Illumina Diagnostics Ltd

Illumina Diagnostics

Inspection report

Pilgrim Primary Care Centre
Pelham Road
Immingham
DN40 1JW
Tel: 01469570729
www.theroxtonpractice.nhs.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?	Requires Improvement
Are services effective?	Good
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Good

Summary of findings

Overall summary

- The service had enough staff to care for patients and keep them safe. Staff had training in most key skills, understood how to protect patients from abuse, and managed safety well. The service did not have agreed systems and processes in place to safely prescribe, administer, record and store medicines. Infection risk and safety incidents were well managed. The service had a robust process for safety incidents and lessons learned were embedded in practice.
- Staff provided safe care and treatment and made patients comfortable when needed. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients, supported them to make decisions about their care, and had access to useful information.
- Staff treated patients 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 patients and carers.
- The service planned care to meet patients' individual needs and made it easy for people to give feedback.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Governance processes were in place, however, we found that the audit processes for some areas needed further development. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients to plan and manage services and all staff were committed to improving services continually.

However:

- The Pilgrim Primary Medical Centre resuscitation trolley was an open trolley and not lockable.
- A written procedure for the frequency of resuscitation trolley, blood monitoring kits and anaphylaxis kits checks, and accountabilities was not in place.
- Monitoring of the frequency of resuscitation trolley blood monitoring kits and anaphylaxis kits checks was not in place.
- Two Legionella risk assessments action plans were not signed to confirm the actions were implemented.
- Two of the external yellow clinical waste bins locks were broken at Pilgrim Primary Medical Centre.
- Three COSHH risk assessment was not signed and dated.
- 'Pause and Check' audits were not completed.
- 'Surgical Safety' audits were not completed.
- An annual audit plan was not in place.
- There was limited medicines governance and oversight of medicines processes.
- A medicines management policy and independent prescribing policy was not in place.
- Medicines were left on the worktop and the medicines cupboard and door entry to the treatment room were seen to be unlocked.
- Two agency sonographers allied health profession registrations had expired on the 28 February 2022.
- The service level agreement with the sonographer had expired on the 28 February 2022.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good 	See the summary above for details. We rated this service as good because it was effective, caring, responsive and well led. We rated safe as requires improvement.

Summary of findings

Contents

Summary of this inspection

Background to Illumina Diagnostics

Illumina Diagnostics is managed by Illumina Diagnostics Limited. The service provides a Non-Obstetric Ultrasound Service (NOUS) in the community, based in primary care centres across North East and North Lincolnshire covering population of over 300,000. In addition, an Ultrasound Guided Injection service also based in primary care centres is provided across North East Lincolnshire and Grimsby. The service provided services to those patients over the age of 18 years. During the inspection we visited the Pilgrim Primary Care Centre and Freshney Green Primary Care Centre.

Pilgrim Primary Care Centre is a purpose build medical centre and is the main centre registered to provide this service. The centre houses a GP (General Practitioner) Practice as well as a broad range of community delivered services. The building is fully compliant with Equality Act.

The service will eventually provide services through eight satellite centres and a mobile ultrasound across Lincolnshire and Humber. Currently, two satellite centres only are operating and are Freshney Green Primary Care Centre in Grimsby and the Ironstone Centre, which is based in Scunthorpe, South Humberside.

Currently the service operates from Pilgrim Primary Care Centre on Tuesdays, Freshney Green Primary Care Centre Monday to Friday and at Ironstone Centre five days a week.

The registered manager and nominated individual are supported by the Illumina leadership team which comprise of eight experienced individuals whose experience range from that of a GP (General Practitioner), administration and finance. Included within this team are two specialists a consultant orthopaedic surgeon and consultant radiologist. A total of seven sonographers support the team; three male and four female sonographers. The service could also access medical GP support through the Pilgrim Primary Care Centre.

The hospital is registered to provide the following regulated activity:

- Diagnostic and screening procedure
- Treatment of disease, disorder, or injury

The hospital has a manager registered with the Care Quality Commission (CQC).

This is the hospitals first inspection since registration on the 8 January 2021. A community-based ultrasound service is provided.

How we carried out this inspection

How we carried out this inspection

During the inspection visit, the inspection team:

- Visited two locations, looked at the quality of the overall environment and observed how staff were caring for patients.
- We collected information for all three sites.
- Spoke with the Registered Manager, Nominated Individual, Centre Manager, and the Lead Sonographer.

Summary of this inspection

- Spoke with eight staff members.
- Reviewed nine patient care records and treatment records.
- Attended five patient consultations.

Reviewed 85 policies, procedures and other documents which related to the running of the service.

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

Areas for improvement

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

Action the service MUST take to improve:

The service must ensure that medicines governance and the oversight of medicines processes is in place. Reg 12(1)(2)(g)

The service must ensure that a medicines management policy and independent prescribing policy is available for staff. Reg 12(1)(2)(g)

The service must ensure that all medicines are locked in a secure place when not in use. Reg 12(1)(2)(g)

The service must ensure monitoring of the frequency of resuscitation trolley, blood monitoring kits and anaphylaxis kits checks is in place and ensure that the checks agreed are completed. Reg 17 (1)(2)(a)(d)(ii)

Action the service SHOULD take to improve:

The service should ensure that the resuscitation trolleys have tamper evident seals so that resuscitation drugs are stored in tamper-evident containers. Reg 15 (1)(b)

The service should ensure that all clinical waste bins are secure. Reg 15 (1)(b)

The service should consider the implementation of a written procedure regarding frequency of resuscitation trolley, blood monitoring kits and anaphylaxis kits checks and accountabilities to ensure that the checks agreed are completed.

