Yourgene Health UK Ltd

Yourgene-Health

Inspection report

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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	Inspected but not rated
Are services safe?	Inspected but not rated
Are services effective?	Inspected but not rated
Are services caring?	Inspected but not rated
Are services responsive to people's needs?	Inspected but not rated
Are services well-led?	Inspected but not rated

Summary of findings

Overall summary

We did not rate this service. This is because CQC does not apply a rating to independent laboratory services.

- The service did not have an effective process for carrying out checks on company directors in line with regulatory requirements for fit and proper persons who were directors.
- Leaders did not always carry out relevant checks for employed staff as part of their recruitment processes.
- The service did not have clear guidance for mandatory training.
- The service did not have in date assessments for fire, electrical appliances, or hazardous substances.

However:

- The service had enough staff to provide the right level of service. Staff had training in key skills and managed safety incidents well and learned lessons from them.
- The service was planned to meet the needs of people using their service and made it easy for people to contact the service when needed and receive laboratory results promptly.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff felt respected, supported, and valued. Staff were clear about their roles and accountabilities. All staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Inspected but not rated	

Summary of findings

Contents

Summary of this inspection

Background to Yourgene-Health

Yourgene Health is a genomic services medical laboratory within Yourgene Health UK Limited which provides a non-invasive prenatal screening test (NIPT) for pregnant women using their own CE marked IONA test. CE marked certifies that a product has met EU health, safety, and environmental requirements. They also provide, out of CQC's regulatory scope, genomic services for example covid testing and clinical research support services. The Yourgene genomic services laboratory is managed as a separate department within Yourgene Health and in line with this has its own quality management system. Yourgene Health's other activities include reagent kit and instrumentation manufacturing. The activities other than NIPT do not come under CQC's Scope of Registration and therefore were not inspected.

The NIPT assay estimates the risk of a foetus being affected with Trisomy 21 (Down's syndrome), Trisomy 18 (Edwards' syndrome) or Trisomy 13 (Patau's syndrome). Where requested, the assay also provides additional screening of sex determination, sex chromosome aneuploidy and autosomal aneuploidy. Yourgene Health was registered with CQC on 1 June 2022. Previously they operated under the name of City Labs and later Premaitha Health which was registered in 2015 with CQC.

Yourgene Health does not have direct contact with patients/customers. They have service level agreements with companies to provide NIPT testing for their patients/customers. They receive the blood sample from the companies via post or courier.

Yourgene genomic services is accredited with the United Kingdom Accreditation Service (UKAS) standards ISO 15189 for the NIPT service and Covid testing. The United Kingdom Accreditation Service (UKAS) is recognised by the government as the sole national accreditation body.

The service is regulated to provide diagnostic and screening procedures and there is a registered manager in post.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. The inspection was announced 24hrs prior to our on-site inspection on 12 July 2023.

We looked at four key questions: is the service safe, effective, responsive, and well led. We did not inspect caring as the service does not have direct contact and interaction with patients.

The inspection team consisted of two inspectors and a specialist advisor and was overseen by an operations manager.

During the inspection visit, the inspection team:

- Inspected the pathology laboratories where the NIPT testing took place.
- Spoke with 11 staff: including the laboratory director, laboratory manager, operations manager, vice president, head of quality assurance and regulatory affairs, quality assurance manager, technical quality specialist, and 3 scientists.
- Looked at 2 training files and 5 recruitment files.
- Looked at 3 patient records.
- Looked at a range of policies, procedures and other documents relating to the running of the service.

Summary of this inspection

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 take appropriate actions to implement effective recruitment processes in line with the requirements for fit and proper persons employed. (Regulation 19(1)(2)).
- The service must take appropriate actions to implement effective recruitment processes in line with the requirements for fit and proper persons: directors. This includes checks to confirm the person's history relating to financial and management conduct, disclosure and barring service checks (DBS) and to confirm the person is of good character. (Regulation 5(a)(d)).
- The service must ensure they define mandatory training standards to prevent ambiguities. The service must ensure training is delivered adequately and they have oversight of compliance which is monitored effectively. (Regulation 17)
- The service must ensure that risk assessments are in date for fire, hazardous substances, heating and ventilation and electrical equipment and that there is a process to ensure that assessment schedules are accurate. (Regulation 15 (1)(b)).

