staff (not directly employed by the service) had completed mandatory training at recommended intervals.
- There were limited systems in place for staff to seek guidance in the event of identifying or escalating a safeguarding concern.
- Cleaning check sheets were not regularly completed.

Are services effective?

Not sufficient evidence to rate

We do not currently rate effective, however we found:

- The service did not have effective systems and processes in place to ensure that staff were competent for their roles as the registered manager did not maintain oversight of training compliance and competencies for sonographers who worked at the service.
- There was a lack of clinical audit in place to allow the service to make improvements based on findings.

However, we also found:

- Policies and guidance were reviewed on a regular basis. Policies were well organised and accessible to staff within the service.
- Staff understood how and when to assess whether a woman had the capacity to make decisions about their care.

Are services caring?

Good

We rated caring as **Good** because:

- Staff told us they cared for women with compassion. Feedback from women confirmed that staff treated them well and with kindness.
- Staff provided emotional support to women to minimise their distress.

Summary of this inspection

- Staff involved women and those close to them in examinations and decisions about their care.

Are services responsive?

Good

We rated responsive as **Good** because:

- The service mostly took account of women's individual needs.
- The service planned and provided services in a way that met the needs of local people.
- People could access the service when they needed it. Due to the nature of service provided, there were no national recommended waiting times.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with staff.

Are services well-led?

Requires improvement

We rated well-led as **Requires improvement** because:

- There was limited processes and oversight in place to ensure staff had the appropriate competencies to carry out their role.
- The registered manager had not identified several risks the service faced.
- There was a lack of managerial oversight in relation to infection prevention and control processes.
- Confidential patient information was not always stored in a secure manner.

However, we also found:

- Staff described an open culture.
- The service provided a variety of methods to engage with women and visitors.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	N/A	Good	Good	Requires improvement	Good
Overall	Good	Not rated	Good	Good	Requires improvement	Good

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are diagnostic imaging services safe?

Good

We rated safe as **good.**

Mandatory training

- **There were no systems or processes in place to ensure that staff had completed mandatory training at recommended intervals.**
- Both sonographers working at the service held posts within NHS trusts. At the time of our inspection, the registered manager was unable to provide documentation to evidence sonographers compliance with mandatory training. Therefore, we were unable to gain assurances that staff had received the necessary training to safely and effectively carry out their role.
- Sonographers received basic life support training as part of their role at external NHS organisations. However, we were unable to verify dates of training completion as the service did not hold this information at the time of our inspection.
- After our inspection, the registered manager forwarded evidence that both sonographers had previously completed a variety of mandatory training courses including but not limited to; adults and child safeguarding, infection prevention and control and information governance. However, we could not gain assurances that there were effective systems and processes in place to maintain oversight of staffs' mandatory training outside of the service.
- For staff directly employed by the service, mandatory training was provided through an online system. The service relied on sonographers to complete mandatory training in their NHS roles.
- We reviewed training records for the sonography assistant and registered manager (the only staff directly employed by the service) and saw that they had completed mandatory training in several subjects including but not limited to; hand hygiene, infection control, recording information, person centred care and safeguarding adults within the last 12 months.

Safeguarding

- **There were limited systems in place for staff to seek guidance in the event of identifying or escalating a safeguarding concern. However, staff understood how to protect women from abuse and the service had systems and processes in place to work with other agencies if required.**
- We saw evidence that staff directly employed by the service had completed safeguarding adults level two training. However, there were no systems, processes or oversight in place to ensure that sonographers who worked at the service had received safeguarding training in their posts within the NHS.
- We could not gain assurances that all staff had received and were up to date with safeguarding adults and children training (sonographers) in line with national guidance. This was not in line with the national guidance which states that staff should have completed level two safeguarding children training. The service saw children aged 16 to 17 years as patients and adult women using the service did sometimes bring children with them to appointments.

