

Taunton Road Medical Centre

Quality Report

12-14 Taunton Road Medical Centre
Bridgwater
Somerset
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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?

Are services caring?

Good 

Are services responsive?

Good 

Are services well-led?

Outstanding 

Summary of findings

Letter from the Chief Inspector of Hospitals

Taunton Road Medical Centre in Bridgwater, is operated by Somerset Early Scans Limited. They are based on the first floor in the GP surgery of the same name. This service provides obstetric ultrasound scanning for pregnant women from 18 years of age, scanning from six weeks of pregnancy to full term. They also provide non-invasive pre-natal test and women's health scans. The service is provided to self-funding women across Somerset.

The service provided the single specialty core service, diagnostic imaging. We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 25 July 2019.

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.

This was our first inspection of the service since the service opened in September 2014 and re-registered in 2016, this was due to change in their legal identity. We rated it as **Good** overall.

We found the following areas of good practice:

- A safe service was provided. Staff had the experience, qualifications and skills, and had completed mandatory training. They understood how to protect people from abuse and report incidents.
- The service had a suitable environment and equipment available. Staff knew how to reduce the risk of cross infection.
- Records of women's care and treatment were completed, and a clear referral pathway was available to refer on to other services if a scan identified a concern or anomaly.
- An effective service was delivered based on national guidance and an audit programme had been developed to monitor the outcomes for women. Staff followed mental capacity and consent legislation to make sure they were meeting the needs of the women who used the service.
- Staff received induction based on their needs and those of the service. This was to help make sure they were competent in their role and included checks of relevant registration with their professional bodies. All staff had a wealth of knowledge as they worked in similar fields in their other roles in the NHS.
- Staff worked with other healthcare providers when needed.
- A high level of care and support was provided within the service. Staff cared for women and their family/friends with compassion, kindness, dignity and respect.
- Staff explained in detail and in a language women and those close to them could understand about the scan and outcomes. Women and those close to them had time to ask questions and look at their report and were involved in any decision making required.
- Staff provided emotional support to women and their family/friends to help minimise their distress following upsetting news. They followed up with the women post scan to continue to offer emotional support and signpost them to other organisations that could also offer support and guidance.
- The service was responsive to the needs of women and their families/friends. Women were able to access an appointment when they needed it and information was provided online about the services offered.

Summary of findings

- Concerns and complaints were investigated, and the outcome fed back to those who had raised them. Lessons were learned and shared with all staff.
- The service was well-led with strong leadership and a positive culture was promoted and present among staff. The service engaged with women and their families/friends, and staff, to help plan and improve service provision.
- The provider monitored and reviewed service quality to safeguarded high standards of care. There were systems to identify risks and plans to eliminate or reduce them.

However, some areas needed further improvement:

- Evidence of Disclosure and Barring Service checks (DBS) were not always in place before staff started work.
- References for new staff did not always contain information about their conduct from senior staff from their last place of work .

Following our inspection, we told the provider they should make improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Dr Nigel Acheson

Deputy Chief Inspector of Hospitals, London and the South

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Good



Summary of each main service

- This is a diagnostic imaging service run by Somerset Early Scans Limited. The service is based in Bridgwater, Somerset. We rated the service as good because it was safe, caring and responsive. We rated well-led as outstanding. We do not rate effective for this type of service.

Summary of findings

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Good 

Taunton Road Medical Centre

Services we looked at

Diagnostic imaging.

Summary of this inspection

Background to Taunton Road Medical Centre

Taunton Road Medical Centre is operated by Somerset Early Scans Limited. The service opened in September 2014 and re-registered in 2016 due to change of legal entity. This service has not previously been inspected.

The service has had a registered manager in post since they first registered in 2014 and they remained with the service when they re-registered with us in 2016.

The service was registered to provide the regulated activity diagnostic and screening procedures at this location.

Our inspection team

The inspection was led by a CQC inspector. The inspection team was overseen by Mary Cridge, Head of Hospital Inspection for the South West.

Information about Taunton Road Medical Centre

Taunton Road Medical Centre is a small service, running clinics two to three times a week.

The clinic offers the following scans:

- Early scans from six to 12 weeks gestation
- Second and third trimester scans from 12 weeks to 42 weeks gestation.
- Second trimester viability scan

Other services offered include:

- Non-invasive prenatal testing
- Women's health scans
- Pre In vitro fertilisation (IVF) tests

The prenatal test is a type of non-invasive prenatal screening. It looks at fragments of the baby's DNA in the woman's blood to provide accurate information about the likelihood for the most common chromosomal conditions from as early as 10 weeks gestation.

All women accessing the service self-refer to the clinic and are private (self-funding) patients.

Facilities include a scan room containing one ultrasound machine and a waiting area.

In total there are five members of staff; two doctors (one is the registered manager), two nurse practitioners and an administration assistant who supports the team from another location.

During the inspection, we visited the clinic and spoke with two staff including the registered manager, and a nurse practitioner. We spoke with one patient and a relative. We also reviewed 10 sets of patient records, and relevant policies and documents.

We reviewed data submitted as part of the provider information request, data covered the period from November 2017 to October 2018. The provider also gave us their activity data from 1 November 2018 to 31 March 2019. For example, the number of appointments.

There were no special reviews or investigations ongoing by the CQC at any time during the 12 months before this inspection.

