FERRITIN
For discrete analyzers
Method: Turbidimetry
Product Code: 1418-0273 4 x 16 ml (R1) + 4 x 16 ml (R2)
1418-0274 2 x 8 ml (R1) + 2 x 8 ml (R2)
Store at 2 – 8 °C
For in vitro use

INTENDED USE
MEDICON Ferritin is a set of immunoturbidimetric reagents for the quantitative determination of Ferritin in human serum or plasma, with BECKMAN COULTER AU400/600/800/IVD/40/2700/5400 and other discrete 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 may be exceptionally high.

METHOD PRINCIPLE
The turbidimetric method is applied. When the sample is mixed with the appropriate buffer (R1) and latex particles coated with anti-Ferritin (R2), Ferritin reacts with the antibodies leading to agglutination of latex particles. This agglutination is detected as turbidity change at 800 nm and it is proportional to Ferritin concentration in the sample.

METHOD LIMITATIONS
In samples from patients that have undergone therapy or have been diagnosed with the use of preparations containing monoclonal rabbit antibodies, heterogeneous antibodies may be found in increased quantities.

WARRANTS – PRECAUTIONS
● This test 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 from MEDICON upon request.

REAGENT PREPARATION
R1 is ready to use and can be placed 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. Visit bar code recognition by BECKMAN COULTER AU series analyzers.

REAGENT DETERIORATION
The reagent shall 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 90days if stored refrigerated on the instrument.

SAMPLE
Serum, heparinized or EDTA-collected plasma. Ferritin is stable in serum/plasma up to 7 days at 2 – 8 °C and up to 8 months at -20 °C.

CALIBRATION
MEDICON provides the Ferritin calibrator (1478-0275), traceable to the 3rd International Standard for Ferritin NIBSC 84/372. Recalibrate the assay every 15 days. Recalibration is also needed following preventive maintenance or replacement of a critical part of the analyzer, when using a new reagent kit or a new reagent lot number, or when Quality Control results are out of range.

QUALITY CONTROL
MEDICON provides the following products for quality control: Ferritin Medicon Control (Cat. No. 1478-0276) 2x1ml (low) + 2x1ml (high).

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
Automated biochemistry 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

Linearity
The assay is linear within measuring range 6.0 – 450 ng/ml.

Prozone Tolerance
No hook effect is observed up to 10,000 ng/ml.

Sensitivity
The lowest detectable level of Ferritin is estimated at 4 ng/ml.

The lowest detection limit (DDL) 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 DDL is calculated as the absolute mean plus three standard deviations.

Precision

<table>
<thead>
<tr>
<th>Level</th>
<th>Within run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>ng/ml</td>
<td>%CV</td>
<td>%CV</td>
</tr>
<tr>
<td>48.6</td>
<td>2.16</td>
<td>3.30</td>
</tr>
<tr>
<td>131</td>
<td>1.06</td>
<td>2.08</td>
</tr>
<tr>
<td>278</td>
<td>1.18</td>
<td>2.62</td>
</tr>
</tbody>
</table>

Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Interference

- Lipemic: insignificant to up 1000 mg/dL, intralipid®
- Hemoglobin: insignificant to up 500 mg/dL
- Non Conj. Bilirubin: insignificant to up 40 mg/dL
- Conj. Bilirubin: insignificant to up 40 mg/dL
- RF: insignificant to up 1040 UI/mL
- Acetic acid: insignificant to up 3 mg/dL

Refer to Young for further information on interfering substances.

Method Comparison
A comparison was performed between this reagent and another commercially available product. The results were as follows on a BECKMAN COULTER AU series analyzer:

Y = 0.94X + 6.29, R²=0.998
N=127
Sample range: 4 – 404 ng/mL

BIBLIOGRAPHY

SYMBOLS

- Biohazard (ISO 15223/rev. EN860/ISO7000)
- Manufacture (ISO 15223/rev. EN860)
- Current enough for installation (ISO 15223/rev. EN860)
- Production Date (ISO 15223/rev. EN860/ISO7000)
- For in vitro use (ISO 15223/rev. EN860)