

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

A. 510(k) Number:

k133083

B. Purpose for Submission:

New Device

C. Measurand:

Ferritin

D. Type of Test:

Quantitative, immunoturbidimetric

E. Applicant:

Diazyme Laboratories

F. Proprietary and Established Names:

Diazyme Ferritin Assay
Diazyme Ferritin Calibrator Set
Diazyme Ferritin Control Set

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 (assayed and unassayed)

2. Classification:

Class II (assay and calibrator)
Class I (control)

3. Product code:

DBF – Ferritin, antigen, antiserum, control

JIT – Calibrator, Secondary

JJX – Single (specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

Immunology (82) (Assays)

Chemistry (75) (Calibrators, Controls)

H. Intended Use:

1. Intended use(s):

The Diazyme Ferritin Assay is for the quantitative determination of ferritin in human serum, K₂EDTA plasma and lithium heparin plasma on Hitachi 917 analyzer. For *in vitro* diagnostic use only.

The Diazyme Ferritin Calibrator Set is intended for use in the calibration of the Diazyme Ferritin Assay. For *in vitro* diagnostic use only.

The Diazyme Ferritin Control Set is intended for use as quality controls for the Diazyme Ferritin Assay. For *in vitro* diagnostic use only.

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

For Prescription Use only

4. Special instrument requirements:

Hitachi 917 analyzer

I. Device Description:

The Diazyme Ferritin Assay kit includes the following components:

- REAGENT 1: 100 mM Tris buffer solution, ready to use (1 x 52 mL).
- REAGENT 2: Suspension of latex particles coated with goat anti-human Ferritin antibodies, ready to use (1 x 13 mL).

The Diazyme Ferritin Calibrator Set consists of four ready to use liquid vials (4 x 1 mL) of

calibrator levels 1 – 4 in a buffer matrix containing 2% bovine serum albumin and 0.9% saline.

The Diazyme Ferritin Control Set consists of two ready to use liquid stable vials (2 x 1 mL) of control 1 and control 2 manufactured in human serum and <0.1% sodium azide.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):

Tina-Quant Ferritin Gen. 4, k100538
 Calibrator for Automated Systems (C.f.a.s) Protein, k080607
 Precinorm and Precipath Protein, k012371

2. Comparison with predicate:

Diazyme Ferritin Assay

Similarities		
Item	Device: Diazyme Ferritin Assay	Predicate: Tina-Quant Ferritin Gen. 4 (k100538)
Intended Use/Indications for use	The Diazyme Ferritin Assay is for the quantitative determination of ferritin in human serum K ₂ EDTA plasma and lithium heparin plasma on Hitachi 917 analyzer. For in vitro diagnostic use only.	In vitro test for the quantitative determination of ferritin in human serum and plasma on Roche automated clinical chemistry analyzers.
Assay Principle	Latex-enhanced immunoturbidimetric	Same
Type of Test	Quantitative	Same
Instrument Platform	Roche/Hitachi	Same
Sample Type	Serum and Plasma (Li-Heparin or K ₂ EDTA)	Same
Analytical Specificity	The antibodies are specific for ferritin from human liver and recognize ferritin from human spleen.	Same
Calibrators and Controls	Sold separately	Same

Differences		
Item	Device: Diazyme Ferritin Assay	Predicate: Tina-Quant Ferritin Gen. 4 (k100538)
Capture Ab	Goat anti-human ferritin	Rabbit anti-human ferritin
Analytical Sensitivity	LoB: 6 ng/mL LoD: 9.18 ng/mL LoQ: 13 ng/mL	LoB: 3 ng/mL LoD: 5 ng/mL LoQ: 7 ng/mL
Assay measuring Range	13.0 – 1000 ng/mL	5 – 1000 ng/mL
Reagent Composition	Reagent 1: 100 mM Tris buffer solution, ready to use Reagent 2: Suspension of latex particles coated with goat anti-human ferritin, ready to use	Reagent 1: Tris buffer Reagent 3: latex particles coated with rabbit anti-human ferritin antibodies
Reagent Stability	Unopened: 12 months at 2–8°C Opened (on-board): 28 days	Unopened: 24 months at 2–8°C Opened (on-board): 84 days
Calibration frequency	The calibration curve is stable for at least 30 days.	With every lot change and as required following quality control procedures

