

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k040879

B. Purpose for Submission:

New device

C. Analyte:

Ferritin

D. Type of Test:

Quantitative, latex particle enhanced immunoturbidimetric assay

E. Applicant:

Instrumentation Laboratory Co.

F. Proprietary and Established Names:

Quantex Ferritin

G. Regulatory Information:

1. Regulation section:

21CFR § 866.5340 Ferritin Immunological Test System

21CFR § 862.1660 Quality Control Material (Assayed and Unassayed)

21CFR § 862.1150 Calibrator

2. Classification:

Class II, Class I, Class II

3. Product Code:

DBF, Ferritin, Antigen, Antiserum, Control

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

JIT, Calibrator, Secondary

4. Panel:

Immunology, 82

H. Intended Use:

1. Intended use(s):

Quantex Ferritin is an automated latex enhanced immunoassay for the quantitative determination of ferritin in human serum or EDTA plasma on Clinical Chemistry Systems.

The Quantex Ferritin controls 1/11 are intended for use in monitoring the quality control of results obtained with the quantex ferritin reagents by turbidimetry.

The Quantex Ferritin standard multipoint is intended for use in establishing the calibration curve for the quantex Ferritin reagents by turbidimetry.

2. Indication(s) for use:

Quantex Ferritin is intended as a latex enhanced immunoturbidimetric assay for the quantitative determination of ferritin in human serum or EDTA plasma on Clinical Chemistry Systems, and aids in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

The Quantex Ferritin controls 1/11 are intended for use in monitoring the quality control of results obtained with the quantex ferritin reagents by turbidimetry.

The Quantex Ferritin standard multipoint is intended for use in establishing the calibration curve for the quantex Ferritin reagents by turbidimetry.

3. Special condition for use statement(s):

The device is for prescription use only.

4. Special instrument Requirements:

For use on ILAB™ 900/1800 (K932467)

I. Device Description:

Quantex Ferritin consists of Ferritin R1 (Buffer) Ready to Use and Ferritin R2 (Latex) Ready to use. The Quantex Ferritin controls contain ferritin at two levels, low and high levels (lyophilized). The Quantex Ferritin standard multipoint consists of four levels of calibrators. The controls and calibrators are sold separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Abbott's AxSYM Ferritin

2. Predicate K number(s):

K935847

3. Comparison with predicate:

Item	Device	Predicate
Similarities		
	Quantex Ferritin	Abbott's AxSYM
Intended use	Quantitative <i>in vitro</i> diagnostic determination of ferritin	Same
Storage conditions	Refrigerate at 2-8° C until expired	Same
Sample type	Serum, EDTA plasma	Serum, sodium heparin plasma
Differences		
Methodology	Particle enhanced immunoturbidimetry	Microplate enzyme immunoassay (EIA)
Calibrators	TRIS buffer containing human ferritin at four different levels, stabilizer and <0.1% sodium azide (sold separately)	Ferritin (human spleen) prepared in phosphate buffer at two levels with protein stabilizers and <0.1% sodium azide
Controls	Lyophilized solution of buffer with human ferritin at two different levels, stabilizers and <0.1 % sodium azide (sold separately)	Three levels of ferritin (human spleen) prepared in phosphate buffer with protein stabilizers.

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

None referenced

L. Test Principle:

Quantex Ferritin is a latex particle enhanced immunoturbidimetric assay to quantify ferritin in human serum or EDTA plasma. The Quantex Ferritin Latex reagent is a suspension of polystyrene latex particles of uniform size coated with rabbit IgG anti-ferritin. When a sample containing ferritin is mixed with the latex reagent and the reaction buffer included in the kit, a clear agglutination occurs. The degree of agglutination is directly proportional to the concentration of ferritin in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

M. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

A precision study was performed on an ILAB 900/1800 using Quantex Ferritin controls I/II (low and high) run in replicates of six twice a day over five days (n=60). The within run, between run and total %CV were calculated according to NCCLS protocol.

