

My Baby Enterprises Ltd

My Baby Enterprises Ltd

Inspection report

265 Barlow Moor Road
Manchester
M21 7GJ
Tel: 01616671599
www.mybabycompany.co.uk

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

Ratings

Overall rating for this location		Good	
Are services safe?		Good	
Are services effective?		Inspected but not rated	
Are services caring?		Good	
Are services responsive to people's needs?		Good	
Are services well-led?		Requires Improvement	

Summary of findings

Overall summary

We have not previously rated this service. We rated it as good because:

- The service had enough staff to care for women and keep them safe. Staff had training in key skills, understood how to protect women from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records. The service managed safety incidents well and learnt lessons from them. Staff collected safety information and used it to improve the service.
- Staff provided good care and treatment. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of the women, provided information that advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers.
- The service planned care to meet the needs of the local people, took account of women's individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for their results.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the services vision and values and how to apply them in their work. Staff felt respected, supported and valued. They were focussed on the needs of women receiving care. Staff were clear about their roles and accountabilities. The service engaged well with women and the community to plan and manage services and all staff were committed to improving services continually.

However:

- Staff files did not always contain previous employer references, application forms, employment history or photographic identification.
- The service did not keep records of staff appraisals or 1:1s, staff meetings or carry out any audits such as hand hygiene or cleaning audits. Following the inspection, we were told by the service leadership team that they had implemented these.

Summary of findings

Our judgements about each of the main services

Service

Diagnostic and screening services

Rating

Good



Summary of each main service

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- Staff provided good care and treatment. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of the women, provided information that advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers.
- The service planned care to meet the needs of the local people, took account of women's individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for their results.
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Summary of findings

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Summary of this inspection

Background to My Baby Enterprises Ltd

My Baby Enterprises Ltd, trading as My Baby Company Ltd, has one location at Chorlton-cum-Hardy which they opened in 2016 and a satellite service at Chorley, where the main offices are located, which they opened in 2017. The service has been registered with the Care Quality Commission since 12th October 2016

The service had a registered manager in place since initial registration. The service provides a range of baby keep sake ultrasound scans in 2D, 3D and 4D during pregnancy for women aged 18 and over. They also facilitate Non Invasive Prenatal Testing (NIPT) via external companies. The service also offers to take the blood or saliva samples for these tests if the women choose to do this. It is registered to provide the regulated activity of diagnostic and screening procedures. We have not previously inspected this service.

How we carried out this inspection

Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology. Two inspectors, with support from an offsite inspection manager, carried out the inspection on 30 November 2021. On 6th December 2021 two inspectors, supported by an offsite inspection manager, attended the Chorley offices to review documentation such as patients records and staff records. We spoke with three members of staff including the registered manager/company director, area manager and an ultrasound technician. We spoke with two women and their respective partners who had used the service and reviewed feedback on an independent website browser platform. We reviewed a range of policies, procedures and other documents relating to the running of the service. We reviewed six full sets of patient records which included consent forms and scan reports. We reviewed the centralised appointment system.

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

Outstanding practice

We found the following outstanding practice:

- The service worked with a cancer charity at a local NHS trust to provide memory bears for both men and women with a terminal cancer diagnosis. The heartbeat of the patient s recorded and placed inside one of their memory bears for the family to keep.

Areas for improvement

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

Action the service MUST take to improve:

Summary of this inspection

- The provider must have in place recruitment processes which ensure staff are suitably qualified, competent, skilled and experienced persons to ensure provision of a safe service which includes all relevant staff details such as pre employment checks and references and that records are kept which reflect this. The manager must ensure that they meet the requirements of Schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. (Regulation 19).
- The provider must have effective governance processes to ensure the safe and effective delivery of care. The provider must ensure that meeting minutes and staff appraisals/1:1s are minuted/documentated appropriately and that audits are carried out where necessary (Regulation 17).

