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

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ABSTRACT

The Ferritin Rapid Test Cassette is a chromatographic immunoassay designed for qualitative self-testing of ferritin in human whole blood to screen for potential iron deficiency. This study evaluated its diagnostic performance—sensitivity, specificity, accuracy, and precision—using Chemiluminescent Immunoassay (CLIA) as the reference standard. A total of 102 specimens (23 ferritin-abnormal and 79 ferritin-normal) were tested. The assay showed 91.3% sensitivity (95% CI: 72.0–98.9), 96.2% specificity (95% CI: 89.3–99.2), and 95.1% overall accuracy (95% CI: 88.9–98.4). No cross-reactivity was observed with HAMA, RF, or human hemoglobin. Both intra- and inter-assay precision exceeded 99% across clinically relevant ferritin levels (0, 30, 100 ng/mL). These results demonstrate that the Ferritin Rapid Test Cassette is a rapid, accurate, and user-friendly tool for self-assessment of ferritin levels, aiding in early detection of iron deficiency and anemia.

Keywords: *Ferritin; Iron Deficiency Anemia; Rapid Self-Test Cassette; CLIA; Chromatographic Immunoassay; Whole Blood; Self-Testing.*

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1. INTRODUCTION

Iron deficiency anemia (IDA) remains a leading cause of morbidity worldwide, particularly among women of reproductive age, children, and pregnant individuals. Ferritin, a key intracellular iron-storage protein, serves as a reliable biomarker of body iron stores—levels below 30 ng/mL are indicative of iron deficiency even before hemoglobin drops.

Traditional CLIA and ELISA tests, while accurate, are confined to laboratories due to equipment, personnel, and time constraints. The growing demand for home-based or point-of-care testing has accelerated the development of immunochromatographic self-tests.

The Ferritin Rapid Test Cassette (Whole Blood) is designed for qualitative detection of ferritin using a fingerstick blood sample, with results in 5 minutes. This study evaluates its clinical performance relative to CLIA, assessing sensitivity, specificity, accuracy, cross-reactivity, and precision under self-testing conditions.

2. MATERIALS AND METHODS

Specimen Collection

A total of 102 samples (23 ferritin-abnormal, 79 ferritin-normal) were collected from both symptomatic and asymptomatic participants. Specimens were obtained via fingerstick or venous puncture and analyzed within 24 hours. Storage was at 2–8 °C to maintain stability.

Test Kit and Reference Method

Device: Ferritin Rapid Test Cassette (Whole Blood, Self-Testing Kit)

Reference: Commercial Chemiluminescent Immunoassay (CLIA) ferritin kit (quantitative).

Testing Procedure
Clean fingertip with alcohol pad and puncture with lancet.
Collect blood up to the mark on the capillary dropper and dispense into the sample well.
Add one drop of buffer.
Read results at 5 minutes (results after 10 minutes invalid).

Interpretation:
Two lines (T + C): Normal ferritin (≥30 ng/mL).
One line (C only): Low ferritin (<30 ng/mL).
No control line: Invalid test (repeat required).

Performance Metrics
Evaluated parameters included diagnostic sensitivity, specificity, accuracy versus CLIA; cross-reactivity and interference from HAMA, RF, hemoglobin, and serum proteins; intra- and inter-assay precision across 3 production lots.

3. RESULTS

Diagnostic Accuracy

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

Sensitivity: 91.3% (95% CI: 72.0–98.9%)
Specificity: 96.2% (95% CI: 89.3–99.2%)
Accuracy: 95.1% (95% CI: 88.9–98.4%)

Kappa value: 0.86 — indicating strong agreement with CLIA.
Cross-Reactivity and Interference

No interference observed with HAMA, RF, hemoglobin, or serum proteins. Spiked samples showed identical results to CLIA, confirming specificity.

Precision
Intra-assay reproducibility: 100% correct identification at 0, 30, and 100 ng/mL. Inter-assay precision: >99% correct identification across 3 lots, demonstrating excellent repeatability even under variable user conditions.

4. DISCUSSION

The Ferritin Rapid Test Cassette provides a qualitative, home-based screening tool for iron deficiency. Its 95.1% diagnostic accuracy and 91.3% sensitivity meet international standards for self-testing, ensuring reliable early detection.

Unlike hemoglobin tests that identify late-stage anemia, ferritin testing detects iron depletion before anemia onset, enabling preventive health management.

Comparison with Conventional Methods
Compared to CLIA, the rapid test offers faster results (5 minutes vs. hours), no specialized equipment or training, fingerstick blood instead of venipuncture, and high concordance ($\kappa = 0.86$). While quantitative CLIA remains necessary for treatment monitoring, the Ferritin Rapid Test Cassette serves effectively as a first-line self-test for screening.

Limitations
Provides qualitative rather than quantitative results. User-dependent variability may affect results. Ferritin elevation during inflammation may mask deficiency. Not validated for patients with hepatic or splenic dysfunction.

5. CONCLUSION

The Ferritin Rapid Test Cassette is a reliable, precise, and convenient self-testing device for qualitative ferritin detection. Its high sensitivity (91.3%), specificity (96.2%), and reproducibility (>99%) confirm its suitability for self-administration

and early diagnosis of iron deficiency. While confirmatory CLIA testing remains recommended for abnormal results, this test substantially improves access to preliminary screening, particularly in low-resource or home settings.

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