

***We are the regulator:** Our job is to check whether hospitals, care homes and care services are meeting essential standards.*

Building Three

Lisieux Way, Taunton, TA1 2LB

Tel: 01823346714

Date of Inspection: 04 February 2014

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We inspected the following standards as part of a routine inspection. This is what we found:

| | |
|--|---------------------|
| Cleanliness and infection control | ✓ Met this standard |
| Safety and suitability of premises | ✓ Met this standard |
| Supporting workers | ✓ Met this standard |
| Assessing and monitoring the quality of service provision | ✓ Met this standard |

Details about this location

| | |
|-------------------------|--|
| Registered Provider | Integrated Pathology Partnerships (iPP) |
| Overview of the service | Building Three is a purpose designed fully equipped laboratory providing routine pathology services excluding blood transfusion, to primary and secondary care providers across Somerset. The laboratory does not have any direct contact with patients. |
| Type of service | Diagnostic and/or screening service |
| Regulated activity | Diagnostic and screening procedures |

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Summary of this inspection

Why we carried out this inspection

This was a routine inspection to check that essential standards of quality and safety referred to on the front page were being met. We sometimes describe this as a scheduled inspection.

This was an announced inspection.

How we carried out this inspection

We looked at the personal care or treatment records of people who use the service, carried out a visit on 4 February 2014, talked with staff and reviewed information given to us by the provider. We reviewed information sent to us by other regulators or the Department of Health.

What people told us and what we found

Building Three had been set up with the help of a specialist pathology service and had been equipped to a high standard with laboratory services on two floors. The service had been accredited with the Clinical Pathology Accreditation (CPA). The CPA assessed and declared the competence of medical laboratories in the public and independent sector. The service did not have any direct contact with patients.

During our visit we met with senior management and laboratory staff. We were shown around all areas of the building and were able to observe practices within the laboratories.

The service followed appropriate procedures which meant that acceptable levels of cleanliness were maintained. Effective infection control procedures meant risks of the spread of infection were minimised.

Staff confirmed that they received appropriate levels of training and support. They confirmed they had received a range of mandatory training and training in more specialised topics appropriate to their role.

The service had effective procedures in place which monitored and improved the quality of the service they provided. We saw the service completed regular internal audits. The service was also monitored by other external agencies which helped to ensure that standards were maintained.

You can see our judgements on the front page of this report.

More information about the provider

Please see our website www.cqc.org.uk for more information, including our most recent

judgements against the essential standards. You can contact us using the telephone number on the back of the report if you have additional questions.

There is a glossary at the back of this report which has definitions for words and phrases we use in the report.

Our judgements for each standard inspected

Cleanliness and infection control

✓ Met this standard

People should be cared for in a clean environment and protected from the risk of infection

Our judgement

The provider was meeting this standard.

People were protected from the risk of infection because appropriate guidance had been followed.

The service provided a clean and hygienic environment.

Reasons for our judgement

Appropriate procedures were in place which monitored and maintained the standards of cleanliness. We found the standards of cleanliness in all areas to be of a high standard. We were informed each area had a designated member of staff who took the lead in infection control procedures. The service used an external cleaning contractor for general cleaning and laboratory staff maintained the responsibility for the cleaning of work benches within the laboratories.

Staff had up to date knowledge and guidance about how to reduce the risk of the spread of infection. Staff told us they had received training in infection control. We were able to see evidence of this when we looked at a staff training matrix. The service also had policies and procedures relating to infection control which had been regularly reviewed.

Procedures were in place to reduce the risk of the spread of infection. In each laboratory we visited we saw staff had access to appropriate personal protective clothing. We observed staff wearing white coats in designated areas and they removed these before leaving the laboratory. Staff also had access to eye protection and disposable gloves. Staff ensured we were provided with protective clothing before we entered designated areas. Appropriate hand washing facilities and sanitising gels were in place in each area we visited.

We saw appropriate measures had been taken to minimise risks to staff. In one area we looked at there was a separate laboratory which dealt with samples that could pose a significant risk to others. An example of this was where there were risks of tuberculosis. Staff spoken with were very clear about the procedures they needed to follow should an incident occur.

