FERRITIN SYSTEM PACK

(Latex Turbidimetry Method)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI37	Ferritin System Pack	1x40 + 1x10 ml
UNI37A	Ferritin System Pack	2x40 + 2x10 ml

INTENDED USE

For the quantitative determination ferritin human serum or plasma.

PRINCIPLE

Latex particles coated with specific anti-human ferritin are agglutinated when mixed with samples containing ferritin. The agglutination causes an absorbance change, dependent upon the ferritin contents of the sample that can be quantified by comparison from a calibrator of known ferritin concentration.

CLINICAL SIGNIFICANCE

Serum ferritin concentration usually reflects body iron stores and is considered one of the most reliable indicators of iron status of patients Whereas low serum concentrations of ferritin are always indicative of an iron deficiency, elevated concentrations can occur for variety of 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.

REAGENT COMPOSITION

Reagent 1 : Diluent	Tris Buffer 20 mmol/L, pH 8,2. Preservative.
Reagent 2 : Latex	Latex particles coated with rabbit IgG anti-human ferritin pH 8.2. Preservative.
Reagent 3 : Ultima Ferritin Calibrator	Calibrator. Ferrtin concentration is stated on the vial.

PREPARATION

Ferritin Calibrator: Reconstitute (⟶) with 3.0 mL of distilled water. Mix gently and incubate at room temperature for about 10 minutes before testing.

STABILITY AND STORAGE

All the components of the kit are stable until the expiration date on the label when stored tightly closed at +2-+8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Do not freeze; frozen Latex or Diluent could change the functionality of the test .

Reagent deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND HANDLING

- Fresh serum. Stable 7 days at +2-+8°C . The samples with presence of fibrin should be centrifuged before testing Do not use highly hemolized or lipemic samples.

CALIBRATION

The calibration is stable for at least 1 month.

Recalibrate when control results are out of specified values; when using a different lot of reagent and when the instrument is adjusted.

Calibration curve: Prepare the following dilutions of the Ferritin Calibrator using NaCl 9 g/L. To obtain the concentration of each dilution, multiply using the dilution factor shown in the next table:

Calibration dilution	1	2	3	4	5	6
Ultima ferritin calibrator (µL)	–	25	50	100	200	400
NaCl 9 g/L (µL)	400	375	350	300	200	--
Dilution Factor	0	1/16	1/8	1/4	1/2	1,0

CALCULATIONS

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.

QUALITY CONTROL:

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances

EXPECTED VALUES

Men : 30- 220 µg/L

Women : 20- 110 µg/L

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: Up to 600 µg/L. Samples with higher values should be diluted 1/5 in NaCl 9 g/L and retested. The upper linearity limit increases as the sample volume and the sensitivity decrease.

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Detection limit: 5.04 µg/L.
Quantification limit: Values under 6.6 µg/L may give non-reproducible results.
Prozone effect: No prozone effect was detected at least up to 9000 µg/L.
Precision:

Intra-assay precision Within run (n=20)	Mean (µg/L)	SD (µg/L)	CV (%)
Sample 1	50.87	1.92	3.77
Sample 2	102.76	1.85	1.80

Inter-assay precision Run to run (n=20)	Mean (µg/L)	SD (µg/L)	CV (%)
Sample 1	21.93	1.0	4.57

Method comparison: The reagent was compared to another commercially available Ferritin reagent by testing 20 samples (male and female) The coefficient of correlation (r) was 0.999and the equation y = 1.0023 x - 0.1738 µg/L
Performance characteristics depend on the analyzer used.

INTERFERENCES
Bilirubin (40 mg/dL), hemoglobin (5 g/L), y and rheumatoid factor (750 IU/ml), do not interfere. Lipids (≥ 2,5 g/L) do interfere. Other substances may interfere .
PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious. MSDS will be provided on request.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400
(Fully Auto Biochemistry Analyzer)

Test Name	FERRITIN
Full Name	FERRITIN
Pri Wave	546 nm
Sec Wave	-
Assay/point	Fixed Time
Start	10
End	33
Decimal	2
Unit	µg/L
Linearity Range Low	5.04
Linearity Range High	600
Sample Volume	18 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (R2) Volume	40 µl
Substrate Depleted	-
Linearity	600 µg/L
Out Of Linearity Range	-
Calibration Type	Spline
Points	6

Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE
Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

BIBLIOGRAPHY
1. Knovich MA et al., Blood Rev. 2009 23(3)-95-104
2. Mazza J etal. Can Med Assoc J 1978; 119: 884-886
3. Rodriguez Perez J et al. Revista Clinica Espafiola 1980:

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

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