diatron

UIBC

UNSATURATED IRON BINDING CAPACITY

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

2°C 8°C REF 1419-0282 **Packaging:** 6 x 27 mL (R1) + 6 x 4.5 mL (R2) + 6 x 1.5 mL (R3) Σ 540

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

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
The determined concentration of iron in serum is usually Fe (III) bound to serum transferrin and does not include the iron contained in serum as part of the free hemoglobin. Only about one third of transferrin iron binding sites are taken up by Fe (III); normally serum transferrin has a high iron binding capacity. That is named unsaturated, or dormant, iron binding capacity. UIBC measurement can be used in combination with the concentration of serum iron for the determination of total iron binding capacity (TIBC), that is, the maximum concentration of iron that serum proteins—mainly transferrin—can bind. TIBC is reduced in chronic infections, malignancy, iron poisoning, kidney disease, Kwashiorkor type pellagra, and thalassemia. Common causes of TIBC increase include iron deficiency anemia, advanced pregnancy, oral contraception and infectious hepatitis.

METHOD PRINCIPLE
The Nitrozo-PSAP method is used. Unsaturated Iron Binding Capacity (UIBC) is determined by adding at alkaline pH an excess of iron to the sample, in order to saturate the iron binding sites of transferring. After reduction the unbound iron reacts with Nitroso-PSAP to form a coloured complex. The difference between the amount of iron added and the amount of iron measured represents the Unsaturated Iron Binding Capacity.

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

Tris Buffer (pH 8.4) 500 mM
FeCl2
Nitroso – PSAP
Preservative

⚠ **WARNINGS – PRECAUTIONS**

- The reagent has been manufactured for in vitro diagnostics use only. In vitro diagnostics may be dangerous. Use according to the proper laboratory techniques; that is, avoid inhalation and contact with the eyes and skin.
- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- 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 of all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
Reconstitute R1 with all of the contents of R3. Mix gently until it is completely dissolved. The reconstituted reagent R1 and R2 are ready to use. Vials bear barcodes for recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
The reagent should not be used:

- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to high temperature or sunlight.

⚠ **SHELF LIFE**
Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8°C. Reconstituted R1 and opened R2 can be stored for 1 month in the cooled reagent tray of 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 haemolyzed, 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, UIBC 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 serum calibration. Calibrate the assay every 3 weeks. Perform a Reagent Blank measurement every 1 week. 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 Lev.1 & 2 (1578-0901-12 & 1578-0902-12) for quality control. Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for UIBC should be verified with the corresponding working protocol. Results outside the specified values 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

- UIBC Calibrator
- Diatron Pictus® analyzer
- Quality control materials
- Common laboratory equipment

REFERENCE INTERVALS
Serum: 155 – 300 µg/dL
Each laboratory should determine its own expected values as dictated by good laboratory practice.

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: The assay is linear within measuring range 51 – 400 µg/dL. When values exceed this range samples should be diluted accordingly.
Lowest Detection Limit: The lowest detectable level of UIBC is estimated at 3 µg/dL.
The lowest detection limit (LDL) 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**
140	1.11
248	0.90
Level (µg/dL)	**TOTAL %CV**
140	1.92
248	1.94

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

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	50 mg/dL
Conj. Bilirubin	50 mg/dL
Ascorbic Acid	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Y = 0.929X – 4.835 R=0.9798 N=65 Sample range = 24 – 406 µg/dL

BIBLIOGRAPHY

1. Tietz NW, ed. Clinical guide to laboratory tests, 3rd ed. Philadelphia: WB Saunders Company, 1995:376-377.
2. Fairbanks VF, Klee GG. Biochemical aspects of hematology. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia: WB Saunders Company, 1999; 1698-1703.
3. Woo J, Henry JB. Metabolic intermediates and inorganic ions. In: Henry JB, ed. Clinical diagnosis and management by laboratory methods. Philadelphia Saunders Company, 1996:188-190.
4. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev.2:36pp.
5. Perrotta G. Iron and total iron binding capacity. In: Kaplan LA, Pesce AJ, eds. Clinical chemistry theory, analysis, and correlation. St Louis: Mosby, 1996:714pp.
6. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

⚠ **LABEL ELEMENTS**

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P201: Obtain special instructions before use.	**H290:** May be corrosive to metals.
P280: Wear protective gloves/protective clothing/eye protection/face protection.	**H300:** Fatal if swallowed
P302+P352: IF ON SKIN: Wash with plenty of water.	**H302:** Harmful if swallowed.
P308+P313: IF exposed or concerned: Get medical advice/attention.	**EUH032:** Contact with acids liberates very toxic gas.
P321: Specific treatment (see supplemental first aid instruction on this label)	**H312:** Harmful in contact with skin.
P362+P364: Take off contaminated clothing and wash it before reuse.	**H315:** Causes skin irritation.
	H317: May cause an allergic skin reaction.
	H319: Causes serious eye irritation.
	H373: May cause damage to organs through prolonged or repeated exposure
	H400: Very toxic to aquatic life.
	H351: Suspected of causing cancer
	H361d: Suspected of damaging the unborn child.
	H400: Very toxic to aquatic life.
	H410: Very toxic to aquatic life with long lasting effects.
	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

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