The service should consider that all legionella risk assessments are signed as completed.

The service should consider that the COSHH risk assessment is signed and dated.

The service should consider the introduction of ‘Pause and Check’ audits.

The service should consider the introduction of ‘Surgical Safety’ audits.

The service should consider the implementation of an annual audit plan.

Our findings

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Requires Improvement

Mandatory training

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

Staff received and kept up to date with their mandatory training; the mandatory training was comprehensive and met the needs of patients and staff. The mandatory training compliance threshold was 80%. Staff training records confirmed all staff were 100% compliant in respect of completion of mandatory training.

Staff confirmed that the three agency sonographer staff had provided certification which confirmed they had completed their mandatory training subjects.

Additional training on dementia awareness, chaperone, compassion in practice, challenging behaviour was also available. The training matrix confirmed two clinical staff and one administrator had completed the three-yearly dementia awareness training and one clinical staff member had completed the three yearly challenging behaviour training. All staff had also completed the equality and diversity pre-assessment training.

The training needs analysis (2022/23) confirmed the additional staff training required following the staff appraisal process. Additional training included muscular skeletal, sign language and male chaperone training.

Managers monitored mandatory training and alerted staff when they needed to update their training. The training matrix was colour coded, for example a red colour meant training was due for the individual concerned. Staff said this system alerted them whether staff training was up to date, booked, due or was expiring within three-months.

Safeguarding

Staff understood how to protect patients 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.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff knew how to make a safeguarding referral and who to inform if they had concerns. The service had an identified safeguarding lead who attended external safeguarding meetings. The safeguarding lead had completed level three adult and children's safeguarding training.

The safeguarding lead informed the practices multi-disciplinary team in adult and children's safeguarding updates and policy changes and communicated these to the Illumina diagnostics directors. The lead sonographer then informed the staff across the service of these updates.

Staff were informed by appropriate guidance which included local adult and children's safeguarding guidance, female genital mutilation (FGM) guidance and the North East Lincolnshire Council safeguarding policies and procedures. The FGM flow chart guidance was displayed in the main patient waiting area at Pilgrim Primary Care Centre.

Staff said there had been no safeguarding referrals since registration and should safeguarding concerns be raised, they were escalated, and the lead sonographer would complete a safeguarding referral. Staff could access a single point of access number for support.

Staff received training specific for their role on how to recognise and report abuse. Staff completed three-yearly adult and children's safeguarding training. Level one and two safeguarding training was completed by all staff groups through an online package and training records confirmed this training was up to date. Level three safeguarding training was a face to face session through an external provider which was completed by the safeguarding lead.

Staff could give examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act. Staff said patients with specific needs or characteristics were identified through the referral process. These characteristics and / or needs were identified on their patient record and referral forms. We reviewed patient records including three referral forms and saw protected characteristics identified if relevant to that patient.

Cleanliness, infection control and hygiene

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 two locations visited were visibly clean and had suitable furnishings which were clean and well-maintained.

Training records confirmed that all staff had completed infection prevention and control training.

Staff followed infection control principles including the use of personal protective equipment (PPE). Staff wore PPE, which included gloves, masks and apron's when treating a patient. We observed five patient consultations during the inspection and noted that clinical staff always wore masks, gloves, and aprons during the diagnostic examination. Staff cleaned the local environment and equipment, after patient contact.

Hand gel was located throughout the practice for the use of staff and patients. We observed different staff members frequently gel their hands. Clinical staff's arms were also bare beneath the elbows. Handwash guidance was displayed above sinks.

For ultrasound examinations we saw ultrasound gel sachets in use and government guidance 'Good infection prevention practice: using ultrasound gel' was followed (updated 12 February 2021).

Cleaning schedules identified cleaning regimes. The cleaning audits for the three locations demonstrated good standards of hygiene were being maintained. Compliance was 99.1% at Ironstone Centre (December 2021) and 100% compliance at Freshney Green Primary Care Centre (May 2022). No compliance issues were noted at the Pilgrim Primary Care Centre.

Good

Diagnostic and screening services

The annual IPC (Infection Prevention and Control) audits for all three locations compliance ranged from 89% at Ironstone Centre to 99% at Pilgrim primary Care Centre.

Health and Safety Executive Legionella risk assessments were in place. The recommendations from the assessments were actioned by the provider for the Pilgrim Primary Care Centre. The Ironstone Centre and Freshney Green Primary Care Centre risk assessments were not confirmed as completed.

The link practitioner infection control annual action plan for 2021/2022 confirmed audits had taken place. These audits included the annual environmental audit, ongoing hand hygiene and the use of PPE. Training records confirmed 100% compliance against the PPE and hygiene audits. Five new starters assessments were planned for July 2022.

Staff said patient's infectious status was monitored and infectious patients were not treated at the clinic. To monitor patient's health status, initial patient contact by the administration staff took place two-weeks before the diagnostic test followed by a text the night prior to the patients planned appointment were sent to ascertain the patient's infectious status.

In response to Covid, staff completed twice weekly lateral flow tests. Covid vaccination was taken up by most staff members. Where necessary a staff NHS Covid self-isolation risk assessment was completed.

We saw the completed Covid -19 site risk assessment dated 1 December 2020.

