Order references

Reagents

REF		CONT
FNCOL-B00	*Universal kit*	1 x 50 ml R1 + 1 x 5 ml R2
FNCOL-H00	*Universal kit*	2 x 50 ml R1 + 1 x 15 ml R2

Other necessary products

REF		CONT
FNRGK-000	*Ferritin Calibrators Kit (5 Levels)*	5 x 1 ml
FNCON-002	*Ferritin Control*	1 x 2 ml

Field of application - Purpose

In vitro diagnostic reagent for the quantitative determination of ferritin in samples of human origin by immunocolorimetry on photometric systems.

Medical benefit - Scientific validity

Ferritin is a protein synthesised by the liver, and is the main element of the iron reserve. In fact, this protein includes a core of iron (II), which can be used for the formation of haemoglobin, for example. Despite the low serum ferritin concentration, this latter reflects the cellular concentration of ferritin quite accurately.
A high serum ferritin concentration may signify a liver problem (as a result of alcoholism, etc.). Serum ferritin concentration may increase in the case of numerous blood transfusions, but also in the case of chronic infections, chronic inflammation (rheumatoid arthritis, etc.) or kidney disease.
An iron deficiency, which is one of the most common disorders in humans, can also be detected by the assay of ferritin. The serum concentration in ferritin will then be low.

Method principle

The gold particles in colloidal form are stabilized using polyclonal immunoglobulin G directed specifically against human ferritin. The reaction of these conjugates with human ferritin present in a biological sample and causes the specific agglutination of the gold particles. This agglutination, directly proportional to the concentration of the ferritin in the sample, is read at 546 nm and 600 nm.

Warning and precautions

- For in vitro diagnostic use only.
- Must be handled by qualified personnel under the responsibility of a biologist.
- The human-origin products have been screened and found negative for HIV 1 and 2 antibodies, HCV antibodies and HBAg, but they must nevertheless be handled as potentially infectious products.
- These products contain sodium azide. Products containing sodium azide must be handled with care: avoid ingestion and contact with the skin or mucous membranes.
- Sodium azide becomes explosive on contact with heavy metals such as copper or lead.

Samples

Collection conditions

Collect specimens using standard laboratory techniques; use only suitable procedures, tubes or collection containers.

Sample type

Fresh serum

Storage and stability of specimens

Temperature	Stability
- 20 °C	≤ 1 years
4 - 8 °C	≤ 7 days
20 - 25 °C	≤ 7 days

This information comes from data originating from “Tietz Clinical Guide to Laboratory Tests” and from “WHO”.

Reagents

Composition and concentrations/Storage

Active ingredients:
Reagent R1: none.
Reagent R2: Suspension of gold particles coated with polyclonal Immunoglobulin G (± 4.5 mg/ml) directed specifically against human ferritin.

Other ingredients:
Reagent R1: buffer, polymer, inorganic salt and preservative.
Reagent R2: buffer, inorganic salt and preservative.

Storage temperature:
Reagent R1: 2 - 8°C.
Reagent R2: 2 - 8°C

Preparation

Ready to use.

Storage and stability

Reagents are stable until the expiration date printed on the packaging (months passed), under the following recommended storage and handling conditions:

- Unopened vial stored at temperature indicated on packaging.
- Opened vial: closed immediately after use or placed on closed analyser intended for this purpose, not contaminated by handling and stored at the temperature indicated on the packaging.

Note:

- Do not freeze the reagents.
- Nanoparticle-based reagents can settle over time. It may be necessary to delicately mix by repeated turning.

Other materials required

Usual laboratory equipment including an analytical system equipped with a photometric detector.

Calibration

Calibration

The calibration curve is performed by using the calibration kit indicated in the “Order references” section. The zero point of the calibration curve is performed with physiological saline solution.

Traceability

The method has been standardised with a benchmark method traceable to the international standard as described in the associated calibrators data sheet (see the “Order references” section).
Calibrate the method when the reagent batch number changes or in case of change in performance (contact the manufacturer if the changes persist) or if quality control requires it.

Quality control

The frequency of controls and the confidence limits must be adapted to the laboratory requirements. The results must be within the defined confidence limits. Each laboratory shall establish corrective measures to be taken if results fall outside the defined limits. Comply with current legislation in the country and local guidelines relating to quality control.
The calibration curve and its stability can be validated using the control materials indicated in the “Order references” section.

Reference values

	Reference values
Newborns	25 - 200 µg/L
1 month	200 - 600 µg/L
2 - 5 months	50 - 200 µg/L
6 months - 15 years	7 - 140 µg/L
Adults (male)	20 - 250 µg/L
Adults (female)	10 - 120 µg/L

International units: µg/L
Conventional units: ng/mL

This information coming from data originating from “Clinical guide to laboratory tests”. Each laboratory must check the validity of its values and if necessary establish its own reference values, depending on the population examined.

