

# *The importance of quality management for clinical biochemistry tests*

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**Abstract:** Clinical biochemical tests are an important basis for doctors' diagnosis and treatment, and are directly related to the treatment effect of patients. With the improvement of medical technology, modern medical testing technology is widely used in the medical field, therefore, the role played by clinical biochemical test quality management in hospital management is also increasingly important. At present, many hospitals do not pay enough attention to the quality management of clinical biochemical tests, and still remain on the surface form, without recognising the importance of quality management for biochemical tests. In order to promote the further development of the medical testing industry, this paper mainly discusses the quality management of clinical biochemical tests.

## **1. The significance of quality management of clinical biochemical tests**

With the development of society and the increasing size and number of medical institutions, the quality management of clinical biochemical tests is receiving more and more attention. As people become more health conscious, medical institutions are paying more and more attention to clinical biochemistry tests. For hospitals, clinical biochemical tests are an important basis for clinical diagnosis and an important tool for treatment and monitoring of changes in patients' conditions. There are many clinical biochemical tests performed in hospitals, such as routine blood tests, liver function and electrolytes. Most of these tests are in-laboratory tests, the main purpose of which is to diagnose and treat the patient's condition. Generally speaking, clinical biochemical tests are carried out in hospitals using certain equipment, such as haematology analysers for routine blood tests and fully automated biochemistry machines for routine urine tests.

There are many tests in the laboratory, and there are many problems in the actual testing process: firstly, there are differences in the quality of the patients and in the instruments used, so there are significant differences in the tests performed in the laboratory; secondly, some tests cannot be carried out properly because the staff are not skilled in the operation of the instruments and equipment. For example, some hospitals are not equipped with special doctors and nurses to operate the laboratory; some hospitals are equipped with professional doctors and nurses to be responsible for the development of biochemical testing projects, but due to limited manpower to ensure that all projects are carried out at the same time; some hospitals are not equipped with special equipment for the laboratory to complete the task of testing in the laboratory. These reasons have led to significant

problems in the actual testing of clinical biochemical tests, which are not conducive to the diagnosis and treatment of patients' conditions in hospitals[1-2].

## **2. Quality management elements of the inspection system**

### **2.1 Quality management of instruments**

**Purchase and installation of instruments and equipment:** Before purchasing equipment, the laboratory department should organise relevant personnel to consider the performance of laboratory instruments and equipment, the use of the environment, operators and other comprehensive consideration to ensure that the instruments and equipment meet the relevant requirements. When the equipment is installed, the instruments and equipment should be thoroughly checked to confirm that their performance meets the requirements before they are put into use. After the commissioning of the new instrument is completed, a comprehensive performance test should be carried out to ensure that all performance indicators meet the standard requirements. During the installation process, attention should be paid to avoid external impact to avoid affecting the normal use of the instrument; in clinical applications, the operation should be in strict accordance with the instructions.

**Monitoring and verification of test quality:** A key aspect of biochemical testing is the testing and verification of test results. In the course of using biochemical instruments, various problems will inevitably arise. To avoid affecting test results, the laboratory should regularly review and monitor test results. The results of each project are monitored through the use of quality monitoring software; each project is fully monitored through the use of quality control tools. If anomalies occur, effective measures should be taken to deal with them in a timely manner.

**Quality assurance:** The laboratory department should establish a comprehensive quality assurance system, which includes a quality management system, a system of operating procedures, and a management system of instruments and equipment.

**Equipment maintenance:** In order to ensure the normal use of instruments and equipment, the laboratory should regularly inspect and maintain the laboratory biochemical testing equipment, and if abnormalities occur, they should be repaired in a timely manner.

### **2.2 Quality management of quality reagents**

The quality of mass reagents is directly related to the accuracy of the test results, so they should be controlled and managed in strict accordance with quality standards when they are used.

Regular checks are carried out on the quality reagents to check for expiry or spoilage. The mass reagents are tested at regular intervals and their concentrations are recorded.

