**Ferritin**

For the Quantitative Determination of Ferritin Levels in Serum and Plasma

**INTENDED USE**

The K-ASSAY® Ferritin assay is an in vitro diagnostic reagent for the quantitative determination of ferritin (an iron-storing protein) in human serum and plasma by immunoturbidimetric assay on the Roche / Hitachi 917 and other analyzers. Measurements of ferritin aid in the diagnosis of diseases affecting iron overload and iron deficiency anemia. FOR IN VITRO DIAGNOSTIC USE.

**INTRODUCTION AND SUMMARY**

Ferritin is an iron-containing protein with a molecular weight of approximately 450,000 daltons. It is found mainly in the human liver and spleen, where its function is to eliminate and store iron, and is also found in small amounts in human serum. Ferritin is decreased in iron deficiency anemia and increased in iron overload. Ferritin levels correlate with and are useful in evaluation of total body storage iron.

The K-ASSAY® Ferritin is a latex-enhanced immunoturbidimetric assay, developed to accurately and reproducibly measure ferritin levels in serum and plasma samples.

**PRINCIPLE OF TEST**

When an antigen-antibody reaction occurs between ferritin in a sample and an anti-ferritin antibody, which has been sensitized to latex particles, agglutination occurs. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of ferritin in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known ferritin concentration.

**KIT COMPOSITION**

- **Reagents (Liquid stable)**
  - R1: Buffer Reagent: Glycine buffer solution (170 mM)
  - R2: Latex Suspension: 0.07 w/v% suspension of latex particles sensitized with rabbit anti-human ferritin antibody.

- **Parameters for other automated analyzers are available.**

**WARNINGS AND PRECAUTIONS**

FOR IN VITRO DIAGNOSTIC USE. Rx only.

- Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.
- Do not mix or use reagents from one test kit with those from a different lot number.
- Do not use reagents past their expiration date stated on each reagent container label.
- Do not pipette by mouth. Avoid ingestion and contact with skin.

**STORAGE AND HANDLING**

All reagents should be stored refrigerated (2-8°C) and protected from light. Return all reagents to 2-8°C promptly after use.

**REAGENT STABILITY**

Discard reagents if they become contaminated. Evidence of obvious precipitation in reagent 2 (R-2) solution is cause to discard. Opened reagents can be used for 1 month if stored at 2-8°C.

**SPECIMEN COLLECTION AND PREPARATION**

**Serum**

Blood should be collected from a patient and the serum separated as soon as possible. Soon after the blood is drawn, it should be allowed to clot, centrifuged, and the serum separated from the clot tube. For highly turbid samples, it is recommended that the sample be spun and the lipid layer be removed. It is recommended that the specimen collection be carried out in accordance with the NCCLS document M29-A2. After sampling, the specimen should be immediately stored at 2-8°C and assayed as soon as possible. If the assay cannot be performed within 24 hours, then the sample should be tightly capped and frozen at -20°C. Avoid repeated freeze-thaw cycles. Samples should be thawed at room temperature in a water bath or air. Undiluted samples should be used for this assay.

**Plasma**

Whole blood is collected in sodium EDTA or sodium heparin anticoagulant. After collection, immediately centrifuge. In the U.S., follow NCCLS guideline H3-A2. If the assay cannot be performed within 24 hours, then the sample should be tightly capped and frozen at -20°C. Avoid repeated freeze-thaw cycles. Samples should be thawed at room temperature in a water bath or air. Undiluted samples should be used for this assay.

**PROCEDURE**

**Materials Supplied**

KAI-095 Ferritin Assay

- Reagent 1 (R-1) Buffer Solution: 1 x 18 mL
- Reagent 2 (R-2) Latex Suspension: 1 x 9 mL

**Materials Required But Not Supplied**

Calibrators: K-ASSAY® Ferritin Calibrator, Cat. No. KAI094C, 4 Calibrators: 100, 200, 500, 1,000 ng/mL.