Environment and equipment

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

The design of the environment followed national guidance, health building note 6. This guidance identified except for acoustic shielding, for patient privacy, there are no specific construction requirements associated with the use of ultrasound. The clinical rooms we saw at both sites allowed for patient privacy.

We observed close circuit television on the premises and saw keypad entry at access points to ensure the premises was secure.

At Pilgrim Primary Care Centre, the clinical room was located on the ground floor of the building; whilst office space for staff was located on the first floor. The waiting area was shared with the GP practice and minor treatment centre which was also based in the building.

At Freshney Green Primary Care Centre, the service had a dedicated suite of rooms and waiting area located on the ground floor of the building. Patients could alert staff to their arrival using a touch screen based by the entry door to the unit.

Both buildings were compliant against the Equality Act 2010, for example, toilet areas had call bells in place should the patient require assistance and these facilities could accommodate patients with disabilities.

Portable appliance testing records for both locations confirmed checks took place in 2022. The service started operating from the Ironstone Centre building on the 30 November 2021 with all brand-new equipment which included an ultrasound machine; PAT testing was scheduled.

Good

Diagnostic and screening services

The lift in last service was on the 20 January 2022; the battery was replaced following this on the 25 January 2022.

Illumina Diagnostics shared resuscitation equipment with the GP practice it was located in. The resuscitation trolley records for both Freshney Green Primary Care Centre and Ironstone Centre confirmed that monthly checks had taken place.

In Pilgrim Primary Care Centre, the resuscitation trolley was in the corridor of the minor treatment centre. We observed that the trolley was not lockable which meant that anyone passing by could access it. With staff present we undertook random checks of the equipment and drugs in the resuscitation trolley and found all to be in date. The May 2022 defibrillator checks confirmed that checks were completed every working day. We reviewed some of the resuscitation trolley, blood sugar monitoring kit and anaphylaxis check lists and saw that weekly checks had not always taken place. We escalated this finding to the Pilgrim Primary Care Centre manager. On discussion with staff it was also confirmed there was no written procedure regarding frequency of checks and accountabilities for ensuring the checks agreed were completed.

We were not provided with evidence to confirm that the blood sugar monitoring kit checks at Ironstone were completed, however, records confirmed this equipment had been checked every four to nine days on the Freshney Green Primary Care Centre site.

The static ultrasound equipment was serviced annually; the last service was the 24 May 2022 and no issues were identified. The service purchased a mobile ultrasound unit in November 2021 and staff said it was due or its first service. Staff said that ultrasound equipment was replaced every five-years.

We saw completed documentation which confirmed that staff had received training and updates in the use of the ultrasound machine. The latest ultrasound manuals and disinfection guidelines were also provided as part of the training session.

The mobile ultrasound equipment used by the sonographer who had a service level agreement with the service and was serviced on the 23 July 2021 and no concerns were identified.

Business continuity plans were in place and in the event of an information technology (IT) failure staff would contact an IT consultant. Service records for the IT system confirmed the last service was on the 20 April 2022. Staff said records were backed up in case of IT failure; reports were saved in the patients' clinical records and all images were saved on the picture archiving and communication system.

Staff disposed of clinical waste safely in designated bins in the clinical room. The bags when full were taken out to large lockable bins where it was stored until the waste disposal team arrived. At Pilgrim Primary Care Centre, we checked the outdoor bins and found that two locks were broken. We were told that staff had been made aware that these bins should remain locked and saw this communicated through the manager meeting minutes dated 4 May 2022. We escalated this to the centres manager who arranged for the delivery of two new lockable bins. Following the inspection, the provider confirmed by video that all the bin's locks were now working.

Controlled substances hazardous to health (COSHH) were locked in a separate cleaning cupboard which could only be accessed by designated people at the practice. This room had a keycode lock and the code was only known by designated staff. The provider had completed a COSHH risk assessment which was not signed or dated.

Good

Diagnostic and screening services

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration

Staff responded promptly to any sudden deterioration in a patient's health in that staff would initially contact a practice GP for the initial support of the unwell patient. The service emergency protocol confirmed that should a patient deteriorate staff would call for an ambulance.

Staff confirmed when patients experienced a complication following their procedure, they should contact their GP in the first instance.

The ultrasound reporting guidelines (v1) and the emergency pathway was followed with respect to patient scans. In an emergency staff discussed the scan with the GP and contacted the referrer by phone. Escalation to the radiologist would occur in the event of an unexpected or significant finding and the images were sent for immediate review.

Staff training records confirmed that 100% of staff had completed annual basic life support and defibrillator training.

Sepsis protocols were in place. Sepsis training was not a standalone training but incorporated within the infection control training. Training records confirmed all staff groups had completed the infection control training. The practice manager has since confirmed they were going to source standalone sepsis training.

We asked to see surgical safety audits data: this information was not provided.

Patients with suspected deep vein thrombosis referrals were seen on the day of referral.

Staff confirmed and we observed during five patients' consultations that the 'pause and check' and three points of identification were used to identify the patient. To date no pause and check audits had taken place.

During the observation of a patient consultation we observed that patient's health status, medications and the location of any pain was discussed. Patients were also informed of any potential post diagnostic complications.

Staff said that should aggressive or violent incidents take place; staff would dial 999 and ask for the police. Staff could also receive additional support through one-to-one meetings, occupational health and counselling services.

