BIOLABO
www.biolabo.fr

MANUFACTURER:
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IRON Direct Method (Ferene)

Reagent for quantitative determination of iron in human serum and plasma.

I REF K1108	**R1** 3 x 18 mL	**R2** 1 x 6 mL
I REF K2108	**R1** 2 x 40 mL	**R2** 1 x 9 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of iron in human serum or plasma to screen its level.

GENERALITIES (1)

Serum iron concentration connotes the Fe^{3+} bound to the serum transferrin and does not include the iron contained in serum as free hemoglobin. Serum iron concentration is decreased in many but not all patients with iron deficiency anemia and in chronic inflammatory disorders such as infection, immunization, and myocardial infarction. Greater than normal concentrations of serum iron occur in iron loading disorders such as hemochromatosis, in acute iron poisoning in children, and after oral ingestion of iron medication or parenteral iron administration or acute hepatitis.

PRINCIPLE (4)

After dissociation of iron-transferrin bound in acid medium, ascorbic acid reduces Fe3+ iron into Fe2+ iron. Fe2+ iron then form a colored complex with 3 -(2-Pyridyl) -5, -6-difuryl-1, -2, -4-triazine-disulfonate (Ferene). The absorbance thus measured at 600 nm (580-620) is directly proportional to the amount of iron in the specimen. Thiourea is added in the reagent to prevent the copper interference.

I REAGENTS COMPOSITION

R1 **FE1** Reducing Reagent

Citric acid	150	mmol/L
Ascorbic acid	30	mmol/L
Thiourea	27	mmol/L

R2 **FE1** Chromogen Reagent

Ferene	8	mmol/L

EUH210: Safety data sheet available on request

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened:

- Until expiry date stated on the label.

Once opened:

- 2 separated reagents are stable for at least 6 months

Discard reagents if cloudy or if reagent blank at 620 nm > 0.100.

SPECIMEN COLLECTION AND HANDLING (6)

Morning unhemolyzed serum. Draw blood before other specimens that require anticoagulants. Do not use EDTA, oxalate or citrate.
Heparinized plasma
Serum iron is stable in specimen for:

- 4 days at room temperature.
- 1 week stored 2-8°C.

LIMITS (3) (5)

Iron medications affect serum levels for up to 2-4 weeks following administration.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

REFRENCE INTERVALS (2)

Age	(µg/dL)	(µmol/L)
New born	100-250	[17.9-44.8]
Infant	40-100	[7.2-17.9]
Children	50-120	[9.0-21.5]
Men	65-175	[11.6-31.3]
Women	50-170	[9.0-30.4]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On KENZA 240TX, 37°C, 620 nm

Linearity Range: between 13 µg/dL (LQ) and 2000 µg/dL

Detection limit: approx. 1 µg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High Level*
Mean (µg/dL)	25	136	266
S.D. µg/dL	1	1.8	3.2
C.V. %	4.1	1.3	1.2

Between Run N = 20	*Low level*	*Normal level*	*High level*
Mean (µg/dL)	26	140	275
S.D. µg/dL	1.5	3.9	5.8
C.V. %	5.7	2.7	2.1

Comparison studies with liquid available reagent:
Realized on automated analyzer with specimens (n=122) between 17 and 290 µg/dL

$y = 0.9987 x + 0.3847$ $r = 0.9974$

Analytical sensitivity: approx. 0,008 abs for 10 µg/dL

Interferences:

Turbidity	Negative interference from 0.043 abs
Total bilirubin	No interference up to 560 µmol/L
Direct bilirubin	No interference up to 504 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 966 mg/dL
Hemoglobin	Negative interference from 62 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration stability: 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on KENZA 450TX/ISE and KENZA ONE are available on request.

CALIBRATION (7)

- REF 95015 Multicalibrator traceable to SRM 3126

The calibration frequency depends on proper instrument functions and on the preservation of reagents.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- REF 95012 Urinary controls
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum
2. If control is still out of range, use a new vial of calibrator
3. If control is still out of range, calibrate with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1698-1704.*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 634-639*

(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-361 to 3-364*

(4) *FERENE: a new spectrophotometric reagent for IRON. Douglas J. HENNESY, Gary R. REID, Frank E.SMITH, and Stephen L. THOMPSON, CAN.J. Chem. (1984) 62, p.721-724*

(5) *A systematic evaluation of bathophenanthroline, ferrozine and ferene in an ICSH-based method for the measurement of serum iron. D.P.DERMAN, A. GREEN, TH. BOTHWELL, B. GRAHAM, L. MC. NAMARA, A.P. Mac PHAIL and RD BAYNES Ann Clin. Biochem. 1989 ; 26 p.144-147.*

(6) *HENRY RJ, (Ed) Clin. Chem., Principles and technics, (2ème éd.), Harper and Row, (1974) p.682-695.*

(7) *SRM: Standard Reference Material ®*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with