**ORDER INFORMATION**

**REF** | **Kit size**  
GD8437 00 | 1x40 + 1x10 ml  
KL8437 00 | 1x40 + 1x10 ml  
BK8437 00 | 2x(30+8 ml)  

**CLINICAL SIGNIFICANCE**\(^{(3,7)}\)

Ferritin is the major iron storage compound in the body and is considered one of the most reliable indicators of iron status of patients. A clinical evaluation of serum ferritin is an index of iron stores. Whereas low serum concentrations of ferritin are always indicative of an iron deficiency, elevated concentrations can occur for various reasons. Thus, although elevated concentrations often indicate an excessive iron intake, they are also caused by liver disease, chronic inflammation and malignancies. Pregnant women, blood donors, hemodialysis patients, adolescents and children are groups particularly at risk. Plasma ferritin is also increased in patients with hemosiderosis or hemochromatosis.

**METHOD PRINCIPLE**

The latex particles coated with anti human ferritin are agglutinated when they react with samples that contain ferritin. The latex particles agglutination is proportional to the concentration of the ferritin in the sample and can be measured by turbidimetry.\(^{(1,2)}\)

**COMPOSITION**

Reagent A-Diluent  
Glycine buffer 20 mmol/l, pH 8.2.

Reagent B-Latex  
Latex particles coated with polyclonal anti-human ferritin antibodies, pH 8.2.

**PREPARATION OF THE REAGENTS**

Reagent A: ready to use.  
Reagent B: is ready to use.  
Shake gently the vial before use.

**CALCULATION**

Calculate the absorbance difference \((A_2-A_1)\) of each point of the calibration curve and plot the values obtained against the ferritin concentration of each calibrator dilution. Ferritin concentration in the sample is calculated by interpolation of its \((A_2-A_1)\) in the calibration curve.

**REFERENCE VALUES** \(^{(3,7)}\)

<table>
<thead>
<tr>
<th>Group</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>7 – 140 µg/l</td>
</tr>
<tr>
<td>Men</td>
<td>20 – 250 µg/l</td>
</tr>
<tr>
<td>Women</td>
<td>20 – 200 µg/l</td>
</tr>
</tbody>
</table>

It is recommended that each laboratory establishes its own reference range according to the examined population.

**QUALITY CONTROL**

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns. Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.

**ANALYTICAL PERFORMANCE**

**Linearity**

The method is linear up to 300 µg/l, under the described assay conditions. Samples with higher concentrations should be diluted 1:5 with NaCl 9 g/l and retested again.

**Detection limit**

Values less than 3 µg/l give non-reproducible results.

**Analytical sensitivity**

2.07 mA / µg/l

**Prozone effect**

Prozone effect is not observed up to 4000 µg/l of ferritin.
Precision

<table>
<thead>
<tr>
<th></th>
<th>Mean (µg/l)</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-assay n=10</td>
<td>65</td>
<td>3.56</td>
</tr>
<tr>
<td>Inter-assay n=10</td>
<td>178</td>
<td>1.87</td>
</tr>
</tbody>
</table>

Accuracy

Results obtained with this reagent did not show systematic differences when compared with commercial reagents of similar characteristics. Details of comparison are available on request.

Interferences

Bilirubin (20 mg/dl), hemoglobin (10 g/l) and rheumatoid factors (600 UI/ml) do not interfere. Lipemia interferes. Other substances may interfere[8].

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Note:

1. Calibrator dilutions in plastic tubes should be avoided as ferritin antigen may coat to the walls of plastic tubes.
2. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
3. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
4. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

Precautions in use

The reagents contain inactive components such as preservatives (Sodium azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/ECC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes.

The reagents from human donors have given negative results to anti-HIV 1/2, HBsAg and anti-HCV. It is recommended to handle with caution.

The use of the laboratory reagents according to good laboratory practice is recommended[9].

Waste Management

Please refer to local legal requirement.

REFERENCES