

Rightangled Limited

# Rightangled HQ

## 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

Good 

Are services safe?

Good 

Are services effective?

Insufficient evidence to rate 

Are services caring?

Insufficient evidence to rate 

Are services responsive to people's needs?

Good 

Are services well-led?

Good 

# Summary of findings

## Overall summary

We rated it as good because:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- The service had enough staff with the right qualifications, skills, training and experience.
- Although the service was not patient facing, they collected and reviewed patient feedback to make improvements as needed.
- 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.
- Staff felt respected, supported and valued. The service had an open culture where patients, and staff could raise concerns without fear.
- Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact.

However:

- Although the service had taken steps to strengthen their governance processes, more time was needed to embed the revised governance structures further to the company's growth. This included completing the introduction of a quality management system.

### **Victoria Vallance**

Director of Secondary and Specialist Healthcare

# Summary of findings

## Our judgements about each of the main services

Service	Rating	Summary of each main service
<b>Diagnostic and screening services</b>	Good 	Diagnostic screening was the main activity at this service. See the overall summary for details.



# Summary of findings

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# Summary of this inspection

## Background to Rightangled HQ

Rightangled HQ is operated by Rightangled Limited. The service opened in August 2017, having previously offered services under a different location. Rightangled HQ specialises in home testing services for DNA, infection and blood testing. The service offers blood testing for a range of conditions (26 in total) such as diabetes, cholesterol, thyroid function, fertility, prostate health, female and male hormones, immunity health and heart health.

The service was not in scope of CQC registration for the tests provided but was registered with the CQC due to the service level agreements with medical consultants. Patients would purchase home kits using the website as the service was not patient facing. The service was in the process of launching a pharmacist led online pharmacy service with a dispensary on site (which was out of scope for CQC registration and will not be included in the report).

The clinic has a registered manager in post. A registered manager is a person who has registered with the CQC to manage the service. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

The main service provided is diagnostic screening. This is the first inspection of the service since registration in 2017. Our inspection team was led by a CQC lead inspector and an assistant inspector.

For the last 12 months, the breakdown of activity was:

- Blood testing – 73
- DNA testing – 112
- Covid testing - 8144

## How we carried out this inspection

We reviewed documents that related to the running of the service including policies and standard operating procedures, meeting minutes, staff training records, results of surveys, audits and patient feedback.

We interviewed 11 staff members including the management team, administrative staff and research staff.

We carried out a short announced inspection on 4 May 2022. The service was not patient facing which meant we could not speak with patients, but we were able to review patient feedback information.

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.

# Summary of this inspection

## **Action the service SHOULD take to improve:**

- The service should ensure that the risk register is updated ensuring that older risks have been closed.
- The service should continue to embed and strengthen governance structures and processes.
- The service should ensure that the introduction of the quality management system is completed.






# Our findings

## Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Good	Insufficient evidence to rate	Insufficient evidence to rate	Good	Good	Good
Overall	Good	Insufficient evidence to rate	Insufficient evidence to rate	Good	Good	Good

# Diagnostic and screening services

Safe	Good 
Effective	Insufficient evidence to rate 
Caring	Insufficient evidence to rate 
Responsive	Good 
Well-led	Good 

## Are Diagnostic and screening services safe?

Good 

We rated it as good.

### Mandatory training

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

Staff received and kept up to date with their mandatory training. The training was delivered via an e-learning platform by an external provider. Some training sessions were delivered face to face; for example, staff told us there was a recent session on social media. As of April 2022, the mandatory training compliance rate for all staff was 100%. Managers monitored mandatory training and alerted staff when they needed to update their training.

New starters completed a one week induction which included enrolling on the e-learning modules for mandatory training. The registered manager told us that the service had plans to bring the training modules in house to have more control and flexibility on how it was managed.

### Safeguarding

**Staff had training on how to recognise and report abuse and they knew how to apply it.**

Staff could access the service's safeguarding policy on the internal drive. Although the service was not patient facing and did not provide treatment, staff completed Safeguarding Adults - Level 1 training as part of mandatory training. The compliance officer was the safeguarding lead for the service and had completed Safeguarding Adults - Level 2 training.

The registered manager told us there had been zero safeguarding referrals.