Action the service SHOULD take to improve:

- The service should have a recruitment policy to outline pre-employment checks required. (Regulation 17).
- The service should update the health and safety policy with the current first aiders and their correct contact details. (Regulation 17).

Our findings

Overview of ratings

Our ratings for this location are:

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

Inspected but not rated

Diagnostic and screening services

Safe	Inspected but not rated
Effective	Inspected but not rated
Caring	Inspected but not rated
Responsive	Inspected but not rated
Well-led	Inspected but not rated

Is the service safe?

Inspected but not rated

We did not rate this service.

Mandatory training

The service did not have clearly defined mandatory training for all staff and did not always have oversight to make sure everyone completed it.

The service did not have a specific policy or compliance matrix for mandatory training. This made it unclear what training staff were required to have and what training staff had completed.

The new starters policy had a list of mandatory training in the appendix. These were: quality manual; personal development and training; induction of new staff; all policies; document management; change management; non-conformance; audit and inspections; customer feedback and all specific standard operating procedures (SOPS) relating to the role. This policy also had an appendix 2 which listed additional mandatory training for scientific staff. These were: laboratory working practice guidelines; emergency plan; all general SOPS; prevention of contaminations and degradations; labelling and storage of samples and reagents and all technical SOPs relating to the role. Much of this mandatory training was delivered by staff reading and reviewing the policies and SOPs. The new starters policy did not specify how often training should be repeated.

The service documented the completion of the new starters mandatory training on the induction programme form. However, this form included additional training which was not in the induction mandatory training appendices. This additional training consisted of fire safety, health and safety and display screen equipment (DSE) and was delivered through an on-line training system. Staff also received additional training in patient confidentiality and ethics; general data protections regulations (GDPR); data integrity; document training and non-conformance and equipment asset management training which were delivered by the quality department. The health and safety manager was responsible for the on-line learning however we were informed they had left their position the week before our inspection. The quality department delivered their training by having discussions with new starters.

The manager monitored training compliance in the induction and probation reviews and in the twice-yearly staff appraisals, and this was also discussed in management meetings.

The service did not provide training in equality and diversity. Equality and diversity training promotes working appropriately amongst an equal and diverse workforce and includes anti-discriminatory practices and how to report inappropriate or offensive behaviour.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect themselves and others from infection and prevent cross contamination of specimens. They kept equipment and the premises visibly clean.

The service had strict working protocols in place to minimise the risk of cross infection and contamination. The service also had a cross infection operational policy which provided guidance to staff on measures to take to avoid cross contamination.

The service had not reported any healthcare-acquired infections or outbreaks during the past 12 months.

The laboratory area was clean and had suitable furnishings which were clean and well-maintained. Staff followed infection control principles including the use of personal protective equipment (PPE) and we observed good practice by the staff during the inspection wearing lab coats, gloves and suitable clothing such as footwear and covered legs.

There was a good supply of cleaning equipment such as sterile wipes, wall mounted hand gel and wall mounted paper towels throughout the service. However, the specimen room did not have hand soap or paper towels available to dry hands. The service used isopropanol alcohol (IPA) 70% strength for cleaning and when the lab was not in use the cleaning schedule had been marked as N/A (not applicable) to evidence this.

There were spillage kits available to clean up spills in the laboratory area. The purpose of the spillage kit reduces the risk of contamination and injury. Some staff had specific training in managing spillages however none of the non-invasive prenatal screening test (NIPT) staff had received this training. The managers told us that the risk of a spillage in the NIPT lab was minimal and therefore did not require specific training for the NIPT staff, however they could request assistance from trained spillage staff from other parts of the laboratory.

There were no specific infection control audits in 2023 scheduled. However, the quality assurance team performed monthly lab walks which included physical checks of areas and review of the laboratory paperwork. We reviewed 2 cleaning schedules which were carried out weekly and had been completed. The service's recent lab walk inspection identified some missing cleaning checks; this was raised in their report to managers and measures were put in place to improve this.

The service required any new employees had the hepatitis B vaccination which protects staff who are exposed to blood and body fluids from contracting hepatitis B. All staff had received this vaccination.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well. However, the service did not have in date assessments for fire, electrical appliances, or hazardous substances.