Good

Diagnostic imaging

- After our inspection, the registered manager forwarded evidence that one sonographer had completed safeguarding adults level two and safeguarding children level two within recommended timeframes. For the additional sonographer, we saw evidence they had completed safeguarding adults level one and children level two within recommended timeframes. The registered manager acknowledged that he did not have evidence of safeguarding adults level two training for this member of staff and advised they would send this once received. However, after our inspection, he advised that the sonographer did not require safeguarding level two training in their other place of work. The registered manager advised they would send evidence of completed level two safeguarding adults training however at the time of publication we had not received this.
- The registered manager was the service's safeguarding lead and had been trained to level two safeguarding adults. There was no access to a level three safeguarding trained person within the service. We raised our concerns with the registered manager who advised they were due to complete a designated safeguarding officer (Level three Safeguarding) course. After our inspection, we saw evidence that the registered manager had completed a designated safeguarding officer (level three) training course on 14 March 2019.
- The service had accepted women aged 16 to 17 years. From 22 September 2018 to 26 February 2019, four women under 18 years of age had visited the service. There was no child safeguarding policy in place and the service's statement of purpose outlined the ages of patients eligible for examination and stated women aged 18 years of age and over. We raised our concerns at the time of inspection and the registered manager immediately suspended the service for those aged 16 to 17.
- The service had an adult safeguarding policy in place which had been reviewed in July 2018. The policy outlined various types of abuse including but not limited to; female genital mutilation (FGM), domestic violence and neglect. The policy provided clear guidance to staff on how to report and escalate any identified adult safeguarding concerns.
- The policy also referenced the local authority safeguarding adults guidelines (Southend, Essex and Thurrock (SET) Safeguarding Adults Guidelines, Version 4.3), and links to further information on how to raise safeguarding concerns relating to children (those under 18 years of age).
- Whilst the service's policy referred to safeguarding children, details were limited and focused more around children who may visit the service with relatives rather than as a patient aged 16 to 17 years.
- We spoke with two members of staff about their knowledge of safeguarding processes. Staff were clear on the potential signs of safeguarding concerns and how to appropriately escalate concerns when necessary.
- The service had a chaperone policy in place. Chaperone signage was displayed in the waiting room offering this service to women upon request.
- We reviewed the employee files and were unable to gain assurances that all staff had received a disclosure and barring service (DBS) check prior to commencement in post.
- We raised our concerns with the registered manager who advised he had carried out a DBS for the sonography assistant who was directly employed by the service. However, the service did not hold evidence of DBS checks for sonographers who worked at the service as they relied upon sonographers other roles within the NHS as assurance of DBS checks in place. In addition, one sonographer had been provided through an agency. The registered manager relied on this as assurance of DBS in place.
- After our inspection, the registered manager forwarded evidence of recent DBS checks for both sonographers and the sonography assistant who worked at the service. Both sonographers had new DBS checks carried out following our inspection and the registered manager also forward a previous DBS (2016) for one member of staff. However, at the time of our short notice announced inspection, there was a lack of systems and processes in place to maintain effective oversight of staff DBS records.

Cleanliness, infection control and hygiene

Good

Diagnostic imaging

- **The service had limited systems and processes in place to monitor compliance for infection prevention and control policy and practices.**
- All areas we inspected were visibly clean and free from clutter.
- Staff kept themselves, equipment and the premises clean. There were some control measures to prevent the spread of infection.
- The service had an infection prevention and control (IPC) policy in place. This provided guidance to staff on several IPC related processes including but not limited to; hand washing, equipment cleaning, blood taking procedures and needle stick injuries.
- Staff told us they completed daily, weekly and monthly cleaning tasks as per checklists. Our review of cleaning checklists showed that paperwork had not been completed on a regular basis.
- From December 2018 to 24 February 2019, there were six documented daily checks and four weekly checks for the scanning room area. We raised our concerns with the registered manager who advised that cleaning was carried out regularly, and this was a lack of documentation and oversight on their part.
- At our return unannounced visit on 7 March 2019, we requested to see completed cleaning checks for the previous week. Staff advised that all documentation relating to cleaning had been removed after our initial inspection on 26 February 2019. We raised our concerns with the registered manager who advised documentation had been removed to revise documentation. Whilst clinical and non-clinical areas appeared clean, there was no documentary evidence available to demonstrate that regular cleaning had taken place.
- There were no infection prevention and control audits in use such as clinical waste disposal or hand hygiene audits. Therefore, we could not gain assurances that there were effective systems and processes in place to oversee and monitor compliance with IPC best practice and policy.
- Alcohol hand gel was available at regular intervals throughout the service. Staff had access to personal protective equipment when carrying out ultrasound examinations or taking blood samples for non-invasive prenatal testing purposes.
- Staff told us that the ultrasound examination couch, probe and other equipment was cleaned after each woman in between scans using antibacterial wipes. We saw staff cleaning equipment during our inspection.
- Hand washing facilities were available in the ultrasound examination room. We saw staff washing their hands at regular intervals prior to and after patient examination.
- During our initial announced inspection, we saw that waste was generally handled and disposed of in a safe manner to help prevent and control the spread of infection.
- However, on our return unannounced visit on 7 March 2019, we found that the cupboard containing cleaning fluids and mop heads was locked. Staff could not access this equipment as they did not have keys held on site. Therefore, we were unable to gain assurances that effective cleaning could take place as staff could not access the necessary equipment.
- We also found used gloves and couch roll (used to cover the ultrasound bed) in a black domestic bin liner. We raised our concerns with the registered manager who advised with immediate effect, all used gloves would be placed within clinical waste bins.
- Chairs within the waiting area were wipe clean to ensure effective cleaning processes could take place.
- There was a set 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.

