VIDAS® FT4 (FT4N)

℞ only IVD

VIDAS® FT4 is an automated quantitative enzyme immunoassay for use on the instruments of the VIDAS® family, for the determination of free thyroxine (FT4) in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). Measurement of Free Thyroxin is intended for use as an aid in the diagnosis and treatment monitoring of thyroid disorders.

SUMMARY AND EXPLANATION OF THE TEST

From the moment it is secreted into the blood stream, thyroxine or tetraiodothyronine (T4), produced by the thyroid gland, is predominantly (> 99.9%) bound to carrier proteins: TBG (Thyroxine Binding Globulin), TBPA (Thyroxine Binding PreAlbumin), albumin. The fraction that remains free (FT4) is considered as the active part of the hormone. The mechanisms regulating thyroid function have a direct effect on the concentration of this free fraction, which explains why it is relatively independent of the concentration of carrier proteins (1-2).

In patients with hyperthyroidism, the FT4 concentration increases, whereas in patients with hypothyroidism it generally decreases.

Patients on hormone replacement therapy (LT4) may have an elevation of FT4, although clinically they are euthyroid.

The VIDAS® FT4 test aids in diagnosing thyroid disorders.

The FT4N assay must be used in conjunction with other tests, such as TSH, as well as a clinical examination of the patient.

PRINCIPLE OF THE PROCEDURE

The assay principle combines an enzyme immunoassay competition method with a final fluorescent detection (ELFA).

The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR® several times.

The sample is collected and transferred into the well containing an alkaline phosphatase-labeled mouse anti-T4 antibody (conjugate). The antigen present in the sample and the T4 antigen coated on the interior of the SPR® compete for the available sites on the specific anti-T4 antibody conjugated to alkaline phosphatase.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR®. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is inversely proportional to the concentration of antigen present in the sample. At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

CONTENT OF THE KIT (60 TESTS):

60 FT4N Strips	STR	Ready-to-use.
60 FT4N SPR®s 2 x 30	SPR®	Ready-to-use. Interior of SPR®s coated with thyroxine.
FT4N Control 1 x 2 mL (liquid)	C1	Ready-to-use. Human serum* + L-thyroxine + sodium azide (1 g/L). MLE data indicate the confidence interval in pmol/L ("Control C1 Dose Value Range").
FT4N Calibrator 1 x 2 mL (liquid)	S1	Ready-to-use. Human serum * + sodium azide (1 g/L). MLE data indicate the concentration in pmol/L ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value ("Calibrator (S1) RFV Range").
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit or • MLE barcodes printed on the box label.		
1 Package insert provided in the kit or downloadable from www.biomerieux.com/techlib.		

* This product has been tested with FDA cleared or approved methods, or with any other methods that are equivalent to FDA cleared or approved methods and shown to be negative for HBs antigen, antibodies to HIV1, HIV2 and HCV. However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, usual safety procedures should be observed when handling.

The SPR®

The interior of the SPR® is coated during production with thyroxine. Each SPR® is identified by the FT4N code. Only remove the required number of SPR®s 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 fluorimetric reading is performed. The wells in the center section contain the various reagents required for the assay.

Description of the FT4N strip

Wells	Reagents
1	Sample well.
2 - 3 - 4	Empty wells.
5	Conjugate: alkaline phosphatase-labeled anti-T4 antibody + 1 g/L Methylisothiazolone (MIT) (400 µL).
6	Wash buffer: Tris-NaCl (0.05 mol/L) pH 7.4 + 1 g/L Methylisothiazolone (MIT) (600 µL).
7	Wash buffer: Tris-Tween, NaCl (0.05 mol/L) pH 7.4 + 1 g/L Methylisothiazolone (MIT) (600 µL).
8	Wash buffer: diethanolamine* (1.1 mol/L or 11.5%) pH 9.8 + 1 g/L sodium azide (600 µL).
9	Empty well.
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + 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 Material Safety Data Sheet.

MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED

- Pipette with disposable tip to dispense 100 µL.
- Powderless, disposable gloves.
- For other specific materials and disposables, please refer to the Instrument User's Manual.
- VIDAS® family of instruments: VIDAS® or miniVIDAS®.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- **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).
- Do not use the SPR®s if the pouch is pierced or if the dot sealing a SPR® is detached.
- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the label.
- Do not mix reagents (or disposables) from different lots.
- **Use powderless gloves** as powder has been reported to cause false results for certain enzyme immunoassay tests.
- Kit reagents contain 1 g/L sodium azide which can 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 in well 8 contains a harmful agent (11.5% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The substrate in 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 up thoroughly after treatment with liquid detergent or a solution of household bleach containing at least 0.5% sodium hypochlorite. See the User's Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The instrument should be regularly cleaned and decontaminated (see the User's Manual).

