# 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 deficency 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 fom a violet coloured complex. Intensity of the complex formed is directly proportional to the amount of Iron present in the sample.

**REACTION**

$$Fe(III) \xrightarrow{\text{Acidic medium}} Fe(II)$$

$$Fe(II) + \text{ferrozine} \longrightarrow \text{Violet coloured complex}$$

**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 unheamolysed 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 serumfor 7days 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**

µmol/L = µg/dlx 0.179

**EXPECTED VALUES**

| | | | |
|---|---|---|---|
| Serum Iron | (Males) | :60 - 160 | µg/dl |
| | (Females) | :35 - 145 | µg/dl |
| | (Neonates) | :150 - 220 | µg/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 µg/dl
**Linearity :** 1000 µg/dl
**Measuring range :** 5.0 - 1000 µg/dl

**PRECISION**

| Intra-assay precision Within run (n=20) | Mean (µg/dl) | SD (µg/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 (µg/dll) | SD (µg/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
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.

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**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.

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 thetestasthe 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% or0.1 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 | Lot Number |
| CONT | Content | | Storage Temperature |
| | Expiry Date | IVD | In Vitro Diagnostics |

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