Action the service SHOULD take to improve:

- The service had in place servicing and checking of some equipment such as the scanning machines, this was not true of all equipment. The service should ensure that all equipment checks, such as the first aid kit that we were told was checked monthly by staff, is documented as having been carried out and audits carried out to ensure compliance.
- The service should ensure that all lone working is risk assessed and that it is included in their policies. Following the inspection, we were sent a lone working policy and lone working risk assessment that we were told had been kept in a different file to the policies folder.
- The service should ensure that their policies are reviewed and updated in line with their policy recommendations.

Our findings






Overview of ratings

Our ratings for this location are:

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

Diagnostic and screening services

Good 

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

Are Diagnostic and screening services safe?

Good 

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

Mandatory Training.

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

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

The registered manager and area manager had a process in place to ensure all staff completed their mandatory training in a timely way.

Staff had protected time within their working hours to complete their mandatory training.

Safeguarding.

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

We reviewed three staff files within which it was highlighted that staff had completed safeguarding training to the appropriate level required.

Staff that we spoke with were able to articulate to us what they would do if they had a safeguarding concern.

We were shown two examples where they had acted upon safeguarding concerns.

Staff were trained to level three child and adult safeguarding training.

Cleanliness, infection control and hygiene.

Diagnostic and screening services

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

We observed during our inspection that all areas and equipment in the boutique was visibly clean and well maintained.

Staff followed infection control principles including the use of personal protective equipment (PPE).

The service did not have a water supply into their part of the building but had access to a bathroom upstairs in the building in which they were located. We reviewed these and they were visibly clean. We were shown by staff a portable sink they used during times of high acuity when they had limited time to walk to the upstairs bathroom. This facilitated handwashing as per World Health Organisation recommendations.

There were hand gels available throughout the clinic and we observed these being used during our inspection by staff and service users.

Each working day staff documented in a diary that they had completed the recommended cleaning. The area manager performed weekly visual inspections of this cleaning that were signed off by her in a book that we were shown.

Staff that we spoke with told us that appointments were only for 20 minutes to allow at least 10 minutes to clean all equipment prior to the next patient.

Environment and equipment.

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

The service had suitable facilities and had enough equipment to meet the needs of women using this service. Staff completed regular checks of stock, first aid kit and equipment.

We observed sharps bins being used correctly and clinical waste being stored and disposed of correctly during our inspection.

We were shown evidence of the dates and times that where the manager had requested that their external clinical waste company had attended to remove the sharps bins and clinical waste and were contracted to dispose of them appropriately.

We were shown evidence that highlighted that equipment, such as the ultrasound scanners, were serviced as per manufacturers recommendations and that gas and fire safety checks were all compliant and in date also.

Fire extinguishers were accessible inside the entrance to the building.

Assessing and responding to patient risk.

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

Diagnostic and screening services

The service only used latex free nitrile gloves when facilitating care to prevent any risk to women with a latex allergy.

The service leaders told us they will not perform ultrasound scans more frequently than advised by the British Medical Ultrasound Society (BMUS), which is not prior to 10 weeks gestation and no more frequently than two weeks.

Staff completed mandatory training in health and safety, emergency first aid and fire safety.

The service stated on their consent form they cannot carry out any ultrasound scan if the woman had experienced abdominal pain and/or vaginal bleeding.

Women are advised to have a sweet, fizzy drink prior to attending for the scan. Women who are intolerant to sugar are advised to have a snack that suits their dietary requirements and some fizzy water.

Women are not routinely advised to bring their NHS maternity notes with them. They advised women on their consent form they receive prior to attending an appointment they should always attend all of their NHS recommended scans as they are non-diagnostic, non-screening and non-medical.

We reviewed two sets of women's notes where an abnormality or concern had been highlighted and where they had been referred on for further support.

The service had sterile ultrasound gel that they told us they used for women who were deemed as high risk such as those with a stoma, as per British Medical Ultrasound Society (BMUS) recommendations.

We observed a first aid kit that we were told was checked monthly by staff. However, there was no documentation to support this and no audit to ensure compliance.

Staffing.

The service had enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and staff a full induction.

The service did not use bank or agency staff.

The registered manager told us in the event of sickness, staff would be sent to help from either the leadership team or their satellite ultrasound boutique to cover.

Records.

