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Quality Control Method for Pathogenic Microbiological Testing based on Consistency Calibration

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Abstract: Commonly used test quality control methods use comparison, efficacy function diagrams and other ways to analyze the factors affecting the quality of the test, through the direct interference of the influencing factors to achieve quality control. This control method is not only inefficient, but also easy to ignore the error of the analysis process, resulting in poor quality control, low implementation rate and efficiency. In response to the above problems, we study the quality control method of pathogenic microbiological testing based on consistency calibration. Based on the analysis of factors affecting the quality of pathogenic microbiological testing, the test data of pathogenic microbiological testing methods are pre-processed to remove the more obvious error data in the test data. Through a combination of normal calibration and consistency calibration, the test data with higher test accuracy is used as a reference to achieve quality control of pathogenic microbiological tests. The case validation study shows that the method has strong control stability, and the method can improve the test accuracy by about 3.7%.

Keywords: Consistency calibration; Pathogenic microorganisms; Microbiological testing; Quality control

1. Introduction

Pathogenic microbiological testing can play an important role in the detection of hospital-acquired infections and has been widely used in epidemiology and infectious diseases. The traditional methods of detection of pathogenic microorganisms are also commonly used in clinical microbiological testing, mainly including morphological testing; culture of pathogenic microorganisms combined with their biochemical properties for detection and identification; and immunological techniques to detect specific anti-reduction of pathogenic microorganisms in samples. However, these techniques have the disadvantages of being time-consuming and having poor sensitivity and specificity, which can easily lead to untimely reporting or incorrect identification results. Because the current process of pathogenic microbiological testing still requires a large number of manual operations, this microbiological testing quality control method ignores the impact of manual factors and other unknown factors on the quality of pathogenic microbiological testing when conducting quality management, resulting in large errors in quality control, which cannot effectively control the quality of testing when applied in practice. The above-mentioned traditional pathogenic microbiological test quality control methods in the application are ignored because of the pathogenic microbiological test process of different interference factors on the impact of quality control, resulting in test quality control when the control level fluctuates, the control method implementation rate is low, the quality control effect is not good.

The purpose of consistency calibration is to compare the consistency of the results obtained by different methods and to be able to objectively evaluate the quality of method implementation [1]. When doing data analysis, the problem of consistency checking is often faced, i.e., to determine whether different models or analysis methods are consistent in predicting results, whether the results of the model are consistent with the actual results, etc. In addition, consistency testing has a wide range of applications in clinical experiments [2]. Based on the above, in order to improve the stability of the test quality control method, this paper will study the quality control method of pathogenic microbiological test based on consistency checking, in order to guarantee the accuracy of microbiological test results.

2. Quality Control Method for Pathogenic Microbiological Testing based on Consistency Calibration

2.1. Analysis of factors affecting the quality of pathogenic microbiological tests

Accurate pathogenic microbiological testing can effectively determine the patient's disease, which can assist clinicians in formulating targeted treatment, plans to effectively improve the health of patients. However, through actual clinical observation, it is known that many

factors will adversely affect the accuracy of the test results, so only after they are effectively clarified can targeted quality control strategies be proposed, and the relevant influencing factors are analyzed as follows [3].

(One) Human influencing factors. In order to ensure the accuracy of test results, strict requirements are imposed on test personnel, so the specialized technical level of test personnel becomes the key, and microbiological samples are tested in strict accordance with physiological and morphological reactions. At present, many hospitals' microbiological testing departments, although they have updated and introduced many microbiological testing equipment, however, many testers lack solid professional knowledge, operating experience and judgment ability, thus to a greater extent, the accuracy of the test results have a greater adverse impact on the quality of pathogenic microbiological testing cannot be accurately controlled.

(Two) The quality of pathogenic microbiological specimens influencing factors. Such factors include the following: when the microbiological samples are collected and not sent to the laboratory within the specified time, so when the normal testing time is exceeded, microbiological samples are more likely to be adversely affected and contaminated phenomenon. Some of the sample collection personnel in the process of collection and processing of samples cannot take reasonable measures, and therefore will have a greater adverse impact on the pathogenic microbial determination value.