Saline (0.9% w/v NaCl)

Roche / Hitachi 917 or other chemistry analyzer

**Assay Procedure**

An example of automated application:

- Sample: 7 µL
  - R1 (Buffer Reagent): 140 µL
  - R2 (Latex Reagent): 70 µL
- Rate, 600 nm (man.) / 800 nm (sub)

Note: Allow all reagents and specimens to warm to room temperature. Mix all reagents gently before using.

**QUANTITY CONTROL**

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-assay variations greater than 3% have been shown to interfere with the assay, however, intra-assay variations 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 Value</th>
<th>% Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>103</td>
<td>102.7</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

(Wi=within, B=Wi=between)

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

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.

\[
y = 0.899 - 9.4037 \\
r = 0.997 \\
n = 64 \\
x = Company A’s Ferritin \\
y = K-ASSAY® Ferritin \\
Slope 95% CI = 0.9612 to 1.0456 \\
Y-Intercept 95% CI = 2.9608 to -2.3018 \\
\]

Linearity

Linearity was tested at the low and high range. The K-ASSAY® Ferritin has a linear range of 2–1,000 ng/mL.

Lower Limit of Detection

The analytical sensitivity is 2 ng/mL. This means that when saline and serum containing 2 ng/mL of ferritin are tested 10 times, + 2 SD of the respective results do not overlap each other.

Prozone

No hook effect seen up to 30,000 ng/mL ferritin.

MATRIX COMPARISON

Serum vs. Sodium EDTA Plasma

\[
y = 0.9856x + 0.2193 \\
r = 0.997 \\
n = 20 \\
x = Serum \\
y = EDTA-2Na Plasma \\
Slope 95% CI = 0.9612 to 1.0456 \\
Y-Intercept 95% CI = 2.9608 to -2.3018 \\
\]

Serum vs. Sodium Heparin Plasma

\[
y = 0.9856x - 0.5524 \\
r = 0.998 \\
n = 20 \\
x = Serum \\
y = Sodium Heparin Plasma \\
Slope 95% CI = 0.9612 to 1.0456 \\
Y-Intercept 95% CI = 2.9608 to -2.3018 \\
\]

EXPECTED VALUES

226 normal male serum samples and 206 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 = 206): The reference range was 2-110 ng/mL

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

REFERENCES


LABELING SYMBOLS

K-ASSAY® Ferritin

EU AUTHORIZED REPRESENTATIVE

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive
Seattle, WA 98168 USA

TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094

ORDERING / PRICING / TECHNICAL INFORMATION

采用了的K-ASSAY® Ferritin和另一家公司Ferritin在日立917上进行了性能评估，结果如下。统计计算使用线性回归。在该对比研究中使用的样本是来自亚洲病人的血清样本。

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y = 0.899 - 9.4037 \\
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\]

线性

线性在低和高范围内测试。K-ASSAY® Ferritin具有线性范围为2–1,000 ng/mL。

下限检测

该分析的灵敏度为2 ng/mL。这意味着当含2 ng/mL的铁蛋白的生理盐水和血清分别检测10次时，+2 SD的各个结果不重叠。

PROZON

没有钩形效应，最高为30,000 ng/mL的血清。

矩阵对比

血清 vs. 肝素钠EDTA

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y = 0.9856x + 0.2193 \\
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y = EDTA-2Na Plasma \\
Slope 95% CI = 0.9612 to 1.0456 \\
Y-Intercept 95% CI = 2.9608 to -2.3018 \\
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血清 vs. 肝素钠

\[
y = 0.9856x - 0.5524 \\
r = 0.998 \\
n = 20 \\
x = Serum \\
y = Sodium Heparin Plasma \\
Slope 95% CI = 0.9612 to 1.0456 \\
Y-Intercept 95% CI = 2.9608 to -2.3339 \\
\]

预期值

226名正常男性血清样本和206名正常女性血清样本用于铁蛋白的测定。

男性 (n = 226): 参考范围为7-253 ng/mL
女性 (n = 206): 参考范围为2-110 ng/mL

建议各实验室建立自己的预期范围。

参考文献