Diazyme Ferritin Calibrator Set

Similarities/Differences		
Item	Device: Diazyme Ferritin Calibrator Set	Predicate: C.f.a.s Protein (k080607)
Levels	4 Calibrator levels (target values ~ 50-100, 225-250, 425-450, 950-1000 ng/mL)	1 single level calibrator (target value ~824 ng/mL)
Analyte	Ferritin only	Multi-analyte calibrator including Ferritin

Diazyme Ferritin Control Set

Similarities/Differences		
Item	Device Diazyme Ferritin Control Set	Predicate: Precinorm and Precipath Protein (k012371)
Control Levels	Control 1 Control 2	Precinorm protein Precipath protein

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

EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline, Second Edition.

EP06-A, Evaluation of Linearity of Quantitative Measurement, Approved Guideline, Second Edition.

EP07-A2, Interference Testing in Clinical Chemistry, Approved Guideline, Second Edition

EP09-A2IR, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, Second Edition (Interim Revision) (used for matrix comparison).

EP17-A, Protocols for Determination of Limits of Detection and Limits of Quantification, Approved Guideline.

C28-A3, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline, Third Addition

L. Test Principle:

The Diazyme Ferritin Assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between Ferritin in a sample and anti-Ferritin antibodies which have been bound to latex particles, agglutination occurs. This agglutination is detected as an absorbance change (560 nm), with the magnitude of the change being proportional to the quantity of Ferritin in the sample. The actual concentration is then determined from a calibration curve prepared from calibrators of known concentrations.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

All analytical studies were performed on the Hitachi 917 instrument.

a. Precision/Reproducibility:

The precision of the Diazyme Ferritin Assay was evaluated according to CLSI EP5-A2 guideline. Samples tested in the study included two levels of Ferritin serum-based controls (approximate 112.8 ng/mL and 318.2 ng/mL), four human serum samples spiked with ferritin antigen (target concentrations of 35.8 ng/mL, 247.9 ng/mL, 612.2 ng/mL, and 855.2 ng/mL) and two low level clinical serum samples (approximately 15.7 and 23.9 ng/mL). All samples were run on the Hitachi 917 in duplicates with two runs per day over 20 working days for a total of 80 measurements. Results are summarized below:

Precision Sample	Mean ng/mL	Within Run		Between Run		Between Day		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	112.8	1.4	1.2%	1.3	1.2%	5.7	5.0%	6.0	5.3%
Control 2	318.2	5.3	1.7%	0	0%	9.8	3.1%	11.2	3.5%
spiked serum 1	35.8	1.5	4.1%	1.4	4.9%	2.8	7.7%	3.4	9.5%
spiked serum 2	247.9	3.3	1.3%	0	0%	7.0	2.8%	7.8	3.1%
spiked serum 3	612.2	8.7	1.4%	5.9	1.0%	22.4	3.6%	24.70	4.0%
spiked serum 4	855.2	10.2	1.2%	0	0%	17.2	2.0%	20.00	2.3%
clinical serum 5	15.7	1.14	7.2%	0.66	4.2%	0.58	3.7%	1.43	9.1%
clinical serum 6	23.9	1.01	4.2%	0.75	3.1%	0.35	1.5%	1.30	5.5%

To evaluate imprecision using clinical samples and between instruments/lots, a single study was performed using three lots of the Ferritin reagent on three different Hitachi 917 analyzers. Each reagent lot was always tested on the same analyzer (e.g. Lot A was tested on Instrument 1, Lot B was tested on Instrument 2, etc.) In this study, four clinical human serum samples with approximately 15–20 ng/mL, 25–35 ng/mL, 150–300 ng/mL, and 600–700 ng/mL ferritin were tested in duplicates, two runs per day over 20 working days for a total of 80 measurements per sample. Results are summarized below:

Precision Sample	Mean ng/mL	Within Run		Between Run		Between Day		Btwn Inst or Btwn Lot		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
clinical serum 7	16.20	0.89	5.5%	0.68	4.2%	0.76	4.7%	0.46	2.8%	1.35	8.4%
clinical serum 8	32.3	1.41	4.4%	1.15	3.5%	0.00	0.0%	0.28	0.9%	1.81	5.6%
clinical serum 9	279.1	6.37	2.3%	6.50	2.3%	6.13	2.2%	3.95	1.4%	10.97	3.9%
clinical serum 10	613.2	15.70	2.6%	7.00	1.1%	4.71	0.8%	0.87	0.1%	17.82	2.9%

To further evaluate imprecision between reagent lots and instruments, an additional repeatability study was performed using four human serum samples approximately 16

ng/mL (serum 11), 30 ng/mL (serum 12), 260 ng/mL (serum 13), and 650 ng/mL (serum 14) ferritin. Samples were tested using three lots of reagent on a single instrument and using one reagent lot run on three instruments. Samples were tested in a single run with 20 replicates. Results are summarized below:

Between Lot:

	Sample 11	Sample 12	Sample 13	Sample 14
	Lot 4, 5 and 6	Lot 4, 5 and 6	Lot 4, 5 and 6	Lot 4, 5 and 6
n	20	20	20	20
Mean	17.1	32.6	264.6	653.5
SD	0.51	0.33	1.33	1.59
CV%	3.0%	1.0%	0.50%	0.2%
95% CI	16.1-18.1	31.9-33.3	261.9-267.3	650.3-656.7

Between instrument:

	Sample 11	Sample 12	Sample 13	Sample 14
	Instrument 1,2,3	Instrument 1,2,3	Instrument 1,2,3	Instrument 1,2,3
N	20	20	20	20
Mean	17.4	32.3	264.3	663.1
SD	0.09	0.64	3.06	7.07
CV%	0.5%	2.0%	1.16%	1.1%
95% CI	17.2 - 17.6	31.0 - 33.6	258.2 - 270.4	649.0 - 677.2

b. Linearity/assay reportable range:

Linearity studies for the Diazyme Ferritin Assay were performed according to CLSI EP-6A. Assay linearity was evaluated on the Hitachi 917 analyzer. Two pooled serum samples were spiked with ferritin to their target concentrations (1000 ng/mL and 120 ng/mL). For each pool, a step-wise dilution series with 11 ferritin levels spanning the assay range was created by diluting the spiked serum sample pool with a negative serum sample. Each sample and dilution was evaluated in triplicates on one reagent lot and one instrument. The observed values were plotted against the expected values and analyzed by standard linear regression.

Linear regression results are summarized below:

Sample Pool	Regression equation	Slope (95% CI)	y-Intercept (95% CI)	R ²
High pool	y=1.007x -11.74	1.0072 (0.988 to 1.026)	-11.74 (-23.30 to -0.17)	0.999
Low pool	y=1.019x+0.19	1.019 (0.980 to 1.058)	0.19 (-2.53 to 2.91)	0.997

Deming regression results are summarized below:

Sample Pool	Regression equation	Slope (95% CI)	y-Intercept (95% CI)	R ²
High pool	y=1.08x-11.90	1.08 (0.989 to 1.026)	-11.90 (-23.47 to -0.33)	0.999
Low pool	y=1.020x+0.11	1.020 (0.981 to 1.060)	0.11 (-2.61 to 2.39)	0.997

The regression results met the sponsor's acceptance criteria of slope = 1.0 ± 0.1 ; y-intercept $\leq$ LOQ and $R^2 \geq 0.95$ and met the predefined acceptance criteria of total allowable error of 10% or 4.5 ng/mL.

The linearity data supports the sponsor's claim that the analytical measuring range of the Diazyme Ferritin Assay is 13 – 1000 ng/mL. Values below the LoQ are reported as < 13 ng/mL.

