Analytical Performance Evaluation of the Gazelle™ Ferritin FIA Point-of-Care Test Compared with a Reference Laboratory Assay in India

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INTRODUCTION

- Timely and accurate ferritin measurement is critical for the diagnosis and management of iron deficiency and iron overload disorders, particularly in settings where access to centralized laboratory testing is limited.
- Point-of-care (POC) diagnostics offer the potential to expand access to testing while reducing turnaround time.
- The Gazelle™ Reader, used with the Gazelle™ Ferritin FIA Test Kit, is a portable, battery-operated in vitro diagnostic device designed for quantitative ferritin measurement across a range of environmental conditions.



Figure 1. This study was conducted at a Therapeutic Drug Monitoring (TDM) laboratory in Mumbai, India. 31% of adolescent girls in India are iron deficient.[1]

OBJECTIVE

Evaluate the analytical performance of the Gazelle Ferritin FIA Test Kit against the Roche Ferritin Assay under typical-use laboratory conditions in Mumbai, India.

METHODS AND MATERIALS

- This single-center, non-randomized comparative study was conducted at a Therapeutic Drug Monitoring (TDM) laboratory in Mumbai, India.
- Whole blood samples with known ferritin values were procured and collected into EDTA tubes.
- Samples were stored at 4°C and tested within five days of collection.
- Ferritin levels were measured using both the Gazelle Ferritin FIA Test and the Roche Ferritin Assay. A total of 298 samples were tested, of which 275 unique patient samples were included in the primary analysis following predefined exclusions.
- To ensure adequate distribution across the assay's analytical range, 19 additional diluted samples were tested, resulting in 294 total measurements.
- Performance was evaluated using correlation analysis and mean percent error relative to the reference method.

RESULTS

275 unique samples analyzed:
- 46.2% female; 53.7% male
- Mean age: 57 years (female), 58 years (male)
- Strong agreement with the Roche reference assay; mean percent error = -8.6
- Device operated reliably across study conditions

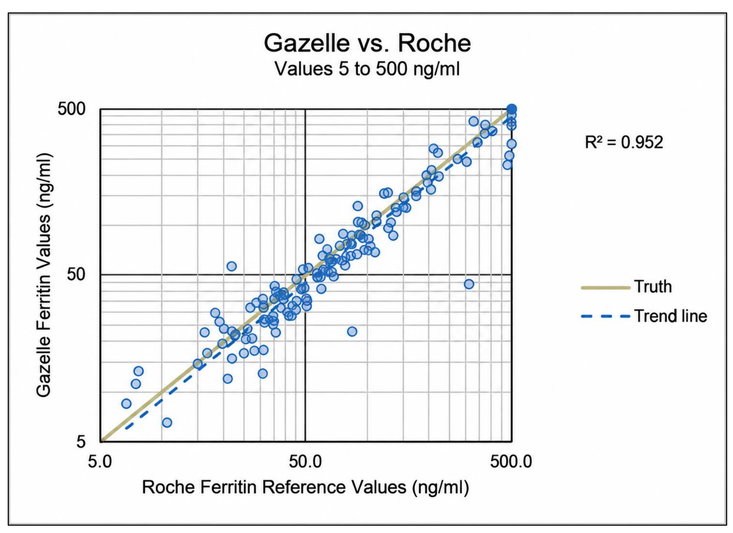


Figure 2. Comparison of Gazelle™ Ferritin FIA and Roche Ferritin Assay measurements from 5–500 ng/ml. Linear regression demonstrated strong agreement (R^2 = 0.952).

KEY PERFORMANCE RESULTS

95% coefficient of determination (R^2)

-8.6% mean percent error[2]

275 unique patient samples in primary analysis

294 total measurements



Figure 3. The Gazelle™ Reader, used with the Gazelle™ Ferritin FIA Test Kit, is designed for a range of environmental conditions.

CONCLUSIONS

- The Gazelle Ferritin FIA Test Kit demonstrates high correlation and acceptable agreement with a standard laboratory-based ferritin assay.
- Gazelle's portability, operational flexibility (including battery use and tolerance to varied environmental conditions), and ease of use make it a promising POC solution for decentralized settings.
- Broader implementation of this technology could enhance access to ferritin testing and support timely clinical decision-making, particularly in resource-constrained environments.

Gazelle's portability, operational flexibility, and ease of use make it a promising point-of-care solution for decentralized settings.

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References:

1. Ministry of Health and Family Welfare, Government of India; UNICEF. Comprehensive National Nutrition Survey (CNNS), 2016–2018. New Delhi: MoHFW; 2019.
2. Negative value indicates modest negative bias vs. reference method.



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