Staffing

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

The service had staff to keep patients safe. Currently, the service employed three whole time equivalent (wte) sonographers, the registered manager and a business manager and 3.6 wte administration / reception staff.

Three agency sonographers were employed to work for the service at the Ironstone site which had opened on 30 November 2021. Staff told us that these agency sonographers had completed a period of induction and clinical supervision took place through one of the permanent sonographers at the service. We saw three completed induction checklists for the agency sonographers and the staff handbook the agency sonographers were given as part of their

induction to the service. Evidence provided of allied health profession registration status confirmed the renewal dates for two of the agency sonographers had expired on the 28 February 2022. We contacted the provider who confirmed there had been a typo on the document and resubmitted the document which confirmed renewal dates for registration were in 2024.

One sonographer / physiotherapist had a service level agreement with the service, dated until 28 February 2022; the provider was informed that the service level agreement had expired.

Staff received out of hours support by either contacting the lead sonographer, consultant radiologist or a designated GP by phone if they were not on site.

The service recruitment and retention policy detailed the recruitment process and the required checks the potential employee went through prior to a job offer. We saw that allied health professional's registration status was checked and this information was held by the company. All staff had completed disclosure and baring checks. We reviewed two staff members personal files which confirmed the necessary checks were completed.

Staff completed an induction process; we reviewed one staff members induction documentation and saw that it had been completed and signed off by a senior manager.

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.

Records were stored securely and could only be accessed through a designated password/pass card.

The service used the same electronic patients' records system as local GPs (General Practitioners) and the wider local health economy which meant healthcare professionals could access patient information and ultrasound results immediately. Staff said records were backed up in case the technology failed; reports were saved in the patients' clinical records and all images were saved on the picture archiving and communication system.

Patient notes were comprehensive, and all staff could access them easily. We reviewed nine patient records and three referral forms and noted patient histories, medicines, the type of injections with batch numbers if given and the referral information were captured.

The provider confirmed that they completed records audits to ensure that staff had the appropriate level of access to patients' records. The 30 June 2021 and 30 March 2022 audits confirmed staff members access to the records was appropriate and no actions were required.

Medicines

The service did not have agreed systems and processes in place to safely prescribe, administer, record and store medicines.

We observed medicines governance and the oversight of medicines processes required improvement. The service did not have an identified pharmacist to advise on medicines governance and medicines oversite processes. The

designated medicines lead agreed these processes required further development. We were told that should the need arise staff could approach the pharmacists based in Pilgrim Primary Care Centre for advice. Following the inspection, the provider confirmed senior pharmacist support had been arranged to support the service through a service level agreement which commenced on the 1 June 2022.

We saw the medicines cupboard was lockable, however, when we revisited the clinical room on the Pilgrim Primary Care Centre location, the room door was unlocked, steroid vials were found on the work top and the medicines cupboard left unlocked. We escalated this practise to the staff member who was with the inspector.

The injection policy and risk assessment dated 1 March 2022 identified the current control measures on the Pilgrim Primary Care Centre location were not being followed in respect of the storage of injections in a locked cupboard when not in use. This meant that the staff member was not following current policy and could constitute a risk should any of the medicine vials go missing. Following the inspection, the registered manager confirmed that actions had been taken to ensure that medicines were always stored securely.

The service purchased steroid vials for injection from the onsite pharmacy. We asked what stock monitoring process was in place and were told that no stock audits were undertaken which meant the provider had no way to assure themselves that stock levels were correct, and processes followed.

The service did not provide temperature-controlled storage and we saw no evidence that temperatures were monitored in the clinical treatment room at Pilgrim Primary Care Centre. The impact of this meant the stability of medicines could not be assured, prior to administering to patients.

Staff confirmed there was no medicines management policy or independent prescribing policy which meant staff had no written guidance on the prescription, administration, storage and recording of medicines in use.

We saw confirmation that one sonographer had completed their independent prescriber and supplementary prescribing courses.

Staff confirmed that the steroid injection and location of the injection was prescribed by the patients GP prior to the ultrasound guided injection. However, they said they would on occasion use their professional judgement as to the placement of the injection which meant the injection could be given in a different location to that prescribed by the GP. Should this occur the prescribing GP was not informed of this change in injection placement.

During an observation of a patient consultation we observed that prior to the steroid being given intramuscularly the sonographer checked the patients details and informed them of any potential side effects post injection. The patient was also asked to wait in the surgery for 15 minutes before leaving in case of any immediate reactions to the medicine. The prescribed medicine once given was documented as given in the patients notes.

Anaphylaxis kits were kept in a box in the clinical room and on the resuscitation trolley in the minor injuries' unit at Pilgrim Primary Care Centre. We were told these kits were checked monthly, although, we noted on some of the audit documentation that weekly checks were identified to take place. We reviewed random anaphylaxis, kit check lists whilst on site and found five to eight weekly checks had taken place. This failure to follow policy was escalated with the provider.

Good

Diagnostic and screening services

At Freshney Green Primary Care Centre the anaphylaxis kit checks were completed monthly, however, one completed document sent as evidence did not have any dates against the checks made. We reviewed a second document which confirmed checks were completed monthly from 4 May 2021 to the 6 April 2022. Following inspection, we reviewed more anaphylaxis kit check documentation and noted monthly checks were completed from December 2020 until the 26 April 2022 across the three sites.