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

The consent forms and ultrasound scan reports were stored electronically for 25 years as per their policy and in line with national guidance.

Diagnostic and screening services

All staff had completed information governance training and record keeping as part of their mandatory training in line with their company policies.

We observed staff maintaining the confidentiality of women by not having the computer screen in a position that was visible to unauthorised and were not left unattended when open.

Women receive a letter outlining the Non-invasive prenatal testing (NIPT) test results following on from an initial telephone call. We observed this template letter which outlines to the woman that she should discuss her results with her healthcare provider. Within this letter it also highlights external agencies where they can discuss their results.

Incident reporting, learning and improvement.

The service had systems in place to manage safety incidents well. Staff knew how to recognise and report incidents and near misses. Managers had the knowledge to investigate incidents and shared lessons learned with the whole team. When things went wrong, staff knew their responsibility of apologising to women and providing them with honest information and suitable support.

The service had not had any incidents or accidents in the 12 month period immediately prior to our inspection. However, staff were able to articulate to us which incidents they would record in the accident book and how they would escalate to the registered manager.

We reviewed the accident book and there was only one incident recorded in there.

Are Diagnostic and screening services effective?

Inspected but not rated 

We have not previously rated this service. We inspected but could not rate this 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 protected the rights of women subject to the Mental Health Act 1983.

The service followed guidance and recommendations from the British Medical Ultrasound Society (BMUS).

Staff monitored the effectiveness of care and treatment. All of the ultrasound scans performed were peer reviewed by a colleague. They used the findings to make improvements and achieved good outcomes for women.

Nutrition and hydration.

Staff took account of women's individual needs where fluid was necessary to achieve good ultrasound images.

Diagnostic and screening services

Staff gave women appropriate information about fluid intake prior to attending for their appointment.

The service provided free drinks and/or sweet treats to women where necessary which may help gain a clearer image.

Patient outcomes.

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements for women's care.

The service had an established process in place to peer review all ultrasound scans.

Competent staff.

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients.

The registered manager made sure staff received any specialist training for their role.

We were told by the leadership team that they held 1:1 appraisal meetings with all staff every six months. Also, that their future plans were to hold these on a quarterly basis. Following the inspection we requested, and received, the agenda for the one to ones and an example of a completed one to one. The headings for both were the same and comprehensive. However, there was limited documentation about what conversations took place.

Multi-disciplinary working.

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

We observed good teamwork between all colleagues during our inspection.

Staff that we spoke with during our inspection told us that all colleagues were supportive to provide good care.

During our inspection we were shown women's records where staff had worked with external health and social care professionals to benefit both women and their unborn babies.

Seven day services.

The service provided ultrasound scanning services six days per week between Monday to Saturday at either this location or their satellite clinic in Chorley.

Several women whom provided feedback stated that the staff had gone out of their way to ensure they were seen in a timely way.

Health promotion.

Diagnostic and screening services

The service provided a range of free literature and resources from external companies that offered practical support and advice to women on how to lead healthier lives.

Consent, Mental Capacity act and Deprivation of Liberty Safeguards.

Staff supported women to make informed decisions about their care and treatment. They followed national guidance to gain women's consent. They knew how to support women who were experiencing mental ill health.

Staff always had access to up-to-date, accurate and comprehensive information on women's care and treatment. All staff had access to an electronic records system that they could all update.

We observed from the feedback that women shared and heard from the women and partners that we spoke with, that staff gave them all of the information necessary to make an informed choice about which ultrasound package to choose.

We were shown evidence that where staff had had concerns regarding women's mental health, they had referred to appropriate external professionals in line with national and local policy.

We reviewed six consent forms that women were sent electronically prior to their appointment and had to be signed and returned prior to their ultrasound scan being carried out.

The service followed BMUS guidance regarding the frequency of ultrasound scanning in pregnancy.

Consent forms and ultrasound scan records were stored electronically and were accessible to all authorised staff.

Are Diagnostic and screening services caring?

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

Compassionate care.

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

We observed and read of positive examples when staff provided compassionate care to women. In an independent online feedback service where 267 service users had provided feedback about the service 99.6% rated the service as 3* and above whilst 97.5% rated them the top rating of 5*.

