SYMBOL KEYS

	Temperature limitation		Manufacturer		This way up	SC	Smart card (RFID)
	Use by		Consult Instructions for use	Σ	Contains sufficient for <n> tests	CT	Cuvettes
	Date of Manufacture	REF	Catalogue Number	EC REP	Authorised Representative in the European Community	R1	Activation Buffer
LOT	Batch Number/ Lot Number	IVD	*In vitro* Diagnostic Medical Device			R2	Latex Reagent

TULIP DIAGNOSTICS (P) LTD.

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MANUFACTURING UNIT: PLOT NOS. 92/96, PHASE II C, VERNA IND. EST., VERNA, GOA-403 722, INDIA.

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

1221/VER-01

CE

turbosmart™

Ferritin

IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF SERUM FERRITIN ON TURBOSMART™

SUMMARY

The majority of iron in humans, is integrated within the globin proteins that facilitate the transport of oxygen throughout body. In addition to its role in respiration, iron is also utilized as an enzymatic cofactor in numerous other reactions. Despite iron's integral role within the body, it also has potential to be highly toxic by facilitating the formation of free radicals.

Disorders of iron metabolism are among the most common diseases of humans and encompass a broad spectrum of diseases with diverse clinical manifestations, ranging from anemia to iron overload, and possibly to neurodegenerative diseases. Thus, carefully regulated mechanisms has evolved to transport iron across biological membranes, distribute it throughout the body, and store it in inert form until needed.

Ferritin is a major iron storage protein essential in iron homeostasis and is involved in wide range of physiologic and pathologic processes[1]. Clinically, serum ferritin is most commonly used in combination with other iron parameters to gauge the iron status of a patient and is most useful in diagnosis of iron deficiency[1]. Serum ferritin serves a critical role in management of both iron deficiency and iron overload[1]. Elevated serum and tissue ferritin is linked to coronary artery disease, malignancy, and poor outcomes following stem cell transplantation. Ferritin is directly implicated in sideroblastic anaemias, neurodegenerative disorders, and hemophagocytic syndrome.

Information regarding the concentration of ferritin in human serum can be obtained by using **turbosmart™ Ferritin** reagent.

PRESENTATION

REF	108790020	108790060
Σ	20 Tests	60 Tests
R1	20 Tests	3 x 20 Tests
R2	20 Tests	3 x 20 Tests
SC	1 No.	1 No.
CT	20 Nos.	60 Nos.

REAGENT

turbosmart™ Ferritin assay contains:

1. R1 **turbosmart™ Ferritin Activation buffer:** Ready to use.
2. R2 **turbosmart™ Ferritin Latex Reagent:** A ready to use solution of latex agglutinating sera (latex coated with anti-human ferritin antibody).
3. SC **turbosmart™ Ferritin RFID: Card with Ferritin master calibration curve** calibrated with standard traceable against the 1st International Standard (IS) NIBSC (National Institute for Biological Standards and Control) NIBSC WHO 1st IS 80/602 (human liver).

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity, and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagents at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent and activation buffer is as per the expiry date mentioned on the respective vial labels.
3. Once opened the reagents are stable for 75 days when stored at 2-8°C provide the reagents are not contaminated.
4. Store the **turbosmart™** RFID card at a clean dry place. The **turbosmart™** RFID card data once transferred into **turbosmart™** analyzer is valid upto the use of labelled number of tests within 75 days.

PRINCIPLE

turbosmart™ Ferritin is a turbidimetric immunoassay for the detection of ferritin in human serum and is based on the principle of agglutination reaction. The test specimen is mixed with the activation buffer (R1) and **turbosmart™ Ferritin** agglutinating sera (R2: latex anti-human ferritin antibody reagent) and allowed to react. Presence of ferritin in the test specimen forms an insoluble complex producing a turbidity, which is measured at wavelength ~ 650 nm. The resulting turbidity corresponds to the concentration of ferritin in the test specimen.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents that are 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. Reagents contain 0.09% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large

quantities of water.