Resuscitation drugs were in the resuscitation trolley in the minor treatment centre at the Pilgrim Primary Care Centre; this was an open trolley and not lockable. We raised this with the provider and the provider immediately ordered a lockable resuscitation trolley for the Roxton Pilgrim Primary Medical Centre location. Following inspection, the provider sent confirmation that a lockable resuscitation trolley had been ordered. Risk assessments were not completed in respect of only having the one resuscitation trolley in the practice which was shared by three services.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support. Managers ensured that actions from patient safety alerts were implemented and monitored.

An incident policy and procedure were available to staff. Staff knew what incidents to report and how to report them. We asked staff about their knowledge of the 'Duty of Candour' and staff were aware of what it meant and how to implement this. Staff told us that they completed 'Duty of Candour' training as part of their induction to the service. Staff knew this meant they were open and transparent and gave patients and families a full explanation when things went wrong.

The service worked closely with the local commissioning group when incidents occur. Incidents are documented via the local commissioning groups incident reporting system. The form once completed is flagged to the governance team at the clinical commission group who follow this up further.

The service had an incident register. Staff confirmed and we saw that the service had four incidents during the last 12-months. These incidents related to one incorrect referral and three post scan processes.

Staff received feedback from investigation of incidents, at staff meetings and at the quarterly directors' meetings.

Managers said staff would be debriefed and supported staff after any serious incident.

Managers ensured that actions from patient safety alerts were implemented and monitored.

Are Diagnostic and screening services effective?

Inspected but not rated

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.

Handwash guidance was displayed above sinks.

Good

Diagnostic and screening services

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. For ultrasound examinations government guidance 'Good infection prevention practice: using ultrasound gel' was followed (updated 12 February 2021).

All protocols were stored on the company's shared drive. We saw these were reviewed and followed the British Ultrasound Society guidance. This information was placed on the ultrasound machines.

Staff said and we saw that patients with specific needs or characteristics were identified through the referral process.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain.

During our observations of patient consultations, we observed that staff asked if the patient was in pain and made sure they were comfortable before proceeding with their diagnostic investigation.

Pain management audits were not completed by the service.

Patient outcomes

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

Illumina diagnostics did not participate in patient-reported outcome measures.

The service did not participate in relevant national clinical audits.

However, feedback from GPs (General Practitioners) and the clinical commissioning groups ensured that key performance indicators were being met against the service provided.

Discussions had taken place about scans and the service had received positive feedback about the quality of their scans from both the NHS Trust and an independent hospital. We were told that the scans had not resulted in patients' pathways being changed.

The service did not have an identified annual audit plan; however, case review audits took place. These case review audits were completed by consultant and sonographer staff and the outcomes were shared amongst the staff so that the information which resulted from the audits was understood.

Two ultrasound guided injection and non-obstetric ultrasound audits were undertaken by the consultant radiologist and orthopaedic consultant. The audits outcomes were identified and suggestions for future practise made.

The image case review of 31 cases on the 3 February 2022 identified outcomes. One case outcome was to review the reporting process with the possibility of including additional information regarding location.

The patient feedback graphs from the undated patient survey confirmed that 98.50% (798 responses) of patients felt the staff made them feel at ease on the day of their visit. However, four patients identified they were not made to feel at ease. No further detail was provided as to how these patients experiences could have improved. Following the inspection, the provider confirmed that live patient surveys took place. We received some additional patient surveys which had dated positive comments included.

Good

Diagnostic and screening services

Patient feedback from the undated patient survey confirmed that 92.64% (743 responses) of patients were satisfied they had been given clear preparation guidelines prior to their appointment. However, four patients identified they were not given clear guidance prior to their appointment. No further detail was provided as to how these patients experiences could have improved. Following inspection the provider said that due to the anonymity of the feedback they were unable to follow up on comments made.

Competent staff

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

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

We saw that allied health professional's registration status was checked and this information was held by the company. We reviewed two staff members personal files which confirmed the necessary checks were completed.

Evidence provided of allied health profession registration status confirmed the renewal dates for the three agency sonographers were current.

Managers gave all new staff a full induction tailored to their role before they started work.

Managers supported staff to develop through yearly, constructive appraisals of their work. We received confirmation that 100% of staff had received an appraisal in the last 12-months. Staff confirmed that the agency locum staff provided a copy of their latest annual appraisal.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Staff told us that due to the pandemic the sonographers had not been able to access training related to their speciality.

We saw completed documentation which confirmed that staff had received training and updates in the use of the ultrasound machine. The latest ultrasound manuals and disinfection guidelines were also provided as part of the training session.

The agency sonographers attended monthly supervision with the lead sonographer for the service.

Managers identified poor staff performance promptly and supported staff to improve.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide safe care.

Staff held quarterly multidisciplinary meetings with the local clinical commissioning groups to discuss patients and improve their care.

Multidisciplinary meetings were held quarterly with GPs and sonographer staff.

Good

Diagnostic and screening services

Staff met on occasion with the local NHS Trust, the last meeting took place in November 2021 where the North East Lincolnshire patient referrals were discussed. An agreement was reached to take on 100 patients per week who were long waiters of over 13 weeks per week. However, we were told that these patients mostly fell into the over 36 week wait.

Staff worked across health care disciplines and with other agencies when required to care for patients.

One sonographer was employed through a service level agreement to undertake ultrasound guided injections.

A consultant radiologist and orthopaedic consultant provided expert advice to the service and provided an independent review of service quality.

Seven-day services

Key services were available to support timely patient care.

