

Nu-Gen Ultrasound Ltd

Quality Report

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

Ratings

Overall rating for this location	Good	
Are services safe?	Good	
Are services effective?		
Are services caring?	Good	
Are services responsive?	Good	
Are services well-led?	Good	

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Overall summary

Nu-Gen Ultrasound Ltd is operated by Nu-Gen Ultrasound Ltd. Facilities include one consultation room and a reception area.

The service comes under the diagnostic imaging core service but they undertake baby keepsake in women aged 16 and over. Baby keepsake scanning is the sole activity, these are not diagnostic.

We inspected this service using our comprehensive inspection methodology. We undertook an unannounced inspection on 7 February 2019. To get to the heart of women's 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.

Services we rate

We rated it as **Good** overall.

We found good practice:

- Staff managed potential risks to the women whilst they were being scanned. Staff managed infection control risks, they had a system in place to manage deteriorating patients which all staff were aware of and they knew how to report incidents.
- The service was appropriately staffed and all staff members received the mandatory training they needed to carry out the job safely. The service ensured that staff were fully competent to carry out their roles.

- The service provided care and treatment based on national guidance and the service had relevant policies and procedures in place to ensure its effectiveness and high standards.
- Staff treated women who used the service with kindness and compassion and would provide any emotional support if it was needed.
- Staff always involved the women who used the service in the care they received and took their individual needs into account.
- The service was planned to meet the needs of local people and women could access the service at the time that best suited them.
- Staff engaged with women who used the service and valued their feedback. Staff had the appropriate systems in place to deal with any concerns or complaints, although they had not received any since it opened.
- The registered manager had the skills and training to manage the service appropriately and created a positive, open and honest culture within the service.

However we found the following areas that require improvement;

- The service did not carry out peer reviewed audits in line with national guidance.
- The registered manager did not receive an appraisal specific to the sonographer role.

Summary of findings

Contents

Summary of this inspection

	Page
Background to Nu-Gen Ultrasound Ltd	5
Our inspection team	5
Information about Nu-Gen Ultrasound Ltd	5
The five questions we ask about services and what we found	6

Detailed findings from this inspection

Overview of ratings	8
Outstanding practice	17
Areas for improvement	17

Good



Nu-Gen Ultrasound Ltd

Services we looked at:

Diagnostic imaging

Summary of this inspection

Background to Nu-Gen Ultrasound Ltd

Nu-Gen Ultrasound Ltd is operated by Nu-Gen Ultrasound Ltd. The service opened in August 2017. It is a private service providing keepsake baby scans in Walsall, West Midlands. The service primarily serves the communities of Walsall. It also accepts women from outside this area.

The service has had a registered manager in post since it opened. The registered manager is also a registered nurse and carried out all the scanning at the service.

Our inspection team

The team that inspected the service comprised one CQC lead inspector. The inspection was overseen by Katherine Williams, Inspection Manager.

Information about Nu-Gen Ultrasound Ltd

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited this service. We spoke with two staff including the registered manager and receptionist. We spoke with three women and one relative. During our inspection we reviewed four sets of women's records.

All women who used the service were private paying for the service. This service provided keepsake mementos and were not undertaking any form of clinical or diagnostic screening.

The service opened Tuesday (10am – 5pm), Thursday (10am – 7pm), Friday (10am – 7pm) and Saturday (10am – 4pm).

There were no special reviews or investigations of the service on going by the CQC at any time during the 12 months before this inspection. The service had not been inspected before this time.

Activity (February 2018 - January 2019)

- In the reporting period the service saw 985 women. All of these women were privately funded.

Track record on safety

- Zero never events
- Zero clinical incidents

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:

Good



- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect women from abuse and the service. Staff had training on how to recognise and report abuse and they knew how to apply it.
- The service controlled infection risk well. Staff kept themselves, equipment and the premises visibly clean. They used control measures to prevent the spread of infection.
- The service had suitable premises and equipment and looked after them well.
- Staff had systems in place to protect women. They kept clear records and signposted to support when necessary.
- Staff kept records of women's personal details. Records were clear, up-to-date and easily available to all staff providing care. Staff had paper records.
- The service had systems in place to manage safety incidents well. Staff could recognise incidents and would report them appropriately. When things went wrong, staff told us they would apologise and give women honest information and suitable support.

Are services effective?

- The service provided care and treatment based on national guidance and evidence of its effectiveness. The registered manager checked they followed relevant guidance.
- The service mostly made sure staff were competent for their roles. Managers appraised staff's work performance and provided support and monitor the effectiveness of the service.
- Staff of different kinds worked together as a team to benefit women.
- Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. Staff understood their roles and responsibilities under the Mental Capacity Act 2005.

