INTRODUCTION
Ferritin is an iron-containing protein with a molecular weight of approximately 450 kD. It is found mainly in the human liver and spleen, where its function is to eliminate and store iron in the body, and is also found in small amounts in human serum. This amount varies according to the movement of iron in the body, and hepatitis and malignant tumors, may be seen to increase due to cell destruction or tumor cell production, independent of iron reserves. Consequently, the measurement of ferritin is considered to be useful in the diagnosis, treatment, assessment of disease progression, and postoperative prognosis for such disease conditions.

METHOD PRINCIPLE
When an antigen-antibody reaction occurs between ferritin in a sample and anti-ferritin antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of ferritin in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

REAGENTS
Package
1-Reagent 1 x 40.5 ml
2-Reagent 1 x 24 ml

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and contamination!

Concentrations in the test
suspension of latex particles sensitized with anti-ferritin (rabbit) antibodies (pH 7.3) 0.07 w/v% glycine buffer solution (pH 8.3)

WARNINGS AND NOTES
- Product for in vitro diagnostic use only.
- After measurements are taken, reagent bottles should be capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT
- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN
Serum.
If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided. Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
The reagents are ready to use.
These reagents may be used in automatic analysers according to their user manual. Applications for analysers are available on request. These reagents may be used directly in Hitachi 911/912 analysers.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:
1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES

<table>
<thead>
<tr>
<th>Serum</th>
<th>ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>male</td>
<td>20 – 250</td>
</tr>
<tr>
<td>female</td>
<td>10 – 120</td>
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</tbody>
</table>

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL II (Cat. No 4-290) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY FERRITIN CALBRATORS kit (Cat. No 4-491) is recommended.
Calibrators and 0.9% NaCl should be used for calibration.
Calibration stability depends on type of analyser used for analysis. The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using the automatic analysers Hitachi 912 and Hitachi 917. Results may vary if a different instrument is used.

- Sensitivity: 9.2 ng/ml.
- Linearity: up to 1200 ng/ml.
For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- Specificity / Interferences
Haemoglobin up to 0.98 g/dl, bilirubin up to 62 mg/dl, RF up to 520 IU/ml, triglycerides up to 500 mg/dl do not interfere with the test.

- Precision

<table>
<thead>
<tr>
<th></th>
<th>Mean [ng/ml]</th>
<th>SD [ng/ml]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>level 1</td>
<td>32.35</td>
<td>0.96</td>
<td>2.98</td>
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<tr>
<td>level 2</td>
<td>1028.95</td>
<td>18.35</td>
<td>1.78</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th>Mean [ng/ml]</th>
<th>SD [ng/ml]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>level 1</td>
<td>16.47</td>
<td>0.87</td>
<td>5.31</td>
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<tr>
<td>level 2</td>
<td>105.18</td>
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<tr>
<td>level 3</td>
<td>428.71</td>
<td>3.52</td>
<td>0.82</td>
</tr>
</tbody>
</table>

CORMAY FERRITIN page 1
Method comparison
A comparison between ferritin values determined at Hitachi 912 (y) and at Advia 1650 (x) using 28 samples gave following results:

\[ y = 0.8682 \times - 0.9027 \text{ ng/ml} \]

\[ R = 0.9950 \quad (R – \text{correlation coefficient}) \]

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

Date of issue: 09. 2017.