The NIPT pathology departments were part of the Yourgene Health Service building. Entry into the service was by keycard and there was CCTV security for the building. We observed a visitors and staff signing in register at the entrance of the building.

Inspected but not rated

Diagnostic and screening services

There was a safe system for the storage and disposal of specimens. Staff disposed of clinical waste safely. Clinical waste was stored in sealed containers and waste was regularly collected from a contracted specialist waste disposal company.

Those reagents and consumables that required temperature control were stored in fridges and freezers in the laboratory. All temperature-controlled storage was monitored electronically with inbuilt gauges and alarms. Reagents and consumables kept at room temperature were stored appropriately.

There was an inventory of all equipment which recorded the serial number, location, record of contracted maintenance, and who the asset (equipment) was assigned to. We observed the certificates for equipment calibrations and servicing. All NIPT related equipment was in date for servicing and calibration.

The service had a schedule for the gas, electrical and portable appliance testing (PAT) of equipment which indicated the frequency these checks were due for each item. However, the completion dates for these were not completed on the schedule we observed. This meant that it appeared that these checks had not yet been carried out. The services portable appliance testing (PAT) spreadsheet indicated that this is completed yearly with the next completion to take place on 19 July 2023 however we did not see evidence of the PAT test for July 2022. The service did not have a PAT register and the PAT testing labels observed whilst on site did not have clearly written dates on them.

The fire safety assessment was carried out in July 2022 and the recommended review date was February 2023. This identified several concerns and had requested the completion of an action plan. However, the follow up assessment had not been carried out to give assurance that the actions from the fire assessment had been completed. This was raised with the registered manager and nominated individual for an immediate update. They provided us with post inspection feedback that most, but not all, of the actions had been carried out. There was a weekly fire test, and we observed the fire safety alarm test during our inspection. We observed that the fire extinguishers had been serviced and were in date.

The service arranged for blood samples and plasma to be sent in the post or via courier and the locked post box would be checked by staff daily. They used cardboard in accordance with UN3373 regulations for the transition of biological hazards to ensure packaging was strong enough to withstand the conditions of transport for specimens.

The service had trained first aiders from each department and their contact details were listed on notice boards. However, the information in the health and safety policy for first aiders was not updated in line with the new premises which could lead to confusion when contacting the first aider.

The service did not use airflow cabinets or have any positive pressure in the NIPT laboratory. They used a heating ventilation and air conditioning unit (HVAC). We did not see evidence of the servicing and maintenance for the HVAC unit.

The service had recently started monthly equipment meetings to oversee each assigned item of equipment (known as an asset) to ensure that they were maintained and calibrated. We randomly selected two asset records to review, and these evidenced that they had been calibrated and were in date. We reviewed a further 4 calibration assessments/ certificates and maintenance assessments/certificates for equipment which were complete and in date.

Assessing and responding to patient risk

Senior staff completed and updated risk assessments and removed or minimised risk.

Inspected but not rated

Diagnostic and screening services

The service did not deal directly with patients and requests for NIPT testing were made through referral by other healthcare providers. The service carried out training with these providers to ensure patient consent was completed correctly and providers followed the service's inclusion and exclusion criteria. The service's inclusion criteria required that the person be more than 10 weeks pregnant and that they had a scan prior to being referred to rule out vanishing twin syndrome. Vanishing twin syndrome is a condition in which one of the set of twins or multiple embryos dies in utero, disappears or gets reabsorbed.

The service used software to monitor tests and identify any errors. The service was easily accessible for contracted companies to make contact if they had concerns.

The service had carried out risk assessments for sample testing and equipment, and these were reviewed regularly by the senior team. There was a standard operating procedure for each specimen and risk assessment.

The service specified that blood samples should be 10mls; however, they would liaise with the provider through their electronic communication portal if there was not enough blood in the sample to discuss whether they should continue with the testing or await a new sample. This included discussions around those patients where it was difficult to take the required amount of blood and the provider may wish to proceed with less than 10mls.

Laboratory staffing

The service had enough laboratory staff with the right qualifications, skills, training and experience to provide the right level of service. Managers regularly reviewed and adjusted staffing levels and skill mix.