Environment and equipment

- **The service had suitable premises and looked after them well.**

Good

Diagnostic imaging

- The service was accessible to those with additional mobility needs. All clinical and non-clinical areas were located on the ground floor.
- The service consisted of a waiting area, ultrasound room, administrative area and toilet.
- All waiting areas had oversight from the reception desk meaning women and visitors were not left unattended at any time.
- The premises were well lit and clearly signed to indicate clinical and non-clinical areas.
- Both fire extinguishers had been recently serviced. Fire exit routes were clearly marked.
- There were effective systems in place to ensure that sonography equipment was maintained on a regular basis. We saw that equipment contracts were in date to cover equipment maintenance and failure.
- Clinical waste and sharps (needles) were stored correctly in colour coded bags. Sharps boxes were within safe fill limits to prevent and control the spread of infection and minimise the risk of needlestick injury. However, we noted one box had been assembled and was lacking an assembly date and signature. We raised our concerns to the registered manager on the day of our inspection.
- During our second inspection on 7 March 2019, despite raising this on the initial inspection, we saw that sharps box still lacked an assembly date and signature. We raised our concerns again with the registered manager who forwarded email confirmation that this had been completed after our return unannounced inspection.
- Equipment in the service had been safety tested and serviced in line with manufacturers recommendations, with future testing due in August 2019. Equipment maintenance and safety testing was carried out under a contract currently in place.
- Non-invasive prenatal testing (NIPT) kits came in individual packs, one per woman. The kit contained individual needles, a tourniquet (used to obtain blood samples through applying pressure on the arm) and vials for blood samples.
- The non-invasive prenatal test (NIPT) procedure provided clear instructions on the labelling, packaging and method of postage. In addition, the package was sent via recorded delivery to enable tracking.

Assessing and responding to patient risk

- **Staff completed and updated risk assessment for each woman. They kept clear records and referred anomalies to other NHS services where required.**
- Due to the nature of services provided, the service did not have an emergency resuscitation trolley.
- A first aid kit was in an accessible area within the service. Supplies were in date and well organised. The accident book was kept with the first aid kit to ensure accidents and injuries were recorded.
- The service had a document named 'emergency and significant event policy'. This document outlined key guidance for staff in the event of major emergencies (such as accident, fire) and action staff should take. Staff we spoke with were clear to call 999 in an emergency in the event of medical collapse of a patient.
- Informed consent documentation placed emphasis on the fact that 4D scans were elective and non-diagnostic. Wellbeing checks during the scan processes included the gestational age of the baby and various biometric measurements. Documentation clearly stated that any measurements taking during scanning did not supersede those made at NHS appointments. This information was also given to women verbally, prior to scanning taking place to ensure that women continued to attend regular care within the NHS which was provided for diagnostic purposes.
- There were clear systems and processes in place to refer women with any identified ultrasound anomalies or concerns (maternal or foetal) to the local NHS trust's early pregnancy assessment unit (EPAU) or maternity service.
- There was a referral policy to EPAU or the local maternity service in place. The policy placed emphasis on the importance of a plan of where the woman was to go and what to do next in the event of unexpected findings.

Good

Diagnostic imaging

- Referring clinicians completed a referral form for women to take to the local NHS trust EPAU or maternity service. We reviewed one medical record where onward referral was required. Referral had taken place in a timely manner, with a copy of the referral form held securely on the computer system within the service.
- Staff we spoke with were clear on referral processes to NHS services.
- The service's website made clear that all scanning procedures were for souvenir purposes only and not diagnostic.The service made clear to women the scans offered, should not be considered as a replacement for NHS care during pregnancy and encouraged women to attend NHS appointments to ensure medical needs during pregnancy were identified and met.
- Length of scan times were monitored to ensure that no scan exceeded 20 minutes. This was in line to maintain ultrasound exposure to the principle of ALARA (as low as reasonably achievable). The ALARA principle is used to ensure that excessive tissue heating does not occur during ultrasound examination. Doppler recordings of heartbeat sounds were limited to 20 seconds duration.

