diatron

FERRITIN

For use on Diatron Pictus® series analyzers

Method: Turbidimetry
Product Code: 1419-0273, 1419-0274
Package: 6x8 mL (R1) + 6x4 mL (R2), 6x32 mL (R1) + 6x16 mL (R2)
Store at: 2 – 8°C
For *in vitro* use

INTENDED USE
Reagents for the quantitative immunoturbidimetric determination of Ferritin in human serum or plasma, specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
Serum ferritin 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, sideroblastic 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".

The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
Reagent 1:
Tris Buffer (pH 7.2): 120 mM
Non reactive components and preservatives
Reagent 2:
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.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT 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 Pictus® series 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 28 days if stored in the cooled reagent tray of Pictus® series analyzers.

SAMPLE
Serum or plasma samples collected with heparin or EDTA anticoagulant should be used. Ferritin is stable in serum and plasma up to 7 days at 2°– 8°C and up to 6 months at –20°C.

CALIBRATION
Diatron provides Ferritin Calibrator (1478-0275), traceable to the 3rd International Standard for Ferritin NIBSC 94/572. Calibrate the assay every 14 days on Pictus® series 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 provides the Ferritin Control or the the 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 material
- Diatron Pictus® P400/P700/P500
- 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® series 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.

	Pictus® P400	Pictus® P700/P500 series
Linearity	Up to 450 ng/mL	Up to 450 ng/mL
Hook effect:	> 40000 ng/mL	> 40000 ng/mL
Lowest detection limit	6.9 ng/mL	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® P400			Pictus® P700/P500 series		
Level (ng/mL)	Within Run CV%	Total CV%	Level (ng/mL)	Within Run CV%	Total CV%
42.2	4.15	5.95	52.0	5.23	5.68
140	3.75	4.25	124	4.88	5.13
304	3.45	4.15	301	4.14	4.75

Interference: Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500 series
Lipemia	Insignificant up to Intralipid® 700 mg/dl	Insignificant up to 900 mg/dl Intralipid®
Hemoglobin	Insignificant up to 450 mg/dL	Insignificant up to 450 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P400
Y = 0.905X – 5.992 R=0.989 N=80 Sample range: 27 – 504 ng/mL
Pictus® P700/P500 series
Y = 0.909X + 4.507 R=0.9915 N=45 Sample range: 13.8 – 447 ng/mL

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
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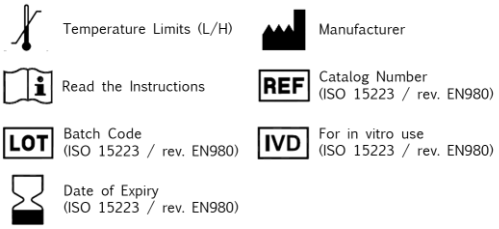
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
5. Bernard A., Lauwerys R. Turbidimetric latex immunoassay for serum ferritin. Journal of Immunological methods 1984; 71:141-147.

SYMBOLS


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