4. **As the reagents and RFID card within lots have been matched, reagents or RFID cards from different lots must not be interchanged.**
5. It is recommended that the reagent performance and RFID card calibration must be validated periodically with known controls such as **Turbodyne™ Ferritin** control (Ref: 108710005).
6. Do not use damaged or leaking reagents.
7. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures.
8. Always use fresh clean disposable micropipette tips to aspirate the reagents to prevent contamination.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to specimen collection by approved techniques. Only serum should be used for testing. Specimen should be tested immediately preferably within 3 hours. Should a delay in testing occur, specimen can be stored upto 7 days at 2- 8°C provided they are not contaminated. Specimen should be free from particulate matter. Grossly haemolysed samples should not be analysed because the release of intracellular ferritin can cause an increase in serum ferritin values.

ADDITIONAL MATERIAL REQUIRED

turbosmart™ analyser, Stopwatch, well calibrated micropipettes, disposable tips and incubator.

TEST PROCEDURE

1. Bring reagent and sample to room temperature before use.
2. Select the Ferritin test from the Measure Menu of Instrument.
3. Load the **turbosmart™ Ferritin** test data from the RFID card (Provided with the kit) to the analyser as described in the Instrument User Manual. The Instrument is ready to perform the Ferritin test.
4. The instrument will indicate to place cuvette with R1 + sample in the reading chamber.
5. Take a disposable cuvette (provided in the kit) and add 200µl R1 to the cuvette using fresh clean disposable micropipette tips.
6. Then add 20µl sample and incubate the cuvette for 5 minutes.
7. Place the cuvette with R1 + sample in the **turbosmart™** reading chamber.
8. Long Press "Test"key. The instrument will mix the sample and then indicate to add R2.
9. Long press **turbosmart™** electronic Pipette to dispense 50µl R2 reagent to the cuvette with R1+sample.
10. The reaction will start and the counter will start in the display. Results will be displayed on completion of reaction.

SPECIFIC PERFORMANCE CHARACTERISTICS

Measuring Range

The Measuring Range of **turbosmart™ Ferritin** is 10-600 µg/L.

Detection limit / Analytical Sensitivity

Detection limit: 5 µg/L

The detection limit represents the lowest measurable ferritin concentration that can be distinguished from zero.

Precision

Intra-assay precision	n	Mean µg/L	SD	CV (%)
Sample 1	10	70.97	3.1	4.37
Sample 2	10	100.5	3.64	3.62
Sample 3	10	250.07	5.77	2.31

Inter-assay precision	n	Mean µg/L	SD	CV (%)
Sample 1	10	69.51	3.29	4.73
Sample 2	10	101.41	3.45	3.4
Sample 3	10	251.4	7.15	2.84

Interference

No interference was observed by Bilirubin upto 60 mg/dl, Rheumatoid factor upto 600 IU/ml, Haemoglobin upto 500 mg/dl & lipids upto 15 g/L.

REFERENCE VALUES

The reference values of serum ferritin in normal population are:

- Males (> 5 years) : 15-200 µg/L
- Females (> 5 years) : 15-150 µg/L
- Children (< 5 years):12-200 µg/L

Above reference range is considered in absence of any coexistence of infection and inflammation. In case infection and inflammation coexists than iron deficiency may exist where Ferritin is < 30 µg/L.

It is recommended that each laboratory should establish its own reference range.

REMARKS

1. Hypothyroidism and ascorbate deficiency are known to lower serum ferritin values[1].
2. Ferritin levels are not particularly useful in end-stage renal disease to predict bioavailable iron[1]. However, evidence based guidelines exist to guide appropriate iron therapy in these cases.
3. Increased serum ferritin can be suggestive of iron overload but is also seen in conjunction with liver parenchymal damage, infections, inflammation and malignant diseases without any quantitative relationship to the iron reserve[3].
4. Serum ferritin is of limited usefulness during pregnancy because it diminishes late in pregnancy, even when bone marrow iron is present[6].
5. Usage of well-calibrated pipettes and correct procedure is critical for achieving correct results.
6. Diagnosis of iron deficiency or iron overload must not be based solely on serum ferritin levels. The results must be correlated clinically and complemented with other iron estimation parameters.
7. Use only serum as test specimen. Do not use Plasma.
8. Haemolysed or turbid samples are not recommended for use in estimation of ferritin.
9. Values above linearity will be flagged ">". Such samples must be diluted 1:4 with normal saline and retested. The result obtained must be multiplied with the dilution factor.
10. The measuring range of the assay is as indicated in the pack insert. Values outside the measuring range are extrapolated values and should not be considered as accurate.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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