The service had enough staff with the right skills to run the laboratory safely. The laboratory was staffed by a NIPT laboratory manager, a laboratory director, 1 senior scientist and 3 scientists. The laboratory director (also the registered manager) worked at the laboratory for 1.5 days a week and the laboratory manager (also the nominated individual) worked 4 days a week. The service had enough senior clinical staff to provide cover and advice and run the service safely.

The service did not have any vacancies. The managers told us they were able to cover for unplanned sickness or leave through the existing team and did not routinely use bank or agency staff. Sickness rates for NIPT staff were low (1.2%). The year-to-date staff turnover rate was 10.5%. This was mainly because of staff leaving for career progression and due to a reduction in the provider's activities (such as covid-19 testing).

Records

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

Records were comprehensive, and staff could access them easily. Records were electronic and password protected. We observed 5 patient electronic records which were clear, up to date and contained adequate information about the tests performed.

The service also held some paper records for patients such as patient consent forms. The service would retain the paper consent forms for a year, and these were stored in locked archives. Information on the specimen request forms was detailed and in line with the Health and Safety Executives (HSE) requirements. The service used 3 different patient identifiers for example, name, date of birth and reference number to ensure accuracy of the sample.

Inspected but not rated

Diagnostic and screening services

The service used an electronic secure portal for all referrals and notes. The referring providers could access this, so they had an immediate view of results. All test results would be returned through the portal.

Medicines

The service did not prescribe, administer, or store any medicines for patients.

Incidents

The service managed safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. Managers ensured that actions from safety alerts were implemented and monitored.

Staff knew what incidents to report and how to report them. Staff raised concerns and reported incidents and near misses in line with the service's policy. There was an incident reporting log for staff to complete and this was sent to the senior management team for investigation.

We observed policies for the identification and control of non-conformance and procedures for raising non-conformances. These included a description of what to report and the responsibilities for investigator. However, the non-compliance policies only covered deviation from clinical procedures. Health and safety and staff related incidents were not recorded as non-conformance but were managed on a separate incident log by the health and safety manager.

There had been no serious incidents reported in the past year. Incidents were discussed in the monthly service quality meeting. Trends were analysed and investigated by the senior team.

Is the service effective?

Inspected but not rated

We did not rate this service.

Evidence-based care and treatment

The service followed national guidance when presenting and interpreting results. Managers made sure staff followed quality control procedures.

Staff followed up-to-date policies and standard operating procedures to plan and deliver high quality care according to best practice and national guidance.

There were internal and external quality control systems. We observed 3 external quality assurance audits carried out by the External Quality Assessment (EQA) service. These audits were anonymised and then tested by an external company to check that results were consistent and reliable. The reports we reviewed were compliant with the audit indicators.

The service had a programme of regular audits which were stored on the electronic system and covered all of the organisation. The two audits relevant to the NIPT service were sample receipt and sample processing and analysis of results and reporting.

Inspected but not rated

Diagnostic and screening services

Patient outcomes

Staff monitored the effectiveness of their service. They used the findings to make improvements and achieved good outcomes. The service had ISO151819 accreditation.

The service participated in relevant clinical audits both internal and external. Managers and staff carried out a varied programme of repeated audits to check improvement over time.

The service had key performance indicators for the management of samples. Records for January and April 2023 showed the service achieved some of these internal performance standards: -

- The maximum limit for number of rejected samples was 10%. The service achieved the target during January 2023 (1.2% of samples rejected) and April 2023 (0.8% of samples rejected). The reasons for rejected samples were for non-clinical reasons such as the wrong tube type or low volume of sample.
- The service had very low rates of inaccurate results. The service had 0.8% discordant results for January 2023 and no discordant results for April 2023. A discordant result is when the test result differs to the result of another service. When discordant results were obtained the sample was retested.

Managers and staff used the results to improve patients' outcomes. We saw evidence of investigations to review when things had not gone to plan, and actions put in place. For example, the service had a maximum target of 5% for sample failure rate. The sample failure rate was 16% in April 2023. We saw this had been raised in the quality meetings and board meetings and additional checks introduced to mitigate the risk of incorrect results.

The service did not diagnose conditions, they provided a test result to the referring health care professionals to review and make the diagnosis.

Managers and staff carried out a comprehensive programme of repeated audits to check improvement over time and shared results with staff to ensure learning was identified and understood. The audit schedule was managed and monitored monthly and there were no overdue audits.