(Three) Irregularities in the operation of factors. Accurate judgment of microbial test results can effectively provide the basis for subsequent testing and treatment, so if the sample cannot be standardized operation, will have a greater adverse impact on the microbial test results.

In addition to the above-mentioned factors, the sterilization of pathogenic microbiological testing tools, quality and other parameters will also affect the quality of pathogenic microbiological testing. Regardless of the development of testing technology, the pathogenic microbiology medium is still the core and key to the technology. Therefore, the quality of the culture medium is the basis of microbiological testing, the accuracy and reliability of the test results. The preparation and use of culture media is an important part of the microbiological testing work. The quality of the medium itself, whether it is properly preserved, whether the preparation and use of the correct microbial growth, isolation, identification and test results play a vital role.

Because of the many factors affecting the quality and stability of pathogenic microorganisms, coupled with the impact of random unknown factors in the testing process, only by understanding the specific impact of different known and controllable factors on the quality and stability of pathogenic microorganisms, we can target effective quality control and fundamentally ensure the credibility and validity of pathogenic microorganisms test results. From the perspective of the above analyzed factors affecting the quality of pathogenic microbiological tests, the pathogenic microbiological test data are processed to achieve quality control of pathogenic microbiological tests by controlling the error range of the test data.

2.2. Pre-processing of pathogenic microbiological test data

The pathogenic microbiological tests widely used today are affected by the interference factors mentioned in 1.1 during the test process, and to achieve accurate test quality control, the test data of each test method will be preprocessed in this section.

If the test data set for a particular pathogenic microbiological test method is X , the data in the test data set are processed according to the following equation [4].

$$\bar{X} = \frac{I_1 + I_2 + \mathrm{L} + I_i}{n} \tag{1}$$

$$S = \sqrt{\frac{\sum_{i=1}^{n} (x_i - x)^2}{n-1}} \tag{2}$$

$$C = \frac{S}{\bar{X}} \times 100\% \tag{3}$$

In the above equations (1) to (3), $\bar{X}$ is the arithmetic mean of the test data set. I_i is a reference indicator in the process of testing for pathogenic microorganisms. i is the corresponding number of tests. S is the standard deviation of the test data set. x_i is the specific microbiological test index data. C Is the coefficient of variation of the test data set. Since the process of pathogenic microorganism testing usually requires multiple tests to be performed on the test target, the data processed after the above steps are cleaned in order to avoid, to the greatest extent possible, serious data bias caused by the large variability between the data.

In this study, the fuzzy clustering algorithm was chosen to clean the data processed by the above process. The cluster centers of fuzzy clustering were randomly selected, and the range of clustering distance of this cluster center was determined by the size of the affiliation between the data and the cluster center. The fuzzy clustering division matrix was calculated according to the following formula [5].

$$u_{ij} = \frac{1}{\left[\sum_{i=1}^{c} \left(\frac{\left\| x_j - v_i \right\|}{\left\| x_j - v_{i+1} \right\|} \right)^{\frac{1}{m-1}} \right]} \tag{4}$$

In equation (4), c is the number of clustering categories. v_j is clustering centers. x_j is the test data after the above processing. m is the weighted index, also known as the

smoothing parameter, $m \in [1,+\infty)$. After fuzzy division of the data in the test dataset according to the division matrix, the clustering center is updated and the affiliation division is performed again until the fuzzy clustering algorithm converges. The data processed by the fuzzy clustering algorithm is the cleaned data. Using the consistency check theory to analyze the pre-processed pathogenic microorganism test data, the test data error control within a certain range to achieve test quality control.

2.3. Consistency verification processing inspection data to achieve quality control

Before performing consistency checks on pathogenic microbiological test data, it is necessary to perform normality tests on the data. In this paper, the normality test was performed using the W method and the D method. The specific test procedure is shown below.

When the content of the data samples to be calibrated is within the interval of 30 to 150, the W-method test is selected.

