### Automated Method (Example)

**Instrument**: Hitachi 717

**Test**: Ferritin (FER)

**ASSAY CODE**: (2 POINT) : (27) - (42)

**SAMPLE VOLUME**: (R1) (3) (R1 VOLUME) 180 (20) (NO)

**R2 VOLUME**: (90) (20) (NO)

**VALIDATION**

**TEMPERATURE**: 37°C

**WAVELENGTH**

**CALIB. METHOD**

**SENSITIVITY LIMIT**

**ABS. LIMIT**

**PROZONE LIMIT**

**EXPECTED VALUE**

**PANIC VALUE**

**INSTRUMENT FACTOR**: 1.00

* * *

Use isotonic saline as STD (1)

* 2-5 Input concentration of calibrators

Parameters for other automated analyzers are available.

### Calibration

A five-point calibration curve should be made using the K-ASSAY® Ferritin Calibrator and saline (0 ng/mL). In our laboratory, the calibration curve was stable for at least 4 weeks. It is recommended that the user determine calibration frequency on their analyzer as the calibration curve stability may change due to analyzer condition and use. Calibration is recommended whenever a new lot of reagent is used or when quality control material is outside the specified range.

### Quality Control

A quality control program is recommended for all clinical testing laboratories. It is recommended that controls, both normal and abnormal, be run with each batch of samples to monitor the procedure. Each laboratory should establish its own control range by assigning the control a sufficient number of times to generate a valid mean and acceptable range.

### Calculations

Ferritin levels are determined using the prepared calibration curve.
**LIMITATIONS OF PROCEDURE**

The measurable range for this ferritin test kit is between 2 ng/mL and 1,000 ng/mL. If the ferritin concentrations are greater than the highest calibrator value, dilute the sample with isotonic saline and re-assay. Multiply the result by the dilution factor to compensate for the dilution. Performance of this assay has only been evaluated on adult specimens. Since a reference range is only available for adult specimens, this assay should only be used for adults. Intra-fat concentrations greater than 3% have been shown to interfere with the assay, however, intra-lipid concentrations up to 5% do not interfere with the assay.

**PERFORMANCE**

**Recovery**

When a serum sample with a known ferritin value is assayed, the results obtained should be within ±8%.

<table>
<thead>
<tr>
<th>Assigned Value</th>
<th>Measured</th>
<th>% Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>103</td>
<td>102.1</td>
</tr>
<tr>
<td>Sample 2</td>
<td>254</td>
<td>249.9</td>
</tr>
<tr>
<td>Sample 3</td>
<td>509</td>
<td>493.6</td>
</tr>
<tr>
<td>Sample 4</td>
<td>16</td>
<td>15.6</td>
</tr>
</tbody>
</table>

**Precision**

(Within Run)

Acceptance Criteria: When a sample is repeatedly assayed 10 times, the absorbance C.V. is less than 7%.

Serum control samples were assayed 21 times on the same day.

<table>
<thead>
<tr>
<th>Control I</th>
<th>Control II</th>
<th>Control III</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=21</td>
<td>N=21</td>
<td>N=21</td>
</tr>
<tr>
<td>Mean=14.9</td>
<td>Mean=100.0</td>
<td>Mean=431.1</td>
</tr>
<tr>
<td>Low=13.8</td>
<td>Low=98.7</td>
<td>Low=427.6</td>
</tr>
<tr>
<td>High=19.5</td>
<td>High=101.2</td>
<td>High=435.5</td>
</tr>
<tr>
<td>SD=0.600</td>
<td>SD=2.203</td>
<td>CV=4.03%</td>
</tr>
<tr>
<td>CV=0.65%</td>
<td>CV=0.51%</td>
<td>CV=0.51%</td>
</tr>
</tbody>
</table>

(Between Runs)

Serum control samples were assayed on 20 different days.

<table>
<thead>
<tr>
<th>Control I</th>
<th>Control II</th>
<th>Control III</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=20</td>
<td>N=20</td>
<td>N=20</td>
</tr>
<tr>
<td>Mean=16.5</td>
<td>Mean=105.2</td>
<td>Mean=428.7</td>
</tr>
<tr>
<td>Low=15.4</td>
<td>Low=102.7</td>
<td>Low=421.0</td>
</tr>
<tr>
<td>High=18.1</td>
<td>High=107.6</td>
<td>High=432.6</td>
</tr>
<tr>
<td>SD=0.733</td>
<td>SD=1.522</td>
<td>SD=2.510</td>
</tr>
<tr>
<td>CV=4.45%</td>
<td>CV=1.45%</td>
<td>CV=0.59%</td>
</tr>
</tbody>
</table>

**Accuracy / Correlation**

A comparison of the K-ASSAY® Ferritin and another company’s Ferritin on the Hitachi 917 was performed with the following results. Statistics were calculated by linear regression. Samples used in the correlation study were serum samples from Asian patients.

- For the company A’s Ferritin:
  - Y-Intercept 95% CI = -3.3343 (-6.2109 to -0.4578)
  - Slope 95% CI = 0.9956 (0.9753 to 1.0159)
  - R² = 0.971

- For the Company B’s Ferritin:
  - Y-Intercept 95% CI = -2.0030 (-3.6359 to -0.3702)
  - Slope 95% CI = 0.9978 (0.9842 to 1.0114)
  - R² = 0.980

**EXPECTED VALUES**

226 normal male serum samples and 205 normal female serum samples were assayed for ferritin on a Roche/Hitachi 917 analyzer.

- Male (n = 226): The reference range was 7-253 ng/mL
- Female (n = 205): The reference range was 2-110 ng/mL

It is recommended that each laboratory establish its own expected range.

**REFERENCES**


**LABELING SYMBOLS**

- **LOT**
- **REF**
- **REV**
- **Manufacturer**
- **CR**

**CHART**

- **EU AUTHORIZED REPRESENTATIVE**
  - K-ASSAY® Ferritin
  - Rev. 2017-02-01
  - ADVENA LTD.
    - Tower Business Centre, 2nd Flr.,
    - Tower Street, Swaraj, BKR 4013 Malta

**ORDERING / PRICING / TECHNICAL INFORMATION**

- **KAMIYA BIOMEDICAL COMPANY**
  - 12779 Gateway Drive
  - Seattle, WA 98168 USA
  - TEL: (206) 575-8068 / (800) 526-4925
  - FAX: (206) 575-8094

**LABELING SYMBOLS**

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- **REF**
- **REV**

**CHART**

- **EU AUTHORIZED REPRESENTATIVE**
  - K-ASSAY® Ferritin
  - Rev. 2017-02-01
  - Authorized Representative in the European Community