However, we also found the following areas that require improvement:

- While staff monitored patient outcomes through their activity and patient feedback, peer review audits were not completed in line with national guidance.

Summary of this inspection

- The registered manager did not have an appraisal specific to the sonographer role.

Are services caring?

We rated it as **Good** because:

- Staff cared for women with compassion. Feedback from women confirmed that staff treated them well and with kindness.
- Staff provided emotional support to women to minimise their distress.
- Staff involved women and those close to them in decisions about their care and treatment.

Good



Are services responsive?

We rated it as **Good** because:

- The service planned and provided services in a way that met the needs of local people.
- The service took account of women' individual needs.
- Women could access the service when they wanted it.
- The service treated concerns and complaints seriously, investigated them, learned lessons from the results, and shared these with all staff.

Good



Are services well-led?

We rated it as **Good** because:

- The registered manager had the right skills and abilities to run a service providing high-quality sustainable care.
- The service mostly improved service quality and safeguarded high standards of care by creating an environment for good clinical care to flourish.
- Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service collected and managed information well to support all its activities, using secure systems with security safeguards.
- The service engaged well with women, staff, the public and local organisations to plan and manage appropriate services.

Good







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	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Diagnostic imaging

Safe	Good 
Effective	
Caring	Good 
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

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 registered manager and receptionist had basic life support and fire safety training which was updated yearly and safeguarding vulnerable adults and children level one and two. Staff attended a full day of face to face basic life support training yearly on a day when the service was closed.
- The registered manager practiced as a nurse at an NHS trust and carried out continual professional development, which required yearly updated mandatory training. The registered manager was up to date with health and safety, information governance, fire safety, equality and diversity, infection control, food hygiene, basic life support, moving and handling, safeguarding vulnerable children and adults, complaints handling and conflict management and lone working.

Safeguarding

- Staff understood how to protect women from abuse and the service. Staff had training on how to recognise and report abuse and they knew how to apply it.
- Staff were appropriately trained in safeguarding and kept up to date yearly. The registered manager held a level one, two and three safeguarding children training

certificates and level one and two safeguarding adults training certificates. The receptionist held a level one and two safeguarding children and adults training certificates.

- The service had an up to date safeguarding policy in place which was due to be updated in September 2021. The policy outlined the roles and responsibilities of all staff members and outlined what was meant by vulnerable adults and children. Both staff members were aware of this policy.
- Staff members had a good understanding of the safeguarding process. Staff were able to outline what they would do if they suspected any signs of safeguarding abuse and were able to explain the process they would follow.
- Staff had not made any safeguarding referrals since the service opened in August 2017.
- The receptionist could act as a chaperone for women if they requested.

Cleanliness, infection control and hygiene

- The service controlled infection risk well. Staff kept themselves, equipment and the premises visibly clean. They used control measures to prevent the spread of infection.
- The premises were visibly clean and tidy. The reception area, scanning room and toilet were visibly clean. Staff who worked at the service were responsible for cleaning and cleaned every day they were open. There was a cleaning checklist for the scanning room which had been completed and dated

Diagnostic imaging

every day they were open for January. The reception area, office and toilet were also cleaned on a daily basis. Staff at the service had access to disposable gloves and aprons if they were required.

- Staff followed best practice procedures whilst carrying out scans on women. There was a sink in the scanning room. The registered manager washed their hands before and after each scan we observed. Both staff members were bare below the elbows whilst carrying out scans. Staff also cleaned the transducer and couch after each scan.
- Staff carried out regular infection prevention control audits. The receptionist audited the registered managers hand hygiene on a weekly basis to ensure compliance. Staff audited the cleanliness of the premises on a weekly basis. The service got 100% for each of the audits carried out in January 2019.
- The service had an up to date infection control policy.
- The registered manager was the infection control lead for the service.

Environment and equipment

- The service had suitable premises and equipment and looked after them well.
- The service was situated in a single floor, newly refurbished building. It consisted of a combined imaging and consultation room, a reception and a waiting area with a customer toilet, a staff kitchen and toilet and an additional treatment room. There was an ultrasound machine and associated 'short form' couch. There was a television on the wall in the treatment room which mirrored the ultrasound machine positioned so that women could see the images during the scan.
- The service correctly stored all its 'Control of Substances Hazardous to Health' (COSHH) products. Staff had a COSHH folder which lists all of the consumables and they were in a cupboard in a staff area.
- There was no emergency equipment on site but there was access to a first aid kit.
- The service maintained medical equipment appropriately. The ultrasound machine was bought new when the service opened in August 2017. The

registered manager had the ultrasound machine serviced on a yearly basis by an outside company. The outside company would also carry out any repairs if they were ever required.