Activity between 1 November 2018 to 31 March 2019

Appointments - 172

Non-invasive prenatal screening (NIPT) appointments – 41

NIPT screening only – 30

NIPT screening plus scan – eight

Summary of this inspection

Track record on safety between 1 November 2018 to 31 March 2019

- No Never events
- No clinical incidents
- No serious injuries
- No incidences of hospital acquired infection

- No complaints

The provider had a Service Level Agreement with the Medical Practice they were based in for a number of services to include;

- Waste management
- Up keep of the room and waiting area

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?

We rated it as **Good** because:

The service made sure all staff had completed mandatory training in key skills. Staff had substantive posts within a similar field in the NHS and had undertaken mandatory training for these roles.

Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse, and they knew how to apply it.

The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

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

Staff identified and quickly acted upon patients at risk of deterioration.

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

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

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

Good



Are services effective?

We do not rate effective for this core service.

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

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

Summary of this inspection

The service made sure staff were competent for their roles. Managers appraised staff's work performance and provided them with support and development. Staff had a wealth of knowledge from their roles within the NHS to provide the best care to women and their families/friends.

The service was provided at times which were more suited to the service users.

The service gave patients practical support and advice to lead healthier lives. Their website provided women with advice and support about health related topics in pregnancy.

Staff worked together as a team to benefit women and their families/friends. Staff undertook clinics alone but could contact the registered manager for support as required.

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. They understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Health Act 2005.

Are services caring?

We rated it as **Good** because:

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

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

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

Good



Are services responsive?

We rated it as **Good** because:

The service was planned and provided in a way that met the needs of the women and their families/friends who would use the service.

The service took account of women and their families individual needs.

People could access the service when they needed it.

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.

Good



Summary of this inspection

Are services well-led?

We rated it as **Outstanding** because:

Leaders had the integrity, skills and abilities to run the service. They were compassionate and demonstrated the high levels of experience, capacity and capability needed to deliver excellent and sustainable service.

Leaders had a deep understanding of issues, challenges and priorities in their service. They were visible and approachable in the service for women and staff.

The service had a vision for what it wanted to achieve and workable plans to turn it into action.

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

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

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

The 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 service engaged well with women and their families and staff to plan and manage appropriate services.

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in local audits.

Outstanding







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	Outstanding 	Good
Overall	Good	N/A	Good	Good	Outstanding 	Good

Diagnostic imaging

Safe	Good 
Effective	
Caring	Good 
Responsive	Good 
Well-led	Outstanding 

Are diagnostic imaging services safe?

Good 

We rated it as **good**.

Mandatory training

- **The service made sure all staff had completed mandatory training in key skills.**
- Staff undertook mandatory training with this provider and with their substantive posts in the NHS. The registered manager had evidence of training undertaken in their NHS posts. All mandatory training topics were therefore covered, for example, child protection/safeguarding children, adult safeguarding, mental capacity assessment, and fire safety. Fire safety was also provided by the GP service where the provider was based to make sure all staff were aware of procedures in case of a fire. Non-invasive pre-natal screening training was provided by this service as part of their mandatory training.
- The registered manager had a training log of all staff as proof they were up to date. Staff confirmed they completed mandatory training during their quarterly staff meeting.

Safeguarding

- **Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse, and they knew how to apply it.**

- The registered manager was the lead for children and adults safeguarding and was trained to level three in safeguarding children. The service had not made any referrals to any safeguarding teams. A member of staff confirmed they knew how to make referrals.
- All staff received safeguarding training for children and adults to a minimum of level two.
- An adult safeguarding and child safeguarding policy was operated. This contained information how to make safeguarding referrals and where to. The policy also contained information on female genital mutilation (FGM). The policy did not include information on child exploitation. However, the registered manager said she would update this. Following the inspection, the registered manager sent us a copy of their updated policy where this had been added.
- As part of the recruitment procedure all new staff had to have a Disclosure and Barring Service (DBS) check. Enhanced DBS checks used for NHS employment were deemed to be acceptable. We checked the newest member of staff recruitment records. We saw that an application for a DBS had been made but the certificate number had not been recorded when it had been returned. The registered manager said she had seen a copy of this and would obtain the certificate number as a matter of urgency. Evidence of this was sent to us after the inspection.

Cleanliness, infection control and hygiene

Diagnostic imaging

- **The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.**

- There was an infection prevention and control (IPC) policy and procedure, which provided staff with guidance on appropriate IPC practice. All staff had received mandatory IPC training with this provider or as part of their NHS employment.
- The premises were kept clean to reduce the risk of infection, and cleaning schedules were used to monitor its completion. Daily cleaning of the room was completed by cleaning staff employed at the location, but the staff undertook cleaning of the equipment. We reviewed the completion of forms and these were up to date.
- During our inspection, we saw that clinic room and waiting areas were visibly clean. The infection control lead for the service was the registered manager. They made sure all the audits and cleaning schedules were up to date and any areas for action were undertaken.
- In the scan room good infection control practice was observed in line with the provider's policy. The nurse practitioner was observed to wash their hands between each scan to reduce the risk of cross contamination. The abdominal probe of the scan machine was cleaned after each use, using wipes provided, in line with best practice. For cleaning of the transvaginal probe, the nurse practitioner explained the process and cleaning agents used and how this was recorded for their audit. A specialist single use cover was used to cover the transvaginal probe before it was used, and these were disposed of in the clinical waste.
- We were shown the control of substances hazardous to health (COSHH) information sheet for the cleaning agent used for the trans vaginal probe. This provided staff with details on what to do if they split this on them or if it was ingested.
- The IPC policy stated that audits of the transvaginal probes took place three monthly to make sure they

had been cleaned as per manufacturer's guidance. For the timeframe November 2018 and March 2019, this was 100%. Audit of room cleanliness was also 100% for the same timeframe.