The service operated Monday to Friday, however, on occasion additional clinics would operate at the weekends and in the evenings. At Freshney Primary Care Centre the clinic usually took place on a Sunday. Staff told us they could access GP support if needed through the single point of access out of hours service.

When urgent scans were required, such as for deep vein thrombosis, these were completed on the same day the referral was received.

Health promotion

The service signposted patients to other healthcare professionals and information to ensure that patients could access practical support and advice to lead healthier lives.

Staff said they did not provide information directly to assist patients lead healthier lives, however, patient information leaflets were displayed in the primary care centres that patients could access.

We saw that staff assessed each patient's health at every appointment through confirming their previous medical history with them and asking whether they had any health concerns they needed to raise.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

Staff confirmed and we saw the provider had a consent policy.

All patients were sent information regarding their procedure pre appointment so that they could make informed consent.

Written consent was taken before patients received identified ultrasound guided procedures, for example, patients who were given an ultrasound guided steroid injection or a trans-vaginal scan. The patients who attended for an ultrasound gave verbal consent.

Good

Diagnostic and screening services

We observed four patient's consultations where consent was obtained and recorded. Informed consent, education and side effects were discussed during the consultation.

Staff could describe and knew how to access policy on Mental Capacity Act and Deprivation of Liberty Safeguards. Staff had received training in the Mental Capacity Act and Deprivation of Liberty Safeguards. Training records confirmed 100% compliance in these areas. Staff said that were a patient lacked capacity the team would escalate to either the service governance lead or to the single point of access team. The issues would be reviewed, and the scan delayed until consent could be given. Staff said most patients who attended for diagnostic procedures did not have additional issues such as dementia type conditions.

Are Diagnostic and screening services caring?

Good

Compassionate care

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

Staff said female patients could request a female sonographer.

Chaperones were also available for patients if they felt they needed additional support.

We spoke with four patients who all said they had been treated with respect and felt fully informed. Patients said they understood the procedure and what to expect following their procedure.

We observed five patient consultation sessions and observed the clinician was respectful and respected the patient's dignity.

Staff checked the patient's comfort and condition throughout their diagnostic test.

Staff had completed equality and diversity training so they could support the personal, cultural, social and religious needs of patients and how they may relate to care needs.

Emotional support

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

Staff gave patients and those close to them help, emotional support and advice when needed.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them.

We observed patient consultation sessions and saw that patients appeared at ease and comfortable to ask questions. The clinician discussed potential side effects of the treatment, answered the patient's questions and was seen to reassure the patient throughout their consultation.

Good

Diagnostic and screening services

Understanding and involvement of patients and those close to them

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

Procedures were discussed with patients before treatment with expectations being managed versus desired outcomes. The four patients we spoke with all said they understood and had felt fully involved in the discussions about their proposed treatments.

Staff talked with patients, families and carers in a way they could understand, using communication aids where necessary.

Staff said advocacy could be accessed through the single point of access service. The request for an advocate would initially be identified at the referral stage. Patients records confirmed the presence of an advocate was identified when needed.

Patients and their families could give feedback on the service and their treatment.

Staff said diagnostic patients had attended a patient participation group on the 3 May 2022. Currently, the service was in the initial stages of developing this forum.

Patients gave positive feedback about the service, which we saw through the thank-you cards, the patient survey and from discussions with patients.

Are Diagnostic and screening services responsive?

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. It also worked with others in the wider system and local organisations to plan care.

Managers planned and organised services, so they met the changing needs of the local population. Managers had worked closely with the local clinical commissioning groups and the local NHS Trust to take 100 diagnostic referrals per week. These patients were long waiters of over 13 weeks, most fell into the over 36 week wait.

Accessible information standards were applied to the service.

Facilities and premises were appropriate for the services being delivered. Provision for disabled people was available and included large corridors, disabled access and toilet facilities and the use of a lift.

Managers monitored and took action to minimise missed appointments. Should patients not attend appointments, they were given two appointments and if they did not arrive for these appointments the referral was sent back to the referrer.

Good

Diagnostic and screening services

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. Staff said that the administration team on initial patient contact would determine whether the patient required any support or had specific needs. Appointment times could be increased, and everything was fully explained prior to the procedure.

The service could access information leaflets available in languages spoken by the patients and local community.

Patients can also access frequently asked questions and information about their scans from the Illumina Diagnostics website.

Managers made sure staff, and patients, loved ones and carers could get help from interpreters or signers when needed.

Staff could access interpreters through language line to ensure effective patient involvement, communication and involvement at their consultation.

Patients with a visual impairment could receive information in a braille format and large print information leaflets.

Patients with a hearing impairment could request the use of hearing loops.

Patients with learning disabilities could be accompanied by their carer's.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times for treatment were in line with national standards.

Illumina Diagnostics is a small service run on a clinician led basis which provided assessment, diagnosis and patient support services. The service had close links with the community cardiology and dermatology services and was part of the primary care network.

Patients were informed of the clinics working hours which were 9am to 5pm Monday to Friday; with an occasional weekend clinic where required. Following treatment if patients had any concerns, they were advised to seek medical assistance by calling their GP.

The service worked with an orthopaedic surgeon to provide a muscular-skeletal service.

In addition, one sonographer / physiotherapist provided an ultrasound guided injection service through a service level agreement with the service two days a week. Should this person not be available patients would be rebooked for when they were available. This person had worked in this capacity for five years with this provider.