- All electrical devices were in date for their Portal Appliance Testing (PAT).

Assessing and responding to women risk

- Staff had systems in place to protect women. They kept clear records and signposted to support when necessary.
- All scans were for non-clinical purposes and there was no diagnosis involved. Because of this there was no risk assessment done for women. Women were made aware of this beforehand and signed a legal disclaimer to say they understood this was the case.
- The service had a system in place if it suspected there was a problem with the foetus. Staff would print off the scan of the image and a letter and refer the women to the GP or A&E depending on the severity and whether or not the GP was open. The process was written down and placed in reception so staff could refer to it when needed.
- Between 1 February 2018 and 31 January 2019 the service referred 17 out of 985 women to the GP.
- The service followed the British Medical Ultrasound Society (BMUS) and Society of Radiographers checklist called 'Paused and Checked' and carried this out prior to each scan. The service had a poster up reminding staff about this in the scan room.
- Staff had a system in place if a woman deteriorated whilst on site. If a woman seriously deteriorated they would call an ambulance or refer to A&E if needed. Both staff members had basic life support training.
- The service carried out appropriate risk assessments on the premises. The service had a fire risk assessment yearly and had its fire extinguishers serviced yearly. Staff had yearly fire safety training. The service had an evacuation plan in place and carried out weekly fire alarm tests.

Staffing

Diagnostic imaging

- 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.
- The service had two staff members. The registered manager was also the full time registered nurse who carried out the scans, and there was one full time receptionist. Both staff members worked at all times so there was no lone working.
- The service does not use any bank or agency staff at any time.
- The service had no staff vacancies.

Records

- Staff kept records of women's personal details. Records were clear, up-to-date and easily available to all staff providing care. Staff had paper records.
- Staff kept paper records of women's details along with information such as estimated length of pregnancy. Staff also kept a signed consent form. The service kept no information electronically. We reviewed four women records whilst on site and all were filled in clearly and all consent forms had been signed and dated.
- Staff kept records for women who had been referred to outside agencies, such as the early pregnancy unit, GP service and A&E, in a separate locked cabinet.
- The receptionist kept all the days women records behind the desk for that day then locked them in a cupboard in the staff office. The registered manager planned to destroy women records after ten years.
- The registered manager was the information controller for the service.

Medicines

- The service did not use any controlled drugs or medicines.

Incidents

- The service had systems in place to manage safety incidents well. Staff could recognise incidents and would report them appropriately. When things went wrong, staff told us they would apologise and give women honest information and suitable support.

- The service had an incident and accident log book kept behind reception. Staff were able to explain the types of incidents that they would log and report.
- There was a clear process in place for the investigation of incidents. The process was explained in the risk management section of the governance document for the service. Staff were aware of their roles and responsibilities with regards to reporting incidents.
- There had been no incidents at service since it opened in August 2017.
- Staff were able to clearly explain what was meant by duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify women (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
- The service had a duty of candour policy.

Are diagnostic imaging services effective?

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence of its effectiveness. The registered manager checked they followed guidance.
- The registered manager ensured the service provided care in line with national best practice. The registered manager ensured they followed the As Low As Reasonably Achievable (ALARA) principle and kept ultrasound scanning times to a minimum.
- The registered manager kept up to date with the latest information on obstetric ultrasound scanning. The service and registered manager are registered with the The registered manager practiced within their limits and referred to the relevant services if a women attended with something that out of our scope of their practice.
- The services policies were in line with national guidance.

Diagnostic imaging

- There was an 'evidence-based care and effectiveness' section in the governance document which outlined the registered managers commitment to providing evidence based care and operating with their limits.
- The registered manager told us she was assured that staff would not discriminate on the grounds of age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation.
- The service had an up to date equality and diversity policy.

Patient outcomes

- While staff monitored patient outcomes through their activity and patient feedback, peer review audits were not completed in line with national guidance.

Competent staff

- The service mostly made sure staff were competent for their roles. Managers appraised staff's work performance and provided support and monitor the effectiveness of the service.
- All staff at the service had up to date Disclosure and Barring Service (DBS) checks. The registered manager ensured these were updated on a three yearly basis.
- The registered manager also worked as an adult nurse within the NHS so carried on continuous professional development to ensure revalidation as part of that role.
- The registered manager was competent to carry out scans as a sonographer and was a member of the British Medical Ultrasound Society.
- The service had an 'Education, training and continuing professional development' section within the governance document. It outlined the registered manager's commitment to providing opportunities for all staff to take part in further training to update their skills and keep up with the latest developments.
- The registered manager had a yearly appraisal through their NHS role, however they did not have an appraisal specific to this role. The registered manager carried out a documented appraisal for the receptionist on a yearly basis. The receptionist confirmed this had taken place.

