FERRITIN

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

2°C – 8°C

REF 1419-0273 **Packaging:** 6 x 8 mL (R1) + 6 x 4 mL (R2) Σ 300

INTENDED USE
Reagents for In Vitro quantitative automated determination of Ferritin in samples of human serum or plasma from the general patient population. Measurements of Ferritin are to be used as an aid for 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
Serum ferritin test is particularly useful for distinguishing between iron deficiency and anemia due to chronic disorders, because in these cases ferritin levels are increased. Serum ferritin levels below 10 μg/L almost always suggest iron deficiency. Serum ferritin is also increased in other anemias such as aplastic anemia, ferroblastic anemia and chronic hemolytic anemia. In idiopathic hemochromatosis and in multi-transfusion patients it may be exceptionally high. Ferritin is also an acute phase protein, so its concentration is increased in inflammation.

METHOD PRINCIPLE
The turbidimetric method is applied. When sample is mixed with the appropriate buffer (R1) and latex particles coated with anti-Ferritin Fab_2 fraction (R2), ferritin reacts with the antibodies leading to agglutination of latex particles. This agglutination is detected as turbidity change at 750 nm and it is proportional to Ferritin concentration in the sample.

METHOD LIMITATIONS
Samples from patients that have undergone therapy with the preparations containing monoclonal rabbit antibodies, heterophilic or HAMA antibodies may be found in increased quantities. Although the reagent is formulated to exhibit extremely low cross contamination from HAMAs, Heterophilic antibodies and Rheumatoid factors, discordant results must always be interpreted with the possibility of cross contamination. 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)
Tris Buffer (pH 7.2):120 mM Non-reactive components and preservatives	Latex particles coated with rabbit antibodies (Fab)2 against human Ferritin. Non-reactive components and preservatives

⚠ **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 according to universal precautions and good laboratory practices.
- Antisera are raised in clinically healthy animals in monitored facilities under constant surveillance.
- Dispose all waste according to national laws.
- 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!
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
R1 is ready to use and can be placed directly in the corresponding position on the analyzer. R2 needs to be mixed via inversion 5 – 10 times before being placed on the instrument and the stirring must be repeated on a weekly basis. Vials bear barcode 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.

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

⚠ **SAMPLE** Serum, or Li-heparin plasma may be used as specimen. Plasma samples exhibit lower values by 10%. 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. Ferritin remains stable in serum or plasma for 7 days at 2 - 8°C and 6 months at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON Ferritin Calibrator (1478-0275), traceable to the 3rd International Standard for Ferritin NIBSC 94/572. Calibrate the assay every 2 weeks on 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 Immunology Control Levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04 respectively) for quality control. Control target values and limits should fall within the acceptable intervals. Target values for Ferritin 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
- Ferritin calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum/Plasma: Infants:	25 – 200 ng/ml
6 months-15 years:	7 – 142 ng/ml
Adult men:	20 – 300 ng/ml
Adult women:	10 – 120 ng/ml

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 Up to 450 ng/mL
Hook effect: > 40000 ng/mL
Lowest detection limit 4.3 ng/mL

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 (ng/mL)	**Level (ng/mL)**
40.3	40.3
115.8	115.8
Level (ng/mL)	**Level (ng/mL)**
40.3	40.3
115.8	115.8

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

	(Insignificant up to)
Triglycerides	2700 mg/dL
Hemoglobin	450 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 P500 analyzer and another commercially available product. The results were as follows:
Y = 0.909X + 4.507 R=0.9915 N=45 Sample Range: 13.8 – 447 ng/mL

BIBLIOGRAPHY

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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.
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SYMBOLS

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

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Version 4 - Last updated 2020.06.30

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