From: Orin Buetens
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To: Pathologists Laboratory Directors & Laboratory Management
Subject: Ferritin interpretation

In 2009, Dahl Chase sent out a memo suggesting an interpretive comment range for Ferritin assays. This was based on the known variability of reference ranges and concern for the under reporting of iron-deficient anemia.

In years since, the clinical laboratory community has recognized that Ferritin reference ("normal") range determination and standardization are challenging and many laboratories report highly variable ferritin reference intervals, even when using assays from the same vendor. Established ferritin reference ranges have been criticized for including iron-deficient patients in the determination of these ranges, since the true "gold stand" of determining systemic iron stores is bone marrow biopsy. In addition, numerous studies, proficiency data, and quality control statistics confirm there is bias between methods & manufacturers; however, according to the International Consortium for Harmonization of Clinical Laboratory Results, ferritin assays have sufficient harmonization status for medical decision making.

From the patient perspective, iron deficiency, even without overt anemia, may still have clinical consequences. As such, some have argued that higher ferritin thresholds should be used to prevent symptoms before patients develop full blown iron deficiency anemia. Recent studies have also raised the concern that the use of lower ferritin reference ranges leads to a substantial number of iron deficient patients being misdiagnosed as iron sufficient. Overall, the risk-benefit ratio appears to favor the use of higher ferritin cutoffs for most patients.

As mentioned above, the lack of standardization of ferritin assays between test manufacturers can create problems/confusion when the same patient is tested at different laboratories, especially when an exact cut-off is mandated for a therapeutic intervention (e.g. therapeutic phlebotomy). As such, serial evaluation with the same method/laboratory is necessary when following patients. Re-baselining patients may be necessary if patients are tested at different laboratories utilizing different methods. Given the importance of potential bias in this circumstance, we are recommending the addition of this information to the Dahl Chase comment:

The lower limit for ferritin should be 30 for men and 20 for women and the comment as follows:
*In adults under the age of 50, a female serum ferritin **<20 ng/mL** or a male serum ferritin **<30 ng/mL**, should be regarded as evidence of iron deficiency. In adults over the age of 50, a serum ferritin **<45 ng/mL** should be regarded as evidence of iron deficiency. In adults with significant inflammatory disorders or malignancy, a serum ferritin **<80 ng/mL** is presumptive evidence of iron deficiency. Persistently elevated serum ferritin **>1000 ng/mL**, in the absence of significant inflammation, suggests the possibility of hereditary hemochromatosis. Ferritin assays are not standardized between laboratories and test manufacturers. Results can vary depending upon the laboratory where measured. For serial evaluation, testing at the same laboratory should be considered.*

References

1. Iron requirements and iron deficiency in adolescents, Up to Date, March 2025
2. Revising Ferritin Lower Limits: It's Time to Raise the Bar on Iron Deficiency, Michelle L. Parker,a Sherri Storm,b Michelle Sholzberg,c Paul M. Yip,d and Daniel R. Be, riaulte. Special Report JALM, May 2021
3. Diagnostic approach to anemia in adults, Up to Date March 2025