Analytical performances

The analytical performance data below are given as an indication. The results obtained in the laboratory may differ from these.
The analytical performances were determined following the indications of the “Guide technique d’accréditation de vérification (Portée A)/validation (Portée B) des méthodes en biologie médicale”; document SH GTA 04 Révision 01.

Measurement range

6,344 - 500 µg/L
The measurement range is bounded by the quantification and linearity limits. Samples having a concentration greater than the upper limit must be diluted.

Limit of detection

1,953 µg/L
It is the smallest signal expressed as a quantity or concentration that can be distinguished with a given probability from a reagent blank performed in the same conditions.
The evaluation of the limit of detection is based on the statistical analysis of the observed signal differences between the blanks and samples.

Interferences (Analytical specificity)

There is no known cross-reactivity of the antiserum cited or the antibodies used.
The abnormally coloured and particle-containing samples can cause, depending on the analytical system, assay errors. These samples must be clarified chemically or physically before their assay.

Precision

The precision is evaluated using the repeatability (CV within-run) and reproducibility (CV within-calibration).

	Repeatability (n=30)		Reproducibility (n=30)	
	Average (µg/L)	CV (%)	Average (µg/L)	CV (%)
Level 1	55,94	1,93	40,26	9,81
Level 2	131,78	1,74	112,76	4,69
Level 3	333,06	2,90	260,25	4,46

Trueness - Accuracy

Trueness, quantified by the bias, is estimated by comparing the mean obtained in the intermediate precision study, based on internal quality control samples, with the expected target value equated to the “true” value of the tested sample.
Accuracy is defined as the closeness of agreement between a measured value and a true value of a measurand (quantity to be measured).
DiAgam allows a bias of 5% compared to the international standard or compared to a reference method traceable to the international standard when it exists.

Limitations of the method

The results of this test should always be interpreted in relation to the patient’s medical history, clinical signs and other findings.

Prozone

By limiting the linearity to the value of the upper limit of the measurement range, no excess antigen effect was observed for samples with a concentration up to 1500 µg/L.

Matrix effect

The inter-laboratory control samples and controls can yield different results from those obtained with other assay methods because of a matrix effect. In this case, an analysis of the results according to specific target values of the method utilised may be necessary. If in doubt, contact the manufacturer.

Utilisation procedure

Validated automatic applications for different analyzers are available from DiAgam. The utilisation procedure indicated below enables deriving a manual or automatic application of the reagent (NB - comply with the sample/R1/R2 ratios correctly). Please contact the manufacturer for more information.

Mix 20 µl of sample with 250 µl of reagent R1 and incubate the mixture for 5 minutes at 37°C. Then add 50µl of reagent R2 to the reaction mix Then read the optical density at a wavelength of 546 nm (primary wavelength) (OD1 546 nm) and at a wavelength of 600 nm (secondary wavelength) (OD1 600 nm). Incubate at 37°C for 5 min. Perform a second OD measurement at 546 nm (OD2 546 nm) and 600 nm (OD2 600 nm).

This operation must be made with a “reagent blank” sample (. Calibrator 1 of the calibration kit indicated in the “Order references” section), with the calibrators indicated in the “Order references” section and to finish with the samples of unknown concentrations.

In order to obtain the final OD of the sample, it is first necessary to calculate the intermediate ODs as indicated in the following equations:

OD1 intermediate=OD1 (546 nm)-OD1 (600 nm)
OD2 intermediate=OD2 (546 nm)-OD2 (600 nm)

The final OD is finally calculated as shown in the following equation:
OD final=OD2 intermediate-f x OD1 intermediate
Where f is a factor taking account of the difference in volume between the 2 measurements of OD.

The final OD of the "reagent blank" sample as well as the known calibrator concentrations allows a calibration curve to be drawn. The transfer of the OD measured for an unknown sample on this calibration curve enables its concentration to be determined.

Literature

1. Tietz Textbook of Clinical chemistry and molecular Diagnostics, fourth edition, edited by Carl A. Burtis, Edward R. Ashwood, David E. Bruns, 2006
2. Use of Anticoagulants in Diagnostic Laboratory Investigations & Stability of blood, plasma and serum samples. Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.
3. Clinical guide to laboratory tests, second edition, edited by Norbert W. Tietz, 1990
4. CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2007.
5. NCCLS. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Fifth Edition. NCCLS document H4-A5 [ISBN 1-56238-538-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.

Symbols legend

The following symbols may appear on the packaging and the label:

LOT	*Batch code*	BUF	*Buffer*
	Use until	CAL	*Calibrator*
	Manufacturer	H	*High*
IVD	*In vitro diagnostic medical device*	M	*Moderate*
	Temperature (Storage at)	L	*Low*
REF	*Catalogue reference*	4 LEV	*4 levels*
	Read the usage instructions	5 LEV	*5 levels*
REAG	*Reagent*	6 LEV	*6 levels*
KIT	*Kit*	CONTROL	*Control*
CONT	*Content*	CE	*This product meets the requirements of European Directive 98/79 EC concerning in vitro diagnostic medical devices*
Ab	*Antibody or Antisera*		

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