First, the n data in the data sample to be calibrated are sorted in the order from smallest to largest. Assume that the test data sample H_0 is from the normal distribution overall; test data sample H_1 is not from the normal distribution overall. Calculate the statistic according to the following formula.

$$W = \frac{\left[\sum_{i=1}^{n/2} a_i \left(x_{n+1-i} - x_i\right)\right]^2}{\sum_{i=1}^{n} \left(x_i - \overline{x}\right)^2} \tag{5}$$

In formula (5), a_i is the test level, which can be found from the corresponding schedule. According to the test level and data sample content to find the W boundary table, if the calculated W value is not greater than the boundary value, then reject H_0; otherwise receive H_0.

When the sample content is in the range of 150 to 1000, select the D method test. The sample values to be calibrated are arranged in a column in non-decreasing order. The same hypothesis as in (1) is formulated and the statistic is calculated according to the following equation.

$$Y = \frac{\sqrt{n}\left(D - 0.28209\right)}{0.2998}$$
$$D = \frac{\sum_{i=1}^{n}\left(i - \frac{n+1}{2}\right)x_i}{\left(\sqrt{n}\right)^3 \sqrt{\sum_{i=1}^{n}\left(x_i - \frac{n+1}{2}\right)^2}} \tag{6}$$

The critical interval is found from the critical value table of the D-test method, and if the calculated Y value is in the critical interval, the original sample obeys normal distribution, otherwise it does not obey normal distribution. In addition, because the critical value table can only check the critical value of some of the values, for the test conditions to meet the n-value can be calculated using linear interpolation. It should be noted that the W method is applicable to small sample sizes when conducting normality tests, the limitation is to check the table of constants, which is more complicated to calculate in large samples. d method is to compare the gap between the cumulative probability of the actual frequency and the theoretical frequency, find the maximum distance D, and determine whether the actual frequency obeys the gap of the theoretical frequency according to D, so it is more applicable to large samples.

After testing the normality of the data, if the test data of pathogenic microorganism test method 1 and test method 2 both conform to the law of normal distribution, the test data of test method 1 is $N\left(\overline{x}, s\right)$, the test data of test method 2 is $N\left(\overline{y}, s\right)$, $\overline{x}$ and $\overline{y}$ are the sample means of the test data of the two pathogenic microorganism test methods, respectively, and the sample variance s of the two methods are unknown. Comparing whether the means of the two are significantly different, there is.

$$\left|t_{a/2}\left(n_1 + n_2 - 2\right)\right| = \frac{\overline{x} - \overline{y}}{S_1\sqrt{\frac{1}{n_1}} + S_2\sqrt{\frac{1}{n_2}}} \geq t_{a/2}\left(n_1 + n_2 - 2\right) \tag{7}$$

In the above formula, n_1 is the number of pathogenic microorganism test method 1 test data sampling; $\overline{x}$ is the sample mean of test method 1 test data; n_2 is the number of test method 2 test data sampling; $\overline{y}$ is the sample mean of test method 2 test data; S_1 and S_2 are the sample variance of the data of the two pathogenic microorganism test methods; is the significance level, taking the value of 0.05. If the above formula holds, then indicates that there are deviations in the test data of the two test methods, the need to manage the test methods according to the test precision and other parameters of the test method. The testers should analyze these factors affecting the microbiological test results and develop corresponding quality control measures based on the results of the analysis, such as improving the quality and operational skills of the microbiological test personnel, strictly controlling the operational process of the microbiological test, and strictly monitoring the process of sending specimens for testing to ensure the accuracy of the microbiological test results. If the above equation does not hold, it indicates that the deviation of the test result data is within the controllable range and the test can be controlled more reliably.

Thus, the research on the quality control method of pathogenic microbiological testing based on consistency calibration is completed. According to the above research content, the quality control method of pathogenic microorganism test based on consistency calibration proposed

in this paper can effectively reduce the data error in the test process and improve the credibility of the test results.

