# Access
Immunoassay Systems

# FERRITIN

**REF 33020**

## Intended Use

The Access Ferritin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

## Summary and Explanation

Ferritin is a large spherical protein consisting of 24 non-covalently linked subunits and having a molecular weight of approximately 450,000.[1] The subunits form a shell surrounding a central core containing variable amounts of ferric hydroxyphosphate.[2] One molecule of ferritin is capable of binding between 4000 and 5000 atoms of iron, making ferritin the major iron storage protein for the body.[3]

Found chiefly in the cytoplasm of cells of the reticuloendothelial system, it once was thought that ferritin did not appear in plasma or extracellular fluid under normal conditions. However, the development of a sensitive immunoradiometric technique by Addison, et al., in 1972, resulted in the discovery that ferritin is a constituent of all normal human serum.[4] Through this and other work, it was determined that the concentration of ferritin was directly proportional to the total iron stores in the body, resulting in serum ferritin levels becoming a common diagnostic tool in the evaluation of iron status.[4,5,6]

In most normal adults serum ferritin levels ranges from 10–300 ng/mL (µg/L), but concentrations vary with age and sex.[1,4,5,6] There is a sharp rise in serum ferritin levels in the first month of life, coinciding with the depression of bone marrow erythropoiesis.[1] Within two or three months, erythropoiesis becomes reactivated and there is a drop in the concentration of serum ferritin. By six months, the concentration is reduced to fairly low levels where they remain throughout childhood. There is no sex difference until the onset of puberty, at which time ferritin levels rise, particularly in males.[1] There is a significant positive correlation between age and serum ferritin levels in females, but not in males.[5]

Addison, et al., found that patients with iron deficiency anemia have serum ferritin levels approximately one tenth of normal subjects, while patients with iron overload (hemochromatosis, hemosiderosis) have serum ferritin levels much higher than normal.[4] Other studies also suggest that serum ferritin levels provide a sensitive means of detecting iron deficiency at an early stage.[2,5,6] Serum ferritin levels may serve as a tool to monitor the effects of iron therapy, but results should be interpreted with caution, as ferritin levels in these cases may not always reflect the true state of iron stores.[7] In both adults and children, chronic inflammation results in a disproportionate increase in ferritin levels in relation to iron reserves.[8] Elevated ferritin levels also are observed in acute and chronic liver disease, chronic renal failure and in some types of neoplastic disease.[1,6]

Traditionally, the estimation of stainable iron in bone marrow biopsies was the accepted method for the evaluation of body iron stores. However, this method is traumatic for the patient and only semi-quantitative. Other methods, such as serum iron determination, total iron binding capacity (TIBC) and percent saturation of transferrin are subject to diurnal variations and are often imprecise. These latter methods also do not discriminate between depleted iron stores and conditions associated with defective iron release (eg. anemia of chronic disease).[7] The Access Ferritin assay is based on the two-site immunoradiometric assay (IRMA) described by Addison, et al., but utilizes an enzyme labeled antibody in place of the radiolabeled tracer.[4] The measurement of ferritin is very well suited to this assay method as its

very large size easily permits the simultaneous binding of the required two (or more) antibodies.

## Principles of the Procedure

The Access Ferritin assay is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with goat anti-ferritin-alkaline phosphatase conjugate, and paramagnetic particles coated with goat anti-mouse: mouse anti-ferritin complexes. Serum or plasma (heparin) ferritin binds to the immobilized monoclonal anti-ferritin on the solid phase, while the goat anti-ferritin enzyme conjugate reacts with different antigenic sites on the ferritin molecules. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos* 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of ferritin in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

## Product Information

**Access Ferritin Reagent Pack**

**Cat. No. 33020: 100 determinations, 2 packs, 50 tests/pack**

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 28 days after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the reagent pack is damaged (i.e., broken elastomer), discard the pack.
- All antisera are polyclonal unless otherwise indicated.

| | |
|---|---|
| **R1a:** | Paramagnetic particles coated with goat anti mouse IgG: mouse monoclonal anti-ferritin complexes suspended in TRIS buffered saline, with surfactant, bovine serum albumin (BSA), < 0.1% sodium azide, and 0.1% ProClin** 300. |
| **R1b:** | Goat anti-ferritin-alkaline phosphatase (bovine) conjugate in TRIS buffered saline, with surfactant, BSA, protein (goat, mouse), < 0.1% sodium azide, and 0.1% ProClin 300. |

## Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[9]
- Xi. Irritant: 0.1% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

