Inspection Report

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

Labco Huthwaite Pathology Lab

c/o Fresenius Medical Care, Nunn Brook Road, Huthwaite, Sutton-in-Ashfield, NG17 2HU

Tel: 01623445100

Date of Inspection: 20 September 2012

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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	Labco Diagnostics UK Limited
Registered Manager	Mr. Graham Dobbs
Overview of the service	A stand alone purpose built laboratory situated within Fresenius Medical Care (UK) Headquarters building, Huthwaite Nottinghamshire.They undertake routine analysis in the disciplines of clinical chemistry, haematology and microbiology to meet the contracted requirements of service users.
Type of service	Diagnostic and/or screening service
Regulated activity	Diagnostic and screening procedures

Contents

When you read this report, you may find it useful to read the sections towards the back called 'About CQC inspections' and 'How we define our judgements'.

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 20 September 2012 and talked with staff.

What people told us and what we found

Labco Diagnostics UK Limited provided routine Pathology Services within the disciplines of Clinical Chemistry, Haematology and Microbiology.This involved monthly monitoring of dialysis efficiency.

We did not speak with people who used the service because they did not attend the laboratory. The services of the laboratory was contracted by Fresenius Medical Care.

There were suitable systems in place that ensured patients received their results in a timely way. Strict controls ensured that the transportation of samples was undertaken safely. Once arriving at the laboratory the systems in place to identify and analyse specimens was fully automated. The provider ensured that the staff undertaking the tests were trained and competent.

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.

Reasons for our judgement

The manager provided us with a copy of the infection control policy. The policy is presently being amended to reflect that it is now a Labco policy following the changes to the provider.

The manager told us that there were arrangements and licences in place for the safe collection, classification, segregation, storage, handling, transport, treatment and disposal of clinical waste in line with current waste legislation. We saw appropriate identification of waste was being applied.

The laboratory staff ensured that all deliveries of specimens for testing were transported in suitable containers that complied with British standards, this ensured they were sufficiently robust.

Couriers were used to transport the specimens from the patient clinics to the laboratory and policies were in place that demonstrated appropriate risk assessments had been undertaken to ensure they were transported safely.

There was a designated area within the laboratory for the receipt of all specimens.

Standard operating procedures were in place for the spillage of biological material and chemical spills. The procedures covered the actions to take if these occurred either in transit or in the laboratory.

There were cleaning and disinfection policies in place. Staff records demonstrated that they received training in the management of waste, disinfection and decontamination.

Safety and suitability of premises ✓ Met this standard

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

There were no facilities for patients as they were not required to attend the laboratory.

The provider had taken steps to provide an environment that was suitably designed and adequately maintained. In accordance with the provider's quality statement we found that the pathology laboratory had been purpose built. Access to the laboratory was limited to authorised personnel only. All areas were keypad controlled. This demonstrated that appropriate measures were in place to ensure the security of the premises.

The premises were located on the site of another organisation. We saw how there was an agreement with that organisation to enable them to carry out internal audits of the laboratory by a suitably trained assessor who was familiar with the requirements of the Clinical Pathology Accreditation (CPA), which is part of the United Kingdom Accreditation Service (UKAS).

CPA is a voluntary scheme and participants are inspected every four years and have to confirm each year that they are continuing to operate according to strict guidelines.

The laboratory had received accreditation from CPA when it was part of a previous organisation until March 2012. The current registered provider of the laboratory provided us with records that demonstrated they had appropriately notified the CPA of the changes in ownership. A review of the laboratory to meet the required criteria for the accreditation was imminent. The manager of the laboratory told us they had continued to meet the required standards since the change in ownership.

We saw records of the last health and safety audit undertaken in December 2012. Appropriate action plans had been put in place to ensure any areas for improvement were addressed.

We identified that the provider had arrangements in place to meet the Control of Substances Hazardous to Health Regulations 2002. There were documents available that showed how risks created by work with substances hazardous to health were assessed and appropriate control measures were in place. There was use of the appropriate containment level for the biological agents likely to be encountered.

We saw how accidents and incidents were monitored by the manager. The manager told us they were aware of the reporting of injuries, diseases and dangerous occurrences

regulations (RIDDOR), which requires employers to report specified accidents, dangerous occurrences and cases of ill health to Health and Safety Executive.

We saw how the laboratory had standard operating procedures (SOPs) for the general work of the laboratory and for each diagnostic procedure carried out. These identified safe working practices to control any risks.

All safety precautions were in place and tested with regard to all specialist equipment. We saw that equipment was checked daily to indicate the precision and performance. In addition an external quality assurance team checked the performance of the equipment at least monthly.

There were suitable rest rooms for staff and secure areas for personal effects.

Supporting workers ✓ Met this standard

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 deliver care and treatment safely and to an appropriate standard.

Reasons for our judgement

The provider had a system in place to ensure all staff received an induction into their role. Records we looked at showed that staff also had their competency checked for all procedures they carried out, this included direct supervision of these procedures by the training manager.

The staff files we looked at showed that information was held on each person's academic and professional qualifications, induction, training, supervision and annual appraisal.

We examined the provider's quality manual. This showed that the staff working in the laboratory that were required to be registered in accordance with legislation needed to provide proof each year that they remained registered. We saw how the pathology manager had ensured that these checks were being carried out.

The provider may find it useful to note that there were no vaccination records for staff working in the laboratory. This would not ensure that health surveillance and immunisation arrangements were sufficient.

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 in place to identify, assess and manage risks to health, safety and welfare.

Reasons for our judgement

The laboratory provides a service to another organisation Fresenius Medical Care (FMC). FMC operate individual clinics where patients attend for dialysis. We saw how there was an agreement for the pathology laboratory to provide services for FMC. This meant that the laboratory had no direct contact with patients.

We saw how Fresenius had surveyed the clinic managers for their views on the satisfaction of the services they received from the laboratory. The report was shared with the laboratory. The results of this survey indicated that technical advice was readily available from the laboratory, specimen transport was considered good and both urgent and routine reports were received in a timely manner.

We saw that the company was registered with the Data Protection Agency to hold patient and staff information. Staff records showed that the organisation ensured staff working in the laboratory were aware of their legal responsibilities to hold personal information secure, accurate and up to date.

Bi monthly staff meetings held to discuss service improvements.

Continuous audits were undertaken on all systems within the laboratory and records demonstrated that learning took place when issues were identified. Action plans demonstrated that the provider took appropriate action to deal with any issues affecting the quality of the service.

The manager told us that he was in the process of trying to arrange a liaison committee with the organisation they provided services to as part of the quality system.

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 dentists and other services at least once every two years. 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 but we always inspect at least one standard from each of the five key areas every year. We may check fewer key areas in the case of dentists and some other services.

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. We make a judgement about the level of impact on people who use the service (and others, if appropriate to the regulation) from the breach. 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.

Contact us

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