Appropriate procedures were in place for the management and disposal of clinical waste.

Each laboratory had clearly marked bags and bins. These were then transported to collection points where they were securely stored until disposed of by an authorised contractor.

The service followed the guidelines set by the Royal College of Pathologists. This meant appropriate procedures were in place for the handling, storage, retention and disposal of pathology and genetic samples in laboratories.

People should be cared for in safe and accessible surroundings that support their health and welfare

Our judgement

The provider was meeting this standard.

Staff and visitors were protected against the risks of unsafe or unsuitable premises.

Reasons for our judgement

Building Three had been set up with the help of a specialist pathology service and had been equipped to a high standard with laboratory services on two floors. It was located on the outskirts of Taunton, opposite the Taunton NHS ambulance station with good access to main road links. There was ample car parking in front of the building.

Building Three was a purpose designed fully equipped laboratory providing routine pathology services excluding blood transfusion, to primary and secondary care providers across Somerset. The laboratory did not have any direct contact with patients.

One of the laboratories dealt with 'category three microbiology'. This covered biological agents which could cause severe human disease and present a serious hazard to employees; it may present a risk of spreading to the community. This area provided state of the art facilities which reduced the risk of the spread of infection/disease. Access to the laboratory was via an air lock area. This prevented organisms from leaving the laboratory by maintaining set air pressures which were regularly monitored.

Robust systems were in place which meant that only authorised personnel could access the building. Visitors reported to a reception area where they were required to sign a visitor book and were provided with a visitor pass.

Doors to laboratories could only be opened by staff with appropriate passes. There was a designated entrance for deliveries. We saw contractors were unable to access laboratory areas or any part of the building.

There was a separate entrance for employees. Staff used their passes to access the building and when they left the building. The swipe system maintained a 'roll call' of all staff in the building. This information could be printed out in the event of a fire.

In addition to spacious laboratories, there were appropriately located cold rooms, fridges and freezers. There were suitable areas for storage of waste; these were secure and different categories of waste were well segregated.

There was adequate office space and staff had access to a rest area with tea and coffee

making facilities. Staff toilets and changing rooms were also available. Changing rooms also provided shower facilities and lockers. Disabled facilities were also available.

Local and corporate fire risk assessments were in place and last year, the service had been inspected by the local fire brigade. Fire alarm and activation points were tested weekly and fire evacuation training was performed quarterly.

The service had a comprehensive range of risk assessments in place which included the environment, safe working practices, control of substances hazardous to health (COSHH) and waste disposal.

Staff should be properly trained and supervised, and have the chance to develop and improve their skills

Our judgement

The provider was meeting this standard.

Staff were supported to meet the requirements of their role in a safe way and to an appropriate standard.

Reasons for our judgement

We met with the general manager, quality manager, human resources manager and three laboratory staff.

Staff confirmed they received appropriate levels of training and support. They confirmed they had received a range of mandatory training and training in more specialised topics appropriate to their role. This included training and competency monitoring in blood sciences, microbiology and cytology. Comments from staff included "you get the training you need to do the job" and "you wouldn't be able to work in an area unless you had received the right training."

One senior staff member we spoke with explained how staff were supported and staff competencies were monitored. They told us observed practice was carried out on all staff throughout the year. They said this ensured staff remained competent and confident in the tasks they performed. We saw completed records which showed the knowledge and skills of staff had been regularly monitored. All staff spoken with told us they had an annual appraisal and that any requests for additional training were responded to in a timely manner.

We were shown a staff training matrix. This detailed the training completed by staff and identified the due date for refresher training. We saw email alerts were sent to staff when refresher training was due. The quality manager explained that training needs were also discussed at regular 'competency' meetings with individual staff. This meant staff had the skills and training needed for the role they performed.

We saw that newly appointed staff were provided with the skills, information and training appropriate to their role. We looked at the induction records for a staff member who had been recently employed. These showed the staff member had been provided with policies, procedures and mandatory training. We saw that during the 12 week induction period, probationary reviews had been held at four, eight and 12 week intervals to review the skills, training, competencies and quality of the individual's work.

