FERRITIN

Diagnostic reagent for determination of ferritin concentration.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Ambalaj	Ref No	Ambalaj	Ref No	Ambalaj	Ref No	Ambalaj
TAB130	4114 Test	TA132	5 x 10 mL	SAB131	923 Test	KAB131	3273 Test
TAB131	2143 Test	DMT130	990 Test	BY130	6136 Test	MAB130	1697 Test
TA133	3 x 100 mL	RAB130	2769 Test	BY131	4602 Test	MAB131	848 Test
TA130	3 x 50 mL	RAB131	923 Test	NAB130	400 Test	LAB130	3600 Test
TA131	3 x 25 mL	SAB130	1662 Test	KAB130	4364 Test	LAB131	1800 Test

INTENDED USE

The test is applied for the quantitative determination of ferritin in serum.

Ferritin is the major iron storage compound in the body. It consists of a protein shell enclosing a core of a variable amount of iron. Ferritin is present at particularly high concentrations in liver, bone marrow and spleen.

The plasma ferritin is in equilibrium with body stores and variations in the quantity of iron in the storage compartment are reflected in plasma ferritin concentration.

Serum ferritin concentration declines very early in the development of iron deficiency and it serves as a very sensitive indicator of iron deficiency. On the other hand, a large number of chronic concentrations, plasma ferritin is also increased in patients with hemosiderosis. Clinical diagnosis should not be made on the findings of a single test results, however should integrate both cilinical and laboratory data.

TEST PRINCIPLE

Serum ferritin causes agglutination of latex particles coated with anti-human ferritin antibodies. The agglutination of the latex particles is proportional to the ferritin concentration and can be measured by turbidimetry.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 ± 20 nm
Temperature : 37°C
Sample : Serum
Linearity : 4 µg/L - 500 µg/L

REAGENT COMPOSITION

Reagent 1:
Glycine buffer ≤ 185 mmol/L,
Sodium chloride ≤ 125 mmol/L,
Sodium azide ≤ 1.00 g/L,
pH 8.2.

Reagent 2:
Suspension of latex particles coated with anti-human ferritin antibodies,

Sodium azide ≤ 1.00 g/L.

REAGENT PREPARATION

Working Reagent: Pour the contents of a Reagent 2 vial, into a Reagent 1 bottle. Mix thoroughly. Stable for 20 days at 2-8ºC. Smaller Working Reagent volumes can be prepared by mixing: 1 mL of Reagent 2 + 2 mL of Reagent 1. Shake the Reagent 2 vial before pipetting.

Ferritin Standard (S): Reconstitute with 3.00 mL of distilled water. Standard is stable for 1 month at 2-8ºC. Calibration curve: Prepare dilutions of the Ferritin Standard using 9 g/L saline as diluent. Multiply the concentration of the Ferritin Standard by the corresponding factor indicated below to obtain the ferritin concentration of the dilutions.

DILUTION	1	2	3	4	5
Ferritin Standard (µL)	10	20	40	60	80
Saline (µL)	70	60	40	20	
Factor	0.125	0.25	0.5	0.75	1.0

This range is given for orientation only; each laboratory should establish its own reference range.

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Reagents and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

Reagents: absorbance of the blank over 1.600 at 540 nm.

Standard: Presence of moisture.

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analysers cooling specification and carry-over values.

SAMPLE

Serum is collected by standard procedures. Hemolyzed or lipemic samples are not suitable for testing.
Ferritin in serum is stable for 2 days at 2-8ºC and minimum 2 days at -20°C.

For reagents which are related antigen antibody interaction, do not shake the sample, just gently mix.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Calibration curve: Calculate the absorbance difference (AStandard − ABlank) of each point of the calibration curve and plot the values found against the ferritin concentration. Ferritin concentration in the sample is calculated by interpolation of its absorbance (ASample − ABlank) on the calibration curve.

REFERENCE INTERVAL (NORMAL VALUES)*

Serum:

Children	: 7-140 µg/L
Men	: 20 - 250 µg/L
Women	: 20 - 200 µg/L

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

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used.
We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of an Ferritin Standard or an Ferritin Calibrator. We recommend:

ARCHEM Standard (Calibrator)
Cat.No. TA130S

Ferritin concentration is given on the label. Concentration value is traceable to the Biological Reference Material 94/572 (World Health Organization).

Any commercially available Standard or Calibrator suitable for this method may be used.

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 15 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 4 µg/L Ferritin

High Linearity: The test is linear up to 500 µg/L. For higher values dilute sample 1/5 with 9 g/L NaCl and repeat measurement.

Linearity may considerably vary depending on the instrument used.

Precision Studies:

Repeatibility (within run) (Intra-assay)

Mean concentration	CV	n
61 µg/L	2.2%	20
145 µg/L	1.6%	20

Reproducibility (run to run) (Inter-assay)

Mean concentration	CV	n
61 µg/L	3.7%	25
145 µg/L	1.6%	25

Sensitivity (LOD):

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Prozone effect: > 30,000 µg/L

Interferences: Hemoglobin (10 g/L), lipemia (triglycerides 5 g/L), bilirubin (62 mg/dL) and rheumatoid factors (520 IU/mL) do not interfere. Other drugs and substances may interfere.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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3. Tietz Textbook of Clinical Chemistry, 3rd edition. Burtis CA, Ashwood ER. WB Saunders Co., 1999.
4. Young DS. Effects of drugs on clinical laboratory tests, 3th ed. AACC Press, 1997.
5. Worwood M. Ferritin. Blood Reviews 1990; 4: 259-269
6. Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Press, 1999.

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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