Lincolnshire GP and local NHS Trust referrals from March 2021 to March 2022 confirmed year to date 9,285 patients had received diagnostic services through Illumina Diagnostics.

Staff said patients' referrals were triaged against the urgency rating identified on the referral. The ratings applied were routine, sooner and urgent. The sonographer reviewed the referrals to determine which order the referrals would be seen in.

The ultrasound service performance report (2021/22) discussed with the clinical commissioning groups on the 18 May 2022 confirmed 67% to 87% of patients' investigations were undertaken within 10-days of acceptance of referral from September 2021 to March 2022. In the same period 100% of patients' investigations were undertaken within 20 working days of acceptance of referral.

Patients were given a choice of time, date and location prior to their scan.

Managers made sure patients could access services when needed and received treatment within agreed timeframes and national targets.

Staff confirmed that patients were seen within their two week wait and on arrival to the clinic patients were seen within four minutes of arrival to the service.

Following inspection, the provider confirmed they aimed to see patients with a deep vein thrombosis' which is a blood clot in a vein on the same day, urgent referrals within two days and most routine referrals within 10 working days.

The results of scans were entered into patient medical records or emailed to the surgery usually on the same day for the patients GP. Where abnormalities were detected on the scan either the radiologist or orthopaedic consultant reviewed the scan and informed the GP of their findings.

The undated patient survey confirmed that 95.01% (761 responses) of patients said that following their scan they were properly informed as to how you get your results.

Managers worked to keep the number of cancelled appointments to a minimum. Should this occur patients were contacted and offered the choice of their scan on another site or the patients scan was rebooked as soon as possible.

Learning from complaints and concerns

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

Staff understood the policy on complaints and knew how to handle them. We were told that some of the staff had completed complaints training.

Patients, relatives and carers knew how to complain or raise concerns.

Managers investigated complaints and identified themes. Staff knew how to acknowledge complaints and patients received feedback from managers after the investigation into their complaint. Managers shared feedback from complaints with staff.

The service had received two verbal complaints in the last 12-months. We reviewed one of these complaints and saw there was a turnround response of two days and the complainant confirmed their satisfaction with the response provided.

Good

Diagnostic and screening services

The complaints leaflet advised patients on how to raise concerns.

A complaints register was not in place. The complaints received were currently saved in a folder.

Are Diagnostic and screening services well-led?

Good

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

Leaders were seen to be visible and approachable.

The senior team comprised of the registered manager, nominated individual, senior sonographer, company secretary and business and development officer, business and financial support officer, GP medical adviser and consultant radiologist.

A consultant radiologist and consultant orthopaedic surgeon provided expert advice.

Staff could access leadership development programmes and mentoring through their annual appraisal process. One manager had recently been mentored by a chief executive officer from a mental health organisation.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them, however, monitoring of the vision and strategy was not in place.

Staff confirmed and we saw a business plan in place.

Following the inspection, we received a copy of the company vision, objectives and outcomes which were circulated to staff on the 19 August 2021. The five themes attached to the clinical and business outcomes were: integrated teamwork, clinical and business systems, patient partnership, quality and innovation, delivery partnership. Each theme identified objectives, for example, two of the patient partnership objectives related to vulnerable, frail patients and patients with specific needs and to develop a system for regular patient feedback. We saw a common thread through most themes which related to wider system and partnership working so that plans were aligned to the wider health economy.

Culture

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

Good

Diagnostic and screening services

Throughout the inspection we observed, and five different staff told us how well the team worked together and how supported they felt within their roles. We also saw this captured within the staff survey documents we saw.

Staff could access the whistle blowing, being open / Duty of Candour policies.

The service freedom to speak up guardian had protected time to carry out the role when needed.

Staff confirmed appraisal processes were in place for all staff; 100% of staff had an appraisal in 2021 and this appraisal process was completed on the 23 March 2022. The new staff appraisal process for 2022 had commenced and personal development plans were being agreed with staff.

Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. Governance processes were in place, however, we found that the audit processes for some areas needed further development. 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.

Governance within Illumina Diagnostics was developed in line with arrangements agreed within the clinical commissioning group. The governance lead was a clinical lead within the service and clinical governance was managed by the clinical executive. Discussions with staff identified that some were unable to articulate all the governance processes and systems they used, except for clinical governance processes such as the use of audit, patient and GP feedback.

The clinical governance policy described the governance processes in respect of the maintenance of safety, effectiveness and experience.

The organisational structure identified the different teams within the organisation and showed where each area of governance sat for example, the operations director looked after clinical workforce, infection control and clinical equipment. Meeting minutes (14 April 2021) confirmed senior staff accountabilities against specified governance areas.

Although, we saw some examples of audit carried out staff told us that they did not document all these audits and subsequent discussions and learning from them. A formalised annual audit schedule was not in place.

The service monitored reporting and scan turnaround times per site. Staff said this process was completed instantly in the patient record which meant the turnaround time was instantaneous and the scan results were shared through the clinical reporting system.

Staff said monthly peer reviews of scans had taken place and following these audits staff had received feedback and training if required. If the audits identified a patient safety issue, this would be escalated to the managers, it would be investigated and if required an emergency meeting took place. Senior staff which included the directors could also communicate with each other through their personal WHATS App group and the clinical commissioning group contacted if needed.