### Cleanliness, infection control and hygiene

**The service kept the premises visibly clean.**

The service did not have any clinic rooms as it did not provide treatment and was a virtual service. All areas were visibly clean and staff told us that an external company cleaned the building daily. The building had three toilets and we found each toilet had handwashing signs on display.



# Diagnostic and screening services

The service had a fulfilment room which was used to process orders and we found it was clean and well organised. We saw hand gel was available in all areas.

## Environment and equipment

### **The design, maintenance and use of facilities, premises and equipment kept staff safe.**

The service was based in an office over three floors. Each floor had a well-equipped kitchen with fire blankets and in date powder extinguishers suitable for all fire types. The ground floor had a reception area, staff room, disabled access toilet and fulfilment room. The reception area had secure access and there was CCTV in place. The first floor was an open plan communal workspace which was light and had ample space which complied with social distancing. The first floor also had a meeting room and office. The second floor had ample open space and private meeting rooms. Although the service had a fulfilment centre based off site, staff told us that the site was being used for storage as fulfilment took place at the main office.

The service had a first aid kit which had disposable items. We checked a random sample of stock and found all items were in date.

Test kits had CE markings which confirmed that they have been assessed to meet high safety, health, and environmental protection requirements in the European Economic Area (EEA). The registered manager told us that the service was in the process of converting these CE markings to the UK Conformity Assessed (UKCA) marking. The UKCA marking is a new UK product marking that is used for goods being placed on the market in Great Britain. Staff told us the UKCA legislation would come into effect on 1 June 2022.

The compliance officer was leading on the conversion process and had checked that each device matched the relevant technical specification. The registered manager told us that the service would be ready in time for the new legislation.

The compliance officer told us they were registered with MHRA as a Responsible Person (RP). The RP was responsible for safeguarding product users against potential hazards arising from poor distribution practices.

## Assessing and responding to patient risk

### **The service was not patient facing which meant elements of this key line of enquiry was not applicable to the service.**

The registered manager told us that the online form for patients to register their kits included a section on medical history and a test specific questionnaire to complete.

The service had developed an analysis tool which produced a personalised report for the patient. The report would risk assess for any medical conditions and identify the likely response to different medications and lifestyle changes.

## Staffing

### **The service had enough staff with the right qualifications, skills, training and experience.**

The service had 11 staff members and service level agreements (SLA) with three medical consultants.

We reviewed the consultancy agreement and found that it was comprehensive and included responsibilities, intellectual property, insurance and liability. Although the agreement did not have an expiry date, four weeks written

# Diagnostic and screening services

notice was required by either party to terminate the contract. The consultancy agreement also detailed the appropriate checks carried out such as regulatory requirements, professional requirements, accreditations, legal requirements and indemnity insurance. The registered manager was responsible for interviewing consultants, establishing their accreditation level, checking evidence of practice and competency and checking registrations with professional bodies.

Staff vacancy rate for the last 12 months was 28%. The registered manager told us the service had recruited a Human Resources (HR) assistant in April 2022 to help speed up the recruitment process. The service had also set up a referral scheme to reward employees should any of their referrals receive an offer letter and contract.

Staff turnover rates for last 12 months was 9%. The registered manager told us that the service was working to reduce this by introducing additional employee engagement schemes to ensure staff satisfaction in the workplace. The service was in the process of creating cross-department training modules to facilitate staff reassignment to other departments should their roles become redundant.

The service did not use agency staff and the staff sickness rate for the last 12 months was 0.3%.

## Records

**The service did not provide treatment and was not patient facing. This meant elements of this key line of enquiry was not applicable to the service.**

The service used an integrated system which anonymised patients samples as barcodes and staff were able to track the barcode for updates using the dashboard.

The integrated system enabled patients to register the kits online generating a barcode, which meant the laboratory could not see who the sample belonged to. Once the laboratory uploaded the sample results using a secure portal, the service generated personalised reports for patients using their own analysis tool.

## Medicines

**Due to the nature of the service, this key line of enquiry was not inspected as it was not applicable to the service.**

The service did not provide treatment but offered pharmacogenetic information which may be considered as part of the treatment plan for the patient's by the General Practitioner (GP).

## Incidents

**Staff knew what incidents to report and how to report them. Staff had knowledge or understanding of duty of candour.**

The service had a system for reporting incidents and staff knew what incidents to report and how to report them. Staff completed training on Duty of Candour as part of their mandatory training and demonstrated awareness. Staff were open and transparent, and gave patients a full explanation if and when things went wrong.

