

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k052617

B. Purpose for Submission:

New Device

C. Measurand:

Ferritin

D. Type of Test:

Quantitative latex enhanced immunoturbidimetry assay (LIT)

E. Applicant:

Good Biotech Corp

F. Proprietary and Established Names:

Ferritin LIT Assay

Ferritin Calibrator Set

Ferritin Controls, Level-L & Level H

G. Regulatory Information:

1. Regulation section:

21 CFR 866.5340, Ferritin Immunological Test System

21 CFR 862.1150, Calibrator

21 CFR 862.1660, Quality Control Material

2. Classification:

Class II (device and calibrator)

Class I (quality control material)

3. Product code:

DBF- Ferritin, Antigen, Antiserum, Control

JJX- Single (Specified) Analyte Controls (Assayed and Unassayed)

JIT- Calibrator, Secondary

4. Panel:

Immunology 82, Chemistry 75

H. Intended Use:

1. Intended use(s):

Good Biotech Corp. (GBC) Ferritin LIT Assay system is intended to be used for quantitative determination of ferritin in human serum by latex particle enhanced immunoturbidimetry (LIT). Measurement of ferritin aids in the diagnosis of disease affecting iron metabolism.

GBC Ferritin Calibrator Set is intended to be used with GBC Ferritin LIT Assay for the quantitative determination of ferritin in serum samples.

GBC Ferritin Controls are intended to be used as the assayed quality control material for ferritin analysis.

2. Indication(s) for use:

Same as Intended use.

3. Special conditions for use statement(s):

The device is for prescription use only.

4. Special instrument requirements:

The device is intended to be used on the Hitachi Automated Chemistry Analyzer 717 (K872494), 911 (K921661), 917 (K953239) and Beckman Autoanalyzers CX4, CX5, CX7 (K994325).

I. Device Description:

GBF LIT consists of Ferritin R1 (Buffer) and Ferritin R2 (Latex) ready for use. The GBC Calibrator set consists of five levels of calibrators, Levels 1-5. The GBC Controls contain ferritin at two levels: Control Level L (~22.1 mg/L) and Control Level H (~300.1 mg/L) ready for use. The controls and calibrators are sold separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
quantex Ferritin.
quantex Ferritin standard multipoint
quantex Ferritin/Myoglobin/IgE control I/II
2. Predicate 510(k) number(s):
k040879
3. Comparison with predicate:

Similarities		
Item	New Device	Predicate
Intended Use	Quantitative <i>in vitro</i> diagnostic determination of ferritin	Same
Methodology	Latex particle-enhanced immunoturbidimetry	Same
Storage Conditions	Refrigerate at 2-8°C	Same

Differences		
Item	New Device	Predicate
Antibody	Duck anti-ferritin IgY (ΔFc) purified from duck yolk	Rabbit IgG anti-ferritin
Reagent Composition	Reactive Buffer Solution (R1): Glycine Buffer Latex Solution (R2): Solution of suspended latex microparticles sensitized with duck anti-human ferritin IgY (ΔFc)	Ferritin R1 (Buffer): HEPES Buffer Ferritin R2 (Latex): Suspension of polystyrene latex particles coated with IgG anti-human ferritin in a buffer.
Sample Type	Serum	Serum and EDTA plasma
Calibrators	Human ferritin at five different levels, stabilizer and <0.1% sodium azide	Human ferritin at four different levels, stabilizer and <0.1% sodium azide
Controls	Ready to use solution of buffer with human ferritin at two different levels, stabilizers and <0.1% sodium azide	Lyophilized solution of buffer with human ferritin at two different levels, stabilizers and <0.1% sodium azide

K. Standard/Guidance Document Referenced (if applicable):

Replacement Reagent and Instrument Family Policy- FOD #950.