Staff were discreet and responsive and took time to interact with women in a respectful and considerate way.

Diagnostic and screening services

Women's dignity and privacy were maintained throughout their visit. Staff understood women's personal, cultural, and religious needs. The service provided free drinks to all and chocolates to women from the Asian community who preferred these to help their baby move prior to the scan.

Women were able to request a chaperone when booking the appointment if they wished or last minute as highlighted on signage in the service.

Some women fed back that as the ultrasound technician had been unable to gain a clear picture of their baby, they were given a complimentary re scan voucher.

Emotional support.

Staff provided positive examples of providing emotional care.

Staff gave women and their partners help, emotional support and advice when they needed it.

We saw positive examples of emotional care from online feedback from women who had used the service.

Understanding and involvement of patients and those close to them.

Staff supported and involved women and their partners to understand their options and make decisions about their choices.

The service made sure women understood their treatment by providing clear information about scan packages and costs on the website.

Women's feedback stated that staff supported them to make informed decisions about their care and were guided to choose the right scan or package for them depending on the stage of their pregnancy.

Women reported staff took their time to explain the scan procedures and answered any questions. Women understood when and how they would receive their scan images and results

Women could give feedback on the service and their treatment and were encouraged to do this.

Are Diagnostic and screening services responsive?

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

Service delivery to meet the needs of local people.

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

Diagnostic and screening services

Women self-referred to the service and were able to book the type of ultrasound scan they wished at a time and place they chose.

The service was open Tuesday through to Saturday each week and Monday, Tuesday, Friday and Saturday at their satellite clinic at times varying between nine in the morning and eight in the evening.

The service was easily accessible by public transport and had free parking onsite and on the surrounding street.

Meeting people's individual needs.

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

The toilet facilities in this service were located upstairs. Women were made aware of this situation when they were booking their ultrasound scan. Staff accompanied them to the toilet door if they needed to use these facilities.

The reception and scan room were located on the ground floor facilitating wheelchair access to the scanning facilities. Wheelchair users were offered the scanning service at the satellite clinic where all of the facilities were on the ground floor.

Staff had access to an online translation service should this be required.

For women whose spoken language was not English the service would provide information in whichever language was required.

The service offered women a range of baby keepsake and souvenir options which could be purchased at the time of booking or at the reception. These included photographic and video downloads onto a memory stick, heartbeat (the sound of the woman's unborn baby's heartbeat placed inside a teddy bear) bears and gender reveal products.

The service had an equality and diversity policy in place.

Access and flow.

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

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

We saw evidence that as a result of client's feedback informing the service that they would prefer Thursday morning and later appointments on a Friday, the service altered their opening times to improve access for more women to attend.

Women received their ultrasound scan results immediately.

Learning from complaints and concerns.

Diagnostic and screening services

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

We were shown the clients complaint form which included sections such as a summary of the complaint, the action taken and the managers comments. We were told that all complaints would be dealt with by the registered manager.

The registered manager told us during the inspection she discusses negative reviews and complaints as and when they arise, with the team.

The registered manager told us of a theme in complaints was about some service users not wanting to wear a mask during their appointment. She told us she investigated these complaints and reached a conclusion that all service users had to wear a mask unless they could prove exemption in order to consider the welfare of her staff.

Are Diagnostic and screening services well-led?

Requires Improvement 

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

Leadership.

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

The registered manager had employed an area manager to provide leadership and support to the staff working in the company.

We were told of one member of staff who was employed as a receptionist and who they were now training to be an ultrasound technician and phlebotomist.

Vision and strategy.

The service did not have a formally documented vision for what it wanted to achieve or a strategy to turn it into action. The vision articulated to us was focused on improving services for women and aligned to local plans within the wider health economy.

The registered manager of the company told us she is happy with the size of the company and had expanded their range of NIPT screening tests to create a wider choice to meet the needs of our clients and to make them more affordable.

We were told that they had recently commenced working with a new company who provided the NIPT screening tests as they reached more accurate results.

Diagnostic and screening services

Culture.

