FREND™ Thyroid Duo

Free Thyroxine/Thyroid Stimulating Hormone

Intended use

The FREND™ Thyroid Duo (Free Thyroxine/thyroid stimulating hormone) Test System, is a rapid indirect competitive fluorescence immunoassay for the quantitative determina- tion of free thyroxine (FT4) and thyroid stimulating hormone(TSH) in human serum and lithium heparinized plasma specimens using the FREND™ System. Measurements of FT4 and TSH are used in the diagnosis of thyroid disorders.
The FREND™ Thyroid Duo Test System is intended for use in clinical laboratories.
For *in vitro* diagnostic use only. The test is not intended for use in point-of-care settings.

Summary and explanation of test

Human Thyroid Stimulating Hormone (hTSH) or thyrotropin stimulates the secretion of thyroxine (T4) and triiodothyronine (T3) by the thyroid gland.[1] From the moment it is secreted into the blood stream, thyroxine or tetraiodothyronine (T4), produced by the thyroid gland, is predominantly (>99%) bound to the carrier proteins TBG (Thyroxine Binding Globulin), TBPA (Thyroxine Binding PreAlbumin) and albumin. The fraction that remains free (FT4) is considered the active part of the hormone.[2] 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.[3,4]
In patients with hyperthyroidism, the FT4 concentration increases, whereas in patients with hypothyroidism it generally decreases. Patients on levothyroxine hormone replacement therapy (LT4) may have an elevation of FT4, although clinically they are euthyroid.
T3 and T4 are known to have diverse functions in regulating basal metabolic rate, bone growth, neuronal development, and sex maturation.[5] Underproduction of T3 and/or T4 can result in hypothyroidism, while overproduction of these hormones can

result in hyperthyroidism.[6] Because of a negative feedback mechanism, elevation of T3 and T4 suppress the production of TSH.[7] TSH itself is stimulated by thyrotropin releasing hormone (TRH), a tripeptide produced in the hypothalamus.[8]
Primary hypothyroidism occurs when TSH levels are elevated while T3 and/or T4 are underproduced.[9,10] Secondary or tertiary hypothyroidism can occur due to abnormal response of TSH to TRH, while central hypothyroidism occurs from pituitary dysfunction.[11,12]
Primary hyperthyroidism is marked by low levels of TSH and high levels of T3 and/or T4.[9]
Anomalies to these types of classification exist, but TSH testing can (with the aid of other thyroid tests) help a clinician determine the presence of thyroid dysfunction.[13-15]

Principle of the assay

A 70 µL specimen is added to a pretreatment tube containing gold- antibodies and incubated in the FREND AP™ automatically, while free thyroxines react with gold particles bound to antibodies against free thyroxine. After five minutes, 35 µL of sample in the tube is transferred to the sample inlet of a single use FREND™ Thyroid Duo test cartridge and allowed to equilibrate for 30 seconds in the FREND™ AP automatically. The cartridge is then placed into the FREND™ System, which is programmed to begin analysis once the sample has reacted with the reagents. The reaction and analysis time is approximately 4 minutes. The FT4/TSH quantification is based on the ratio of fluore- scence detected by the FREND™ System at the FREND™ Thyroid Duo Test and Reference zones.
The FREND™ System is a bench-top fluorescence reader containing a touchscreen user interface. The System has a slot that accepts the FREND™ Thyroid Duo test cartridge (which contains the reagents and sample), and is programmed to analyze the test when the sample has fully reacted with the on-board cartridge reagents. Results of the test are displayed on the screen and can be printed on an optional printer.