Material	N	Mean	Within-Run %CV	Between-Run %CV	Total %CV
Low control	60	43.2	4.09	3.88	6.62
High control	60	402.8	1.61	1.64	2.29

Additional precision testing was performed at the low end of the assay range (7-25 ng/mL) using a pooled serum sample run in replicates of six twice a day over five days (n=60). The mean is 18.9 ng/mL, with a within-run %CV of 9.8 and a total %CV of 12.3.

b. Linearity/assay reportable range:

Linearity was performed on an ILAB 900/1800 using 3 dilutions of the lowest calibrator (25 ng/mL) to 6.3 ng/mL and 8 dilutions of the highest calibrator (500 ng/mL) to 50 ng/mL of Quantex Ferritin standard multipoint. Each dilution was tested in triplicate with 2 different lots of Quantex ferritin reagents. Testing was done with the automatic and without automatic rerun capability. The reported means were calculated from the pooled results. Data showed R^2 of 0.999 and 1.000 for the two lots of reagents. The graphs showed the curves are linear on both settings.

The ILAB 900/1800 can automatically rerun samples with results above the upper limit of the valid range (500 ng/mL) using a specific percentage of the sample volume. The instrument then automatically recalculates the new sample result. Acceptance criterion was set at $\pm 15\%$ Inaccuracy. Inaccuracy (IA) is calculated according to a formula: $IA = 100 \times \frac{\text{Reported value} - \text{expected value}}{\text{Expected value}}$

Acceptance criteria were met.

The reportable range for the assay is:

25 to 500 ng/mL without the ILab automatic rerun capability

25 to 1600 ng/mL with the ILab automatic rerun capability

c. *Traceability (controls, calibrators, or method):*

Value assignments were determined in multiple runs on ILAB Clinical Chemistry Systems using specific lots of reagents and against a Calibration House standard and to the current 3rd WHO International Standard for Ferritin, Recombinant NIBSC code: 94/572.

The Quantex Ferritin control I/II are obtained from an external source (Denka Seiken). The controls value range is assigned at Biokit by comparison to the Ferritin Calibration House Standard and the current 3rd WHO International Standard for Ferritin, Recombinant NIBSC code: 94/572.

d. *Detection limit:*

To calculate detection limit, saline was analyzed in runs of 6 replicates twice a day over five days (n=60) on one lot of ferritin reagents. The mean value + 3 SD were calculated.

Detection limit = 6.64 ng/mL

e. *Analytical specificity:*

Interference: Interference testing was performed by spiking levels of each interferent into pooled serum and comparing the results against the unspiked sample results. All samples were tested in triplicate with a single lot of ferritin reagent. Acceptance criterion is recovery of $\pm 15\%$ of the unspiked sample result.

- Lipemia interference is lower than 12% for samples with 1000mg/dL triglycerides
- RF interference is lower than 10% for samples with 1500 IU/mL
- No significant interference from bilirubin up to concentrations of 20 mg/dL (340 μ mol/L).
- No significant interference from hemoglobin up to concentrations of 500 mg/dL (0.30 mmol/L).

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

94 patient serum samples ranging from 3.2 to 1000 ng/mL were analyzed using Quantex Ferritin on an ILab 900/1800 and AxSYM Ferritin (predicate device) on an AxSYM immunoassay automatic analyzer. No artificially prepared samples were used in this study. The following results were obtained:

(Plasma) = 0.9293 (Serum) - 0.8847

Slope = (95%CI: 0.9089, 0.9498)

y intercept = (95%CI: -3.8846, 2.1152)

b. Matrix comparison:

Thirty (30) fresh samples were collected in EDTA plasma and with no anticoagulant and run on an ILab 900/1800. Linear regression statistics were applied to the sample matrix data with the following results:

Slope = 0.9497 (95%CI: 0.9265 to 0.9728)

y intercept = 0.0889 (95%CI: -2.4832 to 2.6611)

The data support the application of EDTA anticoagulant for use on the Quantex Ferritin.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a and b are not applicable):

None

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Reference ranges were taken from Tietz: Fundamentals of Clinical Chemistry, 3rd ED., and W.B. Saunders Co., Philadelphia, 1987.

- Newborn infants: 25-200 ng/mL
- 1 month: 200-600 ng/mL
- 2 to 5 months: 50-200 ng/mL
- 6 months to 15 years: 7-142 ng/mL

Adults:

- Males: 20-300 ng/mL
- Females: 10-120 ng/mL

As stated in the product insert, reference ranges may vary with age and sex. Each laboratory should establish each own normal range due to many variables which may affect results.

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.