The service was accredited by United Kingdom Accreditation Service (UKAS) ISO 15189 which is an international standard that specifies the requirements for quality and competence in laboratory environments. It is a standard that requires laboratories to develop robust, reliable quality management systems to establish their competence.

The service conducted internal audits to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination conformed to the requirements of ISO 15189:2012 and were implemented, effective, and maintained.

Competent staff

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

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of the service. Senior clinical staffing consisted of the laboratory director/registered manager who was a consultant pathologist and member of the Royal College of Pathologists who also held a substantive post in the NHS. The laboratory manager/nominated individual was a scientist registered with the health and care professions council (HCPC).

Inspected but not rated

Diagnostic and screening services

The provider had a system in place for the support and supervision of staff through induction, appraisals, training, observation of practice and competency assessments. Each competency was assessed and reviewed in the twice-yearly appraisal. A mid-term appraisal would take place for all staff in October and a year-end appraisal would take place in March. The service reported all staff (100%) involved in NIPT processes had completed their appraisals. We looked at the appraisal records for 2 staff. These were fully completed and showed that during the appraisal staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.

The service's new staff induction programme was reviewed on week 1, month 1, month 3 and followed by a post probation period. New employees were responsible for ensuring their goals were identified and achieved and were expected to identify any training and personal development needs during their induction.

Managers provided new staff with an induction tailored for their role. Staff were given a 72-page staff handbook which covered many areas, ranging from sickness to whistleblowing and GDPR.

Staff were aware of and competent in handling samples. Competency training included four levels from observations, to performing under supervision until the staff member could carry out the activity independently. During our inspection we observed the competency training matrix which monitored the completion of all competencies for each member of staff which enabled the manager to have oversight of compliance for staff. The matrix showed that 95% of the NIPT staff had either completed or were in progress of completing their competencies. Some staff also had extra training in additional responsibilities, of which they had completed 50% of these additional responsibility competencies.

Multidisciplinary working

Staff worked with other providers' teams to benefit patients. They supported each other to provide a good service.

Staff worked with other departments in the company and gave evidence of working alongside customer care, health and safety and culture and performance. The customer service team communicated with the providers (referrers) and supported the service with engagement.

Staff worked across health care disciplines and with other agencies when required. Managers gave us examples of working with external providers in maternity services where they had meetings arranged to discuss the NIPT testing.

The service held regular monthly board meetings, business review meetings, genomic services quality meetings, equipment meetings and all staff "townhall" meetings.

Seven-day services

Services were available to support timely care.

The main, non-regulated, service operated on a 24 hour, 7 day a week basis however the NIPT testing laboratories operated during Monday to Friday 9am to 5pm.

Consent

The service had their own consent form which their providers completed with the patient. Consent was gained in line with legislation and guidance. We looked at 4 consent forms which showed that consent had been obtained from patients and the tests were planned with their agreement. Consent forms had been signed by the patients and showed the suitability and limitations of the tests.

Inspected but not rated

Diagnostic and screening services

The consent form asked the patient if they agreed for their sample/data to be held confidentially and anonymously for the use of auditing and quality control. The consent form had tick boxes to indicate if the patient had agreed to this. The service requested that the paper consent forms were included with the delivery of the sample, where they checked the consent/non consent tick box matched the colour coded sample lid. A red lid indicated that a patient had not consented to their sample being used and a green lid indicated that they have consented to this. The paper consent forms were retained and referred to and this additional check helped prevent errors occurring however further audits were not carried out to check that processes were being adhered to and mistakes were not happening.

Is the service caring?

Inspected but not rated

We did not rate this service since they did not have direct contact with patients.

Is the service responsive?

Inspected but not rated

We did not rate this service.

Service planning and delivery to meet the needs of people.

Managers planned and provided services in a way that met the needs of stakeholders and other health care providers to deliver services.

Managers planned and organised services. The service routinely worked with a broad range of referring organisations such as healthcare providers and maternity services to plan and deliver NIPT tests.

The process of testing was made simple with postal, or courier testing options and the service provided the packaging and consent forms to the providers to ensure they complied with safety in accordance with UN3373 regulation.

The service told us they had regular contact with midwives and clinicians to discuss changes in practices and general updates.

Access and flow

People could access the service when they needed it and received the right tests promptly.