Meetings were held every day in each laboratory which enabled staff to prioritise and

allocate work and to discuss any issues which may have arisen. These were referred to as 'five minute meetings.' The staff we spoke with told us they found these meetings "useful" and "informative". One staff member said "the five minute meetings are excellent. They provide us with updates, any changes and it enables the work to be allocated and organised. We all know who is doing what."

Assessing and monitoring the quality of service provision

✓ Met this standard

The service should have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care

Our judgement

The provider was meeting this standard.

The provider had an effective system to regularly assess and monitor the quality of service provided.

The provider had an effective system in place to identify, assess and manage risks to the health, safety and welfare of staff and visitors.

Reasons for our judgement

The service had procedures in place which monitored and improved the quality of the service they provided. We saw the service completed regular audits which included health and safety, environment, policies and procedures, infection control and staff training.

The views of people who used the service; for example NHS Trusts and primary care providers such as GP practices were sought on a regular basis. We were provided with the results of a primary care survey which had been completed in 2013. This showed a high level of satisfaction with the service provided.

Senior staff spoken with told us they attended departmental and management meetings. They told us this provided them with updates and the opportunity to influence changes. They told us information was fed back to laboratory staff through a 'team brief.' This was confirmed by a member of staff in a laboratory we visited. They told us "we are always sent a copy of the team brief so we know what is going on. It works well."

We met with the quality manager who showed us the computerised quality monitoring system. This provided clear and up to date information on all areas of quality and safety. We saw the service was proactive in identifying and addressing any areas for improvement.

The service also received regular monitoring from external agencies such as the Clinical Pathology Accreditation (CPA). The CPA assessed and declared the competence of medical laboratories in the public and independent sector. We were provided with a copy of the CPA's assessment report which followed a visit to the service in September 2013. The service's quality management system was reported as 'working effectively.' The CPA found the service 'has coped well with an extensive amount of change to its locations, premises, equipment, processes, organisation and management and continues to provide a good service to its users.'

The service was also regulated by The Medicines and Healthcare products Regulatory Agency (MHRA). The MRHA regulated a wide range of materials from medicines and medical devices to blood and therapeutic products/services that are derived from tissue engineering. We were informed the service had not yet received a visit from the MRHA.

About CQC inspections

We are the regulator of health and social care in England.

All providers of regulated health and social care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards everyone should be able to expect when they receive care.

The essential standards are described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. We regulate against these standards, which we sometimes describe as "government standards".

We carry out unannounced inspections of all care homes, acute hospitals and domiciliary care services in England at least once a year to judge whether or not the essential standards are being met. We carry out inspections of other services less often. All of our inspections are unannounced unless there is a good reason to let the provider know we are coming.

There are 16 essential standards that relate most directly to the quality and safety of care and these are grouped into five key areas. When we inspect we could check all or part of any of the 16 standards at any time depending on the individual circumstances of the service. Because of this we often check different standards at different times.

When we inspect, we always visit and we do things like observe how people are cared for, and we talk to people who use the service, to their carers and to staff. We also review information we have gathered about the provider, check the service's records and check whether the right systems and processes are in place.

We focus on whether or not the provider is meeting the standards and we are guided by whether people are experiencing the outcomes they should be able to expect when the standards are being met. By outcomes we mean the impact care has on the health, safety and welfare of people who use the service, and the experience they have whilst receiving it.

Our inspectors judge if any action is required by the provider of the service to improve the standard of care being provided. Where providers are non-compliant with the regulations, we take enforcement action against them. If we require a service to take action, or if we take enforcement action, we re-inspect it before its next routine inspection was due. This could mean we re-inspect a service several times in one year. We also might decide to re-inspect a service if new concerns emerge about it before the next routine inspection.

In between inspections we continually monitor information we have about providers. The information comes from the public, the provider, other organisations, and from care workers.

You can tell us about your experience of this provider on our website.

How we define our judgements

The following pages show our findings and regulatory judgement for each essential standard or part of the standard that we inspected. Our judgements are based on the ongoing review and analysis of the information gathered by CQC about this provider and the evidence collected during this inspection.

