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Comparative Review of Blood Cell and Immunoassay Analyzers in Sports-Specific Biochemical Laboratories

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Abstract: Sports biochemical laboratories utilize athlete blood samples to conduct physiological assessments, primarily employing blood cell analyzers and immunoassay analyzers. This study systematically reviews the progress and limitations of these two instrument types in this field. A comprehensive literature review shows that comparative studies involving blood cell analyzers have a well-established practical foundation, and results show good comparability between instruments; however, more precise comparative protocols for athlete blood samples characterized by median concentrations remain lacking. In contrast, comparative studies on immunoassay analyzers have predominantly focused on medical laboratories, while key indicators for physiological assessment in athletes have not yet received sufficient attention. The lack of cross-system consistency in immunoassay analyzers remains a critical bottleneck limiting the comparability of longitudinal monitoring data in athletes. For future research, sports biochemical laboratories are advised to: ① establish standardized instrument comparison protocols specifically tailored to athlete median-concentration blood samples; ② prioritize investigation of systematic biases in key hormonal markers—such as testosterone and cortisol—across different immunoassay platforms, and assess their impact on longitudinal physiological assessments; ③ explore the development of specialized instrument comparison quality control systems for sports biochemical laboratories.

Keywords: Comparability; Hematology analyzer; Immunoassay analyzer; Athletes

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1. Introduction

It has become common practice within the same laboratory to operate multiple hematology analyzers and

immunoassay analyzers from different brands or models simultaneously. Such configurations enhance testing efficiency and provide emergency backup in the event of instrument failure; however, they also introduce new challenges: differences in the detection principles, calibration systems, reagent formulations, and reference intervals among these instruments may lead to deviations in test results for the same sample [1-3]. For instance, the platelet counting methodologies of impedance-based and laser scattering-based analyzers differ, which may compromise the accuracy of low-count samples [4-5]; similarly, variations among chemiluminescence systems—such as differences in antigen-antibody affinity and signal amplification mechanisms—can result in systematic deviations in hormone assay values [6-7].

This common issue is particularly prominent in sports-related biochemical laboratories. The samples in such laboratories are primarily used for functional monitoring of athletes and fatigue assessment, and the test results are required for long-term longitudinal comparisons. Unlike clinical laboratories, where sample concentrations span wide ranges of high, medium, and low pathological levels, biochemical parameters in athletes predominantly fall within physiological median ranges. Song Aijing et al. note that this concentration distribution means clinical laboratory comparison protocols cannot be directly applied [5]. Hormonal markers, such as testosterone and cortisol, are core parameters for evaluating an athlete's training adaptation and recovery status; the comparability of their test results directly affects adjustments to training regimens and the identification of overtraining [8–11]. Therefore, there is a pressing practical need to systematically conduct comparative studies on hematology analyzers and immunoanalyzers in sports-related biochemical laboratories, and to establish standardized protocols tailored to this specific application scenario.

Methodologically, and in accordance with ISO 15189 and CNAS-CL02 accreditation standards, laboratories must regularly compare instruments across different testing systems to ensure that test reports generated by different instruments within the same laboratory are consistent and traceable [12,13]. In clinical laboratory testing, such comparative studies primarily follow CLSI EP9-A2/EP09-A3 and WS/T 406-2012 and WS/T 407-2012 [14-17]; these documents form the foundation for achieving internal result inter-acknowledgment within laboratories [18-22]. However, whether these protocols apply to athlete samples, which predominantly feature median concentrations, has not been systematically demonstrated. This review summarizes relevant research progress domestically and internationally, evaluates the applicability of existing methodologies, and explores future directions for instrument comparison studies in sports-related biochemical laboratories.

2. Research methods

Using "instrument comparison," "hematology analyzer," "immunology analyzer," and "sports biochemical laboratory" as keywords, we searched relevant literature in databases such as PubMed and China National Knowledge Infrastructure (CNKI) between January 2014 and August 2026. After excluding duplicate publications, studies with incomplete data, and non-Chinese or non-English-language articles, we finally included the eligible studies for systematic review.

3. Research progress

3.1. Current state of domestic research

Research on comparative studies among different hematology analyzers in China began relatively early, and

its methodological approaches have become increasingly standardized. Most of these studies follow the CLSI EP9-A2 document and the WS/T industry standard, using precision validation, correlation analysis, and bias assessment as their core framework.

