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ORIGINAL RESEARCH

Comparative Analysis of Detection Capabilities for Hepatitis B Antibody, Hepatitis C Antibody, and Syphilis Antibody in Different Medical Institutions in Kaifeng, China

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Objective: This study aimed to analyze the participation and results of the interlaboratory quality assessment for serological biomarkers of infectious diseases, including a five-panel test for hepatitis B, hepatitis C antibodies, and syphilis spirochete antibodies in Kaifeng City, China.

Methods: The assessment conducted by the Center for Clinical Laboratories in Kaifeng City from 2021 to 2022 was retrospectively analyzed. Laboratories participating in the interlaboratory quality assessment activities received two batches of independent clinical laboratory quality control material. These samples were tested in accordance with the provided test instruction manual. The reported results were statistically compared and assessed against those obtained by the clinical testing center.

Results: Data analysis revealed no significant differences in report rates and passing rates among medical institutions of varying levels. However, a significant statistical difference was observed between primary and tertiary hospitals (X^2 = 341.1, $P < 0.05$). Additionally, a similar significant difference was noted in the results obtained using different methodologies (X^2 = 0.997, $P < 0.05$).

Conclusion: The retrospective analysis of interlaboratory quality assessment activities, along with the statistical assessment of test results, assists clinical laboratories in identifying potential systematic and random errors, as well as other factors contributing to control loss. This process facilitates the timely development of effective improvement measures, enhancing test quality and ensuring the provision of accurate and reliable laboratory data for clinical use.

Keywords: 5-panel hepatitis B test, external quality assessment, hepatitis C, retrospective analysis, serum quality control samples, syphilis

Introduction

Clinical laboratory, as an independent medical unit, plays a key role as an auxiliary diagnostic component in clinical diagnostic and therapeutic activities.[1] The accuracy and compliance rate of its test results are pivotal in shaping the diagnostic approaches and treatment plans of clinical physicians.[2] Consequently, the management of test quality and the enhancement of technical capabilities in clinical or independent clinical laboratories are receiving increasing attention at various management levels.[3]

In the present technological era, constructing a comprehensive quality management system, continually enhancing test quality, and ensuring result precision have become imperative.[4,5] In the quality control workflow of clinical laboratories, two key methods are used: first, internal quality control to ensure the stability and consistency of test results; second, external quality assessment to evaluate the performance of individual laboratory against others using similar analytical methods, thereby ensuring result comparability and consistency across different laboratories.[6] Regular participation in external quality assessment activities, organized by healthcare management authorities, not-for-profit

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organizations, or commercial organizations, is essential for clinical laboratories to verify the reliability of their test results.[7] This practice is a fundamental requirement recognized by clinical laboratory administrative management and accreditation bodies in most countries and is a prerequisite for accreditation under the *Accreditation Criteria for the Quality and Competence* (ISO15189:2012) by the China National Accreditation Service for Conformity Assessment (CNAS-CL02).[8,9]

Hepatitis B e antigen (HBeAg) serves as a crucial serological marker for HBV infection. Emerging evidence indicates that the integration of HBV DNA into the host genome typically begins during the HbeAg-positive phase and is associated with early tumorigenic events in the disease progression.[10] Initiating antiviral treatment during the HbeAg-positive chronic infection phase can significantly reduce the intensity and duration of active immune-mediated hepatitis by inhibiting HBV DNA replication. This reduction in viral replication alleviates selective pressure on hepatocyte turnover and decreases hepatocellular clonal expansion.[11] Furthermore, early antiviral intervention that suppresses viral replication can decrease the number of HBV-host DNA integrations with transcriptional activity in patients exhibiting severe viremia.[12] Consequently, it is recommended to use chemiluminescence assays for dynamic quantitative monitoring of diagnostic and therapeutic markers in hepatitis B patients. This approach enhances the accuracy and efficacy of diagnosis and treatment outcomes for viral hepatitis B.

To enhance the testing capabilities of clinical laboratories at all levels of medical institutions in Kaifeng City, China, we retrospectively performed interlaboratory quality assessment for infectious disease markers. The objective of this analysis was to identify potential causes and factors contributing to discrepancies in results, assess the testing capabilities of clinical laboratories at all levels and provide targeted guidance for constructing quality management systems. Continuous improvement in quality management processes and enhancing the compliance rate of test results will furnish clinical physicians with timely and accurate test reports.