- Personal protective equipment, for example gloves, was available to staff.
- There had been no incidence of a healthcare acquired infection in the last 12 months.
- Staff were trained in taking and the management of blood as part of the NIPT screening. While we did not observe this in practice, a member of staff told us how they did this to reduce the risks of cross infection. For example, wearing gloves.

Environment and equipment

- **The design and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.**
- The clinic room used for scanning had curtains to promote privacy while the woman had to remove or alter their clothing. The door was also locked to prevent unauthorised access.
- The environment was suitable for taking blood as part of the NIPT testing. Staff had access to gloves and sharps bins for disposing of sharp instruments, such as needles. The samples were then sent by courier to the manufacturer for testing.
- Sharps bins were provided for the disposal of blood taking equipment. We saw the label on these had been completed to state when it had been first used. Staff told us once it reached the fill line it was closed securely and then disposed of.
- The ultrasound machine at the location had been purchased within the last 12 months; as such, the machine had not yet required an annual service. There was no service plan, but the registered manager said they had access to engineers who would come at short notice. The machine was also under warranty for any breakdowns.
- Quality assurance checks were completed on the ultrasound at the beginning of each session. This was recorded to confirm it had been done.

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- The registered manager told us they regularly checked stocks at the location, and we saw there was adequate storage facilities for consumables.
- Staff followed the fire instructions set out by the location. They had access to fire extinguishers and staff knew where the fire exits were, and they were clearly labelled.
- Clinical waste was disposed of correctly. We saw there were clinical waste bins within the scan room.
- First aid equipment was available within the location where the clinic was based. This also included a resuscitation trolley. We did not check this trolley as it was not the responsibility of this service. This was maintained and checked by staff from the GP surgery. Staff had all received training in basic life support and knew the procedure to follow if a woman collapsed.
- The service had access to latex free covers for the trans vaginal probe in case a woman was allergic to latex. Latex free gloves were also available.
- Portable appliance electrical testing had been completed and the registered manager said they had plans to rebook this when it was next due.

Assessing and responding to patient risk

- **Staff identified and quickly acted upon patients at risk of deterioration.**
 - The service only provided ultrasound scans to women over 18 years of age. The service did not offer emergency tests or treatment.
 - Written and verbal information was given to women who used the service which was clear as to the limits of diagnostic services provided. For example, women had to declare that they understood that scans were not exhaustive and that staff at the service could not confirm possible anomalies; but would refer them to NHS antenatal care providers. There was a pathway for staff to follow if they identified any abnormalities on a scan.
 - If the results given to women who had non-invasive prenatal testing (NIPT) identified they had some risks to their baby staff followed the procedure for referral on to other services in the NHS.
- Best practice guidelines were followed. For example, scans were conducted according to British Medical Ultrasound Society (BMUS) recommendations for ‘as low as reasonably achievable’ (ALARA) principles for safety in ultrasound scanning; for length of scan and frequency of ultrasound waves. The service’s website contained a blog about, “are ultrasound scans safe”. Public Health England (PHE) guidance advises that although there is no clear evidence that ultrasound scans are harmful to the fetus, parents-to-be must decide for themselves if they wish to have ultrasound scans. This is alongside balancing the benefits against the possibility of unconfirmed risks to the unborn child. Staff confirmed they discussed with the women and their family/relatives the use of the scan and its limitations.
 - Staff were trained in basic life support and as they were based in a GP practice, they were able to call for urgent assistance from the duty doctor. An alarm button was in the room to summon help. Staff said they were able to manage women who felt faint but would call for medical support if needed. All staff were either qualified nurses or doctors and were able to identify and determine if a woman needed additional medical support for example, by calling for an ambulance.
 - Staff had access to policies and procedure for the management of unwell women for example, ectopic pregnancy and non-viable pregnancies. They also knew where they needed to refer these women on to for additional treatment.
 - Women were advised and encouraged to continue with their NHS scans and appointments as part of their maternity pathway.
 - There had been no patients transferred from the service to another health care provider in the last 12 months due to an emergency.

Staffing

- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.**
- All staff had the skills, training and knowledge to meet the needs of this service. The registered manager and

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service owner was a qualified GP who also worked within the maternity services for an NHS trust. The two nurse practitioners also had substantive posts within the NHS working in similar roles which included the use of ultrasound. The other member of staff was an obstetrics and gynaecology consultant who also worked in the NHS.

- The service was fully staffed and there were no staffing vacancies. All staff worked on a part time basis with the registered manager covering where needed.
- The two nurse practitioners were registered with the Nursing and Midwifery Council and had additional skills in ultrasound scanning.
- The service had not used any agency or bank staff as they covered all holiday/sickness with their existing staff. There was a process to follow if bank or agency staff were needed to cover any clinics. For example, the registered manager would contact the most appropriate agency to meet the needs of their service.
- Each member of staff covered set clinics each week therefore they did not need any rotas.
- While staff were alone in the clinic room there was always staff available in the GP surgery so there were no risks associated with lone working. This meant that if a woman became unwell staff were able to summon help from the GP surgery if required.
- All staff received a local induction and we saw records to demonstrate this. This included an induction to the service, equipment and environment.

Records

- **Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.**
- All records were held securely within the clinic. The scanning machine was password protected. Records were kept for each woman who attended for a scan, and they were also given a copy to keep. Enough information was obtained and recorded prior to the scan, for example pregnancy history and health, and following the scan the information about the woman and the baby. We observed six sets of these records and all were completed in full.

