**INTENDED USE**
Vitro Ferritin - Turbilatex is a quantitative turbidimetric test for the measurement of Ferritin in human serum or plasma on both manual and automated systems.

**CLINICAL SIGNIFICANCE**
Serum ferritin concentration usually reflects body iron stores and is considered one of the most reliable indicators of iron status of patients. Whereas low serum concentrations of ferritin are always indicative of an iron deficiency, elevated concentrations can occur for variety of reasons. Thus, although elevated concentrations often indicate an excessive iron intake, they are also caused by liver disease, chronic inflammation and malignancies. Pregnant women, blood donors, hemodialysis patients, adolescents and children are groups particularly at risk.

**ASSAY PRINCIPLE**
Ferritin-turbilatex is a quantitative turbidimetric test for the measurement of ferritin in human serum or plasma. Latex particles coated with specific anti-human ferritin are agglutinated when mixed with samples containing ferritin. The agglutination causes an absorbance change, dependent upon the ferritin contents of the sample that can be quantified by comparison from a calibrator of known ferritin concentration.

**PROCEDURE**

- **Wavelength:** 540 nm (530-550)
- **Temperature:** 37°C
- **Cuvette light path:** 1 cm
- **Zero adjustment** against distilled water.

Mix and read the absorbance immediately (A1) and after 5 minutes (A2) of the sample addition.

**CALCULATIONS**
Calculate the absorbance difference (A2-A1) of each point of the calibration curve and plot the values obtained against the ferritin concentration of each calibrator dilution. Ferritin concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve.

**QUALITY CONTROL**
It is recommended that controls (normal and abnormal) be included in:
- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established ferritin values may be routinely used for quality control. Failure to obtain the proper range of values in the assay of control material may indicate:
- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:
- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

**MEASURING RANGE**
Up to 600 µg/L. Samples with higher values should be diluted 1/5 in NaCl 9 g/L and retested. The upper linearity limit increases as the sample volume and the sensitivity decrease.

Detection limit: 5.04 µg/L.
Detection limit: Values under 6.6 µg/L may give non-reproducible results.

**PROZONE EFFECT**
No prozone effect was detected at least up to 9000 µg/L.

**PRECISION**
According to the EPS-A2 standards (CLSI), the reagent has been tested for 20 days, measuring each level per duplicate twice a day (n=80):

**MEASUREMENT**

- **Precision:** 10% at ferritin concentrations of 7 µg/L
- **Precision:** 9% at ferritin concentrations of 340 µg/L
- **Precision:** 8% at ferritin concentrations of 3150 µg/L
- **Precision:** 7% at ferritin concentrations of 10,500 µg/L

**STORAGE & STABILITY**
All the components of the kit are stable under the expiration date on the label when stored tight closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

**Stability:**
- **Preparation & Storage:** Prepare and store immediately.
- **Expiration Date:** See the vial label.
- **Expiration Date:** All the components of the kit are stable until the expiration date.

**SPECIMEN**
- **Fresh Serum:** Stable 7 days at 2-8°C or 3 months at –20°C.
- **Samples with presence of fibrin:** should be centrifuged before testing.

Do not use highly hemolyzed or lipemic samples.

**EC REP**
Medical Device Safety Services
MDSS GmbH, Burckhardtstr. 1
30163 Hannover, Germany.
Method comparison: The reagent was compared to another commercially available Ferritin reagent by testing 144 samples (male and female), with concentrations between 6.97 and 730 µg/L. The coefficient of correlation (r) was 0.988, and the equation y = 0.96x + 1.15
Performance characteristics depend on the analyzer used.

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<tr>
<th></th>
<th>intra-assay (n=80)</th>
<th>Total n=80</th>
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<tbody>
<tr>
<td>Mean(µg/L)</td>
<td>33.4 114.5 289.8</td>
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<tr>
<td>SD</td>
<td>1.7 1.4 2.4</td>
<td>2.1 3.4 7.5</td>
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<tr>
<td>CV (%)</td>
<td>5.1 1.2 0.8</td>
<td>8.3 2.9 2.6</td>
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INTERFERING SUBSTANCES
Bilirubin (40 mg/dL), hemoglobin (5 g/L) and rheumatoid factor (750 UI/mL), do not interfere. Lipids (=2.5 g/L) do interfere. Other substances may interfere.

NOTES
1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However, handle the material as if infectious.
3. Reagent contains 0.1% Sodium azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures.
5. Shake the Vitro FERRITIN latex reagent well before use to disperse the latex particles uniformly and improve test readability.

BIBLIOGRAPHY

SYMBOL DECLARATION

- Manufacturer
- Consult instructions for use
- Batch code (Lot #)
- Catalog number
- Temperature limitation
- In vitro diagnostic medical device
- Use by
- Caution. Consult instructions
- Keep away from light

ORDERING INFORMATION

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