In the last 12 months, the service has not reported any serious incidents or non-reportable incidents.

## Are Diagnostic and screening services effective?

# Diagnostic and screening services

Insufficient evidence to rate 

We do not currently collect sufficient evidence to enable us to rate this key question.

## Evidence-based care and treatment

**The service had clinical reporting manuals explaining the testing markers in kits and staff could easily access policies on shared drives.**

Policies and standard operating procedures were available on shared drives for staff to easily access. We reviewed the company's policies and found they were dated, had version control and detailed.

The service had clinical reporting manuals which detailed the science behind testing certain markers and how consultants would be able to report on the results. The manuals also included case studies and examples. The registered manager told us the clinical reporting manuals were reviewed annually by the Advisory Board. Amendments were made in accordance with the latest clinical guidelines, and where applicable, updates were shared by email with consultants through the service's platform.

Staff told us they were notified of new policies and SOPs either face to face by the registered manager, in the weekly team meeting or via email. Staff told us that all the standard operating procedures were saved on the internal drive and there was a feature which permitted audit trail. This meant it was possible to determine when staff had accessed policies. Staff told us that they signed digitally once they had read the standard operating procedures.

The registered manager told us the service completed audits to review laboratory turnaround times against the invoices received as reimbursements were based on processing times. Where the time exceeded 24 hours, the service provided a refund to customers and submitted a claim to the laboratory.

## Nutrition and hydration

**Due to the nature of the service, this key line of enquiry was not inspected as it was not applicable to the service.**

## Pain relief

**Due to the nature of the service, this key line of enquiry was not inspected as it was not applicable to the service.**

## Patient outcomes

**Due to the nature of the service, this key line of enquiry was not inspected as it was not applicable to the service as it did not provide treatment.**

## Competent staff

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

# Diagnostic and screening services

Managers provided new staff with a full induction tailored to their role before they started work. During the induction, staff received health and safety training and orientation around the standard operating procedures (SOPs). The first formal performance management review (appraisal) was completed on or after six months service and at least annually thereafter. The registered manager told us that performance management reviews may occur in advance of this, following any untoward incident.

We spoke with new starters who told us the induction was informative. All staff completed their mandatory training during induction. The service had department specific SOPs which staff were required to read and sign during their induction.

Managers supported staff to develop through yearly, constructive appraisals of their work. As of April 2022, the completion rate for appraisals was 100% for all staff. The registered manager told us that all customer support staff had completed their training manuals on the products the service offered and had their knowledge check test as part of their end of year appraisal.

Managers made sure staff attended the weekly team meetings or had access to full notes when they could not attend.

The service used to have a check list previously for staff recruitment. However, given the company's growth, the service had introduced a staff onboarding policy for new starters in April 2022 which we found to be comprehensive. The service completed appropriate employee checks which included Disclosure and Barring Service (DBS) checks, references, identification checks, right to work evidence and qualifications. We reviewed eight staff files and found they had been completed fully.

The service had three medical consultants working at the service with service level agreements (SLA). The service received a notification when the consultant had signed digitally the consultancy agreement after which the service would provide the consultant with a demonstration account whilst the validation checks took place and to ensure that they were aligned with the reporting process and met the standards required. Once all the necessary checks had been completed, the account was activated, and consultants could commence reviewing patients results. Consultants also received access to the portal where they could download the clinical reporting manuals and training manuals.

The service had set up a system which allowed them to revoke a healthcare professionals access to patient's data if needed. However, the registered manager told us they had had no concerns regarding the consultants.

## Multidisciplinary working

**Although the service operated independently, where needed, the service had processes in place to allow patients to share information appropriately with their General Practitioners.**

The service provided a virtual service to patients and was not patient facing. Patients accessed their reports via the portal and could download a copy to share with their General Practitioner (GP). The registered manager told us that a patient's GP could also contact the service to discuss reports if needed. The registered manager told us there were plans to launch an appointment system to allow patients to contact consultants.

## Seven-day services

**The service provided a virtual service which meant elements of this key line of enquiry was not applicable to the service.**

# Diagnostic and screening services

Patients were able to email their enquiries to a generic email address or use the live chat service (available Mondays to Fridays 9am to 6pm).