3.1.1. Comparative study of hematology analyzers

Liu Hong conducted a comparative study between Sysmex XN-1000 and Mindray BC-5600 and found that the relative deviations of five key parameters—PLT, HCT, HGB, RBC, and WBC—all met the≥80% criterion, indicating good correlation [23]. Kang Chen et al. compared two complete blood count analyzers, Sysmex XT1800i and XN550, and found that the correlation coefficients (r) for major parameters such as RBC, PLT, HGB, and WBC were all ≥ 0.975, demonstrating comparable results; however, no significant linear correlation was observed between the basophils (BASO) parameters of the two instruments, suggesting that the consistency of differential parameters requires independent evaluation [24]. Zuo Jinhua et al. validated three photometric blood cell analyzers. They found that deviations for all five core parameters were less than half of the permissible error limits specified in the external quality assessment (EQA), confirming comparability of the results [25]. Yao Liteng et al. also confirmed consistent results across two blood cell analyzer models for routine parameters [3].

In sports-related laboratories, Song Aijing et al. pioneered a comparative study of test results from various blood cell analyzers used in sports-related biochemical laboratories. Their findings indicated that complete blood count parameters were comparable across different analyzers; however, they also noted that concentrations in sports-related samples were predominantly within the median range, which differed significantly from those in clinical laboratories, so clinical comparison standards could not be directly applied [5].

3.1.2. Comparative study of immunoassay instruments

In the field of immunoassay, Luo Min et al. validated the performance of seven sex hormones using the Mindray CL6000i, obtaining slopes ranging from 0.94 to 1.05 and correlation coefficients ranging from 0.953 to 0.999 when compared with the Roche methodology, thereby meeting the analytical performance requirements [26]. Han Yuchen et al. compared vitamin B12 detection results using the EXI1800 and the Roche cobas e602, employing Deming regression analysis; the offsets were all <1/4 TEa, indicating comparability [27]. Li Xuying et al. compared the detection of β-HCG and progesterone using the Roche cobas e411 and the Beckman Coulter UniCel DxI 800; the results showed that both instruments exhibited reliable accuracy, good agreement, and the ability to effectively mitigate discrepancies in test results that could challenge clinical diagnosis [28]. Sun Hongzhen et al. proposed an “interval comparison method” based on clinical significance, in which comparison intervals were defined according to the span of reference intervals, offering a novel approach for immunoassay comparison studies [29].

However, Tan Yanguo et al. compared growth hormone measurements across three assay systems—CLEIA (chemiluminescence enzyme immunoassay), ECLIA (electrochemiluminescence immunoassay), and CMIA (chemiluminescence particle immunoassay)—and found consistency only at a few time points. At the same time, overall comparability was poor, indicating significant systematic deviations in growth hormone measurement across different assay systems [30]. Zhang Kai et al. also showed significant deviations among β-HCG assay reagents across generations [7]. Employing linear regression and curve-based calculus as

conversion methods enables the transformation of instrument-measured values—originating from different reference intervals and assay linear ranges—into a unified reference framework, thereby substantially enhancing comparability and concordance [31]. Current laboratory proficiency testing and quality management research predominantly focuses on medical, food, and microbiology laboratories [32–34], whereas studies specifically targeting sports laboratories remain scarce.

In summary, existing domestic research has focused primarily on two areas: first, validating precision and comparability among instruments for routine complete blood count parameters in clinical laboratories; and second, comparing methods for specific immunoassay assays, such as sex hormones, β-HCG, progesterone, vitamin B12, and TSH. However, current research still exhibits notable limitations: firstly, most studies are confined to clinical diagnostic settings, while instrument comparison research tailored to sports biochemical laboratories—particularly in the context of athlete physiological monitoring—is severely lacking; secondly, regarding immunoassay comparisons, there has been a marked deficiency in methodological comparisons for core sports science hormone markers, such as testosterone and cortisol.

3.2. Current state of research abroad

International research on analyzer comparability began earlier and uses more refined methodological approaches. Primary research focuses include: first, the widespread use of Passing-Bablok regression, with particular emphasis on selecting regression models and quantifying bias at clinically relevant decision thresholds; second, growing attention to variations in instrument consistency across different diseases or physiological states.

