1. INTENDED USE
The kit has been designed for the quantitative determination of Ferritin in human serum.
The method can be used for samples over the range of 0-3000 ng/ml.

2. SUMMARY AND EXPLANATION OF THE TEST
Ferritin is a high-molecular iron storage protein (MW approx. 450,000) which can incorporate varying amounts of iron in the form of iron (II) complexes. The iron represents approximately 25% of the total molecular weight.

3. PRINCIPLE OF THE TEST
Sandwich immunoluminometric assay:
Use an anti-ferritin monoclonal antibody to label ABEI, and use another monoclonal antibody to label FITC. Sample, Calibrator or Control, FITC Label, and magnetic microbeads coated with anti-FITC are mixed thoroughly and incubated at 37 °C and cycle washing for 1 time. Then add ABEI Label, incubation and form a sandwich, then washing for the 2nd time. Subsequently, the starter reagents are added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as RLU within 3 seconds and is proportional to the concentration of ferritin present in controls or samples.

4. KIT COMPONENTS
4.1 Material supplies

| Reagent integral for 100 determinations | Nano magnetic microbeads: TRIS buffer, 1.2%(W/V), 0.2% NaN₃, coated with sheep anti-FITC polyclonal antibody. |
| Calibrator low | 2.5ml |
| Calibrator high | 2.5ml |
| ABEI Label: anti-ferritin monoclonal antibody labeled ABEI, contains BSA, 0.2% NaN₃ | 22.5ml |
| FITC Label: anti-ferritin monoclonal antibody labeled FITC, contains BSA, 0.2% NaN₃ | 12.5ml |
| Diluent: | 25ml |

All reagents are provided ready-to-use.

4.2 Preparation of the Reagent Integral
Before the sealing is removed, gentle and careful horizontal shaking of the Reagent Integral is essential (avoid foam formation)! Remove the sealing and turn the small wheel of the magnetic microbeads compartment to and fro, until the colour of the suspension has changed into brown. Place the integral into the reagent area and let it stand there for 30 mins. During this time, the magnetic microbeads are automatically agitated and completely resuspended.

4.3 Storage of the Reagents Integral
- Sealed: Stored at 2-8 °C until the expiry date.
- Opened: Stable for 4 weeks. After this period, it is still possible to keep on using the Reagent Integral provided that the controls are found within the expected ranges.
- Keep upright for storage.
1. Quality Control

- Observe quality control guidelines for medical laboratories.
- Use suitable controls for in-house quality control.

2. Results

12.1 Interpretation of Results

- Reference values: male 25-350ng/ml
  Female 13-232ng/ml
- Results may differ between laboratories due to variations in population and test method. Each laboratory should establish its own reference range.

13. Limitations of the procedure

13.1 Elevated ferritin serum levels have also been found in certain hepatic disorders, acute or chronic inflammations as well as in manifest or latent infections([8]). Therefore, ferritin serum levels may only be interpreted in context with the clinical picture and other diagnostic procedures.

13.2 HAMA

Patient samples containing human anti-mouse antibodies (HAMA) may give falsely elevated or decreased values. Although HAMA-neutralising agents are added, extremely high HAMA serum concentrations may occasionally influence results.

14. Performance Characteristics

14.1 Accuracy

Consider calibrator high of known concentration as a sample, dilute it by 1:2 ratio with diluent, and measure its diluted concentration for 10 times. Then calculate the recovery of measured concentration and expected concentration. The recovery should be within 90% -110%.

14.2 Precision

Intra-assay coefficient of variation was evaluated on Calibrator High repeatedly measured 10 times in the same assay, calculating their coefficient of variation, the results should be ≤10%.

Inter-assay coefficient of variation was evaluated on three batches of kit, repeatedly measured 10 times of Calibrator High, calculating three batches of kit for Calibrator High between the measured values of the coefficients of variation, the results should be <15%.

14.3 Sensitivity

The sensitivity of the assay defined as the concentration of Ferritin equivalent to the mean RLU of 20 replicates of the zero standard plus two standard deviations corresponding to the concentration from the standard curve. The sensitivity is typically less than 1.3 ng/ml.

14.4 Specificity

The specificity of the Ferritin assay system was assessed by measuring the apparent response of the assay to various potentially cross-reactive analytes. The following cross-reactivities were found:

When Human liver ferritin=850ng/ml, the detection results of ferritin >700ng/ml;
When Human spleen ferritin=450ng/ml, the detection results of ferritin >225ng/ml;
When Human heart ferritin=500ng/ml, the detection results of ferritin<5ng/ml.

14.5 Linearity

Conduct a logarithmic transform to the RLU value and concentration value of 5 standards. After a double logarithmic fitting, the absolute value of its linearity should exceed 0.9800.

15. References

4. Deshpande UR, Nadkarni GD, Samuel AM. Serum Ferritin in Thyroid Cancer. Thyroid 1993; 3 (4): 301-303