Before using new reagents, test solutions should be made within the quality control range and tested to prove their conformity before use.

When testing with mass reagents within the QC range, ensure that the testing process meets the relevant requirements, e.g. it must be carried out in a clean environment. When using quality reagents for testing, it is important to ensure that they are within their expiry date. Expired mass reagents can affect the accuracy of their test results and can even lead to serious consequences, so they must be tested and monitored regularly.

When stored in a conditioned environment, the quality reagents must be well sealed in clean containers, while taking care to protect them from light and moisture. The expiry date and packaging integrity of QCs should be checked regularly when in use. If the quality control product used is a chemical reagent, it should be tested regularly. QCs that have been in use for a long time should be replaced or repaired in time to prevent changes in test results due to reagent deterioration during use. When there is a mismatch between the QC and reagents, they should be replaced or repaired in a

timely manner.

When registering QCs and reagents, attention should be paid to the correctness and completeness of the correspondence between QCs and reagents. For example, some QCs and reagents need to be numbered in strict sequence.

### **3. Indoor quality control**

In-house quality control is an important element of clinical biochemical test quality management, which allows for effective control and evaluation of test results and improves the reliability and accuracy of test results. Usually, QC is divided into quantitative QC and quantitative QC.

Qualitative control is the most widely used quality control method in indoor testing, mainly including statistical analysis, linear regression, stability analysis, etc. Statistical analysis is used to control the variation of data indicators such as standard deviation and coefficient of variation; linear regression refers to the regression analysis of a correlation coefficient, which can be used to analyse the trend of this correlation coefficient through an equation; stability analysis refers to the determination of two or more samples at the same time for a period of time to see if the trend between them is consistent.

Quantitative QC refers to the application of specific control criteria in the laboratory to evaluate the results of experiments so that they can be continuously improved in future tests. Quantitative QC metrics commonly used in clinical biochemistry include relative standard deviation, which is the main metric used to evaluate inter-method agreement[3-4].

### **4. Measures to improve the quality management of clinical biochemical tests**

#### **4.1 Improve the quality of inspection personnel and raise awareness of inspection work**

With the continuous development of modern inspection technology, the role played by inspectors in the inspection process is becoming more and more important. Therefore, inspectors are required to have not only solid professional theoretical knowledge, but also a wealth of practical experience.

The quality of test personnel directly affects the quality of the entire test work. To this end, a variety of measures should be taken to improve the quality of testing personnel, so that they can fully grasp the theoretical knowledge of clinical biochemical testing and related technical operational skills, and cultivate their independent working ability. In addition, regular academic lectures on medicine and biology and various forms of business learning activities should be organised to keep them up to date with the latest medical developments and technological trends at home and abroad by holding different types of special lectures or learning activities. Various forms of skills competitions and academic exchange activities should be encouraged and organised to encourage them to participate in various academic exchanges, so as to continuously improve their professional quality and business level.

The role played by laboratory personnel in clinical biochemical testing is very important, so in order to ensure that it can fully play its role, it should start from the following aspects: first of all, to ensure that laboratory personnel can have a high degree of responsibility and dedication. As a clinical biochemical testing personnel, should have a strong sense of enterprise, responsibility and a high degree of responsibility, to be practical, meticulous, careful and meticulous to do a good job in each experimental work. Secondly, the laboratory management should be strengthened. As a qualified clinical biochemistry examiner must have a highly cautious attitude to work as well as rigorous pragmatism, meticulousness, excellence and other good qualities. Strictly implement the rules and regulations and operating procedures, in accordance with the relevant requirements for the correct operation of instruments and equipment and their effective maintenance and maintenance, so that the

experimental equipment is always in the best operating condition.

#### **4.2 Establishment of a sound inspection quality control system**

Quality control of reagents, in the quality control of reagents, the aim should be to ensure the stability of reagents and minimize changes in the process of storage, transportation and use of reagents. In particular, it should be ensured that the reagents have been verified in strict accordance with the regulations before use, and complete verification records should be established to ensure that the reagents are used within the validity period. If new reagents need to be replaced, the experiment should be redone.

