



IRON LR liquid reagent

REF E2905100 R1 5x80 ml/ R2 1x100 ml
E2900550 R1 5x40 ml/ R2 1x50 ml
E290340130 R1 3x40 ml R2 1x30 ml

CE IVD For in vitro medical device

Use

Kit for measurement of iron in serum or plasma
 Colorimetric method without deproteinization.

Summary

Iron measurements are used in the diagnosis and treatment of several diseases related to iron deficiency or disorders of iron metabolism.

Principle

End point analysis. The iron released from transferrin complex at pH acid, reacts, once reduced to ferrous state, with Ferene S giving a stable complex which absorbs at 600 nm. The intensity of colour is directly proportional to iron concentration in the sample.

Reagents

R1	Acetate buffer	1.3 mol/l
	Thiourea	65.0 mmol/l
	Hidroxilamin sulphate	60.0 mmol/l
	Surfactants	
R2	Ferene S	0.65 mmol/l
	Hidroxilamin sulphate	30.0 mmol/l

Reagent Preparation

Reagents are liquid and ready to use. About using a monoreagent ("sample starter" procedure) add to every 4 ml of R1 reagent, 1 ml of R2 reagent. Keep out the reagents from refrigerator only for the use and recap them immediately.

Reagent Storage and Stability

- Store the kit at 2-8°C
- After opening, the vials R1, R2 are stable 90 day if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working solution stability (R1+ R2): 20 days at 2-8°C.

Precaution In Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.

However the reagent should be handled with caution, according to good laboratory practice. Avoid contact with skin and eyes. In case of contact with eyes rinse immediately with plenty of water and seek medical advice.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

Do not use samples with haemolysis and lipoemic. Use only heparine salts as anticoagulants.

- The iron is stable in the samples up to 7 days at 2-8°C

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- It's advisable to use glassware washed by HCl 1N solution and distilled water and disposable test tubes to eliminate any iron contamination.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedure

Wavelength	λ: 600 nm
Working Temperature	37°C
Optical Path	1 cm
Reaction	"End point"

Monoreagent Procedure "sample starter"

	Blank	STD	Sample
Working Reagent	1000µl	1000µl	1000µl
Distilled Water	200 µl	-	-
Sample	-	-	200 µl
Standard	-	200 µl	-

Mix, then incubate 5' at 37°C. Measure the absorbance of sample (EC) and standard (ES) against the reagent blank.

Bireagent Procedure "substrate starter"

	Blank	STD	Sample
Reagent R1	800µl	800µl	800µl
Distilled Water	200 µl	-	-
Sample	-	-	200 µl
Standard	-	200 µl	-

Mix, incubate at 37°C for 1' and then add:
 Reagent R2 200µl 200µl 200µl
 Mix, then incubate 5' at 37°C. Measure the absorbance of sample (EC) and standard (ES) against the reagent blank.

Calculation

$$EC/ES \times \text{conc. STD} = \mu\text{g } (\mu\text{mol/l}) \text{ of iron /dl (L) of sample}$$

The reagent performances are related to 37°C, 1 cm and 600 nm.

Conversion Factor

$$\text{Iron } [\mu\text{g/dl}] \times 0.1791 = \text{Iron } [\mu\text{mol/l}]$$

Reference Values

Man	59 -158 µg/dl (10.6 - 28.2 µmol/l)
Woman	37 -145 µg/dl (6.5 - 26 µmol/l)

Reference values are considered indicative since each laboratory should establish references ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

The performance of the reagent are related to 37°C, 1 cm and 600 nm.

Linearity

The reaction is linear in concentration range between 2.9 and 600 µg/dl (0.52 - 107.46 µmol/l). Samples with values exceeding 600 µg/dl must be diluted with saline solution. Multiply, then, the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High).

Results:

MEAN [µg/dl]	N = 93.45	H = 140.45
S.D.	N = 1.60	H = 1.60
C.V.%	N = 1.71	H = 1.14

"Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (H-N).Results:

MEAN [µg/dl]	N = 94.65	H = 140.73
S.D.	N = 2.28	H = 2.81
C.V.%	N = 2.40	H = 2.00

Analytical sensitivity

The test sensitivity in terms of detection limit is 2.90 µg/dl (0.52 µmol/l).

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor $r = 0.99$

$$y = 1.0507x + 4.4947$$

Interferences

No interference was observed by the presence of:

Bilirubin ≤ 15mg/dl.

Triglycerides ≤ 500 mg/dl

Do not use haemolysed sample.

Quality Controls

It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. (1996).

Higgins T. Clin Chem. 27, 1619 (1981). Artiss J.D. Vinogradov S. Zak Clin. Biochem 14, 311 (1981). Hennessy J.D. et al Can. J. Chem. 62, 721 (1984). Weippl G. et al Blut, 27, 261 (1973).

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
🕒	Use by
🌡️	Storage temperature limits
📖	Read instruction for use
🏭	Gesan Production srl