IRON

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-0120 **Packaging:** 6 x 15 mL (R1) + 6 x 3 mL (R2)

REF 1419-0122 **Packaging:** 6 x 37.5 mL (R1) + 6 x 7.5 mL (R2)

Σ 440

Σ 1122

INTENDED USE

Reagents for In Vitro quantitative automated determination of Iron in samples of human serum or plasma from the general patient population. Measurements of iron are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for the screening, diagnosis and management of Iron metabolism disorders.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE

Iron concentration in serum increases in cases of pernicious, aplastic or hemolytic anemia, hemochromatosis, acute leukemia, molybdosis, acute hepatitis, vitamin B6 deficiency, thalassemia, high iron intake during treatment, repeated blood transfusions, acute iron poisoning, nephritis.
Decrease in iron concentration is observed in iron-deficiency anemia, acute and chronic infections, carcinoma, nephrosis, hypothyroidism, postoperative state, Kwashiorkor. Iron levels may vary widely during the day and from day to day.

METHOD PRINCIPLE

The method uses ferrozine as chromogen. At pH <4.7, Fe (III) is released from transferrin and in the presence of hydroxylamine is reduced to Fe (II) which forms a complex with ferrozine. The absorbance at 550/750nm is proportional to the iron concentration in the sample. The presence of thiourea eliminates any cupric ion interference in the reaction.

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)		Reagent 2 (R2)	
Acetate buffer (pH 4.5):	100 mM	Acetate buffer (pH 4.5):	100 mM
Thiourea:	210 mM	Ferrozine:	6 mM
Hydroxylamine salt:	350 mM		

⚠ **WARNINGS – PRECAUTIONS**

- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- The kit contains thiourea ≤ 2%. Avoid swallowing and contact with skin and mucous membranes.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**

Reagents R1 and R2 are ready-to-use. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**

Unopened, reagents are stable at 2 – 8°C up to the expiry date stated on the label. Once opened, they remain stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Use Serum, or Li-heparin plasma may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible and store properly if analysis cannot take place right after sample separation. After the serum or plasma has been separated from red cells, Iron is stable for 4 days at 15 - 25°C or for up to 7 days at 2 - 8°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to Medicon Master Lot, for calibration. Calibrate the assay every 2 weeks when used on Diatron Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control.
Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- Iron calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum: 70 – 180 μg/dl (men)
60 – 180 μg/dl (women)
95 – 225 μg/dl (infants)
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**

The kit contains thiourea. Flush waste pipes with water after the disposal of undiluted reagent in the drain.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

Linearity Up to 1000 μg/dL
Lowest detection limit 7.0 μg/dL
The lowest detection limit (LD
L) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).\

Pictus® P700 and P500	
Level (μg/dL)	**%CV**
64.8	2.32
182	1.40
Level (μg/dL)	**TOTAL %CV**
64.8	3.47
182	1.95

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Hemoglobin	1650 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and analyzer and another commercially available product. The results were as follows:
Y = 1.032X + 3.124 R=0.9618 N=40 Sample Range: 10.7-142 μg/dL

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, Jr, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.

⚠ **LABEL ELEMENTS**

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P280: Wear protective gloves/protective clothing/eye protection/face protection.	**H290**: May be corrosive to metals.
P301+312: IF SWALLOWED: Seek medical attention if you feel unwell.	**H302**: Harmful if swallowed.
P302+352: IF ON SKIN: Wash with plenty of water/.	**H312**: Harmful in contact with skin.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	**H315**: Causes skin irritation.
P308+313: IF exposed or concerned: Get medical attention.	**H317**: May cause an allergic skin reaction.
P321: Specific treatment (see instructions on label).	**H319**: Causes serious eye irritation.
	H351: Suspected of causing cancer
	H361d: Suspected of damaging the unborn child.
	H373: May cause damage to organs through prolonged or repeated exposure
	H400: Very toxic to aquatic life.
	H411: Toxic to aquatic life with long lasting effects.

SYMBOLS

Manufacturer
IVD *In vitro* diagnostic medical device
Temperature Limit
REF Catalogue Number
Caution
Σ Contains sufficient for <n> tests

* PICTUS®: Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement.

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

Version 4 - Last updated 2020.06.30

CE IVD