Good

Diagnostic and screening services

Management of risk, 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. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

Performance, risk and issues were discussed at board level and at the quarterly meetings with the clinical commissioning groups. The last performance monitoring meeting took place on the 18 May 2022. The performance report (2021/22) confirmed 100% compliance against performance indicators such as triage of referrals once received within one working day, initial contact with the patient within five working days and report of investigation to be sent to referrer within two and five working days of investigation. Monthly activity from this period ranged from 492 to 808 total diagnostic appointments in the month.

The service kept records of their performance against diagnostic waiting times for six week and 13 week plus waiters. These records confirmed service performance over the last year. The six-week performance trend showed an improvement for both North and North East Lincolnshire. In April 2022 72.7% of patients were seen within their six-week window in North East Lincolnshire. In North Lincolnshire performance was higher at 87.7%. We observed that performance for both was just below the diagnostic waiting times and activity (DMO1) targets identified. However, there was a sustained improvement in performance for both since April 2020, considering the Covid-19 pandemic.

Following the inspection, the provider confirmed they had made significant progress in reducing waiting lists since supporting North East Lincolnshire from March 2021 and North Lincolnshire since December 2021. Since taking on the contracts the service have taken 3,981 patients from the local trusts and 4,414 patients from local GP referrals which have ensured waits at the local trust stay low.

The service had not identified a service specific audit schedule; however, we were told of which audits had taken place throughout 2021/22. These audits included handwashing, infection, prevention and control and six-monthly patient imaging scan audits where 10% of patient records were audited. Additional examples included peer reviews of the service, for example, a quality review of imaging took place on the 9 February 2022 which identified no concerns. Three staff also received feedback and learning through the review session on the 3 February 2022 when 31 cases were reviewed, learning and changes to procedure identified.

The sonographer undertook three-monthly audits of patients reports, the image and patient pathway. Following these audits reports were not produced, these audits were described as a ‘learning experience’.

Staff could access internal policies and procedures which related to risk and performance processes, for example, the Central Alerting System (CAS) policy.

The risk register identified individual accountabilities, the controls and measures in place against identified risks which were scored.

Business continuity plans were in place and in the event of an information technology (IT) failure staff would contact an IT consultant. Staff said records were backed up in case of IT failure; reports were saved in the patients’ clinical records and all images were saved on the picture archiving and communication system.

Information Management

Good

Diagnostic and screening services

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.

Information security guidance was available with clear directions on how to maintain information security.

Records could only be accessed through a designated password/pass card.

Data protection and Caldicott Guardian roles were identified amongst the senior team.

The service used the same electronic patients' records system as local GPs and the wider local health economy which meant healthcare professionals could access patient information and ultrasound results immediately.

The service had achieved the international organisation for standardisation (ISO) standard for quality management and information security management. The current ISO certificate expires on the 30 August 2022. Staff said they received no actions from their initial audit. Following this, staff said the company would be re-audited.

The company had also submitted the data protection toolkit which related to data security and data protection. We saw a copy of the data protection toolkit submission on the relevant NHS website.

Performance data was discussed at board level and at the quarterly meetings with the clinical commissioning groups.

Training records confirmed that all staff had completed the annual information governance training.

Engagement

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

Patients could provide feedback on their experiences through the online feedback form through survey monkey. Staff said there had only been feedback from three patients to-date. Following the inspection, the provider confirmed 797 patient responses had been received following surveys.

The patient feedback graphs we saw confirmed that 99.25% (797 responses) of patients were satisfied or extremely satisfied with the service.

Positive feedback was received from patients through the patient survey and cards displayed in the clinic. Patient feedback identified positive experiences and the professionalism of the staff.

Staff said diagnostic patients had attended a patient participation group on the 3 May 2022. Currently, the service was in the initial stages of developing this forum.

Staff meetings took place; however, we were told they were not documented. Staff met at lunchtime each day to discuss the plan for the day.

A staff suggestion box was available.

The service did not have a staff engagement strategy; however, staff feedback was captured through the staff survey to-date, three people had responded to the staff survey (undated) and said they enjoyed working for Illumina Diagnostics. Following inspection, the provider said the staff surveys were live surveys.

The service was an associate member of the primary care network and part of the integrated care partnership which was supporting the development of the community diagnostics hub.

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 research.

The service was working with its primary care network in developing a day where they will look at the priorities of the primary care network.

The service is working towards gaining accreditation in the '45003 Psychological Health and Safety at Work'.

Symptomatic shoulder management learning has taken place over the last 12-months. The orthopaedic consultant adviser completed a paper on shoulder pain management which now informs Illumina Diagnostics practice in this area.

The lead sonographer was a finalist in the Allied Healthcare Professionals Clinical Leadership award.

The provider has worked with providers and commissioners to develop a single integrated diagnostic service across northern Lincolnshire. They were actively supporting the development of community diagnostic centres in Grimsby and Scunthorpe as part of the wider integrated diagnostic system leading to greater interoperability across the area.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose The service must ensure that a medicines management policy and independent prescribing policy is available for staff. Reg 12(1)(2)(g)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose The service must ensure that all medicines are locked in a secure place when not in use. Reg 12(1)(2)(g)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service must ensure monitoring of the frequency of resuscitation trolley, blood monitoring kits and anaphylaxis kits checks is in place and ensure that the checks agreed are completed. Reg 17 (1)(2)(a)(d)(ii)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose

This section is primarily information for the provider

Requirement notices

The service must ensure that medicines governance and the oversight of medicines processes is in place. Reg 12(1)(2)(g)