The performance of instruments and equipment is the key to ensuring the quality of clinical biochemical tests. Laboratories should be equipped with high quality, good performance testing instruments and equipment, and they should be strictly inspected and calibrated, repaired and maintained in a timely manner, and regular training on the maintenance of instruments and equipment should be carried out so that the instruments and equipment are always kept in the best working condition.

Specimens must be collected in strict accordance with the principles of aseptic operation, taking care to prevent contamination. A disposable needle should be used to collect the specimen into the test tube. When collecting blood, attention should be paid to the consistent direction of the needle and to ensure that the needle is perpendicular to the test tube to avoid spillage of blood from the test tube due to wrong direction of force. Blood should be sent for examination immediately after collection and should not be left at room temperature for too long or not sent for examination in time.

#### **4.3 Strengthening clinical biochemistry laboratory information systems**

Clinical biochemistry laboratory information system is a comprehensive upgrade of the traditional manual operation, through the use of computers and other modern high-tech means to replace manual operation, can effectively improve the accuracy, standardization and automation of biochemical tests, thus effectively reducing manual errors, but also to a certain extent to reduce the human factors caused by laboratory quality accidents.

To improve the management functions of the clinical biochemistry laboratory information system so that it can better meet the actual needs of clinical biochemistry testing, on the one hand, it should have a comprehensive grasp of the scope of testing and types of results of all clinical biochemistry tests; on the other hand, it should also actively improve the professional quality of the testing staff to ensure that they can correctly perform clinical biochemistry tests.

The information, intelligence and automation of the specimen management and testing process can be achieved. On the one hand, it allows the laboratory staff to transfer the test results to the laboratory staff for unified entry, so as to avoid confusion in the test results; on the other hand, it allows timely collection of patient specimen information and feedback on the test results, so as to achieve real-time monitoring and dynamic management of each test item; in addition, it enables the laboratory staff to accurately understand the test results of each item, so that they can have a good idea of the actual work and take timely and effective In addition, it enables laboratory staff to accurately understand the results of each project, so that they can have a good understanding of the actual work and take effective measures to solve problems in a timely manner[5].

#### **5. Conclusion**

In the development of modern medicine, clinical biochemical tests are an important basis for disease diagnosis and an important means of clinical treatment and disease prevention, and have an

irreplaceable role. However, with the continuous development of medical technology, various high-tech instruments and equipment are emerging, and the testing methods are becoming more and more advanced, which has put forward higher requirements for clinical biochemical testing. Therefore, we must continuously strengthen the quality management of clinical biochemical tests, improve the quality of laboratory personnel, improve the quality management system and standardize the operation process in order to effectively reduce the quality problems in clinical biochemical tests.

## References

- [1] Liu F, Wang L, Ruan XH, et al. Analysis of the application of quality indicators in clinical biochemistry and pre-immunoassay testing [J]. *Laboratory Medicine and Clinical*, 2016, 13 (6): 858-859.
- [2] Wang Huaizhou, Fang Wen, Chen Mingkun, et al. Effect of vacuum blood collection volume on the results of commonly used clinical biochemical tests [J]. *Laboratory Medicine*, 2017, 32(2): 94-98.
- [3] Meng Leijun, Qiu Chenyu, Zhao Qi, et al. Impact of lean management on the turnaround time of emergency biochemical specimens [J]. *Journal of Clinical Laboratory*, 2017, 35(6): 461-463.
- [4] Zhu Huaihai. Study on the importance of quality management for biochemical testing in hospitals [J]. *Journal of Chinese Medicine Management*, 2020, 28(12):170-171. DOI: 10.16690/j.cnki.1007-9203.2020.12.079.
- [5] Jia Caiyun. Study on the importance of quality management for clinical biochemical testing [J]. *China Health Industry*, 2018, 15(03): 143-144. DOI: 10.16659/j.cnki.1672-5654.2018.03.143.