



# FERRITIN Latex L

Quantitative turbidimetric latex assay for the measurement of Ferritin in human serum



## ORDER INFORMATION

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

## CLINICAL SIGNIFICANCE<sup>(3-7)</sup>

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.<sup>(1, 2)</sup>

## 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.

**Calibration curve:** Prepare dilutions of the Calibrator using NaCl 9 g/l as diluent. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the Ferritin concentration of each point of the curve.

Dilution	1	2	3	4	5
Calibrator (µl)	--	25	50	75	100
NaCl 9 g/l (µl)	100	75	50	25	--
Factor	0	0.25	0.5	0.75	1.0

## STORAGE AND STABILITY

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8 °C and contaminations are prevented during their use. Do not use the reagents after the expiration date.

**Reagent deterioration:** presence of particles and turbidity and increment of blank reagent.

## ANCILLARY EQUIPMENT

- Automatic pipette to measure reagent and sample
- Thermostatic bath at 37 °C
- Spectrophotometer or photometer thermostatable at 37 °C capable to read 650 ± 20 nm

- Analysis cuvettes (optical path = 1 cm)
- NaCl (9 g/l) solution
- Ferritin Calibrator L (Ref. GD8434 00)
- Plasmaprotein Normal Control (Ref. GD8461 00)
- Plasmaprotein Pathological Control (Ref. GD8464 00)
- Plasmaprotein Normal and Pathological Control (Ref. GD8466 00)

## SAMPLES

Fresh serum.

Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

Stable for 7 days at 2-8 °C or 3 months at -20 °C.

## PROCEDURE

1. Prewarm the reagent and the photometer (cuvette holder) to 37 °C.
2. Using distilled water zero the instrument at 650 nm.
3. Pipette into a cuvette:

RA (Diluent)	800 µl
Sample/Calibrator/Water (Blank)	100 µl
RB (Latex)	200 µl

4. Mix well and insert the cuvette into the photometer. Record the absorbance (A<sub>1</sub>) immediately and after 8 minutes (A<sub>2</sub>).

## CALCULATION

Calculate the absorbance difference (A<sub>2</sub>-A<sub>1</sub>) 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<sub>2</sub>-A<sub>1</sub>) in the calibration curve.

## REFERENCE VALUES<sup>(3,7)</sup>

Children	7 – 140 µg/l
Men	20 – 250 µg/l
Women	20 – 200 µg/l

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**

	Mean ( $\mu\text{g/l}$ )	%CV
<b>Intra-assay</b>	65	3.56
n = 10	178	1.87
<b>Inter-assay</b>	65	5.16
n = 10	178	2.90

**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<sup>(8)</sup>.

**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.<sup>(9)</sup>

**Waste Management**

Please refer to local legal requirement.

**REFERENCES**

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