## Health promotion

**Staff gave patients practical support and advice to lead healthier lives.**

The service promoted health through virtual platforms such as Podcasts, social media and blogs. Topics discussed on blogs included diet and nutrition, cardiac health, exercise and fitness, genetics 101 and Covid-19.

## Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

**The service was not patient facing which meant elements of this key line of enquiry was not applicable to the service.**

Although the service was not patient facing, the online booking process included obtaining consent from the patient. Mandatory training for staff included a module on Mental Capacity Act and the completion rate was 100%.

## Are Diagnostic and screening services caring?

Insufficient evidence to rate 

Due to the nature of the service, we could not collect sufficient evidence to enable us to rate this key question.

## Compassionate care

**Although the service was not patient facing, they collected and reviewed patient feedback to make improvements as needed.**

The service completed patient surveys in three stages. The first survey was after receiving the result, the second survey was one month after followed by one final survey after the whole process.

Staff told us that patient survey results indicated a need for a faster turnaround of results from the third party laboratories. The service addressed this by contracting a network of laboratories across the UK, removing any bottle necks that may arise from increase in demand. The service used integrated systems with the laboratories which meant results were reported directly into the system without any delay.

The customer service manager was the first port of call for customers on the telephone, email, live chat and letters. Staff told us that patients reported good customer service from staff both online via email and chat.

The service used the Net Promoter Score (NPS) survey to gauge how patients found the overall service using scores between the value of 1-10. We reviewed the NPS results between 1 January and 14 April 2022 which showed that from 400 responses, 70% of patients scored the service as either 9 or 10 whilst 21% scored between 0 and 6. The overall NPS score for that period of time was +20 (ideal score would be between 0 to 30).

The customer service manager produced a NPS Survey report which analysed all the findings and categorised the feedback into themes. The report included an action plan for the areas where scoring was low, and staff told us that findings were discussed in management meetings.

# Diagnostic and screening services

The customer service manager also reviewed Trust Pilot reviews to identify themes and areas of improvement. Service leads told us they would read the negative comments and take action to make improvements. Staff could give us examples of how patient feedback and lead to improvements in the service. For example, patients fed back that response times for answering telephone calls during the pandemic was slow. Although the service was a small team, they addressed this by implementing a process via email which recorded the same information logged during telephone calls. This meant that patients could log their queries without having to wait for a long time on the telephone.

## Emotional support

**The service was not patient facing which meant elements of this key line of enquiry was not applicable to the service.**

The building had several meeting rooms on the first and second floor which meant staff could have private conversations with patients where needed.

## Understanding and involvement of patients and those close to them

**Due to the nature of the service, this key line of enquiry was not inspected as it was not applicable to the service.**

## Are Diagnostic and screening services responsive?

Good 

We rated it as good.

## Service delivery to meet the needs of local people

**The service was not patient facing which meant elements of this key line of enquiry was not applicable to the service.**

The service had adapted to meet changes in the healthcare environment with the recent pandemic.

## Meeting people's individual needs

**The service was not patient facing which meant elements of this key line of enquiry was not applicable to the service.**

The registered manager told us that patients' needs were self-reported when registering the kits on the service's platform. The assigned medical consultant would take all the relevant information into account when providing their assessments. Patients had the option to be re-assigned to a different practitioner through the platform portal as well as the possibility to disable access to their medical information to any assigned practitioner.

We asked staff about interpreting services and staff told us they would either use online translators or own knowledge as the team was diverse. However, staff told us they did not have many patients whose first language was not English.

## Access and flow

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

# Diagnostic and screening services

Patients would purchase the home testing kits using the website and all tests were sent out with a prepaid tracked postage for patients to use to return samples to the certified laboratory for analysis. Patients would need to register their kit online for samples to be processed. The registered manager told us that the website advises that unregistered kits would not be processed, and the sample would be discarded.

Once the results were back from the laboratory, the assigned consultant would review the reports and sign them off for patients to access. Medical consultants told us that where patients had queries regarding their reports, the service could contact the consultants easily to arrange this. The registered manager told us the service had plans to launch an appointment-based system for patients to have contact with the consultants.

We reviewed the sample turnaround time between April 2021 and April 2022. Results showed that processing times were achieved for 98% of DNA Test results (against target of within 28 days), 75% of blood test results (against target of within five working days) and 95% of Covid PCR tests (against target of less than 48 hours). The service acknowledged that there were drops in turnaround times during the months of July, August and September and told us this was due to the large volume of samples processed during the summer holidays. Another drop in performance was seen during the festive period which could be attributed to the restricted opening hours of the third party laboratories.