- Records were also kept of non-invasive prenatal screening which included a set proforma which was filled in at the appointment, along with a form for recording the woman's consent. We saw four sets of these records and copies of the consent form. One set of records showed how a woman was referred onto NHS services following their results.
- In the event an anomaly was identified, the patient was referred to their local NHS service and there was a pathway to do this. In all cases the woman was advised to take the report, with them. The pathway commenced with a verbal referral handover to both the NHS services and the woman's GP as required.
- The service had an up to date information governance policy and a data retention policy.
- The registered manager was the information governance lead for the service and all staff had completed information governance training.

Medicines

The service did not store or administer any medicines.

Incidents

- **The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.**
- We saw reports and investigations for events that had taken place. All had evidence of investigations and actions taken to prevent it from happening again. Findings were shared at quarterly staff meetings or before if required
- There had been no Ionising Radiation Medical Exposure Regulations (IRMER) reportable incidents in the last 12 months prior to our inspection date.
- There had been no serious incidents reported in the last 12 months prior to our inspection date.
- 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

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incidents' and provider reasonable support to that person. No duty of candour notifications were required to be made in the last 12 months prior to our inspection date.

- The registered manager was aware of the requirements for reporting incidents and submitting notifications to the Care Quality Commission. However, this had not been required.

Are diagnostic imaging services effective?

We do not rate effective for this core service.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.**
 - Staff has access to policies and procedures, which were stored in the clinic room. These had been devised by the registered manager and were in line with current legislation and national evidence-based guidance from professional organisations. For example, the National Institute for Health and Care Excellence (NICE) on miscarriage NG126 and the British Medical Ultrasound Society (BMUS).
 - All policies and protocols we reviewed contained a next renewal date, which ensured they were reviewed by the registered manager in a timely manner.
 - The service followed the ALARA (as low as reasonably achievable) principles, outlined in the 'Guidelines for professional ultrasound practice, 2017' by the Society of Radiographers and BMUS. This meant that staff used minimum frequency levels for a minimum amount of time to achieve the best result.
 - Updates on national guidance were shared with staff at their quarterly staff meetings.
 - The service had a wealth of experience and knowledge among its staff as they all had substantive posts working in the NHS in same field. This also enabled the staff to remain up to date with the latest research and guidance.

- There was an effective audit programme that provided assurance about the quality and safety of the service. Audits were undertaken regularly; for example, cleanliness, consent and equipment. Other audits based on the current guidance included, checking that adnexa were seen during the scan (the adnexa means the parts adjoining an organ) and Non-Invasive Prenatal Testing (NIPT).

Nutrition and hydration

- To improve the quality of the ultrasound image, women were asked to drink extra fluids on the lead up to their appointment. Women who were having scans were encouraged to attend their appointment with a full bladder. This was dependent on whether it was abdominal or trans vaginal.
- Due to the nature of the service, food and drink was not offered to women. However, Staff told us they were able to obtain drinks for women if they felt unwell during the scan.

Pain relief

- Pain was not formerly monitored, as this was not required for the service provision. However, we observed a member of staff asking a woman during the scan if they were comfortable and to say if they were not. Staff told us this was especially important during trans vaginal scans.

Patient outcomes

- **Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.**
 - The registered manager had overall responsibility for governance and quality monitoring.
 - The number of scans completed, number referrals and other data were recorded. This was then reviewed and monitored as part of each quarterly quality assurance report. This was used by the service but not checked against any peers.
- The latest audit of scans was in March 2019 for checking the adnexa. It was important to examine the adnexa during the ultrasound to identify if there was any

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ovarian cysts or pathology that could endanger the pregnancy. Results were seen of this and in 90% of scans (18 out of 20) staff had identified the adnexa. The plan was to re-audit later in the year.

- NIPT, sometimes called non-invasive prenatal screening (NIPS), is a method of determining the risk the fetus will be born with certain genetic abnormalities. This testing analyzes small fragments of DNA that are circulating in a pregnant woman's blood. Unlike most DNA, which is found inside a cell's nucleus, these fragments are free-floating and not within cells, and so are called cell-free DNA (cfDNA). These small fragments usually contain fewer than 200 DNA building blocks (base pairs) and arise when cells die off and get broken down and their contents including DNA, are released into the bloodstream. An audit for NIPT tests between July 2018 to December 2018 was undertaken to make sure staff were meeting the standard set by the manufacturer of the specific test they used. This related to the redraw rate, which was a standard set at 3%. (Redraw rate means they were not able to get a test result). Results showed the service were at zero percent, which was better than the standard set. Previous-audit results had shown a higher than national redraw rate, but this had much improved.
- Staff were fully qualified in identifying an anomaly and understood how to conduct a referral to the NHS. There were clear pathways to do this.
- All referrals to the NHS were recorded as part of their quarterly quality assurance reports. However, there was no arrangements for communication from the NHS on the outcome of these, due to patient confidentiality and data protection regulations.
- We saw the service activity, audit results and patient feedback were discussed at the quarterly team meetings.

Competent staff

- **The service made sure staff were competent for their roles. Managers appraised staff's work performance and provided them with support and development.**
- All staff had the knowledge, skills and experience to demonstrate they were competent in their roles. All

staff had substantive posts in the NHS working in the similar roles and had additional qualifications in the use of ultrasound and could recognise any abnormalities on the scans.

- We reviewed the staff records for the newest member of staff. We saw they had completed a local induction. All staff could access training through the provider or via their substantive posts with the NHS. Some training was specific to this service for example, NIPT. Training records were maintained by the registered manager.

