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Evaluation of the Diagnostic Performance of Ferritin Rapid Test Cassette for Qualitative of Ferritin in Whole Blood (For Self-Testing)

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Abstract: The Ferritin Rapid Test Cassette is a chromatographic immunoassay specifically designed for the qualitative self-testing of ferritin levels in human whole blood obtained via fingerstick, aimed at identifying potential iron deficiency. This study systematically evaluates the performance characteristics of the test, including relative sensitivity, specificity, accuracy, and precision, using chemiluminescent immunoassay (CLIA) as the reference standard. A total of 102 specimens were analyzed, comprising 23 with abnormal ferritin levels and 79 with normal levels, all confirmed by CLIA from both symptomatic and asymptomatic individuals. Results demonstrated high relative sensitivity at 91.3% (95%CI: 72.0%-98.9%) and specificity at 96.2% (95% CI: 89.3%-99.2%), resulting in an overall accuracy of 95.1% (95% CI: 88.9%-98.4%). Importantly, the test showed no cross-reactivity with common interfering substances such as human anti-mouse antibodies (HAMA), rheumatoid factor (RF), or human hemoglobin, thereby affirming its specificity. Furthermore, both intra-assay and inter-assay precision were exceptional, achieving over 99% correct identification of specimens at concentrations of 0 ng/mL, 30 ng/mL, and 100 ng/mL. The limit of detection was established at 30 ng/mL. Collectively, these findings substantiate that the Ferritin Rapid Test Cassette is a reliable, rapid, and user-friendly tool for the qualitative self-assessment of ferritin levels, thereby facilitating the early detection of iron deficiency in various populations.

1. Introduction

Iron deficiency anemia is a global public health issue, particularly affecting children, women of reproductive age and pregnant individuals. It is estimated that at least 20% of menstruating women suffer from iron deficiency, with symptoms such as paleness, fatigue and exertional dyspnea that often develop gradually and go unnoticed[1]. Iron is critical for hemoglobin synthesis and iron depletion-due to inadequate intake, impaired absorption or excessive blood loss-reduces red blood cell production and hemoglobin levels[2].

Ferritin, a cellular iron-storage protein, is a key biomarker for iron status: low ferritin levels (<30

ng/mL) strongly indicate iron deficiency, even in the absence of overt anemia[3]. Low ferritin may also signal underlying conditions like hypothyroidism, vitamin C deficiency or celiac disease[4,5]. Timely detection is crucial for early intervention, especially in vulnerable populations.

Traditional ferritin detection methods (e.g., CLIA) are accurate but require laboratory equipment and trained personnel, limiting accessibility in point-of-care or home settings. Chromatographic immunoassays have emerged as rapid, user-friendly alternatives, enabling qualitative detection with minimal training[6]. The Ferritin Rapid Test Cassette (Whole Blood) is specifically designed for self-testing: it uses fingerstick blood and provides results within 5 minutes. However, comprehensive validation of its diagnostic performance-particularly for self-administered use-is essential before widespread adoption.

This study evaluates the performance of the Ferritin Rapid Test Cassette against CLIA (the gold standard), focusing on its suitability for self-testing by assessing sensitivity, specificity, accuracy, precision and cross-reactivity.

2. Materials and Methods

2.1 Specimen Collection

A total of 102 specimens were collected for analysis, comprising 23 identified as ferritin-abnormal and 79 classified as ferritin-normal, with confirmation achieved through Clinical Laboratory Improvement Amendments (CLIA) standards. These specimens were sourced from both symptomatic and asymptomatic individuals. Blood samples were obtained via fingerstick, simulating self-testing conditions, as well as through traditional venous puncture methods. To maintain sample integrity, specimens that were not tested immediately were stored at a controlled temperature of 2-8 ℃ and analyzed within a 24-hour timeframe. This protocol ensured the stability and reliability of the test results for subsequent evaluation.

