VIDAS® FERRITIN (FER)

IVD

The VIDAS Ferritin (FER) assay is intended for use on the instruments of the VIDAS family (Vitek ImmunoDiagnostic Assay System) as an automated quantitative enzyme linked fluorescent immunoassay (ELFA) for the determination of human ferritin concentration in serum or plasma. The VIDAS Ferritin assay is intended for use as an aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis and iron deficiency anemia.

SUMMARY AND EXPLANATION OF THE TEST

Ferritin is the major storage form for iron in the human body. Ferritin molecules are located in the cells of the reticuloendothelial system, particularly in the liver and in the spleen.

Ferritin consists of a hollow sphere-shaped protein shell composed of 24 protein subunits. In the center of the molecule, iron is found in the form of ferric hydroxyphosphate. Each ferritin molecule can store an average of 4,500 atoms of iron.

Iron deficiency anemia is common. Some of the causes for iron deficiency include inadequate iron intake, pregnancy, hemodialysis, and blood donation. Decreased serum ferritin levels can indicate iron deficiency before anemia occurs, allowing for earlier therapy.

Iron overload occurs in such diseases as thalassemia and sideroblastic anemia. Serum ferritin can be useful in diagnosis of these diseases and also in monitoring therapy.

The serum ferritin level is considered to be an excellent measure of body iron stores, and well correlated with stainable iron in the bone marrow. Determination of serum ferritin concentration is more quantitative and less invasive than bone marrow biopsy.

PRINCIPLE OF THE PROCEDURE

The VIDAS Ferritin (FER) assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as a solid phase for the assay as well as a pipetting device. The SPR is coated at the time of manufacture with mouse monoclonal anti-ferritin antibodies. The VIDAS Ferritin assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. The sample is transferred into the well containing the anti-ferritin antibody conjugated with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR and the ferritin will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich". Wash steps remove unbound conjugate.

A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument ; it is proportional to the ferritin concentration present in the sample.

When the VIDAS Ferritin assay is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.

Kit composition (60 tests):

60 FER Reagent Strips	STR	Ready to use.
60 FER SPRs (2 x 30)	SPR	Ready to use. SPRs coated with mouse monoclonal anti-ferritin antibodies.
FER Control (liquid) (1 x 2 ml)	C1	Ready to use. TRIS buffer (0.1 mol/l, pH 7.4) with human spleen ferritin and protein and chemical stabilizers. MLE data indicate the confidence interval in ng/mL ("Control C1 Dose Value Range").
FER Calibrator (liquid) (1 x 2 ml)	S1	Ready to use. TRIS buffer (0.1 mol/l, pH 7.4) with human spleen ferritin and protein and chemical stabilizers. MLE data indicate the calibrator concentration in ng/mL (1st IRP 80/578) ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value ("Calibrator (S1) RFV Range").
FER Dilution Buffer (liquid) (1 x 25 ml)	R1	Ready to use. TRIS buffer (0.1 mol/l, pH 7.4) and protein and chemical stabilizers.
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit, or • MLE bar codes printed on the box label.		
1 Package Insert provided in the kit or downloadable from www.biomerieux.com/techlib.		

The SPR®

The interior of the SPR is coated during production with mouse monoclonal anti-ferritin immunoglobulins. Each SPR is identified by the "FER" code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening**.

The strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

Description of the FER Reagent Strip

Well	Reagent
1	Sample:
2-3-4	Empty
5	Conjugate: Mouse monoclonal anti-ferritin antibodies conjugated to alkaline phosphatase with 1 g/L sodium azide (600 µl).
6-7	Wash buffer: Sodium phosphate (0.01 mol/l , pH 7.4) with 1 g/L sodium azide (600 µl)
8	Wash buffer: diethanolamine* (1.1 mol/l , or 11.5%, pH 9.8) with 1 g/L sodium azide (600 µl)
9	Empty
10	Reading Cuvette with Substrate: 4-methylumbelliferyl phosphate (0.6 mmol/l) with diethanolamine** (0.62 mol/l or 6.6%, pH 9.2) + 1 g/L sodium azide (300 µl)

* Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.
H373 : May cause damage to organs through prolonged or repeated exposure.
H315 : Causes skin irritation.
H302 : Harmful if swallowed.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P309 + P311 : IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

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For further information, refer to the Safety Data Sheet.