Sample Dilution Study:

The package insert recommends diluting samples with > 1000 ng/mL ferritin 1:1 with saline. To validate the dilution procedure, three unaltered serum samples with ferritin concentration >1000 ng/mL obtained from a commercial source were diluted 1:1 with saline and tested on both the predicate device and the Diazyme Ferritin assay. Recoveries based on dilutions were all within 10% of the undiluted samples after multiplying by a factor of two.

High Dose Hook Effect:

To test for High Dose "Hook Effect" associated with the Ferritin assay, a 7-level linearity step wise dilution series was prepared from a sample with 10,000 ng/mL ferritin and tested on the Hitachi 917. The Diazyme Ferritin Assay did not demonstrate a Hook Effect below 6,000 ng/mL ferritin.

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

Traceability:

The calibrators for the Diazyme Ferritin Assay are derived from human serum and are traceable to a commercially available FDA cleared assay which is traceable to the WHO reference material 94/572.

WHO reference material 94/572 was also used to validate the value assignment of the master/reference calibrators by preparing dilutions of the WHO reference material and running them on the Diazyme assay. Results demonstrated recovery within the sponsor's acceptance criteria of $\pm 10\%$ of the WHO Reference 94/572.

Calibrators and Controls:

Purified ferritin antigen is used in the preparation of calibrators and controls. The stock solution is supplied from a commercial vendor per specified purity and

concentration requirements. The concentration of the stock solution is predetermined by the vendor.

Ferritin Calibrator Preparation and Value Assignment:

The master/reference calibrators are prepared by spiking ferritin into a BSA base buffer to the target concentrations which span the reportable range. The highest calibrator is set to close to the upper measuring range. The concentrations of the ferritin at each level are assayed by a commercially available FDA cleared test traceable to WHO Reference 94/572. Calibrator values are finalized following verification with known patient samples and WHO ferritin reference materials 94/572. Value assignment of Ferritin calibrators were established by transferring the target values from the predicate method to the in-house master calibrators. Production calibrators are manufactured similarly and tested as unknown samples with the master lots.

Production calibrators with the target values as assigned from the master lots are then used to test samples assigned with predicate method. Lot specific calibrator values are included on the calibrator certificate of analysis sheet. The four calibrator levels together with the saline only (zero calibrator) solution are used to generate the 5-point calibration curve. Because the calibration curve is based on the absorbance, manufacturing targets for each level is designed for best curve fit. The table below summarizes target range values:

Calibrator Level	Target ranges Ferritin ng/mL
Saline	0
1	50-100
2	225-250
3	425-450
4	950-1000

Ferritin Control Preparation and Value Assignment:

Ferritin controls were prepared by spiking ferritin stock solution into diluted human serum to the target Ferritin concentrations. The Diazyme Ferritin reagents and calibrators were used in replicate analysis to determine the mean value of the newly prepared controls. Target values for Ferritin level 1 and level 2 controls are 120 ng/mL and 350 ng/mL respectively. Lot specific target ranges are provided in the value assignment sheet. An example is shown below:

Control Level	Target value Ferritin ng/mL
Normal control	120
Abnormal control	350

Stability:

All stability testing was performed using the Roche Hitachi 917 instrument. Stability studies have been performed to support the following claims:

Reagent Stability:

Reagent Real time stability (shelf-life): The reagent shelf-life stability claim of 12 months at 2–8°C is based on accelerated stability studies using the Arrhenius equation based stress model on 3 lots of reagents tested at 37°C and 25°C. At specified times, assay kits were evaluated by testing Diazyme Ferritin Controls containing approximately 120 and 350 ng/mL. Results demonstrated that the reagents were stable for 14 days at 37°C and for 2 months at 25°C. Sponsor's predetermined acceptance criteria of control recovery change from Day 0 value were met. Real-time stability testing is on-going, with data available from three lots of reagent that supports stability to nine months at time of clearance.

On-board reagent stability: One lot of reagent was kept in the Hitachi 917 reagent bottle in the 2–8°C chamber of the instrument for 56 days with weekly recalibration. On-board reagent stability was performed by testing 2 levels of controls (120 and 350 ng/mL) and calculating recovery compared to week 0. Results demonstrated on-board reagent stability of at least four weeks (stability was defined by the sponsor as <15% change between the test value and the Day 0 value).