STORAGE CONDITIONS

- Store the VIDAS® FT4 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 SPR®s.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPR®s 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 prior first opening. Vials are stable during 3 months after first opening when stored according to the assay procedure.

SPECIMENS

Specimen type and collection:

Human serum or plasma (lithium heparin).
Do not use EDTA tubes.

Collection tubes validated:

– Silicone coated glass tube,
– Plastic tube with clot activator,
– Plastic tube with separation gel,
– Plastic tube with lithium heparin,
– Plastic tube with lithium heparin and separation gel.

Note: Collection tubes results may vary from one manufacturer to another depending on the materials and additives used.

A matrix comparison study was performed using 31 sample sets. Each sample set consisted of a reference tube type (Silicone coated glass tube) and one of the blood collection tubes (Plastic tube with clot activator, Plastic tube with clot activator and separation gel, Plastic tube with lithium heparin, Plastic tube with lithium heparin and separation gel) collected from one donor during one draw. Samples between 0.13 ng/dL to 6.45 ng/dL were analyzed on VIDAS® instrument. Passing-Bablok regression was used to compare the samples collected in the reference tube (x) and the samples collected in each collection tube (y) after 24 hours at 18-25°C:

Collection tube	Regression analysis	Correlation coefficient (r)
Plastic tube with clot activator	Y = 0.98X + 0.01	0.999
Plastic tube with separation gel	Y = 1.02X + 0.02	0.999
Plastic tube with lithium heparin	Y = 0.99X - 0.01	0.997
Plastic tube with lithium heparin and separation gel	Y = 1.00X + 0.00	0.999

It is the responsibility of each laboratory to validate the collection tubes used and to follow the manufacturer's recommendations for use.

Specimen preparation

Follow the tube manufacturer's recommendations for use.

Frozen-stored samples: after thawing, all these samples must be homogenized before testing. Mix using a vortex-type mixer. Clarify the samples before testing by centrifugation, if necessary.

Sample-related interference

Interferences have been studied according to the recommendations of CLSI® document EP7-A2.
The following substances, studied in serum at FT4 analyte levels close to the lower and higher limits of the euthyroid range, showed no significant interference up to the concentration indicated, on the instruments of the VIDAS® family.

Bilirubin	22.5 mg/dL
Lipids	750 mg/dL
Hemoglobin	500 mg/dL
HAMA (human anti-mouse antibodies)	0.2 mg/dL
Albumin	6300 mg/dL

However, it is recommended not to use clearly hemolyzed, lipemic or icteric samples and, if possible, to collect a new sample.

The following drugs, showed no significant interference up to the concentration indicated.

Drug	Highest concentration at which no interference was observed
Acetylsalicylic Acid	32.61 mg/dL
Amiodarone	0.58 mg/dL
Carbamazepine	1.5 mg/dL
Danazol	24 mg/dL
Diclofenac	0.315 mg/dL
Diphenyldantoin	2.5 mg/dL
Dipyrone	580.08 mg/dL
Furosemide	0.075 mg/dL
Isotretinonine	1.20 mg/dL
Lithium	13.56 mg/dL
Mefenamic Acid	0.5625 mg/dL
Mestranol	0.002 mg/dL
Methimazole	2.40 mg/dL
Norethindrone	0.001 mg/dL
Phenylbutazone	5 mg/dL
Propanolol	0.20 mg/dL
Propylthiouracil	3.08 mg/dL
Sodium Salicylate	17.37 mg/dL

Specimen stability:

Samples can be stored at 2-8°C in stoppered tubes for up to 8 days; if longer storage is required, freeze the sera or plasma at -25 ± 6°C. Serum-type samples can be stored for 6 months at -25 ± 6°C, with 4 freeze/thaw cycles.
Samples collected in lithium heparin must not be stored for more than 4 months at -25 ± 6°C, with 2 freeze/thaw cycles.

INSTRUCTIONS FOR USE

For complete instructions, see the Instrument User's Manual.

Reading VIDAS® Protocol Test Change (PTC) protocol data and MLE data

When using the assay for the first time:

With the external instrument barcode reader,

1. Scan the PTC barcode(s) at the end of the package insert or downloadable from www.biomerieux.com/techlib. This reading allows VIDAS® PTC protocol data to be transferred to the instrument software for its update.

2. Scan the MLE data on the box label.

Note: If the MLE data have been read before the VIDAS® PTC protocol, read the MLE data again.

