Ferritin MonlabTest®
Latex Turbidimetry.
Quantitative determination of Ferritin.
Only for professional in vitro diagnostic use. Store at 2-8°C.

INTENDED USE
Turbidimetric immunoassay for the quantitative determination of ferritin in human serum or plasma.

PRINCIPLE OF THE METHOD
Ferritin Monlabtest 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.

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 a 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.

REAGENTS

| Diluent (R1) | Tris Buffer 20 mM, pH 8.2. Preservative. |
| Latex (R2) | Anti-human ferritin antibody coated latex particles, pH 8.2. Preservative. |
| Ferritin Calibrator | Calibrator. Ferritin concentration is stated on the vial. |

Ref: MO-165056 Ferritin Control.

PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

PREPARATION
Ferritin Calibrator: Reconstitute (-/+) with 3.0 mL of distilled water. Mix gently and incubate at room temperature for about 10 minutes before testing.

CALIBRATION
Use Ferritin Calibrator Monlabtest Reference MO-165055. The sensitivity of the assay and the target value of the calibrator have been standardized against the 3rd International Standard of Ferritin (94/572, 2008 WHO). Recalibrate when control results are out of specified values; when using a different lot of reagent and when the instrument is adjusted. Calibrator curve: Prepare the following dilutions of the FERR Calibrator using NaCl 9 g/L. To obtain the concentration of each dilution, multiply using the dilution factor shown in the next table:

<table>
<thead>
<tr>
<th>Calibrator dilution</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>NaCl 9 g/L (µL)</td>
<td>100</td>
<td>66,6</td>
<td>66,6</td>
<td>66,6</td>
</tr>
<tr>
<td>Calibrator FERR (µL)</td>
<td>-</td>
<td>33,3</td>
<td>33,3</td>
<td>33,3</td>
</tr>
<tr>
<td>Dilution Factor</td>
<td>0</td>
<td>1/3</td>
<td>2/3</td>
<td>1,0</td>
</tr>
</tbody>
</table>

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents after the expiration date.

Reagent deterioration: Presence of particles and turbidity. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT
- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 540 nm filter.

SAMPLES
Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

PROCEDURE
1. Bring the reagents and the photometer (cuvette holder) to 37°C.
2. Assay conditions:
   - Wavelength: 540 nm (530-550)
   - Temperature: 37°C
   - Cuvette length path: 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette: Diluent (R1) 800 µL, Latex (R2) 200 µL, Calibrator or sample 90 µL.
5. Mix and read the absorbance immediately (A₁) and after 5 minutes (A₂) of the sample addition.

CALCULATIONS
Calculate the absorbance difference (A₁-A₂) 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 (A₁-A₂) in the calibration curve.

QUALITY CONTROL
Control Sera are recommended to monitor the performance of manual and automated assay procedures. It should be used the Ferritin Control Monlabtest (Ref: MO-165056). Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES
Men: 30 – 220 µg/L.
Women: 20 – 110 µg/L.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
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.

Quantification 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 (CLS1), the reagent has been tested for 20 days, measuring each level per duplicate twice a day (n=80):
  - Intra-assay (n=80): Mean (µg/L) 33.4, CV (%) 1,0, 2.4. Total (n=80): Mean (µg/L) 33.4, CV (%) 1,0, 2.8.

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.

INTERFERENCES
Bilirubin (40 mg/dL), hemoglobin (5 g/L), y and rheumatoid factor (750 UI/mL), do not interfere. Lipids (≥ 2.5 g/L) do interfere. Other substances may interfere.

NOTES
Clinical diagnosis should not be based on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

PACKAGING
Ref.: MO-165032
- R1: 1 x 40 mL
- R2: 1 x 10 mL
- Ferritin Calibrator: 1 x 3 mL