Staff told us that the service audited laboratory performance at the time of receiving payment invoices and challenged any results which were not within the timeframe. The service had a dashboard which documented performance times and this data was used when reviewing service level agreements with laboratories.

Consultants advised patients to share the results with their General Practitioners (GPs) as only the patient and assigned consultant would have access to the report.

The service had established a pathway to expedite priority samples for processing with the third-party laboratories. The service did not share any identifiable information other than the patient's sample barcode.

The DNA test kit was currently available to order worldwide, and the website advised patients that processing times would differ for orders outside the UK. The blood and infection test kits were only available in the UK and Channel Islands. Staff told us that the service was in the process of making the test kits available to order from the United States of America.

## Learning from complaints and concerns

**It was easy for people to give feedback and raise concerns about service received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.**

We reviewed the complaints policy and found that it was in date. The policy included information on how to make a complaint, the complaint process, compensation and stated the response time was within 20 days.

The service had a complaints log which documented details about the complaint, outcome, date received, date closed and who signed off the complaint. The complaints log showed there were 17 complaints between June 2021 and October 2021 which related to delays in couriers by third parties. All of the complaints had been settled and closed by the customer service manager.

# Diagnostic and screening services

Managers shared feedback from complaints with staff and learning was used to improve the service. For example, during the pandemic, a recurrent theme for complaints was regarding the delays in obtaining results. The service addressed this by introducing a premium courier service to collect the sample tests on the same day as the test was taken for London based customers within a certain radius. The registered manager confirmed there had been no recent complaints received.

## Are Diagnostic and screening services well-led?

Good 

We rated it as 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 staff.**

The registered manager was the Chief Executive Officer (CEO) for the service. The CEO provided leadership with support from the management team. This included the customer service manager, superintendent pharmacist, compliance officer, operations manager, marketing manager and financial assistant.

The service had an Advisory Board composed of five Non-Executive Directors (NEDs) and the CEO (who was the Chair). Staff we spoke with described the CEO as approachable and visible. NEDs told us they felt the management team was organised and described the registered manager (and CEO) as adept to situations.

### Vision and Strategy

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

The service provided their 2022 Vision and Strategy presentation which stated the strategy's aim was to deliver the right healthcare experience in testing and in treatment tailored to genetics and blood tests. The service had three T's to deliver personalised health services which were tests, technology and treatment.

Although the presentation did not mention which other stakeholders were involved in the development of the vision and strategy, staff we spoke with told us they were given the opportunity to provide feedback. Staff told us that they felt the strategy incorporated the company's values appropriately.

### Culture

**The majority of staff felt respected, supported and valued. The service had an open culture where patients, and staff could raise concerns without fear.**

Staff we spoke with told us they felt supported by their managers and colleagues. Staff described the environment as friendly and told us they felt listened to if they raised concerns. Staff told us they enjoyed working at the service as the culture was like a family and that there was good diversity within the team.

Staff enjoyed the working environment as it allowed them to learn about new products and services. Staff told us they were able to share ideas and that their input was valued. Although staff acknowledged the company was growing, some staff told us they wanted more clarity as this would facilitate their career plans and development.



# Diagnostic and screening services

Staff told us there were social functions on Fridays. The staff area on the ground floor was spacious with comfortable seating, plants and the team area had a snack bar and fruit available. The service had a pool table on the second floor for staff to use during lunch breaks and after work.

The service completed staff surveys post changes in the business. Recent survey results showed some initial reservation by staff with regards to the relocation of the office. Although some staff found the commute more convenient, some staff found it difficult. The registered manager addressed this by inviting staff to visit the premises prior to the move which helped staff get familiar with the area and local amenities. Staff told us that the open plan layout of the new office promoted integrated working.

## Governance

**Although the service needed more time to embed and strengthen governance structures further to the company's growth, staff at all levels were clear about their roles and accountabilities. Staff had regular opportunities to meet, discuss and learn from the performance of the service.**

The service had introduced several new policies in April 2022 to align with the company's growth and the launch of new services. This meant they would not have been embedded at the time of the inspection. We reviewed these policies and found them to be comprehensive. For example, the policy for the Development and Implementation of Procedural Documents included information on how to develop a policy, the ratification process, implementation and the policy register.