When opening a new lot of reagents:

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 information 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 User's Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Assay Procedure

1. **Only remove the required reagents from the refrigerator. They can be used immediately.**
2. Use one "**FT4N**" strip and one "**FT4N**" SPR® from the kit for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed after the required SPR®s have been removed.**
3. The test is identified by the "FT4N" code on the instrument. The calibrator must be identified by "S1", and tested **in duplicate**. If the control is to be tested, it should be identified by "C1".
4. If necessary, clarify the samples by centrifugation.
5. Mix the calibrator, control and samples using a vortex-type mixer (for serum or plasma separated from the pellet).
6. **For this test, the calibrator, control, and sample test portion is 100 µL.**
7. Insert the "**FT4N**" SPR®s and "**FT4N**" strips into the appropriate position on the instrument. Check to make sure the color labels with the assay code on the SPR®s and the Reagent Strips match.
8. Initiate the assay as directed in the User's Manual. All the assay steps are performed automatically by the instrument.
9. Reclose the vials and return them to 2–8°C after pipetting.
10. The assay will be completed within **approximately 40 minutes.** After the assay is completed, remove the SPR®s and strips from the instrument.
11. Dispose of the used SPR®s and strips into an appropriate recipient.

RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer. Fluorescence is measured twice in the Reagent Strip's reading cuvette for each sample tested. The first reading is a background reading of the substrate cuvette before the SPR® is introduced into the substrate. The second reading is taken after incubating the substrate with the enzyme remaining on the interior of the SPR®.
The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. This calculation appears on the result sheet.
Results are automatically calculated by the instrument using calibration curves stored in memory (4-parameter logistic model) and are expressed in ng/dL.

Conversion factors:
From ng/dL to pg/mL (ng/L), multiply by 10
From ng/dL to pmol/L, multiply by 12.87

Sera for free hormone assays should not be diluted.
The result must be expressed as > 6.61ng/dL.

VIDAS® FT4 assay results should be interpreted as part of a complete clinical evaluation and thyroid function assessment, including at least TSH determination.

Interpretation	VIDAS® FT4 (ng/dL)
Hypothyroid	≤ 0.76
Euthyroid	0.77 – 1.51
Hyperthyroid	≥ 1.52

The VIDAS® FT4 assay is standardized against the Elecsys® FT4 assay (Roche Diagnostics).

QUALITY CONTROL

Manufacturer control

A control is included in each VIDAS® FT4 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.

Quality control

User should test at least 2 levels of quality control materials, one normal and one abnormal. Since bioMérieux VIDAS® FT4 assay kit only have one level of quality control material, additional quality control level should be used. Additional quality control may be purchased from commercially available source.

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

LIMITATIONS OF THE METHOD

- Interference may be encountered with certain sera containing antibodies directed against the reagent components. For this reason, assay results should be interpreted taking into consideration the patient's history and the results of any other tests performed.
- Certain drugs may interfere with free thyroid hormone assays (3, 7, 8).
- Samples containing abnormal TBG levels (very high or very low) should be not used with this assay (4, 5).
- No interference was observed with samples containing HAMA (human anti-mouse antibodies) up to 0.2 mg/dL when tested with VIDAS® FT4 assay. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.

PERFORMANCE

Studies performed using VIDAS® FT4 gave the following results:

Measurement range

The VIDAS® FT4 measurement range extends from 0.13 ng/dL up to 6.61 ng/dL. Values below the lower limit of the measurement range are reported as < 0.13 ng/dL. Values above the upper limit of the measurement range are reported as > 6.61 ng/dL.

Reference range / Expected Values

The 2.5th and 97.5th percentiles reference interval for the VIDAS® FT4 assay was determined to be 0.77 -1.51 ng/dL. The 90% confidence interval for the lower limit was 0.70 – 0.79 ng/dL and the 90% confidence interval for the upper limit was 1.41 – 1.59 ng/dL. The reference range was determined by testing a total of 544 apparently healthy subjects from a population > 18 years in age with the following characteristics: 45.5% males, 55.5% female, 83.8% Caucasian, 6.1% African-American, 9.6% Hispanic and 0.5 % Asian. It is recommended that each laboratory establishes its own reference values from a rigorously selected population (6).

Detection and quantitation limits

Studies were performed on both VIDAS® and miniVIDAS® instruments determined according to CLSI® EP17-A2 recommendations. The limits reported below applies for both instruments:

Limit of Blank (LoB): 0.02 ng/dL
Limit of Detection (LoD): 0.07 ng/dL
Limit of Quantitation (LoQ): 0.13 ng/dL

The Limit of Blank (LoB) was determined using one blank sample tested in 12 replicates per day (single run on VIDAS® instrument, 2 runs on miniVIDAS® instrument) for 5 days with each lot (2 lots on one VIDAS® instrument and 1 lot on one miniVIDAS® instrument). N=60 measures per lot on each instrument.