Materials and Methods

Study Materials

External Quality Assurance (EQA) involves multiple laboratories analyzing identical samples, with results collected and feedback provided by an independent external entity.[13,14] The assessment was organized by the Center for Clinical Laboratories in Kaifeng City from 2021 to 2022. The interlaboratory quality assessment samples were supplied by Shanghai Bioyuan Biotechnology Co., Ltd. The assessment encompassed seven items: hepatitis B virus (HBV) surface antigen, HBV surface antibody, HBV e antigen, HBV e antibody, HBV core antibody, hepatitis C virus antibody, and syphilis spirochete antibodies.

Test Methods

Distribution and testing of the quality control serum: A total of ten quality control serum samples were distributed in two instances throughout the year, with five batches distributed at each instance. The quality control samples received for the experiment were liquid-based matrices, with a volume of 1.0 mL per vial. Each test sample was a blind sample, unlabeled for positivity or negativity, and assigned a unique identification number. The laboratory reported results according to the corresponding test item and sample number. Prior to testing, samples were brought to room temperature (18°C–25°C) for at least 30 minutes and gently mixed to avoid bubble formation from agitation. If flocculent precipitates appeared, samples were centrifuged, and the supernatant was used for testing. All tests were performed strictly following the reagent kit instructions, treating the quality control samples in the same manner as clinical specimens, and results were read using the designated equipment. Specifically for HBcAb testing, only the undiluted sample result was reported. Results from diluted samples were not required.

Definition of Primary, Secondary, and Tertiary Healthcare Facilities

Primary healthcare facilities refer to basic health services provided at community health centers or clinics, focusing on routine check-ups and minor illnesses. Secondary healthcare facilities refer to regional hospitals that offer specialized services and treatment for more complex conditions. Tertiary healthcare facilities include large, highly specialized hospitals that provide advanced treatment, research, and expert care for severe or rare conditions. Participating institutions were required to follow the unified protocol established by the Clinical Laboratory Center, including receiving a designated number of quality control samples, completing the testing according to standardized procedures, and submitting the results. The Clinical Laboratory Center then evaluated the quality based on the submitted data.

Statistical Processing

The evaluation method followed the 3rd edition of *Clinical Laboratory Quality Control Techniques*, specifically Chapter 26 on Interlaboratory Quality Evaluation, utilizing the Proficiency test (PT) score evaluation method.[15] A PT score of 80% or higher was deemed acceptable The PT score for each item was calculated using the following formula: (number of samples passed / total number of samples participated) × 100%. The laboratory was considered to have passed this item if it achieved a PT score of 80 or above at least once for this item. To be classified as annually compliant the item had to pass in both instances within the year. Following data aggregation, statistical analysis was conducted using SPSS 22.0 software. Descriptive statistics were reported as frequency and composition ratio (%), and X^2 tests were used for statistical analysis, with $P < 0.05$ indicating a statistically significant difference.

Results

Annual Participation and Performance in Interlaboratory Quality Assessment from 2021 to 2022

A total of 166 laboratories participated in the EQA program between 2021 and 2022. In 2021, 87 laboratories were enrolled, with a result submission rate of 89.6% and a pass rate of 80.7%. In 2022, 79 laboratories participated, achieving a higher submission rate of 93.6% and an improved pass rate of 85.1% (Table 1). These data indicate that both the response rate and the overall performance of participating laboratories showed improvement in 2022 compared to the previous year.