MATERIALS REQUIRED BUT NOT PROVIDED

- Pipette with disposable tips that will dispense 100 µl.
- Powderless disposable gloves.
- For other specific materials and disposables, please refer to the Instrument Operator's Manual
- Instrument of the VIDAS family.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **For professional use only.**
- This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory biosafety manual - WHO - Geneva - latest edition).
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- Consider all patient specimens potentially infectious and observe routine biosafety precautions. Dispose of all used components and other contaminated materials by acceptable procedures for potentially biohazardous human blood products.
- Do not mix reagents or disposables from different lots.
- Powderless gloves are recommended as powder has been reported as a cause of false results in some enzyme immunoassays.
- Kit reagents contain 1 g/L sodium azide which could react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- The wash buffer (well 8) contains a harmful agent (11.5% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The substrate (well 10) contains an irritant agent (6.6% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped thoroughly after treatment with liquid detergent and a solution of household bleach containing at least 0.5 % sodium hypochlorite to inactivate infectious agents. See the Operator's Manual for cleaning spills on or in the instrument. Do not place solutions containing bleach in the autoclave.
- The instrument should be routinely cleaned and decontaminated. See the Operator's Manual for the appropriate procedures.

STORAGE AND HANDLING

- Store the VIDAS Ferritin Kit at 2-8°C.
- **Do not freeze reagents.**
- **Store all unused reagents at 2-8°C.**
- After opening the kit, check that the SPR pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPRs and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.

SPECIMEN COLLECTION AND PREPARATION

Acceptable specimens include serum or plasma (with EDTA or heparin anticoagulant). The use of heat inactivated sera has not been established - do not heat sera. Samples can be stored at 2-8°C in stoppered tubes for up to 2 days. If storage for longer than this is required, freeze samples at -25 ± 6 °C. Avoid repeated cycles of freezing and thawing. If necessary, clarify samples by centrifugation.

INSTRUCTIONS FOR USE

For complete instructions, see the User's Manual.

Reading Master lot data

Before each new lot of reagents is used, enter the specifications (or factory master data) into the instrument using the master lot entry (MLE) data.
If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.
Note: the master lot data need only be entered once for each lot.
It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the User's Manual).

Calibration

Calibration, using the calibrator provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.

The calibrator, identified by S1, must be tested **in duplicate** (see Operator Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Assay Procedure

1. Remove necessary components from the kit and return all unused components to storage at 2-8°C.
2. Allow components to reach room temperature (approximately 30 minutes).
3. Use one "FER" strip and one "FER" SPR for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.**
4. The test is identified by the "FER" code on the instrument. The calibrator must be identified by "S1", and tested **in duplicate**. If the control needs to be tested, it should be identified by "C1".
5. If needed label the FER Reagent Strips with the appropriate sample identification numbers.

6. Mix the calibrator, control and samples using a vortex-type mixer (for serum or plasma separated from the pellet).
7. **For this test, the calibrator, control, and sample test portion is 100 µl.**
8. Insert the "FER" Reagent Strips and SPRs into appropriate position on the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
9. Initiate the assay processing as directed in the Operator's Manual. All steps will be executed automatically by the instrument.
10. Reclose the vials and return them to 2–8°C after pipetting.
11. The assay will be completed within approximately 30 minutes. After the assay is completed, remove the SPRs and strips from the instrument.
12. Dispose of used SPRs and reagent strips in an appropriate recipient.

QUALITY CONTROL

A control is included in each VIDAS Ferritin kit.
This control must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using this control. The instrument will only be able to check the control value if it is identified by C1.
Results cannot be validated if the control value deviates from the expected values.

RESULTS AND INTERPRETATION

Two instrument readings for fluorescence in the Reagent Strip's optical cuvette are taken for each specimen tested. The first reading is a background reading of the cuvette and substrate before the SPR is introduced into the susbtrate. The second reading is taken after the substrate has been exposed to the enzyme conjugate remaining on the interior of the SPR. The background reading is subtracted from the final reading to give a Relative Fluorescence Value (RFV) for the test result.
Samples with concentrations greater than 1200 ng/ml must be diluted 1/10 (1 volume of sample and 9 volumes of diluent buffer (R1)) or 1/100 (1 volume of sample and 99 volumes of diluent buffer (R1)).
If the dilution factor has not been entered when the analysis has been requested (see Operator's Manual), multiply the result by the dilution factor to obtain the Ferritin sample concentration.

A report is printed which records :
- the type of test performed,
- the sample identification,
- the date and time,
- the lot number and the expiration date of the reagent kit being used,
- each sample's RFV and ferritin concentration.

The VIDAS Ferritin test results should be interpreted as part of a complete clinical profile.

Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

PERFORMANCE DATA

Immunological Specificity:

Tested components (human origin)	Concentration (ng/ml)	VIDAS concentration (ng/ml)	Recovery percentage	Mean recovery percentage
Spleen ferritin (NIBSC 80/578)	125	126	100	106
	250	265	106	
	500	542	108	
	1000	1103	110	
Liver ferritin (1st IRP 80/602)	125	157	125	121
	250	283	113	
	500	598	120	
	1000	1274 *	127	
Heart ferritin (Calbiochem Ref. 314484 batch 406075)	125	34	27	28
	250	67	27	
	500	147	29	
	1000	306	31	
Placental ferritin (Calbiochem Ref. 341489 batch 506140)	125	159	127	137
	250	309	124	
	500	694	139	
	1000	1595 *	159	

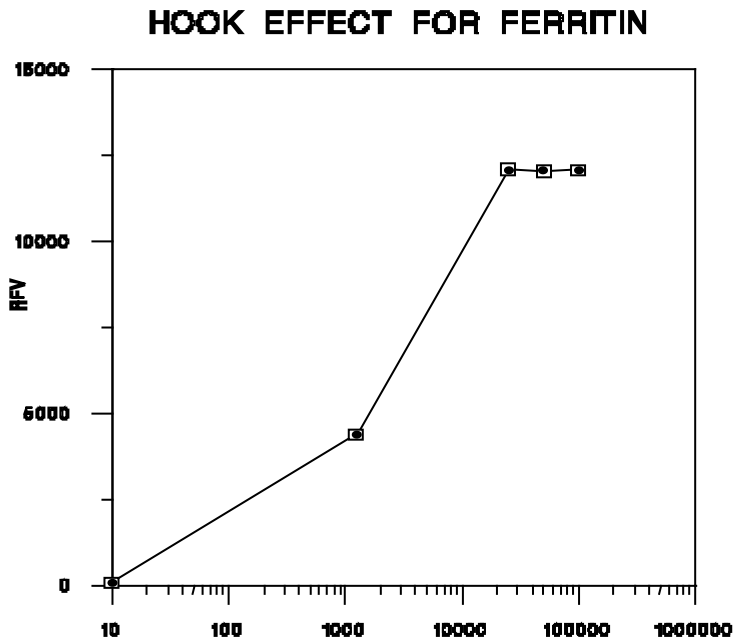
*** extrapolated data.**

Detection limit

The detection limit (assay sensitivity) is defined as the lowest concentration that can be distinguished from zero with 95 % probability. The detection limit for the VIDAS Ferritin assay is 1.5 ng/ml.

Hook Effect

The Hook effect was tested using human spleen ferritin; concentrations were from 10 to 100,000 ng/ml. No hook effect was seen at the concentrations tested.



<----------> ng/ml
Calibration Range

Precision/Reproducibility

Intra-assay precision

Five samples were tested for intra-assay precision. Thirty replicates of each sample were tested in the same run.

Sample	1	2	3	4	5
Mean concentration (ng/ml)	15.3	102	239	466	924
% CV	6.2	4.6	5.0	4.0	4.0

Inter-assay precision on the same instrument

Five samples were tested in 20 runs on the same instrument over an 8 week-period (recalibration was performed every 14 days as described in the Operator's Manual).

Sample	1	2	3	4	5
Mean concentration (ng/ml)	15.1	112	207	492	1044
% CV	5.3	3.5	5.7	3.4	3.0

Inter-instrument inter-assay reproducibility

Five samples were tested in singlet in 8 runs on different instruments.

Sample	1	2	3	4	5
Mean concentration (ng/ml)	14.7	107	211	479	940
% CV	7.6	4.8	7.5	5.7	7.5

Parallelism (Dilution tests)

Three samples were diluted in Ferritin dilution buffer and tested in 3 runs.

Sample	Dilution factor	Expected values (ng/ml)	Measured values (ng/ml)	Recovery percentage
1	1/1		193.7	
	1/2	96.9	96.4	99.5
	1/4	48.4	49.8	102.8
	1/8	24.2	25.9	107.0
	1/16	12.1	13.3	110.0
	1/32	6.1	6.1	100.0
2	1/1		422.5	
	1/2	211.2	202.6	96.0
	1/4	105.6	106.9	101.0
	1/8	52.8	52.3	99.,0
	1/16	26.4	27.2	102.0
	1/32	13.2	13.6	103.0
3	1/1		926.7	
	1/2	463.4	473.8	102.5
	1/4	231.7	251.6	108.0
	1/8	115.8	110.2	95.1
	1/16	57.9	55.6	95.4
	1/32	29.0	30.0	103.6

Recovery tests

Three samples were spiked with known quantities of human spleen ferritin and tested in 3 runs. The measured mean concentration compared to the expected mean concentration is shown below.