Managers monitored sample turnaround times (TATs), delivery times, rejections, failure/redraw rates, and discordant results. They had key performance indicators (KPIs) for these. These are targets services use to monitor, analyse, and optimise care processes to increase patient satisfaction.

All samples were expected to be reported within 2 - 5 days following receipt in the laboratory. If the reporting of a result was going to be beyond this time the healthcare provider would be informed and given a reason for the delay e.g.,

sample failure or instrument fault. The service had effective IT processes in place to monitor the timely processing of incoming samples. If the sample was delayed or lost the healthcare provider would be alerted and a re-draw sample would be collected if appropriate. All samples were returned to the laboratory on a tracked service with Royal mail or tracked with a courier. All packaging complied with UN3373 guidelines.

The turnaround times for results was closely monitored in the monthly quality meetings. We observed the NIPT targets for June 2023. The service received a total of 257 NIPT samples of which 2 were rejected and 4 required a re-draw. Turnaround time (TAT) for within 3 days were 33%, within 5 days were 60% and over 5 days were 40% (compared with 2% in March results). The KPI had not been met for June but had been met for previous months. We saw evidence that managers were aware of this, and investigations were underway to identify, correct and prevent this from re-occurring.

Learning from complaints and concerns

The service enabled stakeholders to give feedback and raise concerns. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.

Companies knew how to give feedback or raise concerns. The provider had a customer complaints and feedback policy which provided guidance on how to manage and respond to complaints and feedback about the service. Feedback could be made by writing, email, telephone, web application or in person. Staff understood the policy on complaints and feedback and knew how to handle them. All complaints and feedback were documented on the electronic system. The customer service team were often the first point of contact for any feedback and would work with the laboratory managers to timely deal with these.

The customer care team managed all NIPT customer queries. They separated customer queries into two main types of queries which were clinical queries for example about results and technical issues or general queries for example mail and stock issues. In the past 12 months the service had received 40 clinical queries of which 90% were answered within 1 working day and 97.5% answered within 2 working days; there were 190 general queries of which 92% were answered within 1 working day and 94.5% answered within 2 working days.

We reviewed a sample of 5 complaints which related to results, and technical issues. The service had detailed the reasons for the complaint and acknowledgement and carried out root cause analysis, corrective actions, preventative actions and management and quality assurance approval. However, 4 of the 5 complaints were not closed within their target date.

The organisation had recently undertaken an audit on complaints and customer feedback to look at the quality and completion of paperwork. They had chosen a sample size of 3 which was 10% of the complaints over the year. This covered all organisational complaints received rather than just NIPT services. The genomic service had carried out an audit for all complaints, compliments and user surveys in June 2023 which had been rescheduled from the 2022 audit schedule. We looked at a sample from the complaints audit carried out on 21 June 2023 which showed compliance with actions identified. These were entered into the electronic system detailing the person responsible and due date. The system was then set up to alert the person if this becomes overdue.

The services complaints process included corrective actions and preventative actions. After at least a month of the corrective action being in place the service would evaluate whether the problem had been eliminated.

Is the service well-led?

Inspected but not rated

Diagnostic and screening services

Inspected but not rated

We did not rate this service.

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 staff. They supported staff to develop their skills.

There was a management structure with clear roles and responsibilities to provide sustainable high-quality care. Specific to the NIPT laboratory there was a laboratory manager who had responsibility and management of the laboratory and the laboratory staff. The laboratory manager reported to the laboratory director who was part of the senior leadership team.

There was good oversight of the challenges the service faced as well as innovative practices.

Staff we spoke with were positive about managers and how they were approachable and open to discussing new ideas and taking onboard any concerns raised. Staff said they received good support when needed and managers were very visible within the service.

We observed good team working and a supportive working relationship during the inspection.

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. Leaders and staff understood and knew how to apply them and monitor progress.

The service had a clear vision and strategy and had a 3-year strategic plan recently devised covering goals, their mission, and their vision. These were displayed on bold posters in the building. However not all staff were fully aware of the visions and strategies.

There was a clear vision underpinned by a set of values which prioritised quality and sustainability. This was supported by a set of policies to ensure the vision was delivered. The service's values were collaboration, recognition, innovation, commitment and integrity with service behaviours identified as 'we care, we dare, we deliver.'