- The registered manager told us they would manage any poor staff performance. The registered manager had not needed to do this since the service had opened.

Multidisciplinary working

- Staff of different kinds worked together as a team to benefit women.
- Both staff members had a positive working relationship with each other and communicated effectively in order to provide a good level of care.
- The service worked well with other organisations. It referred women on to the GP or A&E and always provided good information for the services it was referring women to.

Seven-day services

- The service ran clinics four days per week. It opened Tuesday, Thursday, Friday and Saturday. Opening times varied each day.

Consent and Mental Capacity Act

- Staff understood how and when to assess whether a women had the capacity to make decisions about their care. Staff understood their roles and responsibilities under the Mental Capacity Act 2005.
- Staff always explained the procedure in full to women so women understood what they were consenting to. Staff understood what was meant by consent and women always signed a consent form before they undertook the scan.
- The service was transparent with its pricing and these were displayed on leaflets, on the internet, on the premises and discussed with potential women on the phone.
- Staff members had a good understanding of the Mental Capacity Act 2005. The registered manager received training in the Mental Capacity Act 2005 through their role as a nurse in the NHS.
- The service had a Mental Capacity Act policy.

Are diagnostic imaging services caring?

Diagnostic imaging

Good 

We rated it as **good**.

Compassionate care

- Staff cared for women with compassion. Feedback from women confirmed that staff treated them well and with kindness.
- The service actively sought the views of women. Women were encouraged to leave feedback on social media. The average score for the service was 4.9 out of five based on 88 respondents. Women commented that the service was “Highly recommended”, staff were “very friendly and professional” and “so women” and it was “an excellent place”.
- Staff had a comments box at the reception desk, however, up to now no comments had been left.
- Staff treated women with compassion and kindness. All women told us that staff treated them with compassion and kindness at all times. We observed staff treating women with kindness at all times.
- The registered manager gave examples of treating women compassionately when they were anxious or when women had received distressing or upsetting news with regards to the baby.
- Staff maintained women’s privacy and dignity at all times. Women were scanned in a private examination room with only themselves and relatives present. Women were offered paper towels whilst they were being scanned.
- The receptionist assisted women promptly and was friendly and efficient.

Emotional support

- Staff provided emotional support to women to minimise their distress.
- The service actively encouraged staff to make sure women and their families enjoyed their baby scanning experience.
- Staff discussed procedures with women and they were encouraged to be part of the decision-making process.

- The service had a strong, visible person-centred culture. The registered manager was highly motivated. Women were actively involved in their care.
- Staff understood the impact that women’s scans had on their wellbeing. Staff treated women as individuals.
- The sonographer talked to women during procedures to put them at ease.

Understanding and involvement of women and those close to them

- Staff involved women and those close to them in decisions about their care and treatment.
- Staff communicated with women so that they understood their care, treatment, and condition.
- Women said that staff were thorough, took time to explain procedures to them and they felt comfortable and reassured. Women we spoke with felt they were given adequate information.
- Women were provided with appropriate information about pricing and scan options before their visit.

Are diagnostic imaging services responsive?

Good 

We rated it as **good**.

Service delivery to meet the needs of local people

- The service planned and provided services in a way that met the needs of local people.
- Women’s individual needs and preferences were central to the planning and delivery of the service. The service was flexible and provided choice of scan options and appointment times.
- The service offered early reassurance scans, reassurance scans, 2D gender scans and 3D/4D multi-scans.
- The service provided planned baby keepsake scans for women at their convenience.

Diagnostic imaging

- The environment was appropriate and person centred. There was a comfortable seating area and toilet facilities for women and visitors. The building and facilities were wheelchair accessible.
- Women had good access to the centre by car and public transport. The reception area was clean and tidy with access to magazines, children's toys and toilet facilities for women and relatives.

Meeting people's individual needs

- The service took account of women's individual needs.
- Staff took into account things such as their age, gender or disability and make adjustments where possible. The registered manager gave examples of providing scans for patients who had additional needs and making the appropriate adjustments.
- The service was all on one level and was fully accessible for any women who had limited mobility.
- The registered manager would use a translation service if a woman was a non-English speaker. The registered manager told us they would never use a family member to translate for a woman who used the service.

