



ARCHITECT

SYSTEM

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Ferritin

REF 7K59

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B7K590

Read Highlighted Changes
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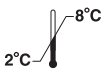


Ferritin



Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

REF	List Number	REAGENT LOT	Reagent Lot
IVD	<i>In Vitro</i> Diagnostic Medical Device	SN	Serial Number
LOT	Lot Number	REACTION VESSELS	Reaction Vessels
	Expiration Date	SAMPLE CUPS	Sample Cups
	Store at 2-8°C	SEPTUM	Septum
	Consult instructions for use	REPLACEMENT CAPS	Replacement Caps
	Manufacturer		

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

NAME

ARCHITECT Ferritin

INTENDED USE

The ARCHITECT Ferritin assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of ferritin in human serum and plasma.

SUMMARY AND EXPLANATION OF TEST

Ferritin is a high-molecular weight iron-containing protein that functions in the body as an iron storage compound. Each ferritin molecule is thought to consist of a spherical protein shell of molecular weight about 460,000 daltons made up of 24 subunits with a variable amount of iron as a core of ferric-oxide-phosphate.^{1,2} It has been demonstrated that the ferritin molecule, when fully saturated, may consist of over 20% iron by weight.²

Approximately 25% of the iron in a normal adult is present in various storage forms.³ About two-thirds of the iron stores in the human body exist in the form of ferritin. The remaining iron stores are contained in insoluble hemosiderin, which most likely represents a form of denatured ferritin.⁴

The availability of sensitive methods for measuring serum ferritin have significantly advanced the ability to detect iron deficiency and overload. Since iron deficiency is present before the onset of anemia, detection of an iron depleted state is important for the control of nutritional anemia. The clinical assessment of iron stores has historically relied on the determination of serum iron, total iron-binding capacity (TIBC) and percent transferrin (ratio of serum iron and TIBC) or direct examination of bone marrow.

The estimation of storable iron in the bone marrow is the traditional method for assessing body iron stores. This biopsy method provides a sensitive index of iron deficiency but has the disadvantage of being subjective and semiquantitative. Low hemoglobin concentration is the most readily available sign of anemia, but a significant fall in circulating hemoglobin cannot be detected until the final stage of iron deficiency anemia. Serum iron, TIBC and percent transferrin saturation do not distinguish iron deficiency as a progressive disease. Also, these measurements are affected by diurnal variation and may not discriminate between depleted iron stores and conditions associated with defective reticuloendothelial release of iron (e.g., anemia of chronic disease).³ Recent literature suggests that ferritin provides a more sensitive, specific and reliable measurement for determining iron deficiency at an early stage.⁹ In patients being given iron orally, serum ferritin measurements have been shown to be useful for monitoring the reaccumulation of iron stores and determining when therapy can be discontinued.¹⁰ In chronic inflammatory disorders, infections, and in chronic renal failure, there is a disproportionate increase in serum ferritin levels in relation to iron stores. The correlation of serum ferritin to body iron stores still exists, however, it is set at a higher level of serum ferritin.^{7,8,10} Numerous studies in the literature demonstrate the usefulness and necessity of serum ferritin measurements in combination with other parameters in determining the rate and degree of body iron overload in such disorders as thalassemia, sideroblastic anemia and in determining the response of patients treated with iron chelating agents.^{5,6} Specifically, the combined use of serum ferritin levels and mean corpuscular volume (MCV) has made differentiation between iron deficiency, beta-thalassemia trait and normal subjects possible at a very high level of accuracy.^{11,12}

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Ferritin assay is a two-step immunoassay to determine the presence of ferritin in human serum and plasma using Chemiluminescent Microparticle Immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-ferritin coated paramagnetic microparticles are combined. Ferritin present in the sample binds to the anti-ferritin coated microparticles. After washing, anti-ferritin acridinium labeled conjugate is added in the second step. Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of ferritin in the sample and the RLUs detected by the ARCHITECT *i* optical system.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Reagent Kit, 100 Tests/500 Tests

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT *i* Systems. Please contact your local distributor.

ARCHITECT Ferritin Reagent Kit (7K59)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL/27.0 mL) Anti-Ferritin (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (mouse and bovine) stabilizers. Preservative: antimicrobial agent.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL/26.3 mL) Anti-Ferritin (rabbit, polyclonal) acridinium labeled Conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 75 ng/mL. Preservative: antimicrobial agent.

Assay Diluent

ARCHITECT *i* Multi-Assay Manual Diluent (7D82-50)

- **MANUAL DILUENT** 1 Bottle (100 mL) ARCHITECT *i* Multi-Assay Manual Diluent containing phosphate buffered saline solution. Preservative: antimicrobial agent.