We viewed the staff records of the newest member of staff. We saw they contained for example, evidence of a curriculum vitae, proof of their professional qualification, picture identification (used on their website), an employment contract, and Disclosure and Barring Service (DBS) check. The service had obtained references. However, these were from peers who worked with this person at this service and in the NHS and did not reflect the views of their employers. The registered manager said they would obtain information about their professional conduct from their employer for this member of staff. This was obtained and contained no information of concern. We were sent a copy of this following our inspection.

- Information provided by the service showed there was a 100% appraisal compliance rate for their staff, except the newest member as they had only been in post since April this year.
- There were processes to confirm clinical staff were fully qualified. The registered manager checked the two nurse practitioners were registered with the Nursing and Midwifery Council and was aware when they were due for revalidation. This was also the same for the qualified doctor.
- The registered manager periodically undertook observations on staff prior to their appraisals to make sure they were competent in their roles.

Multidisciplinary working

- **Staff worked together as a team to benefit women and their families/friends.**

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- We were not able to observe the team working together as each member of staff managed each clinic alone. However, staff told us they maintained communication between each other and reported to the registered manager at the end of each clinic.
- There were clear pathways to refer women to the local NHS trusts. Some of the staff knew the teams they were referring to as they also worked for the same NHS trust.
- The registered manager was a GP in the local area and said the other GPs were readily accessible to refer women to hospital if required. The clinic spoke of a good working relationship to meet the needs of the women.

Seven-day services

- **The service was provided at times which were more suited to the service users.**
- The service was provided on two days one week and three days the following week. This included some early evening appointments. Other clinics could be arranged if demand was high.

Health promotion

- **The service gave patients practical support and advice to lead healthier lives.**
- The service offered women patient information leaflets which detailed information about keeping healthy during pregnancy. The registered manager said they always made sure at the scan that women were taking folic acid as it is very important for the development of the fetus.
- The service website had a blog where staff members wrote about topics which could be accessed by women and their families/friends. For example, diabetes in pregnancy, healthy eating in pregnancy, physical activity and this included about women monitoring their weight.

Consent and Mental Capacity Act

- **Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. They understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Health Act 2005.**

- Women could access the terms and conditions for ultra sound scans via the providers website. When women attended for scanning they were verbally told about the risks and then asked if they wished to continue with the scan. Information about the risks of ultrasound were also found on the service website.
- Consent was obtained from women about sharing the results of their scans with health care professionals for example, their GP and the maternity services if they identified any abnormalities. The reasons for referral was explained as part of their appointment.
- Women undergoing non-invasive prenatal testing had to sign a consent form at their appointment and complete a checklist with a member of staff. We saw a number of these signed by women who had undergone this testing.
- Staff had either completed training in relation to consent, and the Mental Capacity Act (2005), as part of their mandatory training programme with this provider or as part of their NHS substantive post.
- At the time of our inspection the service only saw women over the age of 18 years, but the registered manager was reviewing whether they would offer this service to 16-18-year olds.
- A policy for consent was in place to provide staff with advice and guidance. It also mentioned the procedure for staff to take if they felt a woman had impaired mental capacity. For example, contacting the registered manager for advice.

Are diagnostic imaging services caring?

Good 

We rated caring as **good**.

Compassionate care

- **Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.**
- The scan room enabled women and their relative/friend privacy and dignity. The door was locked to

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prevent anyone from walking in during the scan. We observed a staff member who was very warm, kind and welcoming when they interacted with a woman and their relative.

- Patients and their companions were also able to leave feedback on open social media platforms, which the registered manager said they frequently monitored. We reviewed a selection of reviews; the service had been rated as 'excellent' by 94% of those who had left feedback. All feedback was very positive for example, "the member of staff was brilliant, she explained everything clearly to us and didn't rush, we could ask lots of questions", "the staff member was very efficient and reassuring during the appointment, I would highly recommend this service" and words used in other feedback included "very professional, honest, personal and caring".
- During our inspection, we observed a woman and their relative. They were very grateful for how the member of staff had provided the service as they were very anxious about the outcome of the scan.

Emotional support

- **Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.**
- Staff showed empathy and a constant high standard of care. All staff worked in a similar field in the NHS and all had experience of breaking bad news and providing emotional support to women and their relatives/friends who may have been present with the woman.
- During our inspection while we did not observe this, a member of staff told us they had to break bad news to a woman who had a non-viable pregnancy. The woman had support from a relative and was prepared for bad news prior to this scan due to previous feedback from another provider. The member of staff offered emotional support and guidance and did not rush the appointment, so they had time to ask any questions. They also gave the woman advice on what and where they needed to go next. Staff followed up women by telephone to offer ongoing support and advice.

- The registered manager sent us feedback from a woman who they had to break bad news to following their scan. The feedback was extremely positive with the woman and their partner expressing the staff went "way beyond their responsibilities". They felt the staff were very professional and kind when delivering bad news.
- Women were offered contact details for other services to include charities who could offer support and advice to them. For example, the Miscarriage Association and Ante-Natal Results and Choices (ARC). This is a national charity helping parents and health care professionals through antenatal screening and its consequences.