2.2 Test Kit and Procedure

The materials utilized in this study included the Ferritin Rapid Test kit, which is designed for the convenient assessment of ferritin levels. Each kit comprises essential components, including a test cassette, a capillary dropper, buffer solution, an alcohol pad, a lancet, and simplified self-test instructions to facilitate user understanding. For comparative analysis, the reference method employed was a commercial CLIA (Chemiluminescent Immunoassay) kit, which was utilized according to the manufacturer's guidelines for accurate ferritin quantification.

The testing procedure was meticulously conducted following the instructions provided in the package insert. Initially, the operator washed their hands thoroughly, and the test kit was allowed to equilibrate to room temperature, specifically within the range of 2 to 30 ℃. A fingertip was then sanitized using the supplied alcohol pad, after which a lancet was employed to obtain a sufficient drop of blood. Utilizing the capillary dropper, blood was carefully collected up to the marked line while ensuring that no air bubbles were present, and subsequently dispensed into the sample well of the test cassette. Following this, one drop of buffer solution was added to the sample well, and the results were read at exactly five minutes; any interpretation of results after ten minutes was deemed invalid.

Interpretation of the results was straightforward: a normal result was indicated by the appearance of two lines (T and C), which signified ferritin levels of 30 ng/mL or higher. Conversely, an abnormal result was indicated by the presence of only the control line (C), suggesting ferritin levels below 30 ng/mL. If the control line (C) did not appear, the result was classified as invalid, necessitating retesting with a new cassette to ensure accurate measurement.

3. Results and Discussion

3.1 Results

3.1.1 Accuracy, sensitivity and specificity

The Ferritin Rapid Test Cassette showed high agreement with CLIA across 102 specimens (Table 1):

Table 1 Diagnostic Performance of the Ferritin Rapid Test Cassette Compared to CLIA.

CLIA Result	Rapid Test Abnormal	Rapid Test Normal	Total
Abnormal	21 (True Positives)	2 (False Negatives)	23
Normal	3 (False Positives	76 (True Negatives)	79
Total	24	78	102

Relative sensitivity (abnormal detection rate): 91.3% (95% CI: 72.0%-98.9%).
Specificity (normal detection rate): 96.2% (95% CI: 89.3%-99.2%).
Overall accuracy (total coincidence rate): 95.1% (95% CI: 88.9%-98.4%).
Kappa value: 0.86, indicating high agreement between the rapid test and CLIA.

3.1.2 Cross-reactivity and Interference

To validate reliability in unsupervised self-testing, the test was evaluated for cross-reactivity with substances common in whole blood, including human anti-mouse antibodies (HAMA), rheumatoid factor (RF), human hemoglobin and serum proteins. None of these substances interfered with results: spiked specimens showed consistent agreement with CLIA. This confirms the test's specificity for ferritin, reducing false results in self-test scenarios where users cannot troubleshoot interference.

3.1.3 Precision

Precision was rigorously assessed to ensure reliability during repeated self-test attempts. Intra-assay precision was evaluated using 10 replicate tests on specimens at 0 ng/mL, 30 ng/mL, and 100 ng/mL, covering relevant clinical thresholds and demonstrated 100% correct identification. Inter-assay precision was further confirmed through tests conducted across three production lots over three days, achieving over 99% correct identification, with only one discrepancy attributed to a procedural error, mirroring potential occasional user mistakes. These findings affirm the test's robustness against minor variations in self-testing techniques, which is a critical feature for ensuring accuracy among untrained users.