Culture

Staff felt respected, supported and valued. The service had an open culture where providers and staff could raise concerns without fear.

The service had carried out engagement survey reports in 2020 and 2022 with the 2023 survey about to be launched. This was for all staff employed with Yourgene Health UK since they were unable to break this down to be specific for the NIPT staff. The key areas for the service to better understand were: planning workload, clarifying career paths, clearly defined and formal training, salary and bonus reviews and work-life balance. However, not all leaders were aware of the results and themes which were raised from the staff surveys.

Staff felt supported, valued, and respected. Staff told us they enjoyed working within the service and were kept up to date. The senior management team attended the canteen each month to give updates and summaries from the board reports to staff. This was also displayed on notice boards in the offices.

Wellbeing and the appreciation of staff efforts were recognised. The service published a staff newsletter fortnightly. This provided staff with various company updates. They also provided activities for staff to engage in on different days of the week. These included a breakfast club, mindful yoga, running club, HIIT classes and badminton classes. The service had a social hub where staff could get together for drinks, and they recently had a summer party for all staff. The manager overseeing culture and performance was the company representative for wellbeing and they completed extra qualifications in counselling. Photograph competitions were also arranged.

The culture and performance department was responsible for managing whistleblowing incidents. The staff handbook provided information on what constitutes a whistleblowing and how staff can raise concerns.

Governance

Leaders did not always operate effective governance processes because they did not always carry out relevant checks as part of the recruitment processes, in line with fit and proper persons requirements for directors and persons employed. However, staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The quality assurance manager was responsible for the management of all policies and standard operating procedures (SOPs). Each policy / SOP had a document owner who was responsible for updating the policy. Polices were updated at least every 3 years or sooner if there were any changes to best practice guidance. The document owner received an automated email from the electronic policy system when a policy was near to their review date. If changes to a policy were needed, authorisation and approval would be required from designated approvers. The new /updated policy would then be circulated by email to people on the distribution list as requiring to be read. The electronic policy system monitored when staff had read the document. However, managers did not routinely audit how many staff had read or not read documents. Most policies and SOPS reviewed on screen were within review date and the policies observed were well written and in line with guidelines. However, not all policies and SOPS were on the electronic system, for example the health and safety policies and human resource policies.

There were monthly board meetings, business review meetings, service quality meetings, equipment meetings and an all staff “townhall” meetings as well as 6 monthly management review meetings.

We reviewed several policies. The health and safety policy was effective from June 2021; we were informed by the quality assurance manager that the policy should have been reviewed and updated in June 2022.

We saw a control of substances hazardous to health (COSHH) assessment dated September 2020. We reviewed the COSHH assessment procedure dated 2021 which stated ‘the COSHH assessment will be reviewed if significant changes are made to the workplace, the procedures performed there, the suppliers MSDS, or current regulations and legislation. If no significant changes are made all COSHH assessments will be reviewed annually.’ This meant that the COSHH assessment was out of date.

The service did not have a recruitment policy to outline processes. This meant it was unclear what pre-employment checks were required for new staff and for appointing company directors. We checked recruitment records for 1 director

and 4 staff. All had photograph identification, employment contracts and hepatitis B immunisation evidenced. However, 4 staff files did not have proof of qualifications, did not have any references and none had disclosure and barring service (DBS) checks. This meant that staff were employed without confirmation of their qualifications and the relevant pre-employment checks.

The service did not have a policy for mandatory training. This led to ambiguity as to what training staff must do and how often. It was unclear who was responsible for the oversight of mandatory training and what the compliance rates were.

The path lab manager was responsible for safety alerts from the medicines and healthcare products regulatory agency (MHRA) and submitting statutory notifications to CQC.

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.

The service had a register of risk assessments that had been completed in relation to NIPT processes. The risk assessments were complete and up to date and these were reviewed by the laboratory director and quality assurance team during routine monthly quality assurance meetings.

Health and safety had its own risk register which was not available for us to review as part of our inspection. The health and safety lead had left the organisation the week before we inspected the service. Contingency for the absence of the health and safety manager had not been put in place during our inspection. The senior managers had a separate business risk register which they reviewed in the monthly board meetings.