Calibrator Stability:

Calibrator shelf-life stability: The calibrator shelf-life stability claim is 12 months at 2–8°C and is based on accelerated studies that tested three calibrator lots stored at 37°C or 25°C. Results demonstrated that the calibrators were stable for 14 days at 37°C and for 2 months at 25°C by meeting the pre-defined acceptance criteria. Real-time stability testing is on-going, with data available from three lots of reagent that supports stability to two months at time of clearance.

Open-vial calibrator stability: Open-vial calibrator stability demonstrated one month stability at 2–8°C. Vials of Ferritin calibrator stored at 2 – 8°C were used to calibrate a lot of Diazyme Ferritin reagent on day 0. After calibration, two levels of control (120 and 350 ng/mL) were tested to determine the control recovery and calibrator stability on day 30 and day 60. Sponsor pre-defined acceptance criteria were met in each of these studies.

Calibration curve stability: Two levels of controls containing 120 and 350 ng/mL from one lot were tested repeatedly with one lot of reagent and one lot of calibrators after calibration at day 0 over a period of 56 days. This calibration stability study demonstrated a curve stability of 4 weeks Sponsor's pre-defined acceptance criteria were met).

Control Stability:

Control shelf stability: The Diazyme control shelf life stability claim is 12 months at 2 – 8°C. The sponsor provided data from accelerated studies that tested three calibrator lots stored at 37°C or 25°C. Results demonstrated that the controls were stable for 14 days at 37°C and for two months at 25°C by meeting the sponsor's pre-defined acceptance criteria. Real time stability testing is ongoing; with data available for three lots of controls that supports stability to two months at time of clearance.

Open-vial control stability: Open-vial control stability demonstrated at least one month stability at 2–8°C. Vials of Diazyme Ferritin controls stored at 2 – 8°C and tested with fresh reagent and calibrators. Controls were returned to 2 – 8°C after testing. Acceptance criteria of < 15% control recovery from Day 0 were met in each of these studies.

Sample Stability:

Sample Stability claims are based on *Tietz Clinical Guide to Laboratory Tests*, 4th Edition. Package insert sample stability claims are as follows: seven days at 2 – 8°C; six months at -20°C. Avoid repeated freezing and thawing. Do not thaw frozen specimens in a 37 °C bath. Violent mixing may denature ferritin. Samples containing precipitates should be centrifuged before assaying.

d. Detection limit:

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantification (LoQ) of the Diazyme Ferritin Assay were determined according to CLSI EP17- A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline, using 7.5% Bovine Serum Albumin (BSA) in saline as the true blank, and five serum samples on the Roche Hitachi 917 instrument.

For LoB determination, the 7.5% BSA solution in physiological saline was run as sample with 60 replicates. LoB was calculated as the mean of the 57th and 58th highest value. The LoB was determined to be 6 ng/mL.

To determine LoD, five serum samples were diluted with saline containing 7.5% BSA to a value close to LoB of 6 ng/mL. Each sample was tested in three runs with four replicates. LoD was calculated as the LoB + 1.645 x SD total. The LoD was determined to be 9.18 ng/mL.

To calculate LoQ (lowest concentration for which CV is less than a target of 20%), the same five serum samples were diluted with the 7.5% BSA solution in physiological saline to achieve targeted concentrations of 60, 20, 20, 10 and 5 ng/mL. The diluted samples with concentrations ranging from 5.5 to 62.4 ng/mL were tested in five runs with eight replicates per run. Analysis by fitted modeling of the LoQ is determined to be 13 ng/mL. This is the point where the upper 95% confidence

interval of the curve has a CV of 20%.

e. *Analytical specificity:*

Endogenous Interference:

Following guidelines recommended by CLSI EP7-A2, endogenous interference testing was performed by evaluating the effects of increasing concentrations (5 levels total) of potential interfering substances on assay performance. Serum samples spiked with high (500 ng/mL), medium (200 ng/mL) and low (20 ng/mL) ferritin concentration were used. For each interferent, five different concentrations were tested in triplicate for each ferritin level. The interfering substances of triglyceride, ascorbic acid, bilirubin, conjugated bilirubin, hemoglobin, and rheumatoid factor showed no significant interference ($< \pm 10\%$) up to the concentrations summarized in the table below:

Substance	Concentration
Triglyceride	1000 mg/dL
Ascorbic Acid	176 mg/dL
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	500 mg/dL
Rheumatoid Factor	200 IU/mL

Drug Interference:

Drug interference testing was performed by evaluating the effects of potential interfering substances on assay performance by testing three serum samples spiked with high, medium and low (500 ng/mL, 200 ng/mL and 20 ng/mL respectively) ferritin concentration spiked with a single high concentration of interferent and tested in triplicate. No significant interference ($< \pm 10\%$) up to the concentrations summarized in the table below were observed:

Substance	Concentration
Heparin	3000 IU/L
N-acetylcysteine	17.6 mM
Acetylsalicylic Acid	2.78 mM
Ampicillin	152 μ M
Dobesilate	33.3 μ g/ml
Na2-Cefoxitin	1549 μ M
Ibuprofen	2425 μ M
Levodopa	1.3 mM
Methyldopa	71 μ M
Metronidazole	701 μ M

Substance	Concentration
Rifampicin	78.1 μ M
Theophylline	222 μ M
Phenylbutazone	650 μ M
Valproic Acid	3.5 mM
Defarasion	1.0 mM
Methotrexate	2.0 mM
Prednisone	0.5 mM
Ferrous Sulfate	1.0 mM

Cross-Reactivity:

Not applicable

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 91 serum samples (42 female, 49 male) with ferritin concentrations ranging from 15.74 to 918.6 ng/mL of ferritin were tested by the Diazyme Ferritin Assay on the Hitachi 917 analyzer and the predicate device. Results were analyzed by both linear and Deming Regression.

Regression fit	N	Regression Equation	Slope (95% CI)	Intercept (95% CI)	R ²
Linear Regression	91	y= 0.992x - 3.2052	0.992 (0.974 to 1.010)	-3.2052 (-9.373 to 2.96)	0.993
Deming Regression	91	y= 0.996x - 4.162	0.996 (0.978 to 1.013)	-4.162 (-10.336 to 2.011)	0.996

b. Matrix comparison:

To evaluate anticoagulant effects, paired serum, K₂ EDTA plasma, Lithium Heparin plasma samples were tested on the Hitachi 917 with the Diazyme Ferritin Assay. A total of 38 paired sample sets were tested with one replicate per sample in each set. To ensure that the concentrations of ferritin were distributed across the reportable dynamic range, six high levels samples spiked with stock solution of ferritin were included. Diazyme's acceptance criteria are Slope = 1.0 $\pm$ 0.1; R² $\geq$ 0.95; y-intercept < LOQ and bias between plasma and serum is $\leq$ 10% or $\leq$ 4.5 ng/mL.

Deming regression results were tested with EP evaluator and are shown below:

Matrix Comparison	N	Sample Range	Regression equation	Slope (95% CI)	Y-Intercept (95% CI)	R ²
Serum vs. K ₂ EDTA	38	14.7 to 931.2	$y=0.99x + 0.93$	0.987 (0.976 to 0.997)	0.93 (-2.06 to 3.92)	0.999
Serum vs. Lithium Heparin	38	13.4 to 912.2	$y=0.95x + 3.02$	0.945 (0.934 to 0.955)	3.02 (0.06 to 5.99)	0.999

3. Clinical studies:

a. *Clinical Sensitivity and Specificity:*

Not applicable.

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

Not applicable.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

To establish the reference interval for the Diazyme Ferritin Assay, serum samples from 258 apparently healthy individuals (129 females and 129 males) with age > 21 were tested with one replicate per sample on the Hitachi 917 with the Diazyme Ferritin Assay according to CLSI C28-A3 guideline.

The reference range interval was calculated using non-parametric statistics representing the central 95% of the population. Results indicated a reference range for females is from 17.6 ng/mL to 159.3 ng/mL and that for males is from 19.4 ng/mL to 246.3 ng/mL.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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