3.2 Discussion

3.2.1 Performance Characteristics

The Ferritin Rapid Test Cassette demonstrates exceptional performance as a self-testing tool, achieving an impressive accuracy rate of 95.1%, which significantly exceeds the 90% threshold recommended for point-of-care self-tests. Its high sensitivity of 91.3% ensures that the majority of iron deficiency cases are effectively detected, thereby allowing users to take timely action based on their results. Furthermore, the test boasts a specificity of 96.2%, which reduces the likelihood of false positives, thus minimizing unnecessary medical consultations—an important consideration for individuals conducting self-assessments. The limit of detection is set at 30 ng/mL, aligning with

established clinical guidelines for diagnosing iron deficiency and confirming the test's relevance for self-evaluation. Notably, the rapid turnaround time of just five minutes, combined with a simplified testing procedure that does not require specialized training, enhances the test's accessibility for home use. This is particularly beneficial for menstruating women, pregnant individuals, and those residing in resource-limited settings with limited access to laboratory facilities, facilitating early detection and management of iron deficiency.

3.2.2 Limitations

The Ferritin Rapid Test Cassette presents several important limitations that users should carefully consider. Firstly, it delivers qualitative results by categorizing ferritin levels as either <30 ng/mL or ≥30 ng/mL, lacking the capacity for quantitative measurements. Consequently, it is advisable to pursue confirmatory testing through CLIA for any abnormal results obtained from self-testing. Secondly, user-dependent factors, such as improper blood collection techniques or insufficient sample volume, may lead to inaccuracies in the results. However, the kit's design incorporates a marked capillary dropper, which aids in minimizing this risk. Additionally, it is crucial to interpret results within the appropriate clinical context. Acute inflammation can transiently elevate ferritin levels, potentially obscuring underlying iron deficiency in individuals conducting self-tests. Moreover, the test has not been validated for use in individuals with liver or spleen injuries, conditions that can significantly affect ferritin metabolism. This limitation further restricts the applicability of the Ferritin Rapid Test Cassette in specific populations, highlighting the need for careful consideration of these factors when interpreting test outcomes.

3.2.3 Comparison with Other Diagnostic Methods

The Ferritin Rapid Test Cassette stands out in self-testing scenarios when compared to other diagnostic methods. The gold standard chemiluminescent immunoassay (CLIA) offers precise quantitative results with low variability across a wide range (1–1000 ng/mL), making it critical for confirming abnormal findings and detecting subtle ferritin changes. However, its reliance on laboratory equipment, trained personnel and long turnaround times (hours to days) renders it unsuitable for self-testing or use in resource-limited settings. Similarly, enzyme-linked immunosorbent assays (ELISA) provide accurate results but involve labor-intensive steps that are impractical for untrained users, limiting their value for at-home monitoring.

In contrast, the Ferritin Rapid Test Cassette addresses these limitations by prioritizing self-testing feasibility: it delivers results in 5 minutes, uses a simple fingerstick specimen and requires no specialized training. Unlike lateral flow hemoglobin tests- which only detect overt anemia and miss early iron deficiency-it targets ferritin, a stable marker of iron stores, enabling proactive self-assessment. While it cannot quantify ferritin levels (e.g., for adjusting supplementation or diagnosing conditions like hereditary hemochromatosis), it serves as an effective first-line self-test to identify individuals needing further clinical evaluation. This combination of accessibility and clinical relevance makes it uniquely valuable for democratizing early detection of iron deficiency.

4. Conclusion

The Ferritin Rapid Test Cassette is a highly reliable and user-friendly tool designed for the qualitative self-testing of ferritin levels in whole blood. This test stands out due to its high sensitivity, specificity, and precision, making it an exceptional choice for individuals seeking to monitor their iron levels. Additionally, the test is notably resistant to interference from various substances, which enhances its accuracy and reliability in diverse testing conditions. Its ease of use further supports its suitability for self-administration, particularly among high-risk populations who

may be more susceptible to iron deficiency. While the Ferritin Rapid Test cannot substitute for confirmatory testing conducted under Clinical Laboratory Improvement Amendments (CLIA) standards, it serves as an effective first-line screening tool. By facilitating early detection and timely intervention, this rapid test plays a crucial role in identifying iron deficiency, ultimately contributing to better health outcomes for individuals at risk.

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