Reporting and Qualification Rates by Medical Institution Level

Among the 37 primary healthcare facilities that participated in the assessment, 30 provided valid results. The report rate for primary healthcare facilities was 81.1%, with a passing rate of 60%. For secondary healthcare facilities (36 facilities) the report rate was 100%, and the passing rate was 97.2%. Nine tertiary hospitals and one third-party laboratory also participated, both attaining 100% report and passing rates. Comparisons of report and passing rates across different levels of medical institutions, as assessed by the X^2 test, revealed $X^2 = 2.107$, $P = 0.349$ (>0.05), indicating no statistically significant difference. A comparison between primary and secondary healthcare facilities revealed $X^2 = 1.477$, $P = 0.224$ (>0.05), also indicating no statistically significant difference. Similarly, no significant difference was observed between

Table 1 2021–2022 Annual Laboratory Participation Results and Compliance Report

Year	Participating Laboratories				
	Number	Number of Reports	Number of Passes	Report Rate (%)	Pass Rate (%)
2021 (first instance)	87	80	62	91.9	77.5
2021 (second instance)	87	76	63	87.3	82.9
2021 average	87	78	63	89.6	80.7
2022 (first instance)	79	78	66	98.7	84.6
2022 (second instance)	79	70	60	88.6	85.7
2022 average	79	74	63	93.6	85.1
2021-2022 average	83	76	63	91.5	82.8

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Table 2 Participation and Qualification Status by Medical Institution Level in 2021–2022

Medical Institution Level	Participation Instances	Number of Reports	Number of Passes	Report Rate (%)	Pass Rate (%)
Primary	148	120	72	81.1	60.0
Secondary	144	144	140	100	97.2
Tertiary	36	36	36	100	100
Third-party laboratories	4	4	4	100	100
Total	332	304	252	91.5	82.8

secondary and tertiary institutions (X^2 = 0.023, P = 0.879 > 0.05). However, a significant difference was found between primary and tertiary hospitals (X^2 = 341.1, P < 0.05), as detailed in Table 2.

Testing Methods and Qualification Rates by Medical Institution Level

Testing methods used by laboratories at various levels of medical institutions were analyzed and categorized into three types: colloidal gold, enzyme immunoassay, and chemiluminescence assay. Among these, colloidal gold testing method was used by 22 primary healthcare facility laboratories, 2 secondary institutions, and none at the tertiary level. Enzyme immunoassay was used by 5 primary, 28 secondary, and 7 tertiary institutions. Chemiluminescence assay was used by 3 primary, 5 secondary, and 4 tertiary institutions, as well as one third-party laboratory. Statistical analysis of the testing methods used by different levels of institutions revealed significant differences, with X^2 = 39.5, P = 0.000 < 0.05, based on the X^2 test. Furthermore, comparisons of the qualification rates achieved by the three methodologies revealed significant differences, with X^2 = 0.997, P = 0.007 < 0.05, as detailed in Table 3.

Overall Interlaboratory Quality Assessment Status

The overall compliance rate for the seven projects under interlaboratory quality assessment at hospital system laboratories has been improving annually, particularly over the past three years, with the overall compliance rate consistently exceeding 98%. The individual test passing rates are detailed in Table 4 and Table 5. A comparison of pass rates for the participating laboratories between 2021 and 2022 yielded X^2 = 2.307a and P = 0.889 > 0.05, indicating no statistically significant differences, as presented in Tables 4–6.

Discussion

EQA assesses laboratory operations and the comparability and consistency of results across different laboratories.[16] The quality of laboratory performance is essential for the advancement of laboratory medicine, as only results that are

Table 3 Comparing Testing Methods by Medical Institution Level in 2021–2022

Testing Method	Primary Healthcare Institutions		Secondary Healthcare Institutions		Tertiary Healthcare Institutions		Third-party laboratories		Pass Rate (%)
	Laboratory	Number of Passes	Laboratory	Number of Passes	Laboratory	Number of Passes	Laboratory	Number of Passes	
Colloidal gold method	22	11	2	2	0	0	0	0	54.1
Enzyme immunoassay	5	4	27	26	5	5	0	0	94.5
Chemiluminescence assay	3	3	7	7	4	4	1	1	100
Total	30	18	36	35	9	9	1	1	82.8

Table 4 2021Statistics on Test Results from Participating Laboratories

Test Item	2021 First Round				2021 Second Round				Pass Rate (%)
	Laboratory	Non-Compliant	Compliant	Pass Rate (%)	Laboratory	Non-Compliant	Compliant	Pass Rate (%)	
HBsAg	80	2	78	97.5	76	1	75	98.6	98.1
HBsAb	80	10	70	87.5	76	8	68	89.4	88.4
HBeAg	80	2	78	97.5	76	3	73	96.1	96.7
HBeAb	80	19	61	76.2	76	18	58	76.3	76.2
HBcAb	80	24	56	70.0	76	18	58	76.3	73.1
Anti-HCV	80	11	69	86.3	76	9	67	88.1	87.2
Anti-TP	80	19	61	76.3	76	18	58	76.3	76.3