Sonographer and sonography assistant staffing

- **The service had adequate staffing in place.**
- The service was staffed by one full time sonography assistant (non-clinical) and two sonographers. Both sonographers worked for NHS trusts, one of which was employed for 16 hours a week, the other sonographer was self-employed and worked three hours per week at the service.
- In the event of staff illness, the registered manager told us that access to agency sonographers would be sought. In addition, there was also access to other sonographers within the Hey Baby 4D group. Since clinic opening, the service used an agency sonographer for two Saturday shifts when the clinic first opened in September 2018.

Records

- **Staff kept detailed records of women's care and treatment. Records were clear, up-to-date and easily available to staff.**
- Medical records were well organised, securely stored and accessible. Scan images were held electronically, informed consent documentation was stored for all women in a locked cabinet.
- We reviewed 23 medical records and saw that informed consent had been sought in all cases. Medical records detailed pertinent information including but not limited to; name, date of birth, estimated due date or date of last menstrual period.
- We reviewed a medical record with referral to the local NHS maternity service. We saw that adequate details on the concern were noted, and a copy of the referral had been stored electronically within the individual medical record.
- Wellbeing forms were given to all women where foetal measurements and other observations had taken place. The service did not hold a copy of wellbeing forms as ultrasound only produces a 'snapshot' at time of scanning. Any anomalies were documented at the bottom of consent documentation.
- The service's data protection policy, reviewed in July 2018 provided clear information and guidance on retention periods of medical records and scan images.
- At return unannounced visit on 7 March 2019, we found a black domestic bin liner on the floor in the staff room. The bag contained a printed list of women's names (confidential identifiable information) and reason for attendance/time slots (first name, last name). These findings were not in line with the Hey Baby 4D 'Data Protection' Policy which states: 'all sensitive/confidential information in the building relating to staff and customers should be filed away in lockable cabinets. Access to cabinets should be restricted to contracted employees only'.
- After our return unannounced visit, we raised our concerns with the registered manager (not on site at time of inspection). They advised that the lock had broken on the filing cabinet, and that a replacement

was now in place. In addition, a paper shredder had been purchased to ensure all patient identifiable and confidential information was shredded prior to disposal.

Medicines

- The service did not stock or administer medicines or contrast media for any scanning procedures. These were not required for the type of service offered.

Incidents

- **The service had systems and processes in place to manage patient safety incidents well.**
- The service had no reported clinical or non-clinical incidents from September 2018 to February 2019.
- The service had a policy named 'emergency and significant events' policy. The policy provided guidance for staff of the actions to take in the event of several situations including, but not limited to major emergencies, significant events, near misses and accidents.
- The policy stated that all significant events and near misses were to be entered on the 'quality assurance feedback monitoring form'. We reviewed this document on the day of inspection and saw that since clinic opening, only complaints were documented as there had been no clinical incidents reporting during this time frame.
- As there had been no clinical incidents at the time of our inspection, we were unable to see documentary evidence that patient safety incidents had been recorded, however, the quality assurance feedback monitoring form had specific areas to document actions taken, by who and mitigating steps taken to avoid reoccurrence of potential incidents.
- All staff we spoke with could describe examples of a potential incident and the subsequent action to be taken; staff told us they would report all incidents to the service's registered manager.
- The service 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 patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person. The policy provided guidance for staff on processes to follow in the event of notifying women about any mistakes in care.
- The registered manager described the meaning of the duty of candour and action they would take in event of the duty of candour being required.
- The registered manager advised that if further external investigation was required, for example in the event of a conflict of interest, incident investigation was referred to another director within the Hey Baby 4D franchise.

Are diagnostic imaging services effective?

We do not currently rate effective in diagnostic imaging.

Evidence-based care and treatment

- **The service had systems and processes in place to ensure policies and guidelines were reviewed, current and up-to-date.**
- Policies and guidance were reviewed on a regular basis. Policies were well organised and accessible to staff within the service.
- The service worked in accordance with the 'as low as reasonably achievable' (ALARA) principle. The ALARA principle is used to ensure that excessive tissue heating does not occur during ultrasound examination.
- The service's health and safety policy contained reference to ALARA and highlighted the risk of tissue heating with the use of doppler devices. A doppler device uses high-frequency sound waves to measure the amount of blood flow through arteries and veins and hence produces an audible 'heartbeat'.
- There were no audits carried out in relation to ultrasound scanning. This would have enabled the service to assess if image quality, anomaly identification and report quality were within acceptable limits and to seek service improvements. Image quality was overseen by the registered manager to ensure patient satisfaction of images which were provided for souvenir purposes only.

Good

Diagnostic imaging

Nutrition and hydration

- Due to the nature of service provided, food and drink were not required or provided in the service. However, women and visitors had access to fresh drinking water.

Pain relief

- Sonographers and the sonography assistant would check the woman's comfort during examination.
- Due to the nature of service provided, pain relief was not required.