## Specimen Collection and Preparation

1. Serum and plasma (heparin) are the recommended samples.
2. Observe the following recommendations for handling, processing, and storing blood samples:[10]
   - Collect all blood samples observing routine precautions for venipuncture.
   - Allow serum samples to clot completely before centrifugation.
   - Keep tubes stoppered at all times.
   - Within two hours after centrifugation, transfer at least 500 µL of cell-free sample to a storage tube. Tightly stopper the tube immediately.
   - Store samples tightly stoppered at room temperature (15 to 30°C) for no longer than eight hours.
   - If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8°C.
   - If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20°C or colder.
   - Thaw samples only once.
3. Use the following guidelines when preparing specimens:
   - Ensure residual fibrin and cellular matter has been removed prior to analysis.
   - Follow blood collection tube manufacturer's recommendations for centrifugation.
4. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.
5. Avoid assaying grossly hemolyzed samples in that ferritin can be released from lysed red cells.

## Materials Provided

R1 Access Ferritin Reagent Packs

## Materials Required But Not Provided

1. Access Ferritin Calibrators
   Provided at zero and approximately 10, 50, 200, 500 and 1500 ng/mL (µg/L).
   Cat. No. 33025
2. Quality Control (QC) materials: commercial control material.
3. Access Sample Diluent A
   Cat. No. 81908
4. Access Substrate
   Cat. No. 81906
5. **Access, Access 2, SYNCHRON LXi:**
   Access Wash Buffer II, Cat. No. A16792
   **UniCel DxI:**
   UniCel DxI Wash Buffer II, Cat. No. A16793
   UniCel DxI Access Immunoassay Systems Wash Buffer II, Cat. No A79784 (Diluent pack for use with the UniCel DxI system onboard dilution feature.)

## Procedural Comments

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use ten (10) µL of sample for each determination in addition to the sample container and system dead volumes. Use sixty-six (66) µL of sample in addition to the sample container and system dead volumes for each determination run with the DxI system onboard dilution feature. Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.

4. The system default unit of measure for sample results is ng/mL. To change sample reporting units to the International System of Units (SI units), µg/L, refer to the appropriate system manuals and/or Help system. To manually convert concentrations to the International System, multiply ng/mL by multiplication factor 1.

## Procedure

Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

For assaying samples containing < 1500 ng/mL (µg/L) ferritin, select **Ferritin** as the test name. Select **Dil-Fer** as the test name for assaying samples containing > 1500 ng/mL. Alternatively, DxI users may use the DxI onboard dilution feature by selecting **d-Fer** as the test name for assaying samples containing > 1500 ng/mL. The same reagent pack and calibration curve is used for all assays.

## Calibration Details

An active calibration curve is required for all tests. For the Access Ferritin assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

## Quality Control

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.[11] Include commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

## Results

Patient test results are determined automatically by the system software using a weighted four parameter logistic curve (4PLC) math model. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. Patient test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

## Limitations of the Procedure

1. Samples can be accurately measured within the analytic range of the lower limit of detection and the highest calibrator value (approximately 0.2–1500 ng/mL [µg/L]). The analytic range for the **Dil-Fer** assay is 1300 up to approximately 15,000 ng/mL.
   - If a sample contains less than the lower limit of detection for the assay, report the results as less than that value (i.e., < 0.2 ng/mL [µg/L]). When the DxI system onboard dilution feature is used, the system will report results as less than 1275 ng/mL.
2. To accurately measure samples containing approximately 1500–15,000 ng/mL, select the **Dil-Fer** test. This test uses the **Ferritin** pack. When **Dil-Fer** is requested, the system autodilutes the sample and reads the resulting dose off the **Ferritin** calibration curve. The system multiplies by the dilution factor defined in the software to calculate final test results. Any neat sample reading < 1300 ng/mL in the **Dil-Fer** assay should be retested in the **Ferritin** assay. Samples > 1500 ng/mL in the **Ferritin** assay can be run in the **Dil-Fer** assay or may be assayed with the manual dilution option below.
3. For UniCel DxI systems:
   Samples containing > 1500 ng/mL can be processed using the DxI onboard dilution feature. The DxI system onboard dilution feature automates the dilution process, using one volume

of sample with four volumes of UniCel DxI Access Immunoassay Systems Wash Buffer II, allowing samples to be quantitated up to 7500 ng/mL. The system reports the results adjusted for the dilution.