Other Reagents

ARCHITECT *i* Pre-Trigger Solution

- **PRE-TRIGGER SOLUTION** Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

ARCHITECT *i* Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35 N sodium hydroxide.

ARCHITECT *i* Wash Buffer

NOTE: Bottle and volume varies based on order.

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

WARNINGS AND PRECAUTIONS

- **IVD**
- For *In Vitro* Diagnostic Use
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.


Safety Precautions

- **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens.¹³ Biosafety Level 2¹⁴ or other appropriate biosafety practices^{15,16} should be used for materials that contain or are suspected of containing infectious agents.
- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Handling Precautions

- Do not use reagent kits beyond the expiration date.
- **Do not mix reagents from different reagent kits.**
- Prior to loading the ARCHITECT Ferritin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
- To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
- Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions

-  The ARCHITECT Ferritin Reagent Kit must be stored at 2-8°C and may be used immediately after removal from 2-8°C storage.
- When stored and handled as directed, reagents are stable until the expiration date.
- The ARCHITECT Ferritin Reagent Kit may be stored on-board the ARCHITECT *i* System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking on-board time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored on or off the ARCHITECT *i* System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** After reagents are removed from the system, you must initiate a scan to update the on-board stability timer.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and may require retesting. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT Ferritin assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM prior to performing the assay. For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum (including serum collected in serum separator tubes) or plasma collected in tripotassium EDTA and lithium heparin may be used in the ARCHITECT Ferritin assay. Individual plasma concentration values may differ from serum by more than 10%. Samples in tripotassium EDTA may give values below those of serum, while samples collected in lithium heparin may give values greater than serum values. Other anticoagulants have not been verified for use with the ARCHITECT Ferritin assay. Follow the tube manufacturer's processing instructions for serum or plasma collection tubes.
- When serial specimens are being evaluated, the same type of specimen should be used throughout the study.
- The ARCHITECT *i* System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify the correct specimen types are used in the ARCHITECT Ferritin assay.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal results, inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- For optimal results, serum and plasma specimens should be free of fibrin, red blood cells or other particulate matter.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.

- If testing will be delayed more than 24 hours, remove serum or plasma from the clot, serum separator or red blood cells. Specimens may be stored for up to 7 days at 2-8°C prior to being tested. If testing will be delayed more than 7 days, specimens should be frozen at -10°C or colder. Specimens stored frozen at -10°C or colder for 12 months showed no performance difference.
- Multiple freeze-thaw cycles of specimens should be avoided. Specimens must be mixed THOROUGHLY after thawing, by LOW speed vortexing or by gently inverting, and centrifuged prior to use to remove red blood cells or particulate matter to ensure consistency in the results.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal and international regulations covering the transport of clinical specimens and infectious substances. Specimens may be shipped frozen on dry ice. Prior to shipment, it is recommended that specimens be removed from the clot, serum separator or red blood cells.

PROCEDURE

Materials Provided

- 7K59 ARCHITECT Ferritin Reagent Kit

Materials Required but not Provided

- ARCHITECT *i* System
- ARCHITECT *i* Assay CD-ROM
- 7K59-01 ARCHITECT Ferritin Calibrators
- 7K59-10 ARCHITECT Ferritin Controls
- 7D82-50 ARCHITECT *i* Multi-Assay Manual Diluent
- ARCHITECT *i* **PRE-TRIGGER SOLUTION**
- ARCHITECT *i* **TRIGGER SOLUTION**
- ARCHITECT *i* **WASH BUFFER**
- ARCHITECT *i* **REACTION VESSELS**
- ARCHITECT *i* **SAMPLE CUPS**
- ARCHITECT *i* **SEPTUM**
- ARCHITECT *i* **REPLACEMENT CAPS**
- For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

Assay Procedure

- Before loading the ARCHITECT Ferritin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment:
 - Invert the microparticle bottle 30 times.
 - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
 - Once the microparticles have been resuspended, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Carefully snap the septum onto the top of the bottle.
 - If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
- Order tests.
- Load the ARCHITECT Ferritin Reagent Kit on the ARCHITECT *i* System. Verify that all necessary assay reagents are present. Ensure that septums are present on all reagent bottles.
- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation verify adequate sample cup volume is present prior to running the test.
 - Priority: 70 µL for the first Ferritin test plus 20 µL for each additional Ferritin test from the same sample cup
 - ≤ 3 hours onboard: 150 µL for the first Ferritin test plus 20 µL for each additional Ferritin test from the same sample cup
 - > 3 hours onboard: additional sample volume is required. Refer to the ARCHITECT System Operations Manual, Section 5 for information on sample evaporation and volumes.