Patient outcomes

- **There were some systems and processes in place to monitor patient outcomes.**
- The registered manager monitored the rate of detection of anomalies. Due to the nature of service provided, the service did not routinely monitor or learn of patient outcomes.
- The service did not participate in national audits due to the size of the service.
- The service sought feedback through a variety of methods including social media platforms and feedback through the service's website.

Competent staff

- **There was a lack of systems and processes in place to ensure that staff were competent in their role.**
- The service did not have effective systems and processes in place to ensure that staff were competent for their roles as the registered manager did not maintain oversight of training compliance and competencies for sonographers who worked at the service.
- Due to recent establishment of the service, staff were yet to complete an appraisal.
- We reviewed staff files for both sonographers employed to work at the service. Both staff members also worked at NHS organisations. We saw that staff had completed relevant qualifications in sonography. Of note, sonography is not recognised as a profession by the Health and Care Professions Council (HCPC) and therefore professional registration is not a requirement.
- Staff completed an induction which included familiarisation with the service and premise and a review of all policies in use. We saw from staff records that both sonographers had completed the policy checklist.
- We could not gain assurances that sonographers working at the service had completed relevant training in phlebotomy/venepuncture to enable them to take blood samples for non-invasive prenatal tests.
- We requested assurances after our inspection however, the registered manager was unable to provide assurances for one sonographer. In response to this, the registered manager arranged re-training and advised that they would not carry out non-invasive prenatal blood tests (NIPTs) until training was complete. In the interim, the other sonographer (a registered midwife) was instructed to carry out NIPTs.
- Staff were provided with non-invasive prenatal testing procedure guidance. This ensured that women were told the associated benefits and limitations of this screening method. This service (blood testing) was provided by a third party.
- The registered manager told us that in the future, there were developmental opportunities for the sonography assistant employed by the service. Development opportunities included a phlebotomy (blood taking) course and training to become a sonographer.

Multidisciplinary working

- **We found limited evidence of multidisciplinary working.**
- The registered manager and sonography staff had established a link with the local NHS early pregnancy assessment unit (EPAU) and maternity services to ensure referral in a timely manner.

Good

Diagnostic imaging

- The registered manager maintained oversight of the non-invasive prenatal testing service and processes were in place to track samples, through to receipt in the lab and subsequent results sent through an encrypted email.

Seven-day services

- **The service did not open every day however, staff worked to provide appointment flexibility to accommodate the needs of women.**
- The service opened Saturday 9am to 5pm, Sunday 9am to 2pm, Tuesday 4pm to 8pm and Thursday 5pm to 8pm. Opening times had recently been increased to meet demand.

Consent and Mental Capacity Act

- **Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.**
- All women were given a written consent form prior to examination. The consent form provided information including but not limited to; details on 4D scanning, information around wellbeing checks, what to expect during the scan and what factors could affect if the scan was successful.
- We reviewed 23 medical records and saw that informed consent had been sought and documented in all cases.
- Staff had access to a policy named 'informed consent and Mental Capacity Act (MCA) policy'. The policy was in date and had been regularly reviewed. The policy described capacity assessment, and action to take if a woman lacked capacity. In addition, it provided guidance for staff on the action to take in the event of any safeguarding concerns relating to the woman and their representative.
- After our inspection, the registered manager forwarded evidence that both sonographers had completed MCA training in their other places of work.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

- **Staff cared for women with compassion. Feedback from women confirmed that staff treated them well and with kindness.**
- Throughout the duration of our first day of inspection, we saw that staff greeted women and relatives in a warm and friendly manner, introducing themselves by name.
- A review of feedback showed women were positive about their experience at the service. Many reviews indicated that women had returned to the service for further scans at later stages in pregnancy.
- Feedback described staff as 'wonderful, friendly, helpful and nice'.
- We reviewed online feedback and saw that all reviews, since service opening were positive and described the staff as kind and caring.
- We spoke with one woman who described staff as kind and caring, polite and that they felt well informed about the scanning process.
- Another woman we spoke with described staff as 'kind' and that they had received enough information about the appointment/scanning process.
- The privacy and dignity of women was respected; all scanning took place in a private room. In addition, the waiting area had music playing to ensure conversations could not be overheard. All sensitive discussions took place in the private consultation room.
- Women recalled for non-invasive prenatal test results, or those who had received bad news were supported in the privacy of the examination room and staff told us they gave women as much time as possible to understand what they had been told.
- The service's website offered early reassurance scanning from seven weeks of pregnancy.