L. Test Principle:

The GBF Ferritin LIT assay is a latex particle enhanced immunoturbidimetric assay to quantify ferritin in human serum. When ferritin in the sample is mixed with the latex microparticles sensitized with duck anti-ferritin IgY (ΔFc), agglutination among the latex microparticles occurs based on the antigen-antibody reaction. The agglutination increases the turbidity of the sample and the degree of agglutination is detected by the absorbance change at 570 nm. The value of the absorbance change is proportional to the ferritin concentration of the sample and is recorded by a general chemistry autoanalyzer. Then, the actual ferritin concentration of the sample is determined by interpolation of the calibration curve obtained by standard samples with known ferritin concentrations.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*Total Precision and Within-run Precision:

A precision study was performed on a Hitachi 717 using GBT kit. Test samples with the following ranges (Level I: 300-350 ng/mL, Level II: 50-60 ng/mL and Level III: 15-30 ng/mL) were prepared by pooling different patient samples.

Total precision performance was assayed in all 3 pools in duplicates twice a day for 10 different days (n=60). The acceptance criterion for precision was CV: $\leq 10\%$. The results are summarized in the table below.

# Days	Mean(ng/mL)	SD	CV (%)
10	328.6	2.98	0.91
10	58.2	3.19	5.48
10	23	1.73	7.53

Within-run precision performance was measured 15 times on the 3 level pools. The acceptance criterion for precision was CV: $\leq 10\%$. The results are summarized in the table below.

# Tests= 15	Sample I	Sample II	Sample III
Mean (ng/ml)	333.5	54.9	19.9
S.D.	3.78	2.49	1.75
CV (%)	1.13	4.54	8.79
Max (ng/mL)	339	59	22
Min (ng/mL)	325	50	16

Additional precision testing was performed at the low end of the assay range using a pooled serum sample. The mean was 10.8 ng/mL, with a within-run % CV of 17.89% and a total % CV of 12.3 %. The within run, between run and

total % CV were calculated according to NCCLS protocol.

Inter-lot variability:

The consistency and reproducibility between 5 production lots was tested with three pools of patient samples with different ferritin concentrations (Low: 125 ng/mL, Medium: 500 ng/mL and High: 1000 ng/mL) were serially diluted (dilution fold of 0, 0.2, 0.4, 0.6, 0.8 and 1). All results fall within the acceptance criterion of $R^2 > 0.99$.

b. *Linearity/assay reportable range:*

Linearity was performed by diluting six high ferritin patient samples with ferritin concentration of about 1000 ng/mL using normal saline as diluent (dilution folds of 0, 0.2, 0.4, 0.6, 0.8 and 1) to cover the assay range. GBC Ferritin LIT Assay was linear from 0 to 1000 ng/mL with a slope=1053.1, intercept = -29.56 ng/mL and R^2 value = 0.9979.

The analytical range of Ferritin LIT Assay is 5-1000 ng/mL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The Ferritin Calibrator Set is standardized to the WHO Third International Standard 94/572.

Stability studies were performed and the shelf-life of the reagents was found to be stable for six months at 2-10°C.

d. *Detection limit:*

The definition of the detection limit is the lowest value differentiated from zero. The concentration corresponding to a signal 2 SD above the mean for zero ferritin calibrator is 5 ng/mL.

e. *Analytical specificity:*

i. Interference

Interference is defined as when recovery is more than $\pm 10\%$ of the initial value measured. No significant interference was found up to 60 mg/dL bilirubin C and bilirubin F. In addition, no significant hemolysis was found up to 500 mg/dL hemoglobin and for lipemia (chyle), no significant interference was present up to 2940 turbidity.

f. *Assay cut-off:*

Not provided

2. Comparison studies:

a. *Method comparison with predicate device:*

The assay was compared to the predicate on a study conducted on 50 serum patient samples collected from hospital. By linear regression: (GBC Ferritin LIT) = 1.072 (quantex Ferritin) – 17.729 ng/mL. $R^2=0.9808$.

Instrument-instrument comparison:

A correlation study was performed using 50 patient samples with Ferritin values covering the assay measuring range (5-1000 ng/mL) with representative analyzers from the Beckman CX and Hitachi analyzer families namely, Beckman CX5 and Hitachi 7150. The results are represented in the chart below.