3. Case Validation Study

Pathogenic microbiological testing occupies an important position in modern epidemic prevention and medical work, but due to the rapid mutation of pathogenic microorganisms, defects in existing pathogenic microbiological testing techniques, and interference from other factors during the testing operation, resulting in large fluctuations in the quality of pathogenic microbiological testing. The above paper presents a new pathogenic microbiological test quality control method using the theory of consistency calibration on the problems of the traditional pathogenic microbiological test quality control method. In this section, the effectiveness of this pathogenic microbiological test quality control method will be verified by selecting an example as the object of study.

3.1. Selection of experimental subjects and experimental environment

The object of the case validation was selected from a pathogenic microbiological testing laboratory undergoing two pathogenic microbiological testing projects. Experiments in the pathogenic microbiological testing laboratory in the two cleanliness to meet the qualified standards, the experimental process of testing pathogenic microorganisms, such as instrumentation, reagents and other detailed parameters are shown in table 1 below.

Table 1. Parameter table for pathogenic microbiological testing equipment and reagents (partial only)

Instruments and reagents	Model parameters	Description
Medical refrigerator	HYC-326A	Storage of strains and reagents
Electronic analytical balance	SPS202F	Weighing reagents, samples
Autoclaves	MLS-3020	Sterilization process
PCR amplifiers	BioRad-T100	PCR amplification
0.1% peptone water	Peptone content 10g/L;	Culture medium composition
Mushroom enrichment broth	Peptone content 20g/L; Glucose 1g/L	Culture medium composition
Pathogenic diagnostic serum	——	Targeted diagnosis of pathogenic microorganisms

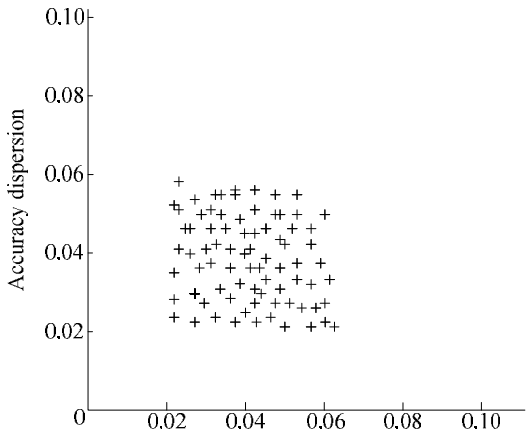
3.2. Experimental procedure

To form the comparison experiment, the pathogenic microbiological test quality control method based on consistency calibration proposed above was compared with the traditional microbiological test quality control method based on probability statistics and the microbiological test quality control method based on efficacy function diagram as comparison groups 1 and 2 from the three perspectives of control level stability and control execution rate and efficiency, respectively. During the comparison experiments, the experimental variables were controlled uniquely so as not to interfere with the experimental results.

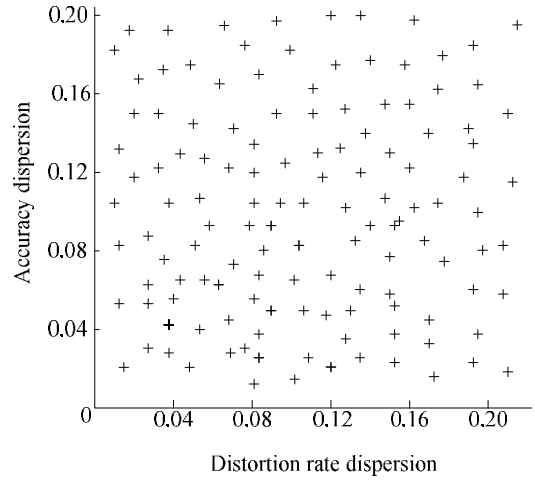
When comparing the stability of the control level of the three quality control methods, the stability of the quality control methods was judged by measuring the discrete fluctuations of the two indicators of the accuracy and distortion rate of the pathogenic microorganism test. The execution rate and efficiency of the test quality control methods are tested by comparing the implementation of the corresponding quality control strategy operations before and after conducting different quality control and the accuracy of the microbiological tests after implementation to compare the execution rate and efficiency of the test quality control methods, so as to visually verify the actual effectiveness of the control methods.