3.2.1. Comparative study of hematology analyzers

Bhola et al. compared the Sysmex XN 3000 with the Horiba Yumizen H2500. In 296 samples, the correlation coefficients for parameters such as WBC, RBC, and HGB were all >0.99, indicating high comparability between the two instruments [35]. Gupta et al. compared agreement among the ADVIA 2120i, Horiba Yumizen H2500, CellaVision, and manual counting in mouse blood cell counting and found that CellaVision showed the best agreement with the manual method [36]. Linko-Parvinen et al. compared HemoScreen with Sysmex XN and reported high correlation for routine whole blood cell parameters, although significant variability was observed for basophils and monocytes; HemoScreen demonstrated higher sensitivity for detecting leukocyte abnormalities, superior specificity compared to Sysmex XN (88% vs. 72%), and fewer false-positive results, making it suitable for use in small medical institutions [37]. Solis-Camarena et al. compared a portable HemoControl hemoglobin analyzer with the Sysmex XN-1000 in a high-altitude setting and found good agreement in HGB concentration measurements (mean deviation: -0.08 g/dL); despite some variability (consistency limits: -1.091 to 0.930), the overall performance was accurate and reliable, rendering it an effective alternative tool in remote or resource-limited settings [38].

3.2.2. Comparative study of immunoassay instruments

In hormone assays, Sharma et al. compared tacrolimus concentration measurements using Abbott CMIA and Snibe CLIA assays and found a strong correlation (r=0.916) [39]. More importantly, Agrawal et al. compared cortisol concentrations measured by four different chemiluminescence analyzers (Advia Centaur XP, Immulite 1000, Cobas e 411, Architect) in patients with various adrenal disorders; they found poor agreement among the analyzers in patients with congenital adrenal hyperplasia, indicating substantial differences in the

comparability of distinct chemiluminescence systems under specific pathological conditions—a finding of considerable significance [40]. Sainz de Medrano et al. measured ProGRP, SCC, and HE4 on both Roche and Abbott platforms; the results showed strong correlations ($r \geq 0.95$), similar areas under the ROC curve, and comparable clinical diagnostic performance, although inter-individual sample variation persisted [41]. Yeoh et al. used the Atellica CI 1900 to assay 14 parameters, including human chorionic gonadotropin and thyroid-stimulating hormone; the assays showed excellent precision, linearity, and agreement, with most indicators having a Sigma value >4, suggesting performance comparable to the Atellica Solution and suitability for small-to-medium-sized laboratories [42].

Shortcomings in international research are equally evident: first, although a wide range of scenarios have been addressed, instrument comparison studies specifically targeting the field of sports science—particularly hormone assays (e.g., testosterone, cortisol) in athlete functional monitoring—remain scarce; second, existing research has predominantly focused on individual diseases or general populations, with insufficient evaluation of the consistency of assay results under physiological exercise conditions (e.g., after high-intensity training or during fatigue recovery phases); third, evidence indicates that the comparability of cortisol measurements across different chemiluminescence systems varies depending on the disease context, yet comparable studies specifically involving athlete populations remain virtually nonexistent.

4. Conclusion

4.1. The comparative methodology is already relatively well-established, yet it still requires optimization tailored to specific application scenarios

The methodological framework for existing comparative studies is relatively well established, with most studies based on CLSI EP9-A2 or EP09-A3 guidelines, integrated with WS/T industry standards, and employing precision validation, correlation analysis, regression analysis, and Bland-Altman consistency analysis. Precision evaluation typically uses 1/3 or 1/4 of the total allowable error specified in CLIA ‘88 as the acceptable criterion, with the optimal regression model selected based on the data characteristics.

However, in sports laboratory settings, selecting statistical methods requires greater caution. The Deming regression, widely used in clinical comparisons, demands that the coefficient of variation between the two instruments remain constant and that the data follow a normal distribution; in contrast, data from athlete samples often exhibit no significant skewness but span a narrower concentration range, making the Passing-Bablok regression—which does not require normality and is robust against outliers—potentially more suitable. Furthermore, criteria for acceptable bias should not be mechanically applied using the commonly adopted clinical metric of 1/2 TEa (allowable total error), as bias assessment at the medical decision level is not applicable in sports settings. It is recommended to reference the “minimum allowable bias” values provided in biological variability databases (e.g., the Ricos database) as benchmarks, or to adopt a bias percentage based on the median concentration interval as an evaluation metric.

4.2. The conventional parameters of hematology analyzers exhibit good comparability across different systems

Based on comprehensive domestic and international studies, core parameters such as WBC, RBC, HGB, PLT, and HCT generally exhibit strong correlations ($r > 0.95$) and acceptable biases across different hematology analyzers. This phenomenon can be explained from the perspective of detection principles: blood cells are

primarily counted and classified based on their physical properties (volume, electrical conductivity, and light scattering characteristics). Although the physical detection principles of different instruments vary (e.g., electrical impedance method, laser scattering method, fluorescence staining method), standardized calibration of reference materials and regular quality control procedures enable consistent quantitative results across devices. For sports laboratories, this implies that if only these conventional parameters need to be monitored, the risk of result interchange between different instruments remains relatively low.