We asked the registered manager how staff were informed of these new policies, what training they received and how they would ensure these policies were embedded. The registered manager told us there had been a team meeting in April 2022 which specifically introduced and reviewed all the company's policies. We reviewed the meeting minutes and saw there was a completed attendance checklist.

The service had five Non-Executive Directors (NEDs) each of whom were clinical academics. Although the service did not have an official process to recruit NEDs, the registered manager told us they had a criteria. The service utilised their connections and networks to recruit NEDs with the relevant expertise. The registered manager told us that the appointment of NEDs was discussed at the Advisory Board and the selection process included reviewing qualifications and completed literature reviews.

The service had Advisory Board meetings which discussed business updates, reviewed the risk register review and presented quarterly reports for the service. Attendees included the registered manager (also the CEO), five Non-Executive Directors (NEDs) and operational manager. We requested the last three meetings minutes and received minutes for January 2020, July 2020 and March 2022. Agenda items included discussion on research plans, new NED appointments and details of the new service proposals. It was agreed in March 2022 to have quarterly NEDS meetings going forward. It was not known if any meetings took place in 2021 as no evidence of this was provided. However, NEDs told us that it had been challenging to arrange meeting in 2021 due to the pandemic. NEDs told us that their tenure was for five years.

NEDs told us that the management teams were organised and although the pandemic had impacted the Advisory Board meetings, there was now a reporting structure which had improved the governance structures. NEDs received the agenda and relevant papers in advance of the meetings in a timely manner. NEDS told us that the agenda had been fluid given the growth of the business and impact of the pandemic.

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We requested the minutes from the last three management meetings. The service had weekly management meetings for each department separately. The service provided the April 2022 meeting minutes for customer service, finance and pharmacy department. Agenda items included discussion on department updates, workflow, targets and projects. However, it was not clear from the minutes who had attended the meetings and there was no standardised agenda covering items such as complaints, incidents or staffing within the agenda. We asked the registered manager about this who told us that governance structures were still in their infancy further to the company's growth and that more time was needed to embed them. The service had recently recruited a compliance officer to address this and ensure compliance with Industry Standards (ISO), Medicines and Healthcare products Regulatory Agency (MHRA) and other regulators. Hence, it was too early for us to test this during this inspection.

The compliance officer would be focussing on the development of policies as the business expanded and would be introducing a Quality Management System (QMS) by July 2022. The QMS would include workforce development, premises, equipment, operational procedures, organisational processes and company policies. The QMS would be aligned to the MHRA principles of Good Distribution and Manufacturing Practice (ISO 9001:2015, ISO 13485:2016) and regulatory requirements.

Managers told us that they submitted monthly management reports to the CEO and these reports were also used as part of their performance reviews. We reviewed the monthly reports for April 2022 for all seven departments and found there was a standardised format. The reports included information on the work completed for the month, work planned for next month, key performance indicators (KPIs) and any issues of concern.

The service was in the process of setting up two additional weekly governance meetings. One of the meetings would focus on policy and procedure development and the other on quality management review. We reviewed the terms of reference for the policy and procedure development meeting and found it was comprehensive. Managers told us there would be a standardised agenda which would include reviewing the risk register, complaints, failed audits and KPIs. The registered manager told us that each meeting would have an action log, an assigned chair and would be minuted. Managers told us that these meetings were due to commence from 18 May 2022.

The service contracted external ISO accredited laboratories which were registered with various UK National External Quality Assessment Site (NEQAS) schemes. The service ensured the laboratories used maintained UKAS accreditations to ensure continuous high standards. The service provided evidence of UKAS certificates for the laboratories used, which were in date.

## Management of risk, issues and performance

**Leaders 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 risk register which was divided into 11 categories such as environment, data, operations, research, market and pharmacy. The register included information such as risk description, category, impact, mitigation, risk owner, timeframe and status. Although we were told the risk register was reviewed at the Advisory Board meeting, we found the risk register was not kept up to date and did not document the last review date or risk owner. There were four entries for 2017 (three for environment and one for data) with timeframes for action ranging between two weeks to three months but all entries still had 'in progress' for their status.