Table 5 2022Statistics on Test Results from Participating Laboratories

Test Item	2022 First Round				2022 Second Round				Pass Rate (%)
	Laboratory	Non-Compliant	Compliant	Pass Rate (%)	Laboratory	Non-Compliant	Compliant	Pass Rate (%)	
HBsAg	78	3	75	96.1	70	2	68	97.1	96.6
HBsAb	77	15	62	80.5	69	7	62	89.8	84.9
HBeAg	77	2	75	97.4	69	2	67	97.1	97.2
HBeAb	77	12	65	84.4	69	11	58	84.1	84.2
HBcAb	77	23	54	70.1	69	19	50	72.4	71.2
Anti-HCV	74	3	71	95.9	66	1	65	98.4	97.1
Anti-TP	73	5	68	93.1	67	2	65	97.1	95.0

Table 6 Comparative Pass Rates for Test Items Among Participating Laboratories in 2021–2022

Test Item	2021	2022	X^2	*P*
HBsAg	98.1	96.6	0.628	0.428
HBsAb	88.4	84.9	0.818	0.366
HBeAg	96.7	97.2	0.056	0.812
HBeAb	76.2	84.2	3.005	0.083
HBcAb	73.1	71.2	0.203	0.652
Anti-HCV	87.2	97.1	9.831	0.002
Anti-TP	76.3	95.0	20.427	0.000
Total	82.5	88.1	8.187	0.004

accurate, reliable, and free from errors are deemed valuable for diagnosis, monitoring, and risk assessment.[17] By reviewing and analyzing the results and testing methodologies from the interlaboratory quality assessment of infectious disease immunological indicators in Kaifeng City for the years 2021 and 2022, as well as the outcomes for various projects, the following observations were made:

1) Statistical analysis of the participation rate, passing rate, and report rate for laboratories at various levels revealed a decrease in local participation in 2022 compared to 2021, attributed to the impact of the COVID-19 pandemic. However, the report rate increased from 89.6% to 91.5%, and the passing rate improved from 80.7% to 85.1%, reflecting a positive trend. Notably, the passing rate at secondary and higher-level medical institutions reached 100%. This indicates a growing enthusiasm and awareness of participation in interlaboratory quality assessment activities among laboratories at all levels.

2) Analysis of results and passing rates for various testing procedures indicated suboptimal outcomes for the hepatitis B core antibody (HBcAb) testing. Contributing factors include: (1) Potential differences in reagent kits and testing methods across laboratories, as well as variations in serum handling. To address these discrepancies, future distributions of quality control materials by the clinical testing center will emphasize and specify that HBcAb does not require dilution and should be tested directly; (2) The HBcAb testing method employs an immuno-capture technique where the absence of color development indicates a positive result. Negligence or inadequate experience among laboratory personnel may lead to misreporting or omissions; (3) Issues with enzyme plates, like leakage and misaligned wells, can result in false positive or false negative outcomes.