The service did not have oversight of environmental safety assessments. The portable appliance testing (PAT), control of substances hazardous to health regulations (COSHH) assessment and fire safety assessment were all out of date. Furthermore, the fire safety assessment in 2022 had raised significant concerns which required actioning which had not taken place at the time of our inspection.

There were also routine staff meetings which took place to discuss day to day issues and to share information on performance standards against organisational objectives. Information relating to performance objectives was monitored by senior managers and cascaded to staff through these team meetings, via emails and staff newsletters.

The service had a risk register that listed the key risks to the service. The quality assurance manager was responsible for maintaining the risk register. Key risks were reviewed at the clinical governance meetings, senior management meetings and board meetings. Actions taken to mitigate risks were incorporated into standard operating procedures that staff were required to follow.

They also had generic audits for records, recruitment files and complaints. Results of audits were used as part of the services continued quality assurance. We reviewed a selection of internal quality audits and saw when errors occurred actions were taken.

Information Management

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure.

Diagnostic and screening services

The head of quality assurance told us they collated and analysed information on performance to look for improvements and routine performance reports were in place detailing performance against key performance indicators.

There were systems in place for the safe storage, circulation and management of electronic and paper-based records such as consent forms, patient records, audit records and meeting minutes. Patient records were accessible for staff and could be easily retrieved. Electronic records were stored on computers with controlled access.

The service used an electronic quality management system for all of their policies and procedures, incidents/ non-conformance reports, complaints, audits and ASSET register (equipment maintenance logs). The quality assurance lead told us that there had not been any data breaches in the last 12 months.

The staff had completed data protection and information governance training as part of their induction. However, it was not clear who had oversight of this and how often the training was required.

Staff could access information such as policies and procedures in electronic format. However, some of the policies we looked at were not version-controlled and did not have a periodic review date.

The laboratory manager ensured equipment was sufficient and appropriate for the service through calibration and certification of assurance through quality assessments.

There were systems to ensure the information used to monitor, manage and report on quality and performance were accurate, valid, reliable and timely.

The service had a contract with an external company to oversee all aspects of their GDPR.

Engagement

Leaders and staff actively and openly engaged with healthcare providers and staff, to plan and manage services. They collaborated with partner organisations to help improve services for patients.

Staff told us they received good support and regular communication from their line managers. Staff routinely participated in team meetings to provide updates on issues, performance and risks. The service had created social groups to encourage communication between staff. The service also ensured information from the governance meetings was cascaded to all staff.

The service had carried out employee surveys in 2020 and 2022 and were planning on another survey in 2023. We saw evidence that this is being planned for July 2023 and being set up by the marketing team. The staff survey completion rate was 44% in 2022, 24% less than in 2020. This survey was for all Yourgene Health Staff and could not be broken down to establish separate results for the NIPT service. The survey aimed to highlight factors that influenced employee's engagement, both negative and positive and to identify improvement themes. The key areas from the 2022 survey which required addressing were planning workloads, clarifying career paths and work-life balance.

Customers were either NHS services or private clinics. The customer care team would deal with any concerns or feedback raised by providers. They would then pass on the information to the laboratory manager and staff. The customer care team managed all NIPT customer queries. The service reported on turnaround times for all enquiries. In the past 12 months the service had received 230 queries of which 91% were answered within 1 working day, and all were answered within 2 working days.

Inspected but not rated

Diagnostic and screening services

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.

Staff told us the service had a positive culture that was focused on learning and improvement. We saw evidence of learning and improvement resulting from findings from audits and incidents and learning was cascaded to staff to improve the service.

Staff were encouraged to make suggestions for the improvement of any aspect of the laboratory service. These suggestions were evaluated, implemented as appropriate and feedback provided to the staff. A total of 11 service improvements/staff suggestions were raised during the period of 01/10/2022 to 30/03/2023 with 6 implemented and 5 in progress.

Managers had arranged an external training event on human error for all staff to attend. Human error training helps to understand human behaviour to minimise human error.

The laboratory owned the end-to-end process for many of their tests for example they produced the tests for the NIPT services. They were involved in research which staff also participated in and there was a culture of improvement and progress embedded in the service by the management team to meet referring providers needs and to ensure the laboratory had up to date technology to aid staff and ensure safety.

There was a good oversight of technology and equipment used and the service invested in new equipment and technology to improve the quality and effectiveness of the service.