

IRON ENVOY

REF FEFE-0850



PIEVY-FEFE-2-v4 (11/2019)

ENGLISH - EN

For *in vitro* diagnostic use, for professional use only

INTENDED USE

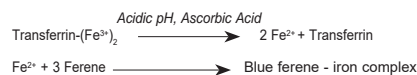
IRON ENVOY is an *in vitro* diagnostic reagent intended for the quantitative determination of total iron in human serum using the Envoy Analyzers.

CLINICAL SIGNIFICANCE ^(1,2)

In human 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 AND PRINCIPLE ^(1,2)

Iron is released from transferrin in acidic pH as a ferric ion Fe³⁺. It is then reduced by the ascorbic acid into ferrous ion Fe²⁺ 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.



REAGENTS

COMPOSITION

IRON ENVOY Reagent 1 contains:

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

IRON ENVOY Reagent 2 contains:

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

WARNINGS AND PRECAUTIONS

- This reagent kit 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.
- Do not interchange reagent vials from different kits.

PREPARATION

The reagents are ready to use.

REAGENT DETERIORATION

The reagent solutions should be clear. Cloudiness would indicate deterioration. Do not use reagent if there is visible evidence of biological, chemical or physical deterioration.

DAMAGED PACKAGING

Do not use the reagent if the damages of packaging might have an effect on the product performance (leakages, pierced boat or bottle).

STORAGE AND STABILITY

Store these reagents at 2 to 8 °C and protected from light. Do not freeze. Do not use after expiration dates indicated on the bottle labels.

On board stability : Refer to § PERFORMANCE DATA.

SAMPLES ^(1,3)

SPECIMENS

- Serum free from hemolysis.
- Do not use other specimens.

WARNINGS AND PRECAUTIONS

According to Good Laboratory Practice, venipuncture should be performed prior to the administration of drugs.

STORAGE AND STABILITY

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

EXPECTED VALUES ⁽⁴⁾

A published total iron reference range is listed below.

Reference Range	Conventional Units	SI Units
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: *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

PROCEDURE

MATERIALS PROVIDED

The IRON ENVOY Reagent Kit includes the following components:

- 8 x 28.6 mL boats of IRON ENVOY Reagent 1
- 8 x 8.7 mL bottles of IRON ENVOY Reagent 2

☞ MATERIALS REQUIRED BUT NOT PROVIDED

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Envoy Analyzer
- General Laboratory Equipment
- Do not use materials that are not required as indicated above

REAGENT INSTALLATION AND USE

Refer to the Operator Manual for information on installing reagents, programming the analyzer, and running, calibrators, controls and samples. The test parameters are available at the end of this Instructions For Use. Before installing, record the installation date on the label. Mix the reagent by gently inverting the reagent bottle several times, open the bottle and insert the unit into the designated position on the reagent tray. Let the reagent equilibrate on the instrument for at least 30 minutes before use.

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 check the accuracy of assays control sera such as ELITROL I and ELITROL II should be used. These controls must be performed and validated before the patient samples are assayed. The control frequency must be at least once a day, after each calibration and 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 guidelines.

CALCULATION

All calculations are performed by the instrument. To calculate the results in SI units (µmol/L), multiply the result in conventional units (µg/dL) by 0.179

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local and legal requirements.

PERFORMANCE DATA ON ENVOY 500+ ANALYZER

MEASURING RANGE

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

LIMIT OF DETECTION (LOD) AND LIMIT OF QUANTIFICATION (LOQ)

Determined according to CLSI[®] EP17-A protocol:
LoD = 3 µg/dL (0.5 µmol/L)
LoQ = 20 µg/dL (3.6 µmol/L).

PRECISION

Determined according to CLSI[®] EP5-A2 protocol.