Understanding and involvement of patients and those close to them

- **Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.**
- We observed information being clearly communicated to a woman and their relative by the member of staff completing the scan. They allowed plenty of time for them to ask questions. They clearly explained the scan findings to them and what they were seeing on the scan. The report and pictures were also explained in detail and the woman and their relative were able to choose the scan pictures.
- Staff also explained about the differences between abdominal and trans vaginal scans and when each would be used. For example, depending on the number of weeks the woman is pregnant meant sometimes they needed to use a trans vaginal scan which would mean an empty bladder. Staff also made sure women had a full bladder for abdominal scans to enhance the scan quality.
- We observed, and staff told us they adapted the language and terminology they used when discussing the procedure to the needs of individual women and their companions.
- Information about the cost, terms and conditions and services available were on the provider's website. The deposit was refundable if the scan was cancelled more than 7 days before appointment.

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- Staff told us if they were required to make a referral to other services for the women they would have already discussed how this would happen prior to the scan and obtained the consent of the woman. Staff fully informed them of the process as this was important even when passing on difficult information.

Are diagnostic imaging services responsive?

Good 

We rated responsive as **good**.

Service delivery to meet the needs of local people

- **The service was planned and provided in a way that met the needs of the women and their families who would use the service.**
- The environment was appropriate for the service being delivered and was patient centred. The scan room was able to accommodate the woman and companion. Children were also welcome to attend. Baby change facilities were also available at the location.
- Toilet facilities were next to the scan room and clearly identifiable for women following their scan.
- Information about services offered at the location were accessible online. The service offered a range of ultrasound scans for women. For pregnant women they were also given details about having a full bladder to help improve the picture quality. However, this was dependent on the scan type. There was also information on the service's website about scans and other topics.
- Clinic days were set but the times varied to help women fit them in around their daily life.
- Following the scan, staff completed the report and printed a copy of this for the woman to take away. The woman and their relative/friend were able to choose the scans pictures they wanted (copy of two). The registered manager told us this could be put on to a memory stick for an additional cost if requested.

- The location of the service was in a GP practice and women and visitors had access to parking. Bus stops were seen close to this location to help woman access the service.

Meeting people's individual needs

- The service took account of women and their families' individual needs. The service provided was tailored to meet the needs of women. Scans for women's health were also offered and these included pelvic ultrasound to look at the womb and ovaries.
- Key information about what different ultrasound scans and what was involved were available on the service's website. It was clear about the type of scan that may be needed depending on the number of weeks the woman was pregnant. This would also be discussed at the appointment.
- The length of appointments provided enough time for the women and their families/friends to ask questions.
- The service had contracted a telephone interpretation service, for staff to use during appointments with non-English speaking women.
- The service was located on the first floor of a GP practice with lift access for people who have difficulty with stairs.
- The scan room was able to accommodate a woman with limited mobility as the couch was height adjustable. The weight limit on the couch was 260kg.
- The scan room was also private in case staff had to break any upsetting news to the woman and their family/friends.
- The registered manager told us they had purchased a new scanning machine to improve the picture quality and with a bigger screen.
- Information leaflets were available, and some had been translated into Polish. The service website stated that women were able to get in touch if other languages or formats were needed.

Access and flow

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

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- All women self-referred to the service. The service offered different booking methods. Women could book their scan appointments, by using the telephone service which operated Monday to Friday 8am to 8pm and Saturday 9am to 5pm or through the service's website.
- At the time of our inspection, there was no waiting list or backlog for appointments. The registered manager said they would book in an extra scan onto a clinic to meet any additional demand.
- The registered manager monitored clinics and if the demand was frequently over 75%, additional clinics would be planned in. If the service also had a waiting time of over one-week additional clinics were added to meet the demand. The busiest times were autumn where extra clinics were arranged.
- The service monitored rates of patient non-attendance. We saw in the quality report with data from November 2018 until 31 March 2019, four women did not attend their appointments. One of these was for non-invasive prenatal testing. Women had to pay a deposit on booking and this was non-refundable except in exceptional circumstances, for example, miscarriage pre-scan.
- The service told us between November 2017 and October 2018 there had been seven delayed scans. Two were due to staffing issues and others included, for example, the disruption caused by snow.
- During our inspection the clinic was running late, but this may have been due to our inspection and that one woman was found to have a non-viable pregnancy which required additional time.
- The registered manager told us that women had to wait between three to five days to get results from their non-invasive prenatal testing. Sometimes this was quicker or if on a bank holiday it could be delayed. This information was relayed to women.
- The service had an up to date complaints policy, which outlined procedures for accepting, investigating, recording and responding to local, informal, verbal and formal complaints about the service. The policy confirmed that all complaints should be acknowledged within three working days and resolved within 20 working days. Verbal complaints would be acknowledged straight away.
- We saw information about how to complain was displayed in the scan room. Information on how to make a complaint was also available on the clinic website.
- The registered manager had overall responsibility for reviewing and responding to complaints. They recorded all complaints and the outcome to these. Where any learning had been identified it was shared at the quarterly team meetings.
- The service had received one formal complaint between November 2017 to October 2018. We saw records of this and the outcome. It was not upheld. Records were also seen of a verbal complaint in 2018 and the outcome and immediate action taken by the registered manager.
- We were told all staff working in the clinic interacted with women, and staff were actively encouraged to ask them if they were happy with the service and identify any potential dissatisfaction while still in the clinic.
- The service used a web platform for people to feedback about the service. This was monitored by the registered manager. We saw that when any concerns or very positive feedback was received the registered manager entered in a comment. Therefore, for any issues the registered manager had documented what actions had been taken.
- The service regularly received written compliments.
- The service had received 37 written compliments between November 2017 and October 2018. The quarterly quality report also documented positive feedback received and this was shared with staff at their team meetings.

