

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

Cellular Pathology Services Limited

Unit 12 Orbital 25 Business Park, Dwight Road
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Date of Inspection: 23 January 2014

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2014

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

Consent to care and treatment	✓	Met this standard
Cleanliness and infection control	✓	Met this standard
Safety, availability and suitability of equipment	✓	Met this standard
Assessing and monitoring the quality of service provision	✓	Met this standard
Records	✓	Met this standard

Details about this location

Registered Provider	Cellular Pathology Services Limited
Registered Manager	Dr. Paul Mitra
Overview of the service	Cellular Pathology Services Limited provide Histopathology and Cytopathology services to clinical and hospital clients. The laboratory does not have 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 unannounced 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 23 January 2014, observed how people were being cared for and talked with staff.

What people told us and what we found

Cellular Pathology Services Limited provide Histopathology and Cytopathology services to clinical and hospital clients. There is no direct access with patients.

We found appropriate systems in place to ensure people's consent for care and treatment was sought.

We identified that there were appropriate systems in place to ensure the cleanliness of the environment and for the prevention of infection.

Appropriate equipment had been provided and fully maintained to ensure that work was carried out safely.

Regular quality audits were undertaken including an annual customer questionnaire and internal and external quality audits.

We found that appropriate records were being maintained, stored and disposed of in line with the Data Protection Act 1998 principles.

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

Consent to care and treatment

✓ Met this standard

Before people are given any examination, care, treatment or support, they should be asked if they agree to it

Our judgement

The provider was meeting this standard.

The provider acted in accordance with legal requirements to obtain consent.

Reasons for our judgement

Appropriate measures were in place to obtain people's consent to process the samples sent to the laboratory.

We found evidence that consent was provided by the medical practitioner who sent the sample to the laboratory for processing on the initial request form that was provided with the sample. If for any reason the signed consent was not present, the laboratory contacted the hospital for consent prior to undertaking any work.

We were told by staff that if a professional requests any information from the laboratory regarding a sample, consent was sought by the laboratory from the original medical practitioner who requested the sample to be analysed before any information is released.

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.

Reasons for our judgement

We observed that procedures were in place to ensure that the restricted laboratory environment was safe for those working within it. This included appropriate clothing and hand washing facilities. We noted that there was appropriate systems and equipment in place to manage any spills of any infectious or hazardous material. Samples are delivered by courier in containers designed to not cause spillage and placed in a hatch before collection by staff to ensure that the laboratory area is not contaminated.

Clinical waste was stored in locked ventilated fire resistant cabinets for the appropriate length of time before being bagged in clinical waste bags and disposed of in either the secure clinical waste bin located outside the premises or through cremation. Clinical waste was collected on a four weekly basis.

We identified that the immunisation status for all staff was up to date and all staff were fully immunised.

We viewed the standard operating procedures which identified the correct ways to work in the laboratory and the measures to take to ensure the environment remained safe. This included a comprehensive cleaning rota and the guidance for the disinfection of instruments used.

People should be safe from harm from unsafe or unsuitable equipment

Our judgement

The provider was meeting this standard.

People were protected from unsafe or unsuitable equipment.

Reasons for our judgement

We found that there was suitable equipment to ensure that work was carried out safely.

We observed that next to each piece of equipment was an up to date data sheet which listed a record of maintenance checks undertaken. This was completed daily and signed when the check has been completed. Monthly in depth maintenance checks and deep cleans were undertaken for all equipment and signed off by the laboratory manager. All maintenance sheets were up to date. Service reports were available for all equipment.

Temperature checks of the fridges and maintenance room, where archive materials were stored, were undertaken to ensure the temperature was kept within the required limits of between two and eight degrees Celsius.

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 that people receive.

Reasons for our judgement

We found evidence of an annual questionnaire sent to all people who used the service to ask their views on the quality of service. The latest questionnaire viewed showed that people were happy with the service provided and that service was generally "above expectation". Any negative comments were reviewed and action taken to resolve these concerns was taken through using the service's complaints procedure.

There were systems in place to address any adverse issues that arose from time to time. This included identifying the issue and the root cause, taking remedial action and identifying any corrective and preventative action that may be needed to improve quality of service.

Feedback from people regarding quality of service was reviewed and if appropriate incorporated into the services 'Quality Policy'.

Annual quality management reviews and audits were undertaken as well as an annual audit by the Clinical Pathology Accreditation (CPA) to ensure quality is controlled and maintained. Since the last inspection by the Care Quality Commission, approval of the service had been granted by the CPA.

We saw records of Health and Safety risk assessments had been carried out on a quarterly basis and appropriate action taken place to address any matters of concern.

Records

✓ Met this standard

People's personal records, including medical records, should be accurate and kept safe and confidential

Our judgement

The provider was meeting this standard.

People were protected from the risks of unsafe or inappropriate care and treatment because accurate and appropriate records were maintained.

Reasons for our judgement

We found that a unique reference number was applied to each specimen which was used for tracking throughout the process to the final results. The number was applied to the initial log sheet and appeared on all records. This ensured that there was a full audit trail and ensured that the correct diagnostic tests were reported on. Two members of staff were present when tests were undertaken to ensure that records were accurate. One member of staff carried out the test and dictating the process while the second member of staff made notes and ensured the records were correct.

Records of equipment maintenance, risk assessments and confidentiality agreements signed by staff were present and up to date.

Personal records, which included the actual specimens and final test results were kept securely on the premises for a period of 30 years. We noted that the original request form which travelled with the sample throughout the process was scanned onto the computer system once the results had been delivered. The paper copy would then be shredded once there was authorisation to do so by the laboratory manager.

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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