NEDS we spoke with corroborated that the risk register was frequently discussed in the Advisory Board meetings and that they had sight of it. We asked the NEDS and registered manager about the risk register not being updated as historical risks from 2017 were still listed. The registered manager and NEDS told us they were aware of this and that

# Diagnostic and screening services

discussions were ongoing to establish a process on how best to archive the risk register to ensure previous learning was not lost. The Advisory Board acknowledged that each risk needed a named person as the registered manager would not be able to address them alone and a last review date was also needed. The registered manager told us that one of the NEDS had expertise in clinical governance and was actively contributing to the risk register work.

Staff told us that the main risk for the business was any possible disruption with the external laboratories which would impact the processing of samples within the agreed timeframes. However, the registered manager told us the service had mitigated this risk by using multiple laboratories instead of relying on one, and by completing regular monthly checks with all laboratories regarding their operations and capacity levels.

The service monitored performance by tracking the sample turnover time, from the time the external laboratory received the samples to the point results were uploaded on the portal. The service developed a report tab in their administration system to track processing times of samples at the lab. The service was able to trigger an email notification to the designated laboratory manager with a list of barcodes that were confirmed to have been received and approaching their due time within the designated 24 hours. The data allowed the service to decide whether the third party laboratories were performing to the desired level or whether improvements in their service level agreements were required.

The service had a business continuity plan policy, which we reviewed and found to be comprehensive. For example, the policy covered the protocol for emergencies such as power cuts and major incidents. Staff told us that they had been involved in the development of the plan.

Staff completed training on Fire Safety as part of their mandatory training. Staff told us the service had a designated first aider.

The service had an effective system and method for receiving and disseminating alerts from the MHRA/Central Alert System (CAS).

## Information Management

**Staff could find the data they needed, in easily accessible formats to understand performance using the dashboard.**

Staff had access to all the information they needed as computer stations were available to access the intranet and internet. Staff were aware of how to use and store confidential information. Staff completed training on Information Governance as part of their mandatory training. The service completed all the relevant technical due diligence needed to ensure the service delivery was effective and that results were secure and encrypted.

The service had a dedicated administration system which enabled the customer service team to access all the relevant information needed to provide support to patients. Information included: details about the patients order, dispatch date, tracking numbers, sample barcode number, sample receipt date at the laboratory, laboratory processing time and date and other relevant information such as patients address and self-reported information by the patient when kits were registered.

The service used a customer management system which enabled the customer service team to better manage all communications with patients in one system. By centralising all patient interactions in one place, this meant any support agent could access and view previous discussions, emails and call logs and in doing so, be able to provide prompt follow up support on any raised tickets by other members of the team.

# Diagnostic and screening services

The website had a Help Centre function which had nine categories. Within each category, frequently asked questions could be found for patients to refer to.

## Engagement

### **Leaders and staff engaged with patients and staff.**

The service held weekly 'town hall' staff meetings where each department provided an update. Staff told us that this meeting was a key platform to share information. We reviewed the minutes for 28 March 2022, 4 April 2022 and 12 April 2022 which showed attendance from all staff including new starters. However, we found there was no standardised agenda to include items such as complaints, staffing, training and new policies. We raised this with the registered manager who told us that the weekly staff meeting was an informal catch up. Managers told us that the service was in the process of setting up additional governance meetings which would incorporate a standardised agenda (Refer to Governance subheading).

The staff survey used a scoring from zero (not at all likely) to four (very likely). Recent survey results showed that 56% of staff felt listened to all the time, 22% most of the time and 22% scored in the middle. When asked if staff were likely to be working for the company in two years, 56% stated very likely, 22% most likely and 22% scored in the middle. When asked how connected staff felt with the service's mission, 78% of staff felt connected.

The service requested patients to complete surveys in three stages and reviewed feedback to identify themes and areas of improvement. Refer to Compassionate Care subheading.

## Learning, continuous improvement and innovation

### **The service had several years of genetic research for developing risk scores which led to the formation and launch of various test kits.**

The service had a research department which had focused on two main projects for the last two months. These were DNA cancer screening test and pharmacogenomic/pharmacogenetic testing panel. Both projects aligned with the service's objective to improve healthcare services by improving access and reducing costs to optimise a better lifestyle and chronic disease prevention.

Most of the NEDs were clinical academics with areas of expertise such as cardiology, nephrology and orthopaedics. NEDS told us they provided advisory support on best practice for research.