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.**

Are diagnostic imaging services well-led?

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Outstanding



We rated well led as **outstanding**.

Leadership

- **Leaders had the integrity, skills and abilities to run the service. They were compassionate and demonstrated the high levels of experience, capacity and capability needed to deliver excellent and sustainable service.**
- Leadership for the service was provided by the director who was also the registered manager. They had been registered with CQC as the manager since the service first registered in 2014 and they remained when the legal entity changed in 2016. The registered manager had recently appointed another doctor who was a consultant in obstetrics and gynaecology to improve their clinical support.
- The registered manager demonstrated enthusiasm for their role and a commitment to improving the quality of the service.
- The registered manager was a GP who had a specialist interest in this area both personally and professionally. The registered manager was compassionate and demonstrated effective leadership and made sure patients were the centre of the service. This was supported by feedback from the staff. The registered manager also worked within this field in a local NHS trust. They had also undertaken additional training in ultrasound scanning. They had brought a wealth of knowledge and experience to make sure they met the needs of the women who used the service.
- Comprehensive and successful leadership strategies were in place to ensure and sustain delivery of the service based on the needs of the woman and their families/partners. Feedback obtained was acted upon and changes to improve the service was made. The registered manager had a deep understanding of issues, challenges and priorities in their service, and the wider field. For example, the registered manager was looking at setting up a charity to fund

Non-invasive prenatal testing (NIPT) for woman as they had to pay privately. But now the NHS had made the decision to start funding these, this charity is no longer required.

- Staff felt supported by the registered manager and could contact them as required.

Vision and strategy

- **The service had a vision for what it wanted to achieve and workable plans to turn it into action.**
- The vision of the organisation was to provide affordable private healthcare that supported the NHS provision and gave individuals choice as well as value. This was on their website for prospective women and their family/friends to see.
- The vision also included the wellbeing of staff and the importance of them being actively involved in the service and by providing feedback and ideas.
- The vision and supporting objectives met the needs of their service users, while remaining achievable. There was a demonstrated commitment to system-wide collaboration. The quarterly dashboard was used to monitor the services objectives and strategy.
- The registered manager had plans in place once the business had grown to recruit more staff and increase the type of scans offered.

Culture

- **Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in their daily work. The service had an open culture where patients, their families and staff could raise concerns without fear.**
- The registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values. The culture centred on the needs and experience of women.
- The registered manager had an inspiring shared purpose, to strive to deliver and motivate staff to succeed. There were high levels of satisfaction across all staff. The service operated an open and honest culture to encourage team working. The culture within

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the service was extremely positive, the staff member we spoke with said they loved and enjoyed their job which was to provide a high-quality service to women and their families/friends.

- Staff were proud of the organisation as a place to work and spoke highly of the culture. Staff at all levels were actively encouraged to speak up and raise concerns, and all policies and procedures positively support this process.
- There was a strong collaboration, team-working and support across all functions and a common focus on improving the quality and sustainability of care and women's experiences. We saw evidence of this through actions taken based on feedback.
- The service valued patient feedback, which could be provided on the external website platform and this was used to improve patient experience.
- The registered manager understood the duty of candour regulation. However, they had not had any incidents which met the criteria where formal duty of candour had been required to be implemented.

Governance

- **Leaders operated effective governance processes throughout the service. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.**
- The registered manager had overall responsibility for governance and quality monitoring. This included investigating incidents and responding to patient complaints.
- Clinical governance was included in the quarterly staff meetings. We saw minutes from the quarterly staff meetings which demonstrated complaints, incidents, audit results, patient feedback, and service changes were documented, discussed and reviewed.
- Prior to the quarterly staff meetings, the registered manager completed a quarterly quality dashboard report on the service. This included activity for the quarter, any complaints, incidents and learning from

these and feedback from women. These dashboards were shared at the staff meetings for review and discussions and were used to make changes to the services provided.

- The registered manager had prepared a list of audits they planned to be carried out each year. We were shown this list and saw evidence audits had been undertaken. For example, consent was audited in November 2018 for the period 1 September 2018 to 31 October 2018. This related to documenting the woman had agreed to referral to the NHS if required. During this period three women had been referred but one record did not have consent documented. The updated audit for March to May 2019 was 100% compliant.
- Governance arrangements were proactively reviewed and reflected best practice. A systematic approach was taken to working with other organisations to improve outcomes. For example, when referring women on to other services. There was an effective audit programme included in their governance arrangements. This provided assurance about the quality and safety of the service. Audits were undertaken on a frequent basis as per the planned list; for example, cleanliness, consent and equipment safety checks. Other audits based on the current guidance and best practice included, checking that adnexa were seen during the scan (the adnexa means the parts adjoining an organ) and Non-Invasive Prenatal Testing (NIPT). Results of these were discussed at the staff meetings and improvements made to the service when required.
- Staff underwent appropriate checks as required by Schedule Three of the Health and Social Care Act for safe recruitment. We reviewed records of the newest recruited member of staff and this demonstrated they were fit and proper. For registered professionals their registration with their professional body was checked to ensure they were registered, which evidenced qualifications relevant to their duties. Proof of their identity and address had been obtained for their Disclosure and Barring Service check (DBS). Copies of this information was retained. A photograph had been obtained for the website, and this was kept in their file.

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- The service had appropriate insurance cover, for example, public and employer's liability. Registered professionals had the required insurance as part of their registration with their professional bodies.
- The service has an annual plan which included planned improvements and areas to monitor. For example, we were shown the latest plan which included upgrading the ultrasound machine which had taken place.