3.3. Experimental results

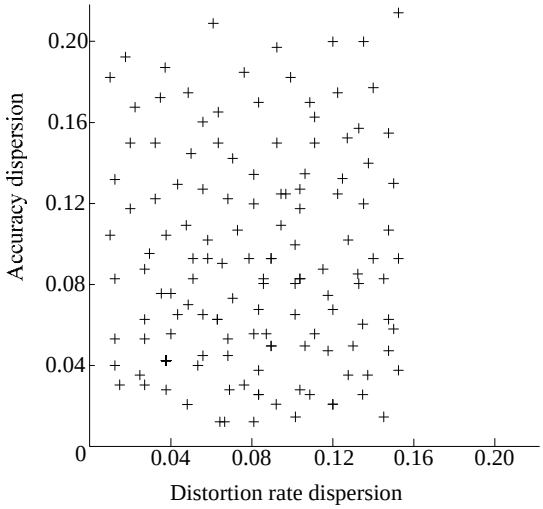
The pathogenic microorganisms were tested under the management of three pathogenic microorganism testing quality control methods, respectively. During the statistical laboratory tests, data were collected on the discrete fluctuations of the two indicators of accuracy and distortion rate of the pathogenic microorganism tests, and the experimental results shown in Figure 1 below were plotted. The relationship between each discrete point in the graph is analyzed and the corresponding experimental conclusions are drawn.



(a) Experimental group method



(b) Comparison group method 1



(c) Comparison group method 2

Figure 1. Quality control method control stability comparison results

Analysis of the data in Figure 1 shows that under the management of the experimental group method, the discrete fluctuations of the two indicators of accuracy and distortion rate during pathogenic microbiological testing are more stable, and the magnitude of their fluctuations is much smaller than the control fluctuations of the other two groups of quality control methods. Under the quality management control of method 1 in the comparison group, the discrete fluctuations of the two indicators of the accuracy and distortion rate of the pathogenic microorganism test showed irregular and violent fluctuations. Under the management control of method 2 in the comparison group, the accuracy rate of pathogenic microbiological tests fluctuated more, and the distortion rate was affected by the fluctuation of accuracy rate, and there were regular fluctuations. The discrete fluctuations of the two indicators of accuracy and distortion rate directly indicate the stability of the quality level of pathogenic microbiological tests under the control of different quality control methods. According to the above analysis, the quality level of pathogenic microbiological tests in the experimental group method is more stable, that is, the error of microbiological tests under the control of the experimental group control method can be maintained within a small interval, and the reliability of test results is improved.

The implementation rate and efficiency test results of the microbiological test quality control methods are shown in table 2 below, and the data in the table were processed and analyzed to derive the practical application effect of the quality control methods.

Table 2. Comparison of the effect of quality control methods

Method	Implementation Rate /%	Efficient /%	Percentage improvement in inspection accuracy /%
Experimental group	84.5	79.8	3.7
Comparison group 1	62.4	56.1	0.9
Comparison group 2	73.9	64.3	1.0

The data in the table shows that the test quality control method proposed in this paper has a better implementation effect.

The conclusion of the above experimental analysis shows that the pathogenic microbiological test quality control method based on consistency verification proposed in this study has more stable control ability and can effectively improve the quality of pathogenic microbiological tests.

4. Conclusion

Pathogenic microbial testing has been using the traditional manual identification and judgment approach, not only the microbiological testing process is cumbersome and time-consuming, and very prone to a variety of errors, it is difficult to ensure the quality level of pathogenic microbial identification results. This paper investigates the quality control method of pathogenic microbiological testing based on consistency verification, and the feasibility of the method is verified by means of example validation. In the future, with the development and maturity of pathogenic microbiological testing technology, the corresponding pathogenic microbiological testing quality control methods need to be continuously optimized and enhanced to achieve synchronous development with pathogenic microbiological testing technology.

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