**Ferritin SR**

Diagnostic reagent for quantitative in vitro determination of ferritin in serum or plasma on DiaSys respons®910

**Order Information**
Cat. No. 1 7245 99 10 924
4 twin containers for 80 determinations each
Cat. No. 1 7245 99 10 926
2 twin containers for 80 determinations each

**Method**
Particle enhanced immunoturbidimetric test

**Principle**
Determination of the ferritin concentration by photometric measurement of antigen-antibody-reaction of latex-particles coated with anti-ferritin antibodies with ferritin present in the sample (agglutination).

**Reagents**

**Components and Concentrations**
- **R1**: Tris Buffer \( \text{pH} \ 7.2 \ \text{120 mmol/L} \)
- **R2**: Latex particles coated with rabbit antibodies against human ferritin

**Storage Instructions and Reagent Stability**
Unopened reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents!

**Warnings and Precautions**
2. The reagents contain sodium azide (\(<\ 0.1\%) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
4. Samples containing heterophilic antibodies can cause falsely elevated results.
5. In very rare cases, samples of patients with gammopathy might give falsified results [8].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
7. For professional use only!

**Waste Management**
Please refer to local legal requirements.

**Reagent Preparation**
The reagents need to be mixed via inversion 5 – 10 times before being placed into the reagent rotor and the mixing must be repeated on a weekly basis.

**Specimen**
Serum or plasma (EDTA, heparin, citrate)

**Stability** [1]:
- 7 days at 20 – 25°C
- 7 days at 2 – 8°C
- 1 year at −20°C
Discard contaminated specimens. Do not use hemolytic samples. Freeze only once.

**Calibrators and Controls**
For calibration DiaSys TruCal Ferritin SR calibrator set is recommended. The assigned calibrator values have been made traceable to the WHO International Standard Ferritin, NIBSC 94/572. For internal quality control DiaSys TruLab Protein controls should be assayed. Each laboratory should establish corrective actions in case of deviations in control recovery.

**Performance Characteristics**
Measuring range up to 500 µg/L ferritin, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).

- Limit of blank** 6 µg/L ferritin
- No prozone effect up to 125000 µg/L ferritin
- On-board stability 3 weeks
- Calibration stability 1 weeks

**Interfering substance**

<table>
<thead>
<tr>
<th>Interferences</th>
<th>Ferritin [µg/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>up to 350 mg/dL</td>
</tr>
<tr>
<td>Bilirubin, conjugated</td>
<td>up to 450 mg/dL</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>up to 65 mg/dL</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 70 mg/dL</td>
</tr>
<tr>
<td>Lipemia (cholesterol)</td>
<td>up to 700 mg/dL</td>
</tr>
<tr>
<td>Lipemia (phosphatidylcholine)</td>
<td>up to 1100 mg/dL</td>
</tr>
</tbody>
</table>

**For further information on interfering substances refer to Young DS [2].**

**Precision**

<table>
<thead>
<tr>
<th>Within run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [µg/L]</td>
<td>41.5</td>
<td>146</td>
<td>211</td>
</tr>
<tr>
<td>Coefficient of variance [%]</td>
<td>4.66</td>
<td>2.62</td>
<td>2.28</td>
</tr>
<tr>
<td>Between run (n=20)</td>
<td>Sample 1</td>
<td>Sample 2</td>
<td>Sample 3</td>
</tr>
<tr>
<td>Mean [µg/L]</td>
<td>49.5</td>
<td>270</td>
<td>394</td>
</tr>
<tr>
<td>Coefficient of variance [%]</td>
<td>5.32</td>
<td>3.85</td>
<td>3.49</td>
</tr>
</tbody>
</table>