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

Staff we met during our inspection were friendly and welcoming to both the women and partners that we observed during our inspection and to us.

The service had a whistle blowing policy which encouraged staff to raise any concerns to the leadership team.

Governance.

Leaders did not consistently operate effective governance processes throughout the service.

We could not be assured that the governance processes supported safe and effective delivery of care.

Processes to ensure that staff were always suitably qualified, competent, skilled and experienced persons to ensure provision of a safe service were not always checked prior to the commencement of employment and were not present or complete in staff records. As such, records we reviewed confirmed that staff CVs and references were not checked by the management.

During our inspection we reviewed the service's 31 policies and procedures which were comprehensive and covered all required subjects for the service. However, they had been issued on 1st August 2020 and all, but one, had expired on 31st July 2021. The coronavirus policy was reviewed on a monthly basis dependent on government advice.

There was no formal checking or audit process for cleaning of the clinics. There were no cleaning schedules in place during our first visit. We observed a diary where the completion of cleaning had been signed for by a staff member each day. The area manager told us that she visually checked the clinic was clean on a weekly basis and documents this in a diary we observed during our inspection. During our second visit we observed that cleaning schedules were in place and being completed by staff.

We were shown a blank "scan room deep clean check list" but were not shown any audits that these were being completed.

However, the registered manager did show us evidence that the servicing and calibration of equipment used to facilitate ultrasound scanning was serviced and calibrated in line with the manufacturer's recommendations.

Management of risk, issues and performance.

Leaders and teams did not always use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

Diagnostic and screening services

The service did not have a risk register. We were told during our inspection that any risk identified was dealt with at the time but the only documented evidence we were shown of this was an example of one staff member who was pregnant and had undergone a risk assessment via the leadership team to ensure her safety at work.

The service had put in place measures to reduce the risk of service users tripping or falling when walking to the toilet which included advising them of the step into the women's toilet, by placing yellow and black hazard tape on the steps and by accompanying women to the toilets. We observed this happening during our inspection. However, there were no documentation to verify that this was done every time or audits to verify that it was being done.

Lone working was not included in the service risk assessment and there was no policy for lone working either. On the day of the inspection the ultrasound technician was lone working as it was a quieter day and there was no need for a receptionist. We were informed this was a regular occurrence. Following the inspection we were sent a lone working policy and a lone working risk assessment that we were told was in a separate file to the policy file we reviewed containing 31 policies.

Information management.

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

Staff had completed mandatory training on information governance and were able to articulate to us how they applied this to in practice.

There were sufficient numbers of computer terminals to enable staff to access all the relevant information that they may require such as policies.

The service had an information governance policy which highlighted the data retention periods and disposal methods which aligned with national recommendations.

Engagement.

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

We were told that the leadership team held regular monthly meetings with staff to give updates to practice as recommended by the British Medical Ultrasound Society (BMUS), to check staff welfare and to address learning from complaints. Following the inspection we requested

and received the meeting agendas for 14th August 2021, 10th September 2021 and 23rd November 2021. Two of these three meeting agendas highlighted all staff attended and were used as an opportunity for training staff in the use of new products and services. The third meeting held on 10th September 2021 focussed on customer service and service user reviews. However, none of the three highlighted that minutes had been documented.

Diagnostic and screening services

The service actively encouraged women to provide feedback in a variety of ways which included verbally, by email, on the company website and on an external social media site.

In an independent online feedback service where 267 service users had provided feedback about the service 99.6% rated the service as 3* and above whilst 97.5% rated them the top rating of 5*.

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

Diagnostic and screening procedures

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

- The provider must have effective governance processes to ensure the safe and effective delivery of care. The provider must ensure that meeting minutes and staff appraisals/1:1s are minuted/documented appropriately and that audits are carried out where necessary (Regulation 17).

Regulated activity

Diagnostic and screening procedures

Regulation

Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

- The provider must have in place recruitment processes which ensure staff are suitably qualified, competent, skilled and experienced persons to ensure provision of a safe service which includes all relevant staff details such as pre employment checks and references and that records are kept which reflect this. The manager must ensure that they meet the requirements of Schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. (Regulation 19).