4. Manual dilution for samples containing > 1500 ng/mL for **Ferritin** assay or > 15,000 ng/mL for **Dil-Fer** assay:
   - For **Ferritin** values > 1500 ng/mL, dilute as follows:
     Dilute one volume of sample with four volumes of Access Ferritin Calibrator S0 (zero), Access Sample Diluent A or Access Wash Buffer II. The pre-dilution factor is 5. Run the dilution with the **Ferritin** or **Dil-Fer** assay. **(Note: a manual pre-diluted sample in the Dil-Fer assay may report a < 1300 ng/mL result.)**
   - For **Dil-Fer** assay values > 15,000 ng/mL, dilute as follows:
     For serum samples, dilute one volume of sample with four volumes of Access Ferritin Calibrator S0 (zero), Access Sample Diluent A or Access Wash Buffer II. The pre-dilution factor is 5. Run the dilution with the **Dil-Fer** assay.
   - Type in the pre-dilution factor when entering the test request. Order the **Ferritin** or **Dil-Fer** test. The system will automatically multiply the result by the pre-dilution factor and report that value.
   - If the pre-dilution factor is not used when entering the request, multiply the calculated value by the pre-dilution factor after assaying the diluted sample using the Access **Ferritin** assay or the **Dil-Fer** assay.
   - If the system reports a pre-diluted **Ferritin** result as < 0.2 ng/mL or a pre-diluted **Dil-Fer** result < 1300 ng/mL, then re-dilute with a lesser dilution.
   - Refer to the appropriate system manuals and/or Help system for additional instructions on processing pre-diluted samples.
5. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples.[12,13]
   Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.
6. The Access Ferritin results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests and other appropriate information.
7. The Access Ferritin assay does not demonstrate any "hook" effect up to 40,000 ng/mL (µg/L). Extremely high quantities of ferritin may cause a “hook” effect.

## Expected Values

1. Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
2. Ferritin concentrations were measured in 113 serum samples from apparently healthy male and female subjects using the Access Ferritin assay. The results were as follows:

| | n | Geometric Mean (ng/mL, µg/L) | 95% Range* (ng/mL, µg/L) |
|---|---|---|---|
| Males | 49 | 105.6 | 23.9–336.2 |
| Females | 64 | 51.4 | 11.0–306.8 |

* Non-parametric estimate of 95% confidence interval.

3. Interpret the results of this test in conjunction with the patient’s clinical presentation.

## Specific Performance Characteristics

### Methods Comparison

A comparison of 153 values using the Access Ferritin assay on the Access Immunoassay System and a commercially available enzyme immunoassay kit gave the following statistical data:

| n | Range of Observations (ng/mL) | Intercept (ng/mL) | Slope | Correlation Coefficient (r) |
|---|---|---|---|---|
| 153 | 2.2–1313.0 | -5.11 | 1.01 | 0.993 |

Comparison of values obtained by assaying clinical samples of serum or plasma (heparin) using the Access Ferritin assay kit gave the following statistical data:

| n | Range of Observations (ng/mL) | Intercept (ng/mL) | Slope | Correlation Coefficient (r) |
|---|---|---|---|---|
| 48 | 6.00–504.64 | -2.83 | 1.05 | 0.999 |

### Dilution Recovery (Linearity)

Gravimetric dilution of two samples containing various ferritin levels with Access Ferritin Calibrator S0 (zero) resulted in the following data:

| Sample 1 | Expected Concentration (ng/mL) | Determined Concentration (ng/mL) | Recovery (%) |
|---|---|---|---|
| Neat | N/A | 949.6 | N/A |
| 1/1.98 | 479.6 | 465.0 | 97.0 |
| 1/4.33 | 219.3 | 216.4 | 98.7 |
| 1/10.80 | 87.9 | 88.2 | 100.3 |
| 1/21.98 | 43.2 | 43.3 | 100.2 |
| 1/39.32 | 24.2 | 24.9 | 102.9 |
| | | **Mean % Recovery** | **99.8** |

| Sample 2 | Expected Concentration (ng/mL) | Determined Concentration (ng/mL) | Recovery (%) |
|---|---|---|---|
| Neat | N/A | 559.3 | N/A |
| 1/1.99 | 281.1 | 291.4 | 103.7 |
| 1/3.13 | 178.7 | 184.1 | 103.0 |
| 1/5.12 | 109.2 | 117.3 | 107.4 |
| 1/10.24 | 54.6 | 59.6 | 109.2 |
| 1/31.66 | 17.7 | 18.0 | 101.7 |
| | | **Mean % Recovery** | **105.0** |

### Imprecision

The **Ferritin** assay exhibits total imprecision of less than 10% across the assay range. One study, using commercially available human serum based control material generating 20 assays, two replicates per assay, over 20 days provided the following data, analyzed via analysis of variance (ANOVA):[14,15]

| Sample | Grand Mean (n=40) (ng/mL) | Within Run (%CV) | Total Imprecision (%CV) |
|---|---|---|---|
| Low | 37.2 | 2.6 | 4.1 |
| Medium | 118.9 | 3.6 | 4.3 |
| High | 311.8 | 3.9 | 6.3 |

The **Dil-Fer** assay exhibits total imprecision of less than 20% across the range of the **Dil-Fer** assay.

