FERRITIN SYSTEM PACK

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200
(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA237	FERRITIN SYSTEM PACK	1X 20+1 X5 ML
BA237A	FERRITIN SYSTEM PACK	2X 20+2 X5 ML
BA237B	FERRITIN SYSTEM PACK	1X 40+1 X10 ML
BA237C	FERRITIN SYSTEM PACK	2X 40+2 X10 ML

Quantitative determination of Ferritin

Store at 2 - 8ºC.

RECOMMENDED USE

Turbidimetric immunoassay for the quantitative determination of ferritin in human serum or plasma.

PRINCIPLE OF THE METHOD

Ferritin-turbilatex is a quantitative turbidimetric test for the measurement of ferritin in human serum or plasma.
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.

REAGENTS

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. Ferritin concentration is stated on the vial.

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.

PREPARATION

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

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:

Calibrator 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

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC 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.

ADDITIONAL EQUIPMENT

Thermostatic bath at 37ºC.
Spectrophotometer or photometer thermostatable at 37ºC with a 540 nm filter.

SAMPLES

- Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
- The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

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.

REFERENCE 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.
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 (n= 20)		inter assay (n =20)
Mean (µg/L)	33.55	112.80	286.8
SD	1.00	0.89	1.66
CV (%)	2.98	0.79	0.58

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 0,999, and the equation y = 1.0052x - 0.1473

Performance characteristics depend on the analyzer used.

INTERFERENCES

Bilirubin (40 mg/dL), hemoglobin (5 g/L), y and rheumatoid factor (750 UI/mL), do not interfere. Lipids (≥ 2,5 g/L) do interfere. Other substances may interfere [5].

Parameter For B Auto 200, Unicorn 230, Unicorn 120 &
Bonavera Chem 200 (Fully Auto Biochemistry Analyzer)

TEST NAME	FERRITIN
FULL NAME	FERRITIN
PRI WAVE	546 nm
SEC WAVE	-
ASSAY/POINT	FIXED TIME
START	18
END	34
DECIMAL	2
UNIT	µg/L
LINEARITY RANGE LOW	30
LINEARITY RANGE HIGH	220
SAMPLE VOLUME	18 µ l
REAGENT 1 (R1) VOLUME	160 µl
REAGENT 1 (R2) VOLUME	40 µl
SUBSATRATE DEPLETED	-
LINEARITY	600 µg/L
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	Spline
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	18 µ l

BIBLIOGRAPHY

1. Knovich MA et al., Blood Rev. 2009 23(3):95-104.
2. Mazza J et al. Can Med Assoc J 1978; 119: 884-886
3. Rodriguez Perez J et al. Revista Clinica Española 1980: 156 (1): 39-43
4. Milman N et al. Eur J Haematol 1994: 53: 16-20.
5. Young DS. Effects of drugs on clinical laboratory test, 5th ed. AACC Press, 1999.

IVD

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