Sample	n	Mean		Within-run CV (%)	Total CV (%)
		µg/dL	µmol/L		
Level 1	80	41	7.3	4.1	5.5
Level 2	80	155	27.8	1.4	2.4
Level 3	80	249	44.6	1.5	1.7

CORRELATION

A comparative study has been performed between an Envoy500 Analyzer and an FDA-approved system equipment (Iron Ferrozine method) on 62 human serum samples according to CLSI[®] EP9-A2 protocol.

The sample concentrations were between 18 and 970 µg/dL (3.2 and 173.7 µmol/L). The parameters of the linear regressions are as follows :
Correlation coefficient: (r) = 1.000
Linear regression: y = 1.003 x - 1 µg/dL (0.2 µmol/L)

LIMITATIONS/ INTERFERENCES

- Do not report results outside of the usable range.

- Studies have been performed to determine the level of interference from different compounds according to CLSI[®] EP7-A2 protocol. Recovery is within ± 10% of initial value of iron concentration of 40 µg/dL, 150 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 1705 mg/dL (19.27 mmol/L).
Ascorbic acid: No significant interference up to 20 mg/dL (1136 µmol/L).
Copper: No significant interference up to 500 µg/dL (78.7 µmol/L).
Acetylsalicylic acid: No significant interference up to 200 mg/dL.
Acetaminophen: No significant interference up to 30.0 mg/dL (1.98 mmol/L).

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

- Many other substances and drugs may interfere. Some of them are listed in Young.^(11,12)

- The results of this assay should only be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

ON BOARD STABILITY/ CALIBRATION FREQUENCY

On board stability : 28 days

Calibration frequency: 28 days

Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

ESPAÑOL - ES

Para el diagnóstico *in vitro*, de uso exclusivo profesional

USO PREVISTO

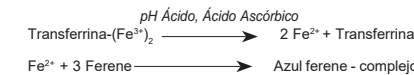
IRON ENVOY es un reactivo de diagnóstico *in vitro* diseñado para la determinación cuantitativa del hierro total en suero humano en los equipos Envoy.

SIGNIFICADO CLÍNICO ^(1,2)

En el cuerpo humano, entre el 65 - el 70% de hierro entran en la composición de la hemoglobina, 25% se almacena en las células como un complejo de hierro de la ferritina y el 3% es transportado por la transferrina. Los niveles de hierro en suero se incrementan en la hemocromatosis o daño en el hígado. Niveles de hierro sérico bajos pueden estar asociados a un aumento de las necesidades, una deficiencia en la dieta o trastornos gastrointestinales (diarrea crónica, sangrado intestinal o de mala absorción). Niveles de hierro sérico siempre se interpreta junto con los datos de saturación de transferrina.

MÉTODO E PRINCIPIO ^(1,2)

El hierro se libera de la transferrina en pH ácido como un ión férrico Fe³⁺. Se reduce entonces por el ácido ascórbico en ion ferroso Fe²⁺ y, finalmente, formar un complejo coloreado con ferene. La absorbancia 578 nm del complejo de hierro ferene es proporcional a la concentración de hierro de la muestra.



REACTIVOS

COMPOSICIÓN

IRON ENVOY Reactivo 1 contiene:

Tiourea	120	mmol/L
Tampón acetato pH 4.5	1	mol/L

IRON ENVOY Reactivo 2 contiene:

Ferene	3	mmol/L
Ácido ascórbico	240	mmol/L
Tiourea	120	mmol/L

ATENCIÓN Y PRECAUCIONES

- Este kit esta únicamente destinado a los profesionales de diagnóstico *in vitro*.

- El reactivo R1 esta clasificado como peligroso:



PELIGRO. Provoca irritación cutánea. Provoca lesiones oculares graves. Llevar guantes/prendas/gafas/máscara de protección. EN CASO DE CONTACTO CON LA PIEL: Lavar con abundante agua y jabón. EN CASO DE CONTACTO CON LOS OJOS: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado. Llamar inmediatamente a un CENTRO DE TOXICOLOGÍA/médico. En caso de irritación cutánea: Consultar a un médico. Quitar las prendas contaminadas y lavarlas antes de volver a usarlas.

