ELITechGroup
CLINICAL SYSTEMS

ELITech Clinical Systems
Selectra Pro Series Analyzers
IRON FERENE

☛*References :*
FEFE-0230 4 x 18.5 mL

Kit composition :
R1 *4 x 14.6 mL* + ***R2*** *4 x 3.9 mL*

***In vitro* diagnostic reagent, for professional use only**

CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)

INTENDED USE
ELITech Clinical Systems IRON FERENE is intended for the quantitative *in vitro* diagnostic determination of total iron in human serum on ELITech Clinical Systems Selectra Pro Series Analyzers. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. It is not intended for use in Point of Care settings*.

CLINICAL SIGNIFICANCE [1-2]
In the body, between 65 - 70% of iron enter into the composition of hemoglobin, 25% is stored in cells as an iron-ferritin complex and 3% is transported by transferrin. Serum iron levels are increased in hemochromatosis or liver damage. Lowered serum iron levels can be associated to increased needs, a dietary deficiency or gastro-intestinal disorders (chronic diarrhea, intestinal bleeding or malabsorption). Serum iron levels is always interpreted along with transferrin saturation data.

METHOD [2]
Colorimetric - Ferene
End Point

PRINCIPLE [1-2]
Iron is released from transferrin in acidic pH as a ferric ion Fe^{3+}. It is then reduced by the ascorbic acid into ferrous ion Fe^{2+} and eventually form a colored complex with ferene. The 578 nm absorbance of the iron-ferene complex is proportional to the iron concentration of the sample.

$$\text{Transferrin-}(Fe^{3+})_2 \xrightarrow{\text{Acidic pH, Ascorbic Acid}} 2\,Fe^{2+} + \text{Transferrin}$$

$$Fe^{2+} + 3\ \text{Ferene} \longrightarrow \text{Blue ferene - iron complex}$$

REAGENTS COMPOSITION
Reagent : R1

Thiourea	120	mmol/L
Acetate buffer, pH 4.5	1	mol/L

Reagent : R2

Ferene	3	mmol/L
Ascorbic acid	240	mmol/L
Thiourea	120	mmol/L

MATERIAL REQUIRED BUT NOT PROVIDED
- ELICAL 2, calibrator, ref.CALI-0580, 4 x 3 mL.
- ELITROL I, control serum, ref.CONT-0080, 10 x 5 mL.
- ELITROL II, control serum, ref.CONT-0180, 10 x 5 mL.
- General Laboratory equipment.

☛PRECAUTIONS AND WARNING
- This reagent is for professional *in vitro* diagnostic use only.
- Reagent R1 is classified as hazardous:

DANGER.Causes skin irritation. Causes serious eye damage. Wear protective gloves/ protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

- For more information, refer to the Safety Data Sheet (SDS).
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.

WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local, state and Federal regulatory requirements.

STABILITY OF REAGENTS
Store at 2-8 °C and protect from light.
The reagent is stable until the expiry date stated on the label.
On board stability: Refer to § PERFORMANCE DATA.

PREPARATION
The reagents are ready to use.

REAGENT DETERIORATION
The reagent solutions should be clear. Cloudiness would indicate deterioration.

SAMPLES [1, 3]
- Specimen
Serum free from hemolysis.

- Storage
Sera are stable for 7 days at room temperature or at 2-8 °C or 1 year at -20 °C.

REFERENCE VALUES [4]

New-born	100 - 250 µg/dL (17.9 - 44.8 µmol/L)
Infant	40 - 100 µg/dL (7.2 - 17.9 µmol/L)
Child	50 - 120 µg/dL (9.0 - 21.5 µmol/L)
Woman	50 - 170 µg/dL (9.0 - 30.4 µmol/L)
Man	65 - 175 µg/dL (11.6 - 31.3 µmol/L)

The range of serum iron levels in clinically healthy individuals can be influenced by a number of well-known factors such as diet, sex, age, menstrual cycle, pregnancy or circadian fluctuations.

Note : *It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only for information.*

Conversion factor : µg/dL x 0.179 = µmol/L

PROCEDURE
See application included in the barcode indicated at the end of the insert.

CALIBRATION
For calibration, multiparametric calibrator Elical 2 must be used. Its value is traceable to the reference material NIST SRM937 (of the National Institute of Standards and Technology).

Calibration frequency: refer to § PERFORMANCE DATA.

QUALITY CONTROL
To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) should be used. These controls should be assayed together with patient samples, at least once a day and after each calibration.The control frequency should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control materials should be used in accordance with local, state, and/or federal guidelines.

PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProM Analyzers

- Measuring range
Determined according to CLSI EP6-A protocol[5], the measuring range is from 20 to 1000 µg/dL (3.6 to 179.1 µmol/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)
Determined according to CLSI EP17-A protocol[6].
LoD = 6 µg/dL (1.1 µmol/L)
LoQ = 20 µg/dL (3.6 µmol/L)

- Precision
Determined according to CLSI EP5-A2 protocol[7].

		Mean		Within-run	Total
	n	µg/dL	µmol/L	CV (%)	
Low level	80	43	7.7	2.0	5.5
Medium level	80	137	24.5	0.4	3.2
High level	80	248	44.4	0.7	3.1

- Correlation
A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-Approved system equipment (ferene colorimetric method) on 99 human serum samples according to CLSI EP9-A2 protocol[8].
The sample concentrations were between 22 and 1048 µg/dL (3.9 and 187.7 µmol/L).

The parameters of the linear regressions are as follows:
Correlation coefficient: (r) = 1.000
Linear regression: y = 1.041 x - 2 µg/dL (0.4 µmol/L)

- Interferences
Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol[9]. Recovery is within ±10% of initial value of iron concentration of 40 µg/dL and 250 µg/dL.

Unconjugated Bilirubin:	No significant interference up to 30 mg/dL (513 µmol/L).
Conjugated Bilirubin:	No significant interference up to 29.5 mg/dL (504 µmol/L).
Triglycerides:	No significant interference up to 3000 mg/dL (33.90 mmol/L).
Ascorbic acid:	No significant interference up to 20 mg/dL (1136 µmol/L).
Copper:	No significant interference up to 500 µg/dL.
Acetylsalicylic acid:	No significant interference up to 200 mg/dL.
Acetaminophen:	No significant interference up to 30.0 mg/dL.

In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[10]
Grossly hemolyzed samples should not be run.

Other compounds may interfere.[11,12]

- On board stability/Calibration frequency
On Board Stability: 28 days
Calibration frequency: 14 days
Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

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*: US FDA only
☛: Modification from previous version

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☛***References :***
FEFE-0230 4 x 18.5 mL

Kit composition :
R1 *4 x 14.6 mL* + ***R2*** *4 x 3.9 mL*

***In vitro* diagnostic reagent, for professional use only**

PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProS Analyzers

- Measuring range
Determined according to CLSI[5] EP6-A protocol, the measuring range is from 20 to 1000 µg/dL (3.6 to 179.1 µmol/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)
Determined according to CLSI[6] EP17-A protocol.
LoD = 7 µg/dL (1.3 µmol/L)
LoQ = 20 µg/dL (3.6 µmol/L)

- Precision
Determined according to CLSI EP5-A2 protocol[7].

		Mean		Within-run	Total
	n	µg/dL	µmol/L	CV (%)	
Low level	80	43	7.7	1.6	2.8
Medium level	80	136	24.4	1.0	1.7
High level	80	246	44.0	0.4	1.0

- Correlation
A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (ferene colorimetric method) on 101 human serum samples according to CLSI EP9-A2 protocol[8].
The sample concentrations were between 20 and 1022 µg/dL (3.6 and 183.0 µmol/L).

The parameters of the linear regressions are as follows:
Correlation coefficient: (r) = 1.000
Linear regression: y = 0.983 x + 1 µg/dL (0.2 µmol/L)

- Interferences
Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol[9]. Recovery is within ±10% of initial value of iron concentration of 40 µg/dL and 250 µg/dL.

Unconjugated Bilirubin:	No significant interference up to 30 mg/dL (513 µmol/L).
Conjugated Bilirubin:	No significant interference up to 29.5 mg/dL (504 µmol/L).
Triglycerides:	No significant interference up to 3000 mg/dL (33.90 mmol/L).
Ascorbic acid:	No significant interference up to 20 mg/dL (1136 µmol/L).
Copper:	No significant interference up to 500 µg/dL.
Acetylsalicylic acid:	No significant interference up to 200 mg/dL.
Acetaminophen:	No significant interference up to 30.0 mg/dL.

In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macro-globulinemia) can cause unreliable results.[10]

Other compounds may interfere.[11,12]

- On board stability/Calibration frequency
On Board Stability: 28 days
Calibration frequency: 14 days
Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

BIBLIOGRAPHY

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☛**SYMBOLS**

IVD *In vitro* diagnostic medical device	Temperature limitation
Consult instruction for use	LOT Batch code
Manufacturer	Use by
REF Catalogue number	R1 Reagent 1
CE European Conformity	R2 Reagent 2

Iron Ferene 0
510 FTNA-FEFE

(03/2016)
FTNA-FEFE-v3

☛: Modification from previous version

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