Managing risks, issues and performance

- **Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact.**
- There was a demonstrated commitment to best practice performance and risk management systems and processes. The organisation reviewed how they functioned and ensured all staff had the skills and knowledge to use those systems and processes effectively. Areas for improvement were identified and addressed quickly and openly.
- The registered manager was responsible for assessment of risks to the service. A risk management policy and audit programme had been developed.
- The registered manager had devised a risk assessment document where 13 risks had been identified and were rated as to the level of risk. Actions to mitigate them had been added. These were kept under review and updated yearly or sooner as required. These were also discussed at the staff meetings.

Managing information

- **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 service invested in innovative and best practice information systems and processes. The information used in reporting, performance management and delivering quality care was consistently found to be

accurate, valid, reliable, timely and relevant. There was a demonstrated commitment at all levels to sharing data and information proactively to drive and support internal decision making and improvement.

- The quarterly dashboard completed by the registered manager prior to the staff meetings contained data about how the service was performing. Staff were able to discuss this at their meetings and if issues were identified actions to address them were implemented.
- The service collected the data from their audits and analysed this. Areas of good practice and where improvements were needed were discussed at the staff meetings. This provided assurance to the registered manager and staff that the service was performing to their high standards.
- There was access for staff to their policies and processes, covering relevant areas.
- The service was registered with the Information Commissioner's Office (ICO), in line with The Data Protection (Changes and Information) Regulations (2018). The ICO is the UK's independent authority set up to uphold information rights.
- The service told us they were compliant with the General Data Protection Regulation (GDPR) 2018. Consent was obtained from women to store their records.
- Women using the service were able to access terms and conditions of the service on their website and this also provided information about costs and method of payment of fees.
- A data retention policy detailed the practice in relation to the retention of personal data and disposal of information.

Engagement

- **The service engaged well with women and their families and staff to plan and manage appropriate services.**
- There were consistently high levels of constructive engagement with staff and people who used the service. Rigorous and constructive challenge from people who used the service, was welcomed and seen as a vital way of holding the service to account.

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- Services were developed with the full participation of those who used them and staff. Feedback from service users was welcomed and was a vital way of improving service provision and quality. The service actively encouraged women and their relatives/friends to provide feedback. They could do this verbal feedback or leave written reviews on the social media platform.
- There was a demonstrated commitment to acting on feedback. The registered manager regularly reflected on information and feedback gathered from women and their relatives/friends to improve quality of care and service delivery. We saw evidence of this on the social media platform where the registered manager had provided feedback on any concerns/issues raised.
- We reviewed the social media platform used by women and their relatives/friends. To date we saw there was 123 reviews and 94% rated this service as excellent. The service sent us the feedback for 2018 up to November 2018 and this was all positive feedback based on 60 reviews.
- The service held quarterly meetings with all staff. Staff were encouraged to give their feedback on service provision and other matters. We saw minutes of these meetings as evidence this took place.
- Staff told us they contacted the registered manager following each clinic to feedback. They were also able to contact the registered manager at any time as required.
- We were shown the staff survey results for 2018. The two staff who were employed by the service had complete it and it was all positive.

Learning, continuous improvement and innovation

- **All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in local audits.**
- The service demonstrated a strong commitment to professional development; which included continuous professional development both in house or with their NHS employers. For example, the registered manager felt the appointment of an obstetrics and gynaecology consultant would help to improve their clinical knowledge.
- Both nurse practitioners won awards at a conference in 2017. This was from the association of early pregnancy units for the best oral presentation. The gave a talk about they work they had done to improve the care of women who had suffered a pregnancy loss.
- Staff were able to attend conferences and training to improve their skills and knowledge. Staff fed back to the wider team at their quarterly team meetings about these.
- The registered manager had plans to improve the service, for example, a new ultrasound machine which had been purchased. Longer term plans once the business had grown included recruitment of sonographer to increase the type of scans on offer and to employ a practice manager.

Outstanding practice and areas for improvement

Outstanding practice

The staff had a wealth of knowledge, skills and experience to meet the needs of women who used the service. All staff were registered with professional bodies and worked within similar fields in the NHS. They had all completed additional skills in ultrasound scanning and were using these skills in both roles. This helped to keep their experience, skills and knowledge up to date. Despite this the staff were aware of where the boundaries of this service and when they needed to refer onto NHS services.

Feedback from people who use the service, and those who are close to them, was continually positive about the care provided. The feedback on the social media platform was exceptional with the clear majority of women and their family/friends rating this service as excellent. All comments were extremely positive praising the staff and one comment was about staff going the extra mile which exceeded their expectations.

The providers website had monthly blogs completed by staff about pregnancy related issues that was accessible to all women and their family/friends. They were

proactive in helping to address pregnancy related issues and concerns for women. Each month they focused on different topics and were written in easy to understand format. These topics included for example, health related topics like diabetes another information about the scans and potential risks of these.

The provider recognised the importance of and demonstrated commitment to best practice performance. Dashboards were used as part of their governance arrangements to monitor performance, and these were proactively reviewed as a staff team and any areas of risk or concern were identified and addressed quickly. The service used a systematic approach to continually improve the quality of its services and safeguarding high standards of care by creating an environment in which excellence in this field would flourish. There were effective structures, processes and systems of accountability to support the delivery of the good quality and sustainable services.

Areas for improvement

Action the provider SHOULD take to improve

The provider should make sure they have a copy of the DBS certificate number when this is returned to the member of staff.

The provider should make sure references come from the most appropriate senior member of staff.