However, the consistency of differential parameters—such as basophils and monocytes—varies across studies; this variability is attributed to the low proportion of these cell types in peripheral blood and considerable differences among instrument-based classification algorithms. When these parameters are used to assess an athlete's immune status, careful interpretation remains essential.

4.3. The comparability of immunoassays varies by assay type, and the sources of systematic bias are complex

Comparison results for immunoassay analyzers vary significantly by analyte. For certain sex hormones, vitamin B12, and β-HCG, overall comparability across systems is favorable; this may be attributed to well-established detection methodologies for these analytes, as well as robust international reference materials and traceable calibration standards.

However, significant systematic biases exist between different chemiluminescence systems for cortisol and growth hormone. Potential sources of these differences include distinct epitopes targeted by antibodies used by different manufacturers, variations in the matrix effects of calibration standards, and differing sensitivities of signal amplification systems to interference from the sample matrix.

This finding carries significant implications for sports laboratories. During different training phases—high-intensity training, recovery, and pre-competition tapering—athletes' hormone levels fluctuate dynamically. If systematic deviations between instruments interact with physiological states, this may lead to "pseudo-variations" in longitudinal monitoring data or mask "true physiological changes."

4.4. There is a significant gap in instrument comparison studies conducted in sports-related biochemical laboratories

First, existing research has gaps. Most current studies focus on clinical patients, with sample sizes spanning a wide range of pathological concentrations—from very low to very high levels. In contrast, athlete samples predominantly reflect physiological median concentrations and lack pathological extremes; consequently, conclusions from existing studies cannot be directly extrapolated to this population.

Second, available research indicators remain limited. Testosterone and cortisol are the most frequently used hormonal biomarkers in sports biomonitoring and carry the most decision-making weight; however, no international multi-platform comparative studies have been conducted specifically on these two hormones in athlete samples. The physiological hormonal fluctuations in athletes under varying training loads may also be affected by systematic biases between different measurement instruments—a critical gap that urgently needs to be addressed.

Third, available protocols have gaps. Clinical comparison protocols are designed around full-concentration coverage, and their bias assessments are predominantly centered on the medical decision level. In contrast, sports laboratories require precision and consistency guarantees near the median concentration.

5. Future research

Based on the above analysis, this paper proposes that future research should focus on advancing the following directions:

First, from a methodological standpoint, directly adopting the clinical full-concentration coverage strategy is inappropriate; instead, researchers should design a tailored densified comparison protocol specifically for the median concentration range. In particular, include at least 3–5 concentration-level samples near the median of the reference range for repeated measurements to improve precision assessment, correlation analysis, and bias quantification in this region. For regression analysis, prioritize the Passing-Bablok method, and report the expected bias at the median concentration along with its 95% confidence interval.

Second, at the indicator level, prioritize selecting core sports-related hormone markers—such as testosterone and cortisol—and conduct systematic comparisons across mainstream immunoassay platforms to determine which platforms yield directly interchangeable results and which show systematic biases requiring conversion or cautious interpretation. Additionally, it is recommended to follow the study design of Agrawal et al. by incorporating samples from different training physiological states (resting state, immediately post-exercise, and recovery phase) for subgroup analyses, thereby assessing whether physiological state influences instrument consistency.

Third, at the level of evaluation criteria, it is recommended to introduce the longitudinal within-individual coefficient of variation as a supplementary comparability metric—specifically, test results from the same athlete sample using different instruments should remain within the permissible range of individual biological variation. By referencing biological variation databases, the "allowable bias" can be set at 0.33× or 0.5× the within-individual coefficient of variation (CVi), rather than mechanically applying clinical EQA standards.

Currently, a significant gap remains in comparative studies of blood cell analysis and immunoassay platforms in sports-related laboratories, particularly regarding the systematic evaluation of cross-platform comparability for core hormonal markers such as testosterone and cortisol. Future research should reference CNAS-GL037 and CLSI EP09-A3, accounting for the concentrated median concentrations in sports-related samples, to establish standardized median-range comparison protocols. Particular attention should be paid to systematic biases in key hormonal markers across different immunoassay platforms and their impact on the comparability of longitudinal monitoring data, thereby providing a methodological foundation for ensuring the scientific validity and reliability of sports-related biochemical monitoring data.

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