### Analytical Specificity/Interferences

Samples containing up to 5 mg/dL (86 µmol/L) bilirubin, lipemic samples containing the equivalent of 900 mg/dL (10.16 mmol/L) triglycerides, and hemolyzed samples containing up to 300 mg/dL (3 g/L) hemoglobin do not affect the concentration of ferritin assayed. Grossly hemolyzed samples should not be used in that ferritin can be released from lysed red cells.

Samples containing 5–9 g/dL (50–90 g/L) albumin do not affect the concentration of ferritin assayed.

The antibodies used in this kit were raised against liver ferritin. Reactivity to spleen ferritin, as demonstrated by spiking recovery in a serum sample, is equivalent to that of liver ferritin.

### Analytical Sensitivity

The lowest detectable level of ferritin distinguishable from zero (Access Ferritin Calibrator S0) with 95% confidence is 0.2 ng/mL (µg/L). This value is determined by processing a complete six-point calibration curve, controls, and ten replicates of the zero calibrator in multiple assays. The analytical sensitivity value is interpolated from the curve at the point that is two standard deviations from the mean measured zero calibrator signal.

# Access
Immunoassay Systems

# FERRITIN CALIBRATORS

## REF 33025

**Intended Use**

The Access Ferritin Calibrators are intended to calibrate the Access Ferritin assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

**Summary and Explanation**

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

**Traceability**

The measurand (analyte) in the Access Ferritin Calibrators is traceable to WHO 3rd International Standard for ferritin (IS 94/572) (human, recombinant). Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

**Product Information**

**Access Ferritin Calibrators**

**Cat. No. 33025: S0–S5, 4.0 mL/vial**

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Signs of possible deterioration are control values out of range.
- Refer to calibration card for exact concentrations.

| | |
|---|---|
| **S0:** | Buffered bovine serum albumin (BSA) matrix with surfactant, < 0.1% sodium azide, and 0.5% ProClin** 300. Contains 0.0 ng/mL (µg/L) ferritin. |
| **S1, S2, S3, S4, S5:** | Human liver ferritin at levels of approximately 10, 50, 200, 500, and 1500 ng/mL (µg/L), respectively, in buffered BSA matrix with surfactant, < 0.1% sodium azide, and 0.5% ProClin 300. |
| **Calibration Card:** | 1 |

**Warnings and Precautions**

- For *in vitro* diagnostic use.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[16]

- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[9]
- Xi. Irritant: 0.5% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

**Procedure**

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

**Calibration Details**

The Access Ferritin Calibrators are provided at six levels – zero and approximately 10, 50, 200, 500, and 1500 ng/mL – prepared gravimetrically from human liver ferritin. Assay calibration data are valid up to 28 days.

Calibrators run in duplicate.

**Limitations of the Procedure**

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

# Access
Immunoassay Systems

# SAMPLE DILUENT A

## REF 81908

**Intended Use**

The Access Sample Diluent A is intended for use with Access assays to dilute patient samples containing analyte concentrations greater than the analyte specific S5 calibrator.

**Summary and Explanation**

The analyte level in patient samples may exceed the level of the specific S5 calibrator. If a quantitative value is required, it will be necessary to dilute the samples in order to determine the analyte concentration.

**Product Information**

**Access Sample Diluent A**
**Cat. No. 81908: 4 mL/vial**

- Provided ready to use.
- Allow the contents to stand for 10 minutes at room temperature.
- Mix gently by inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the vial label when stored at 2 to 10°C.

| | |
|---|---|
| **Diluent:** | Buffered BSA matrix with surfactant, < 0.1% sodium azide, 0.5% ProClin** 300. |

**Warnings and Precautions**

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[9]
- Xi. Irritant: 0.5% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

**Procedure**

Samples can be accurately measured within the analytic range of the lower limit of detection and the highest calibrator value of the specific assay. If a sample contains more analyte than the stated value of the S5 calibrator, dilute the sample following dilution instructions in the specific assay labeling under "Limitations of Procedure" in the reagent pack section. Refer to the appropriate system manuals and/or Help system for instructions on how to enter a sample dilution in a test request.

**Limitations of the Procedure**

If there is evidence of microbial contamination or excessive turbidity in the reagent, discard the vial.

## References


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