Good

Diagnostic imaging

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
- The service openly welcomed up to three additional people to accompany the woman for their scan. This enabled relatives and loved ones to provide support to the woman emotionally, if required.
- The service provided means of contact for women who had any queries relating to their scan or general scanning processes. Details were provided at the initial point of contact or through the service's public website and social media platforms.
- The service did not offer counselling services. All women who had identified anomalies with scan results were referred back to their local NHS trust early pregnancy unit or maternity service.
- Genetic counselling was provided by a third party in the event of receiving a positive non-invasive prenatal test result. The sonographer requested parental permission for their details to be passed to a genetic counsellor, who could explain more about what the results mean and advise them on the next steps to take.

Understanding and involvement of patients and those close to them

- **Staff involved women and those close to the in examinations and decisions about their care.**
- After initial consultations, the service held contact details for women requiring test results from non-invasive prenatal testing (NIPT) to enable feedback of blood test results though arrangement of a face to face consultation.
- Women were advised that they could contact the service at any point for further advice, if required.
- The service's website provided clear information around the costs of ultrasound scanning and non-invasive prenatal testing. For ultrasound scans, a £20 deposit was taken and the point of booking (either on the telephone or online) with balances being settled after the ultrasound appointment had been attended.

Are diagnostic imaging services responsive?

Good

We rated responsive as **good.**

Service delivery to meet the needs of local people

- **The service planned and provided services in a way that met the needs of local people.**
- The service offered a range of ultrasound scanning packages and non-invasive prenatal testing to women from seven weeks gestation (seven weeks of pregnancy).
- The premises and facilities were appropriate for the delivery of service.
- The service was located within a town centre and therefore offered a choice of access by public transport and car parking in the immediate vicinity.
- The service was bright, well lit, offered adequate seating and fresh drinking water to women and their relatives.

Meeting people's individual needs

- **The service mostly took account of patients' individual needs, however there was no access to translation services for women whose first language was not English.**
- The service provided private ultrasound scans and non-invasive prenatal blood tests to self-referring women only. The service did not complete imaging on behalf of the NHS.
- The service clearly advertised scanning package and non-invasive prenatal testing costs on its public website. In addition, staff were available to discuss various packages and costs at the point of booking, if over the telephone.
- The service's public website provided a range of information around various scanning packages and NIPT services that were offered. Information explained

that NIPT testing is not available through the NHS, and outlined the process of testing and how the test identifies various chromosomal abnormalities, as well as the gender of the baby.

- The service offered flexibility in appointments, providing both weekend and evening appointments. Where possible, short notice appointments were facilitated. The service recognised that pregnancy can be a worrying time, hence offering short notice appointments.
- The service did not have access to translation services. However, one member of staff described that they would use the internet to translate if a woman's first language was not English.
- During our return unannounced visit, we saw that a family member translated on behalf of a relative whose first language was not English. This is not considered best practice.
- Staff had access to a chaperone policy. The clinic displayed a poster offering chaperones, on request. In addition, all scans were carried out with an assistant sonographer present.
- Following feedback, appointment times had been amended to provide more time for women and improve the scanning experience therefore giving adequate time to ask any questions a woman may have.
- The premises were all located on ground floor level. There was appropriate access and disabled toilet facilities available.
- The service provided toys to visiting children for use within the waiting area.

Access and flow

- **People could access the service when they needed it. Due to the nature of service provided, there were no national recommended waiting times.**
- Access to the service was on a self-referral basis only. Appointments for early reassurance, gender, growth and wellbeing and 4D scanning packages were offered in a timely manner.
- The service performed carried out ultrasound scans on 518 women and 15 non-invasive prenatal tests from 22 September 2018 to 26 February 2019.
- Women were offered a variety of appointment times, providing flexibility to those who required an appointment outside of normal working hours and at weekends. Bookings were taken either through the website or over the telephone.
- The registered manager monitored how women had accessed the service, for example, through word of mouth, advertising, the internet or social media.
- Whilst the rate of women who 'did not attend' (DNA) were monitored, the service did not routinely call to ascertain the reason for non-attendance. This was because a pregnancy may have ended, and they did not wish to cause additional emotional distress.
- On the day of our inspection, we saw that all women were seen in a timely manner, at intended appointment times.
- We spoke with one woman who advised they were offered a next day appointment upon enquiring at the service. They felt that appointments were offered in a timely manner, at a convenient time which included evenings and weekends.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with staff.**
- The service had a complaints policy in place which had been reviewed in July 2018 (prior to service opening). This provided guidance to staff on processes to be followed in the event of a woman wishing to make a complaint.
- The service had received five complaints from 22 September 2018 (opening) to 26 February 2019. We reviewed all complaints and saw that the service had responded to complaints in a timely manner, and made changes to practice as a result of complaints. For example, the laboratory provider for non-invasive prenatal testing was changed to better meet the

expectations of women (relating to the timeframe for results delivery). Staff were aware of this complaint and could outline the change in service provider for non-invasive prenatal testing.