3) A comparative analysis of different testing methods used across various levels of medical institutions and qualification rates revealed significant disparities in results, with secondary and higher-level institutions demonstrating notably better performance compared to primary-level institutions. Primary healthcare facilities predominantly used the colloidal gold method, while secondary and higher institutions frequently used enzyme immunoassay and chemiluminescence assay. These methodological choices contributed to substantial differences in outcomes. Contributing factors include: (1) The level of the laboratory and its associated hardware requirements and testing timelines vary. Personnel at primary hospitals typically engage in basic screening, where there is less emphasis on sensitivity and specificity, with a focus on rapid screening of suspected positive cases. Primary healthcare facilities predominantly employed the colloidal gold method, which is simple and quick, requiring minimal equipment. This method, however, has lower sensitivity compared to enzyme immunoassay (EIA) and chemiluminescence immunoassay (CLIA) methods, leading to higher rates of false negatives, necessitating repeated verification of results. If results do not align with clinical diagnoses, retesting using dual reagents or alternative methods is recommended; (2) Results assessed by visual inspection can be subject to subjective factors, potentially leading to false positives or false negatives. Therefore, when test results are positive, it is crucial to promptly communicate with doctors to determine appropriate follow-up actions and ensure accurate patient diagnosis; (3) Various serological diagnostic methods, including EIA, CLIA, and Electrochemiluminescence Immunoassay (ECLs), are used to detect viral antigens or antibodies. These methods offer high analytical sensitivity, specificity, and accuracy.[18] Both EIA and fully automated immunoassay analyzers demonstrate high precision and accuracy, achieving negative and positive conformance rates of at least 95%, with a consistency test κ-value ≥ 0.75.[19] Therefore, clinical laboratories should select the most appropriate methodology based on sample volume and cost considerations.

Several diagnostic methods are available for syphilis, but their practical application is often constrained by the nature of the disease and the limitations of each methodology.[20] Diagnosis primarily relies on serological testing, with a common approach being the combination of treponemal and non-treponemal tests to assess disease activity. Laboratories with high sample volumes often use fully automated CLIAs to detect syphilis-specific antibodies.[21] This method is favored for its low labor intensity, high efficiency, and rapid turnaround time.[22] This approach provides high sensitivity, facilitating early detection of antibodies, but it also poses an increased risk of false positives, particularly in low-prevalence populations.[23]

This study has three main limitations: (1) The sample size from 2021–2022 was relatively small and did not include critical concentration gradients such as low-positive results in hepatitis B five-panel testing, which may affect the assessment of borderline result interpretation; (2) The sample distribution across local clinics and private hospitals was uneven, limiting the ability to assess testing stability in smaller institutions; and (3) There was no repeated testing of different reagent batches within the same institution, preventing the evaluation of long-term reproducibility. These limitations underscore the need for future research to optimize sample design, with particular attention to the impact of reagent-instrument compatibility in EQA subgroup assessments, to enhance the scientific rigor of evaluations.

Taken together, participation in EQA enables clinical laboratories to evaluate their testing accuracy by analyzing deviations from target values and to understand the potential impact on patient outcomes. Establishing a standardized EQA program is crucial for accurately interpreting analyte results at clinically relevant decision points.[24,25] This study's analysis reveals that the type of instrumentation is a key factor influencing testing quality. Institutions using fully automated chemiluminescence platforms achieved a 100% pass rate, significantly outperforming primary healthcare facilities relying on manual colloidal gold or ELISA methods. This supports the notion that differences in manual operation proficiency contribute to greater measurement uncertainty. The study not only identifies capability gaps across institutions of different levels and types, but also constructs a complete "data presentation – cause tracing" logic chain. Notably, issues such as "reagent batch effects" and "manual operation errors" align with common challenges reported in national EQA findings for grassroots laboratories. From a public health perspective, the study highlights insufficient sensitivity in testing at primary-level institutions, a direct reflection of the weakness in basic laboratory capacity emphasized in the Law on the Prevention and Treatment of Infectious Diseases. For example, less than 60% of county-level institutions met equipment standards, underscoring a stark contrast with the critical need for effective control of infectious diseases such as hepatitis B and C. These findings provide concrete evidence to inform efforts aimed at reducing regional disparities in disease control. At the level of EQA standardization, this study represents the first systematic analysis of testing heterogeneity in Kaifeng, offering granular, city-level data that complements ongoing efforts to improve inter-laboratory assessments in primary care. It also serves as a practical reference for the formulation of provincial-level standardization policies.

Abbreviations

PT, Proficiency test; EQA, External Quality Assurance; EIA, enzyme immunoassay; CLIA, chemiluminescence immunoassay; ECLs, Electrochemiluminescence ImmunoassayHBe; Ag, Hepatitis B e antigen; HBV, hepatitis B virus.

Data Sharing Statement

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki (as was revised in 2013). The study was approved by Ethics Committee of the Kaifeng Central Hospital (2024ks-lw016). Written informed consent was obtained from all participants.

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Disclosure

The authors declare no conflicts of interest in this work.

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