- If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- ARCHITECT Ferritin Calibrators and ARCHITECT Ferritin Controls should be mixed by gentle inversion prior to use.
- To obtain the recommended volume requirements for the ARCHITECT Ferritin Calibrators and ARCHITECT Ferritin Controls, hold the bottles **vertically** and dispense 4 drops of each calibrator or 3 drops of each control into each respective sample cup.
- Load samples
 - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5
- Press RUN. The ARCHITECT *i* System performs the following function:
 - Moves the sample to the aspiration point
 - Loads a reaction vessel (RV) into the process path
 - Aspirates and transfers sample into the RV
 - Advances the RV one position and transfers microparticles into the RV
 - Mixes, incubates and washes the reaction mixture
 - Adds conjugate to the RV
 - Mixes, incubates and washes the reaction mixture
 - Adds Pre-Trigger and Trigger Solutions
 - Measures chemiluminescent emission to determine the quantity of ferritin in the sample
 - Aspirates contents of RV to liquid waste and unloads RV to solid waste
 - Calculates the result
- For information on ordering patient specimens, calibrators and controls, and general operating procedures refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the ARCHITECT System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures

Specimens with a ferritin value exceeding 2000 ng/mL are flagged with the code “ >2000” and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

- If using the Automated Dilution Protocol, the system performs a 1:20 dilution of the specimen. The system will use the dilution factor to automatically calculate the concentration of the sample before dilution. This will be the reported result.
- Manual dilutions should be performed as follows:
 - The suggested dilution for ferritin is 1:20.
 - For a 1:20 dilution, add 20 µL of the patient specimen to 380 µL of ARCHITECT *i* Multi-Assay Manual Diluent (7D82-50).
 - The operator must enter the dilution factor in the patient or control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution. This will be the reported result. The dilution should be performed so that the diluted result reads greater than 80 ng/mL. If the diluted result reads less than 80 ng/mL, the sample should be retested undiluted.
- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- To perform an ARCHITECT Ferritin calibration, test ARCHITECT Ferritin Calibrators 1 and 2 in duplicate. A single sample of all levels of ARCHITECT Ferritin controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the package insert for controls. Calibrators should be priority loaded.
- Calibration Range: 0 - 1000 ng/mL.

- The assay protocol extends the assay range to 0 - 2000 ng/mL.
- Once an ARCHITECT Ferritin calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
 - A reagent kit with a new lot number is used
 - Controls are out of range
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT Ferritin assay is a single sample of all control levels tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures. Ensure that assay control values are within the concentration ranges specified in the package insert for controls.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT Ferritin assay belongs to method group 1. For the analytical sensitivity calculation, follow method group 1 and divide the result by 2.

RESULTS

The ARCHITECT Ferritin assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, X weighted) to generate a calibration curve.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- If the Ferritin results are inconsistent with clinical evidence, additional testing is supposed to confirm the result.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies.^{17,18} Additional information may be required for diagnosis.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.¹⁹ Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.

EXPECTED VALUES

Evaluation of serum specimens from 32 normal males and 60 normal females with the ARCHITECT Ferritin assay yielded the following results.

Normal Range Summary	No. of Subjects	Median (ng/mL)	Central 95% Interval (ng/mL)
Males	32	75.62	21.81 - 274.66
Females	60	39.42	4.63 - 204.00

These individuals were determined to be normal based on the AxSYM Ferritin Assay. It is recommended that each laboratory establish its own range, which may be unique to the population it serves depending upon geographical, patient, dietary, or environmental factors.

Ferritin levels below 10 ng/mL have been reported as indicative of iron deficiency anemia.^{20,21} There are patients with iron deficiency anemia who have elevated or normal ferritin levels because of other causes, such as hepatocellular disease or iron therapy.^{4,7}

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Ferritin assay is designed to have a precision of ≤ 9 total %CV for concentrations within the range of the low, medium and high control (Panel Members 1-3). A study based on guidance from the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Protocol EP5-T2 was performed for the ARCHITECT Ferritin assay.²² A three member buffered protein based panel (1, 2, and 3) and a three member reconstituted processed human serum panel (4, 5, and 6) were assayed in replicates of two at two separate times per day, for 20 days on one instrument using two lots of reagents and a single calibration for each reagent lot. Data from this study are summarized in the following table.