- The service received 49 compliments detailing positive feedback from 22 September 2018 to 19 November 2018.

Are diagnostic imaging services well-led?

Requires improvement

We rated it well-led **requires improvement.**

Leadership

- The service had a clear leadership structure in place.
- The registered manager was also the company director. The registered manager had been in post since service opening in September 2018.
- At the time of our inspection, the registered manager was in the process of completing a qualifications and credit framework level five in Health and Social Care and children and young people services.
- Sonographers and sonography assistant reported directly to the registered manager.
- During our inspection, we saw the registered manager maintained a visibility within the service, engaging regularly with clinical and non-clinical staff.
- Regular communication took place between the registered manager and staff. Due to the small number of staff in post, staff saw each other on a regular basis to discuss pertinent topics and issues affecting the service. In the event of the registered manager being off-site, staff could contact the registered manager by telephone, however there was no formal deputy in place.
- An example of poor communication was highlighted during our return unannounced visit. Staff did not have keys to the filing cabinet, were unaware it had broken, and experienced difficulties logging on to computer systems as passwords had been changed, without staff being informed.

Vision and strategy

- **Whilst the service did not have a formal vision place, staff demonstrated the service's values.**
- Staff were passionate about providing a positive and happy scanning experience at the service.
- The service's values were 'fun, family, fair and friendly'. The values focused on creating a positive experience for women whilst treating all with fairness and respect.
- The service had a set of fundamental standards which included person centred care, dignity and respect, consent and safety.
- On clinic opening in September 2018, the service initially offered appointments three days a week. To meet increasing demand, and grow the business slowly, a fourth day had been introduced in January 2019. In the future, the service would like to offer transvaginal scanning for early pregnancy (from six weeks gestation) and more opening hours, however at the time of our inspection, no implementation dates had been set.

Culture

- **The registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.**
- The service had a whistleblowing policy in place. We reviewed the policy and noted that it had been reviewed in July 2018.
- We spoke with two members of staff. Both described the culture within the service as open and told us the registered manager was supportive to staff.

Governance

- **There were limited systems and processes in place to maintain the overall governance of the service.**
- The service had a document named 'governance policy' in place. This document outlined the key responsibilities for various staff roles from a governance perspective including, but not limited to; the director, registered manager, sonographer/ ultrasound technician and receptionist. Clinical staff carried out their roles in accordance with this policy

however, the registered manager had limited systems and processes in place to ensure that policies were being adhered to and the quality of service was regularly monitored (lack of regular audit).

- An additional 'clinical governance policy' was in use. This policy detailed various processes in place to maintain high standards, record errors and identify ways to improve service provision. Processes included regular review of the clinical governance and quality assurance audit form, which was used to document errors including but not limited to; complaints, incorrect results provided from a non-invasive prenatal test or if the wrong gender of a baby was revealed.
- If required, franchise director support was provided at request of the registered manager/director.
- There was a lack of oversight and governance in relation to the identification and management of risks the service may face. For more information, please see the 'managing risks, issues and performance' section below.

Managing risks, issues and performance

- **The service had minimal systems in place to identify risk, plan to eliminate or reduce them, and cope with both the expected and unexpected.**
- The registered manager had not identified the need to ensure staff working at the service had completed the required mandatory training, skills (including blood taking) and competencies to carry out their role. In addition, there were no systems or processes in place to ensure that all staff working within the service had received disclosure and barring service (DBS) checks.
- There was a lack of oversight in relation to infection prevention and control processes. Cleaning schedule check sheets (from December 2018 to February 2019) were not completed when indicated on daily, weekly and monthly check sheets. In addition, there were no infection prevention and control (IPC) audits in use to ensure compliance with IPC standards outlined in the service's IPC policy.
- Risk within the service was monitored and overseen through use of a document named 'risk assessment'. We reviewed this document and saw it identified potential hazards, including but not limited to; infection, fire and ultrasound. The document clearly outlined the owner for each risk with action dates and area to indicate when actions were complete. However, we could not gain assurances this document was effectively monitored or overseen due to the identified issues with infection prevention control, lack of documentary evidence for disclosure and barring service checks and the lack of audits in use. These assessments were reviewed as part of governance processes within the service by the owner (and staff where applicable).
- There had been no reported clinical incidents since the service opened in September 2018. The registered manager had not received training in root cause analysis investigation. Root cause analysis training enables an individualto use quality improvement approaches to identify, understand and resolve any root causes of problems or incidents. In the event of a root cause analysis being required, or if investigative support was required, the registered manager advised they would contact the group franchise's director for support.
- At our return unannounced visit, we had still not received copies of DBS checks for all members of staff. The registered manager forwarded evidence of DBS checks after this time. In addition, we were unable to gain assurances that one sonographer working at the service had received the necessary training to safely carry out their role (blood taking, safeguarding adults level two, basic life support and mental capacity act training). In response to the highlighted concerns, the registered manager advised they had put training in place for blood taking, and that this member of staff would not carry out non-invasive prenatal blood tests until this was complete.
- The service had not identified that a lack of formal translation service could pose a risk to patients. This could have posed a risk to expectant mothers if anomaly findings were not communicated and understood correctly.