The Limit of Detection (LoD) was determined using low concentration samples (6 samples on VIDAS® instrument, 4 samples on miniVIDAS® instrument), tested in 5 replicates per day (single run) for 5 days with each lot(2 lots on one VIDAS® instrument and 1 lot on one miniVIDAS® instrument). N=150 measures per lot on VIDAS® instrument and N=100 measures per lot on miniVIDAS® instrument.

The Limit of Quantitation (LoQ), as determined by functional sensitivity, corresponds to the lowest analyte concentration that can be reproducibly measured with a within-laboratory precision CV of ≤ 20 %. It was determined based on the within-laboratory precision profile estimated using 9 low concentration samples tested in 5 replicates per day (single run) for 8 days with 2 lots, on one VIDAS® instrument and one miniVIDAS® instrument. N=40 measures per sample and per lot on each instrument.

Linearity

The VIDAS® FT4 assay is linear over the whole measurement range (0.13 ng/dL to 6.61 ng/dL).The linearity was conducted on the VIDAS® and the miniVIDAS® instruments and evaluated according to the recommendations of CLSI® document EP6-A.

Precision

The study was performed according to the recommendations of CLSI® document EP5-A2. Panel members covering the measuring range were tested in duplicate, in 2 runs per day, for 20 days, on 3 VIDAS® and 3 miniVIDAS® instruments . Testing included 2 lots with 10 days per lot. For each lot, 2 separate calibrations were performed. There were 5 testing days per calibration per lot.

The precision performance characteristics of the VIDAS® FT4 assay using 6 samples tested on VIDAS® instruments, are as follows:

Sample	N	Mean (ng/dL)	Repeatability		Reproducibility	
			SD (ng/dL)	CV (%)	SD (ng/dL)	CV (%)
S1	240	0.31	0.02	6.3	0.04	13.4
S2	240	0.79	0.03	3.6	0.07	8.3
S3	240	1.54	0.05	3.1	0.11	7.4
S4	240	2.57	0.06	2.5	0.13	5.1
S5	240	4.00	0.09	2.3	0.24	5.9
S6	240	5.78	0.17	3.0	0.38	6.5

The precision performance characteristics on 5 samples tested on miniVIDAS® instruments, are as follows:

Sample	N	Mean (ng/dL)	Repeatability		Reproducibility	
			SD (ng/dL)	CV (%)	SD (ng/dL)	CV (%)
P1	240	0.24	0.03	11.2	0.04	15.4
P2	240	0.78	0.03	3.7	0.04	5.6
P3	240	1.45	0.05	3.3	0.07	4.9
P4	240	3.04	0.07	2.3	0.10	3.4
P5	240	5.64	0.11	2.0	0.16	2.8

Specificity

The following substances showed no significant interference with tested FT4 concentrations of approximately 1.2 ng/dL and 2.5 ng/dL:

Tested compound	No interference* observed up to the concentration of	Cross reactivity (%) *
3,5-diiodotyrosine	16.770 µg/dL (167.70 µg/L)	0.00095 %
3,5- diodothyronine	27.310 µg/dL (273.10 µg/L)	0.00040 %
L-triiodothyronine	0.678 µg/dL (6.78 µg/L)	0.02655 %

* The studies were performed according to the recommendation of the CLSI® document EP07-A2 up to the concentration indicated on the VIDAS® and miniVIDAS® instruments.

CORRELATION

Method comparison studies

A study was performed to compare VIDAS® FT4 assay to a commercially available Free T4 EIA according to the recommendations of the CLSI® document EP9-A2.
The VIDAS® FT4 assay was tested on both VIDAS® and miniVIDAS® instruments. Fifty-four (54) samples were included in the study.
The results of the correlations are shown below:

Instrument	n	Range tested (ng/dL)	Slope	95% CI	Intercept	95% CI	Correlation coefficient (r)	95% CI
VIDAS®	54	0.41 – 6.42	1.03	0.99 ; 1.06	-0.02	-0.13 ; 0.05	0.988	0.980 ; 0.993
miniVIDAS®	54	0.52 - 6.35	1.04	1.00 ; 1.08	0.01	-0.06 ; 0.12	0.987	0.977 ; 0.992

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
Rx only	Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner

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
Note:	*Minor typographical, grammar, and formatting changes are not included in the revision history*

Release date	Part Number	Change Type	Change Summary
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