**Method comparison (n=82)**

<table>
<thead>
<tr>
<th>Test x</th>
<th>Competitor Ferritin (Hitachi 917)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test y</td>
<td>DiaSys Ferritin SR (respons®910)</td>
</tr>
<tr>
<td>Slope</td>
<td>0.901</td>
</tr>
<tr>
<td>Intercept</td>
<td>4.76 µg/L</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.996</td>
</tr>
</tbody>
</table>

**Reference Range** [3]

<table>
<thead>
<tr>
<th>Children</th>
<th>4 months – 16 years</th>
<th>15 – 150 µg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>Women &lt; 50 years</td>
<td>15 – 150 µg/L</td>
</tr>
<tr>
<td></td>
<td>Women &gt; 50 years</td>
<td>Approximation to the reference range for men</td>
</tr>
<tr>
<td></td>
<td>Men</td>
<td>30 – 400 µg/L</td>
</tr>
</tbody>
</table>

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

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* special for respons
Literature

**Ferritin SR**

**Application for serum and plasma samples**

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

### Identification

- **This method is usable for analysis:** Yes
- **Twin reaction:** No
- **Name:** FERR
- **Shortcut:**
- **Reagent barcode reference:** 709
- **Host reference:**

### Technic

- **Type:** Fixed time kinetic
- **First reagent:** [µL] 120
- **Blanc correction:** Yes
- **Second reagent:** [µL] 120
- **Blanc correction:** Yes
- **Main wavelength:** [nm] 800
- **Secondary wavelength:** [nm]
- **Polychromatic factor:**
  - 1st reading time [min:sec]: 04:48
  - Last reading time [min:sec]: 10:00
- **Reaction way:** Increasing

#### Linear Kinetics
- **Substrate depletion:** Absorbance limit
- **Linearity:** Maximum deviation [%]

#### Fixed Time Kinetics
- **Substrate depletion:** Absorbance limit
- **Endpoint:** Stability: Largest remaining slope
- **Prozone Limit [%]"

### Sample

- **Diluent:** DILA (NaCl)
- **Hemolysis:**
  - Agent [µL]: 0 (no hemolysis)
  - Sample [µL]: 0
- **Concentration technical limits**:
  - Lower: 3
  - Upper: 500
- **SERUM**
  - Normal volume [µL]: 18
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 27
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 9
  - Above normal dilution (factor): 1
- **URIN**
  - Normal volume [µL]: 18
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 27
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 9
  - Above normal dilution (factor): 1
- **PLASMA**
  - Normal volume [µL]: 18
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 27
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 9
  - Above normal dilution (factor): 1
- **CSF**
  - Normal volume [µL]: 18
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 27
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 9
  - Above normal dilution (factor): 1

### Results

- **Decimals:** 2
- **Units:** µg/L
- **Correlation factor-Offset:** 0.000
- **Correlation factor-Slope:** 1.000

### Range

- **Gender:** Male
- **Age SERUM:** >=30 <=400
- **URINE PLASMA:** >=30 <=400
- **CSF:**
- **Gender:** Female
- **Age SERUM:** < 50 a
- **URINE PLASMA:** >=15 <=150
- **CSF:**

### Contaminants

- **Contaminant 1**
  - Please refer to r910 Carryover Pair Table
- **Wash with Cycle**
  - **Volume [µL]**
    - Contaminant 2: 2
    - Contaminant 3: 4
    - Contaminant 4: 6

### Calibrators details

<table>
<thead>
<tr>
<th>Calibrator list</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cal. 1 Blank</td>
<td>0</td>
</tr>
<tr>
<td>Cal. 2</td>
<td>*</td>
</tr>
<tr>
<td>Cal. 3</td>
<td>*</td>
</tr>
<tr>
<td>Cal. 4</td>
<td>*</td>
</tr>
<tr>
<td>Cal. 5</td>
<td>*</td>
</tr>
<tr>
<td>Cal. 6</td>
<td>*</td>
</tr>
</tbody>
</table>

### Calculations

- **Model:** Cubic Spline
- **Degree:** Auto

* Enter calibrator value