

IRON SYSTEM PACK

(ferrozine Method)

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



Code	Product Name	Pack Size
UNI38	Iron System Pack	1x20+1x5 ml

INTENDED USE

For quantitative determination of Iron in human serum or heparinized plasma.

CLINICAL SIGNIFICANCE

Iron found in blood is mainly present in the hemoglobin of the RBC's. It's role in the body is mainly in the transportation of oxygen and cellular oxidation. Iron is absorbed in the small intestine, and bound to a globulin in the plasma, called transferrin, and transported to the bone marrow for the formation of hemoglobin. Increased serum levels are found in hemolytic anemias, hepatitis, lead and iron poisoning. Decreased serum levels are found in anemias caused by iron deficiency due to insufficient intake or absorption of iron, chronic blood loss, late pregnancy and cancer.

Principle

Iron, bound to Transferrin, is released in an acidic medium and the Ferric ions are reduced to Ferrous ions. The Fe (II) ions react with Ferrozine to form a violet coloured complex. Intensity of the complex formed is directly proportional to the amount of Iron present in the sample.

REACTION



REAGENT COMPOSITION

Reagent 1 : Iron Reagent 1

Reagent 2 : Iron Reagent 2

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2 - +8°C. On board stability: Min 7 days if refrigerated (+8 - +14°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unhemolysed serum

It is recommended to follow NCCLS procedures (or similar standardized procedure).

Stability in serum: Serum, free from hemolysis. Iron is reported to be stable in serum for 7 days at +2-+8°C.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

UNIT CONVERSION

$\mu\text{mol/L} = \mu\text{g/dL} \times 0.179$

EXPECTED VALUES

Serum Iron (Males) : 60 - 160 $\mu\text{g/dL}$
(Females) : 35 - 145 $\mu\text{g/dL}$
(Neonates) : 150 - 220 $\mu\text{g/dL}$

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon system.

Data obtained in your laboratory may differ from these values.

Limit of quantification: 5.0 $\mu\text{g/dL}$

Linearity: 1000 $\mu\text{g/dL}$

Measuring range: 5.0 - 1000 $\mu\text{g/dL}$

PRECISION

Intra-assay precision Within run (n=20)	Mean ($\mu\text{g/dL}$)	SD ($\mu\text{g/dL}$)	CV (%)
Sample 1	127.37	1.88	1.48
Sample 2	240.69	2.35	0.98

Inter-assay precision Run to run (n=20)	Mean ($\mu\text{g/dL}$)	SD ($\mu\text{g/dL}$)	CV (%)
Sample 1	211.97	2.58	1.22

COMPARISON

A comparison between Iron System Pack (y) and commercially available test (x) using 20 samples gave following results:

$y = 0.744 + 21.38 \mu\text{g/dL}$

$r = 0.998$

INTERFERENCES

For diagnostics purpose, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Linearity

This procedure is linear upto 1000 µg/dl. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

WARNING AND PRECAUTIONS

For in vitro diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

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

Test Name	IRON
Full Name	IRON
PRI Wave	578 nm
Sec Wave	-
Assay/point	2 Point End
Start	9
End	33
Decimal	2
Unit	µg/dL
Linearity Range Low	5.0
Linearity Range High	1000
Sample Volume	25 µl
Reagent 1 (R1) Volume	200 µl
Reagent 1 (R2) Volume	50µl
Substrate Depleted/Abs.limit	-
Linearity	1000 µg/dL
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration STD	Refer calibrator value sheet

NOTE









Hemolysis interferes with the test as the hemoglobin present in the RBC's have a very high iron content. All glassware being used for the test should first be rinsed with 1% or 0.1 N HCl and then with good quality deionised water before use.

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

REFERENCES

1. Siedel, J., et. al. (1984) Clin Chem. 30 : 975

Symbols Used On Labels

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

BEA/24/IRO/UN/IFU Ver: 01
09/09/2025