Sample	Amount spiked (ng/ml)	Expected mean concentration (ng/ml)	Measured mean concentration (ng/ml)	Mean recovery percentage
1	0	127.1	127.1	100.0
	5.88	133.0	128.8	96.8
	37.20	164.3	167.1	101.7
	78.00	205.1	211.1	103.1
	529.00	656.1	717.3	109.3
	1163.00	1290.1	> 1200	----
2	0	248.1	248.1	100.0
	5.88	253.9	241.8	95.2
	37.20	285.3	291.8	102.3
	78.00	326.1	315.6	96.8
	529.00	777.1	743.4	95.7
	1163.00	1411.1	> 1200	----
3	0	564.2	564.2	100.0
	5.88	570.1	547.9	96.1
	37.20	601.4	577.9	96.1
	78.00	642.2	632.7	98.5
	529.00	1093.2	1076.5	98.5
	1163.00	1727.2	> 1200	----

Influence of specimen collection

Blood samples were collected from thirty patients. For each patient, five specimens were collected at the same time: in a tube with beads, in a dry glass tube, in a tube with separating gel, in a heparinized tube, and in an EDTA tube. Each sample collected was tested in duplicate and sera from the same donor was tested in the same run. The tube with beads was the reference to which the other methods were compared.

Collection tube	Equation of the line	Correlation coefficient
Dry glass tube	y = 0.95 ref. + 2.34	0.97
Tube with separating gel	y = 1.10 ref. - 1.54	0.99
Tube with heparin (lithium)	y = 0.96 ref. + 0.54	0.99
Tube with EDTA	y = 0.97 ref. - 0.92	0.99

There are no significant differences between the 5 methods of collection.

Interference studies

Heparin

Three pools of human sera were spiked with increasing quantities of heparin.

		Amount of heparin spiked (U/ml)			
		0	0.5	5	50
Ferritin (ng/ml)	Pool 1	16.6	15.9	16.0	16.1
	Pool 2	210	211	224	208
	Pool 3	1019	838	941	951

EDTA

Three pools of human sera were spiked with increasing quantities of EDTA.

		Amount of EDTA spiked (mg/ml)			
		0	1	5	10
Ferritin (ng/ml)	Pool 1	16.6	15.9	17.7	17.0
	Pool 2	210	193	192	197
	Pool 3	1019	908	862	873

These data indicate that EDTA or heparin plasma can be used in the VIDAS FER assay.

Hemoglobin

Three pools of human sera were spiked with increasing quantities of hemoglobin obtained from a lysate of human red blood cells.

		Amount of hemoglobin spiked (µmol/l)						
		0	15	30	60	150	210	300
Ferritin (ng/ml)	Pool 1	14.2	13.7	15.9	15.7	16.5	16.5	16.6
	Pool 2	206	198	188	210	201	216	199
	Pool 3	959	911	980	1031	988	1012	967

Turbidity

Three pools of human sera were spiked with increasing quantities of a lipid solution.

		Amount of triglycerides spiked (mmol/l)				
		0	1.0	2.6	3.0	5.0
Ferritin (ng/ml)	Pool 1	14.5	15.4	15.1	14.5	13.7
	Pool 2	190	198	196	205	193
	Pool 3	955	886	834	847	857
Appearance		Clear	Opalescent		Turbid	

Bilirubin

Three pools of human sera were spiked with increasing quantities of bilirubin.

		Amount of bilirubin spiked (µmol/l)						
		0	25.6	51.3	102.6	256	385	513
Ferritin (ng/ml)	Pool 1	13.3	14.2	15.1	15.4	15.0	14.9	14.5
	Pool 2	193	194	189	191	181	189	200
	Pool 3	931	878	823	947	853	905	947

Although interference linked to the presence of hemoglobin, bilirubin or turbidity has not been observed, using hemolyzed, icteric or lipemic samples is not recommended. If possible, collect a new specimen.

EXPECTED VALUES

Results are given in ng/ml (1st IRP 80/578). Among a group of healthy people, and not infected with hepatitis, 90 % of people were split into the following groups :

- men : 70 to 435 ng/ml
- non-menopausal women : 10 to 160 ng/ml
- menopausal women : 25 to 280 ng/ml

It is advisable for each laboratory to quote its own reference values on a strictly selected population. Establishing reference values for women has to be done from a group of menopausal women; pre-menopausal women often suffer from iron deficiency. Values greater than 250 ng/ml for women and 350 ng/ml for men suggest inflammatory, infectious, hepatic or tumor pathologies or iron storage anomalies (hemochromatosis, idiopathic or secondary).

CORRELATION

Four hundred thirty-three serum specimens were tested at a clinical chemistry laboratory. Samples with ferritin concentrations ranging from 0 ng/ml to 7500 ng/ml were tested using the VIDAS Ferritin assay and a commercially available ferritin EIA. The results of linear regression analysis of the correlation are summarized below:

# of samples	Slope	Intercept	Correlation Coefficient
433	1.30	5.9	0.99

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

WARRANTY

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REVISION HISTORY

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release date	Part Number	Change Type	Change Summary
2015/01	13646C	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) WARNINGS AND PRECAUTIONS
2015/06	13646D	Technical	KIT COMPOSITION (60 tests) INSTRUCTIONS FOR USE

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