Panel Member	Reagent Lot	Instrument	n	Mean Conc.	Within Run SD	%CV	Total SD	%CV
				Value (ng/mL)				
1	1	1	80	20.33	0.723	3.6	0.968	4.8
1	2	1	80	19.08	0.818	4.3	1.217	6.4
2	1	1	80	148.07	5.760	3.9	8.417	5.7
2	2	1	80	145.38	5.303	3.6	8.096	5.6
3	1	1	80	391.47	15.574	4.0	21.593	5.5
3	2	1	80	387.61	13.012	3.4	21.703	5.6
4	1	1	80	421.13	15.847	3.8	25.080	6.0
4	2	1	80	408.61	14.353	3.5	21.504	5.3
5	1	1	80	155.03	5.338	3.4	14.962	9.7
5	2	1	80	149.89	5.226	3.5	15.514	10.3
6	1	1	80	40.52	1.286	3.2	4.500	11.1
6	2	1	80	39.22	1.336	3.4	4.600	11.7

Recovery

The ARCHITECT Ferritin assay is designed to have a mean recovery of $100 \pm 10\%$ when analyzing samples spiked with known amounts of ferritin. Known concentrations of ferritin were added to five human serum specimens. In a study, the concentration of ferritin was determined using the ARCHITECT Ferritin assay and the resulting percent recovery was calculated.

Sample	Endogenous Ferritin Conc. (ng/mL)	Ferritin Added (ng/mL)	Observed Ferritin Conc. (ng/mL)	Percent Recovery
1	21.19	85.72	100.27	92.3
	21.19	262.26	267.77	94.0
	21.19	423.92	440.40	98.9
2	82.17	85.72	171.85	104.6
	82.17	262.26	328.15	93.8
	82.17	423.92	510.35	101.0
3	175.40	85.72	250.67	87.8
	175.40	262.26	404.20	87.2
	175.40	423.92	606.72	101.7
4	246.95	85.72	327.98	94.5
	246.95	262.26	485.28	90.9
	246.95	423.92	662.04	97.9
5	452.76	85.72	550.16	113.6
	452.76	262.26	738.96	109.1
	452.76	423.92	924.84	111.4

Average Recovery: 98.6%

$$\% \text{ Recovery} = \frac{\text{Observed Ferritin Conc. (ng/mL)} - \text{Endogenous Ferritin Conc. (ng/mL)}}{\text{Ferritin Added (ng/mL)}} \times 100$$

Analytical Sensitivity

The ARCHITECT Ferritin assay is designed to have an analytical sensitivity of ≤ 1 ng/mL. Analytical sensitivity is defined as the concentration at two standard deviations from the mean RLJ value of the ARCHITECT Ferritin MasterCheck Level 0 (0.0 ng/mL), and represents the lowest measurable concentration of ferritin that can be distinguished from zero. The mean analytical sensitivity of the ARCHITECT Ferritin assay was calculated to be < 1 ng/mL (n=36 runs).

Interference/Specificity

The ARCHITECT Ferritin assay is designed to have $\leq 10\%$ mean interference from hemoglobin, bilirubin, triglycerides, and protein at the levels indicated below. Potential interference from these four components was studied in the ARCHITECT Ferritin assay. The ARCHITECT Ferritin assay demonstrated $\leq 10\%$ mean interference at the levels indicated below.

- Hemoglobin 200 mg/dL
- Bilirubin 20 mg/dL
- Triglycerides 3000 mg/dL
- Protein 2 g/dL and 12 g/dL

Accuracy by Correlation

The ARCHITECT Ferritin assay demonstrated a slope of 1.2 ± 0.2 and a correlation coefficient (r) of ≥ 0.95 in the 1-1000 ng/mL range when compared to the AxSYM Ferritin assay. A study was performed where specimens were tested using ARCHITECT Ferritin assay and AxSYM Ferritin assay. Data from this study were analyzed using least squares and Passing Bablok regression methods and are summarized in the following table.^{***}

Abbott ARCHITECT Ferritin vs. Abbott AxSYM Ferritin

Method	Number of Specimens	Range* (ng/mL)	Intercept	Slope	Correlation Coefficient
Least Squares	436	1 - 1000 ¹	-4.86	1.18	0.979
Linear Regression	518	1 - 2000 ²	-3.65	1.18	0.986
Passing-Bablok**	436	1 - 1000 ¹	-1.52	1.16	0.979
Linear Regression	518	1 - 2000 ²	-1.89	1.17	0.986

In this evaluation, serum specimens tested on the ARCHITECT Ferritin assay ranged from ¹1.39 to 1510.64 and ²1.39 to 1967.46 ng/mL. Serum specimens tested on the AxSYM Ferritin assay ranged from ¹1.37 to 997.17 and ²1.37 to 1827.47 ng/mL.

* Range established from AxSYM Ferritin values.

** A linear regression method with no special assumptions regarding the distribution of the samples and measurement errors.²³

*** Representative data; results in individual laboratories may vary from these data.

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