We reach one of the following judgements for each essential standard inspected.

✓ Met this standard This means that the standard was being met in that the provider was compliant with the regulation. If we find that standards were met, we take no regulatory action but we may make comments that may be useful to the provider and to the public about minor improvements that could be made.

✗ Action needed This means that the standard was not being met in that the provider was non-compliant with the regulation. We may have set a compliance action requiring the provider to produce a report setting out how and by when changes will be made to make sure they comply with the standard. We monitor the implementation of action plans in these reports and, if necessary, take further action. We may have identified a breach of a regulation which is more serious, and we will make sure action is taken. We will report on this when it is complete.

✗ Enforcement action taken If the breach of the regulation was more serious, or there have been several or continual breaches, we have a range of actions we take using the criminal and/or civil procedures in the Health and Social Care Act 2008 and relevant regulations. These enforcement powers include issuing a warning notice; restricting or suspending the services a provider can offer, or the number of people it can care for; issuing fines and formal cautions; in extreme cases, cancelling a provider or managers registration or prosecuting a manager or provider. These enforcement powers are set out in law and mean that we can take swift, targeted action where services are failing people.

How we define our judgements (continued)

Where we find non-compliance with a regulation (or part of a regulation), we state which part of the regulation has been breached. Only where there is non compliance with one or more of Regulations 9-24 of the Regulated Activity Regulations, will our report include a judgement about the level of impact on people who use the service (and others, if appropriate to the regulation). This could be a minor, moderate or major impact.

Minor impact - people who use the service experienced poor care that had an impact on their health, safety or welfare or there was a risk of this happening. The impact was not significant and the matter could be managed or resolved quickly.

Moderate impact - people who use the service experienced poor care that had a significant effect on their health, safety or welfare or there was a risk of this happening. The matter may need to be resolved quickly.

Major impact - people who use the service experienced poor care that had a serious current or long term impact on their health, safety and welfare, or there was a risk of this happening. The matter needs to be resolved quickly

We decide the most appropriate action to take to ensure that the necessary changes are made. We always follow up to check whether action has been taken to meet the standards.

Glossary of terms we use in this report

Essential standard

The essential standards of quality and safety are described in our *Guidance about compliance: Essential standards of quality and safety*. They consist of a significant number of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. These regulations describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect. A full list of the standards can be found within the *Guidance about compliance*. The 16 essential standards are:

Respecting and involving people who use services - Outcome 1 (Regulation 17)

Consent to care and treatment - Outcome 2 (Regulation 18)

Care and welfare of people who use services - Outcome 4 (Regulation 9)

Meeting Nutritional Needs - Outcome 5 (Regulation 14)

Cooperating with other providers - Outcome 6 (Regulation 24)

Safeguarding people who use services from abuse - Outcome 7 (Regulation 11)

Cleanliness and infection control - Outcome 8 (Regulation 12)

Management of medicines - Outcome 9 (Regulation 13)

Safety and suitability of premises - Outcome 10 (Regulation 15)

Safety, availability and suitability of equipment - Outcome 11 (Regulation 16)

Requirements relating to workers - Outcome 12 (Regulation 21)

Staffing - Outcome 13 (Regulation 22)

Supporting Staff - Outcome 14 (Regulation 23)

Assessing and monitoring the quality of service provision - Outcome 16 (Regulation 10)

Complaints - Outcome 17 (Regulation 19)

Records - Outcome 21 (Regulation 20)

Regulated activity

These are prescribed activities related to care and treatment that require registration with CQC. These are set out in legislation, and reflect the services provided.

Glossary of terms we use in this report (continued)

(Registered) Provider

There are several legal terms relating to the providers of services. These include registered person, service provider and registered manager. The term 'provider' means anyone with a legal responsibility for ensuring that the requirements of the law are carried out. On our website we often refer to providers as a 'service'.

Regulations

We regulate against the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Responsive inspection

This is carried out at any time in relation to identified concerns.

Routine inspection

This is planned and could occur at any time. We sometimes describe this as a scheduled inspection.

Themed inspection

This is targeted to look at specific standards, sectors or types of care.

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