Managing information

- **The service collected, analysed, mostly managed and used information well to support all its activities, using secure electronic systems with security safeguards.**

Good

Diagnostic imaging

- There were clear systems and processes in place for managing information. The service's data protection policy, reviewed in July 2018 provided information and guidance on retention periods of medical records and scan images.
- Medical records were held on file for up to three years. Any scan images taken during consultation were retained for one year (with the exception of images where permission had been given to use these in marketing materials).
- At our initial short notice announced inspection, we saw that written consent forms were stored securely in locked drawers. However, at our return unannounced visit we found some patient identifiable information (patient first and last name and time/type of appointment details) in a black domestic waste bag. We raised our concerns with the registered manager who took steps to ensure this would not happen again.
- Non-invasive prenatal testing results were sent to the registered manager (from a third-party service) using encryption codes to ensure confidentiality.
- The service had secure processes in place to share information to women and other relevant healthcare professionals where required.
- The service had a public website in place to provide information for women on various scan packages and examinations offered.

Engagement

- The service welcomed women's and visitor feedback through a variety of methods. The website had a 'review your experience' option to submit feedback. In addition, social media enabled women to leave reviews of their experiences at the service.
- The registered manager explained that a lot of women were introduced to the service by either friends, family or social media platforms.
- Informal staff meetings took place on a regular basis. These were not formally minuted but notes from previous meetings showed discussion had taken place around topics including, but not limited to; infection prevention and training.

Learning, continuous improvement and innovation

- **The service improved services by learning from when things went well or wrong.**
- The service actively sought feedback and made changes as a result of feedback. For example, clinic opening hours had been amended to provide more appointment availability. In addition, the non-invasive prenatal testing laboratory provider had been amended following feedback regarding expectation for results time frames.
- The service had implemented a lighting system to enhance the gender reveal scan experience. The colour of pink, or blue, was revealed once the gender of the baby had been identified by the sonographer. This service was a choice given to women and not compulsory.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that they act in accordance with the registered Statement of Purpose.
- The provider must ensure that there are systems and processes in place to maintain effective oversight of risk, mandatory training completion, role competencies and disclosure and barring service checks.
- The service must ensure that clinical waste is stored in correct receptacles.
- The service must ensure that confidential personal information is stored in a secure manner.
- The service must ensure that there are established systems and processes in place to safeguard service users from abuse and improper treatment.

Action the provider SHOULD take to improve

- The provider should have systems and processes in place to maintain effective oversight of cleaning schedules for all clinical and non-clinical areas.
- The provider should consider having systems and processes in place to provide support and translation services to women whose first language is not English.
- The service should consider implementing systems or processes to ensure that women are only scanned after seven weeks of pregnancy.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment There was a lack of oversight in relation to staff's completion of mandatory training. The service was not effectively assessing, preventing and detecting the risk of infection. There was a lack of documented cleaning records, used gloves and tissues were stored in domestic waste bins and a sharps container lacked an assembly date and signature.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment The service had no access to a level three trained safeguarding individual for support. The service had no dedicated safeguarding children policy in place. We could not gain assurances that one member of staff had received the recommended safeguarding adults and children training.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance

This section is primarily information for the provider

Requirement notices

The service had limited systems and processes in place to oversee sonographers compliance with mandatory training and disclosure and barring service checks to ensure competence and suitability in role.

Consent documentation containing patient identifiable information was not securely stored.

The service had not recognised a number of risks that the service faced.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose The service was seeing women aged 16 to 17 years of age, which was outside of their conditions of registration. 12 - (2) The registered person must keep under review and where appropriate revise the statement of purpose. (3) the registered person must provide written details of any revision to the statement of purpose to the Commission within 28 days of any such revision.