Access and flow

- People could access the service when they wanted it.
- Women could book appointments through the website, social media or by phone. During this time, they would inform the service the type of scan they wanted and preferred time. The service's appointment system is easy for everyone to use and where possible we try to offer service users an appointment at a date and time to suit their needs, the service tried to accommodate same day appointments if possible.
- The service did not charge women who did not attend. The registered manager was aware that certain unavoidable circumstances may arise from time to time and do not think that financially penalising them was good practice.
- Staff saw women promptly. The registered manager allowed up to half an hour for appointments so that women were always seen on time as the appointments had time built in to potentially over run if there were difficulties getting a good scan image.

- Nu-Gen staff always informed service users about any changes or disruptions that may affect their care with us and will try our up most to avoid disruptions from happening.
- The service did not have any urgent referrals.

Learning from complaints and concerns

- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.
- Information on how to make a complaint was readily accessible to women. For examples, the service had leaflets or a notice in the reception area.
- The service had a comprehensive complaints procedure in place. The registered manager told us they would always try to resolve any complaint by a customer by listening to them and welcoming any suggestions they may have to improve our service.
- The registered manager was aware of their responsibility to respond to complaints. The policy set out that they would respond to any official complaints within ten days.
- The service had not received any formal complaints since it opened up until the time of reporting in November 2018

Are diagnostic imaging services well-led?

Good 

We rated it as **good**.

Leadership

- The registered manager had the right skills and abilities to run a service providing high-quality sustainable care.
- The registered manager worked had the clinical skills and ability in order to ensure that the level of care was safe and appropriate.
- The registered manager could talk about the main issues they faced within the service and could explain the plan they had in place to deal with these.

Diagnostic imaging

- The receptionist said the registered manager was approachable with any issues or problems they may have. The registered manager and receptionist had a close working relationship and worked together on every day the service was open.

Vision and strategy

- The service did not have a documented vision and strategy. The registered manager told us the vision and strategy was 'to continue to provide a first class, friendly and caring service'.
- In the future the registered manager hoped to employ another sonographer on a full time basis and provide a greater variety of scans.

Culture

- Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- All staff member were focussed on creating a positive experience for the women that were scanned. All women told us that they felt there was a positive culture within the service.
- All staff were open and honest. The registered manager had plenty of one to one time with their staff. Staff members were encouraged to raise any concerns and put forward any ideas to improve the service.
- The service had a whistleblowing policy in place for staff.

Governance

- The service mostly improved service quality and safeguarded high standards of care by creating an environment for good clinical care to flourish.
- The service had all the appropriate policies in place in order to safeguard high standards for the care they provided.
- Staff carried out audits to ensure that fundamental standards laid out within the policies were maintained.

- Staff at the service did not have formal sit-down team meetings. Staff could raise any issues or problems with the registered manager at any time and staff told us that the registered manager was responsive and took issues seriously and actioned them as a result.
- The service did not carry out any peer review audits of scans.

Managing risks, issues and performance

- The service undertook a yearly fire assessment check.
- The service undertook yearly health and safety assessment of the location.
- The service had appropriate exclusion criteria which were; no scanning any other parts of the body, no diagnostic scans, would not scan anyone who they felt had issues relating to safeguarding, would not scan anyone who could not consent to the procedure or who did not sign the registration form indicating understanding of the scan, they do not screen for fetal abnormalities and make it clear it's important that women need to attend the 12 and 20 week scans, they do not scan anyone under the age of 16 and they do not perform transvaginal scans.
- The service did not have a risk register.
- The service did not carry out any peer review audits of scans.

Managing information

- The service collected and managed information well to support all its activities, using secure systems with security safeguards.
- All records were confidential and women's' identities were protected. All patients had a unique reference number.
- The registered manager was the data controller for the service.
- The registered manager had information governance training.

Engagement

- The service engaged well with women, staff, the public to plan and manage appropriate services.

Diagnostic imaging

- The registered manager worked closely with their receptionist. Staff had regular input about the service and any changes that might occur. Staff told us they felt engaged with any decisions that were made about the service.
- The service used feedback from patients. The registered manager had made changes to opening times, bringing in earlier appointment times on weekends and later appointments in the week.
- The service used social media to get patient feedback and engaged with patients through this.

Learning, continuous improvement and innovation

- All staff members attended an obstetrics study day on a yearly basis to ensure that they have the most up to date information.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The registered manager should ensure it carries out peer review audits, which were not completed in line with national guidance.
- The registered manager should ensure they have an appraisal related to their sonographer role.