Materials provided

Q'ty	Contents	**Catalogue number**
20	Cartridge	FRTDAP 020
20	Pretreatment tube	
30	Disposable pipette tip	
01	Code chip	
01	Package insert	

Materials required but not provided

- The FREND™ System
- The FREND™ AP
- Micro-pipette capable of delivering 35 and 70 µL
- Personal protective equipment and biohazard waste equipment

Warnings and Precautions

- The FREND™ Thyroid Duo cartridges are intended for *in vitro* diagnostic use only.
- The FREND™ Thyroid Duo cartridges are only to be used on the NanoEntek FREND™ System.
- The FREND™ Thyroid Duo cartridges are disposable, single use devices. Do not reuse them under any circumstances.
- Allow sealed cartridges to come to room temperature for 15-30 minutes prior to use.
- Cartridges and pretreatment tubes should not be frozen.
- Assure the humidity in the laboratory is in the 10-80% range when tests are run.
- Avoid cross-contamination between samples by using a new pipette tip for each new specimen.
- Avoid high humidity, direct sunlight or heat in the area used for cartridge storage.
- Inaccurate results are possible if the sample used is contaminated in any way.
- Using specimens containing clotted fibrin could result in erroneous results.
- Over or under loading the cartridge with sample may result in inaccurate results. Do not use the cartridges beyond the expiration date on the pouch.
- Do not use the cartridge if the pouch is damaged or the seal is broken.
- Perform testing as specified in the Package insert and User manual.
- Keep the cartridge sealed in the pouch until ready for use.
- Use the cartridge immediately after opening the pouch.
- Handle specimens in accordance with the OSHA Standard on Bloodborne Pathogens.
- Human specimens are not used in the preparation of this product, however, since human specimens will be used for samples and other quality control products in the laboratory may be derived from human materials, Use Universal Precautions when handling all specimens and controls. Wear disposable gloves when handling the cartridges and the samples.

- Wash hands thoroughly and often after handling reagent cartridges or samples.
- Do not ingest the silica gel packet found in the cartridge pouch.

Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at the specified temperature. Reagent stability has been demonstrated for twelve months from the date of manufacture.
The expiration date is clearly indicated on the product outer box and the cartridges.

Specimen collection and handling

Serum or lithium heparinized plasma is required for the assay. No special patient preparation is necessary. Collect the appropriate venous blood sample aseptically. For serum, allow the sample to clot for 30 minutes at room temperature. For lithium heparin, centrifuge after collection. Centrifuge the sample for 10 minutes at 3,000 rpm within 2 hours of collection and immediately separate the serum or plasma from the packed cells.
Separated Samples may be stored at 2-8°C for up to 6 hours prior to analysis.
If the analysis is scheduled to be done more than 1 week after collection, the sample should be stored frozen at -20°C or below for future use.
Repeated freeze-thaw cycles should be avoided. Turbid serum samples or samples containing particulate matter such as fibrin clots or visible strands should be recentrifuged before being tested. Prior to assay, slowly bring frozen samples to room temperature and mix gently but thoroughly before testing.
The sample required for the incubation step is 70 µL. The sample required for running the test on the FREND™ Thyroid Duo cartridge is 35 µL.
For optimal results, avoid grossly hemolytic, lipemic, or turbid specimens. Specimens should be free of aggregated fibrin, red blood cells, or other particulate matter. When pipetting into the FREND™ Thyroid Duo cartridge sample inlet, ensure that bubbles in the sample are avoided. Bubbles may restrict flow and result in an incomplete or erroneous test result. Specimen should be free of aggregated fibrin, red blood cells, or other particulate matter. When pipetting into the FREND™ Thyroid Duo cartridge sample inlet, ensure that bubbles in the sample are avoided. Bubbles may restrict flow and result in an incomplete or erroneous test result.

Procedures

Calibration

There is no need for calibration to be performed by the end user. All calibration statistics and information have been electronically stored in the FREND Thyroid Duo Code chip enclosed in a box with FREND Thyroid Duo cartridges. The FREND™ Thyroid Duo Code chip is specific for each manufactured lot of FREND™ Thyroid Duo cartridges. Always run external quality control samples to verify that the FT4/TSH results obtained on the FREND™ System meet the laboratory criteria for acceptability for each lot of FREND™ Thyroid Duo cartridges.

Code chip installation

Please refer to the FREND™ System User Manual for more detailed instructions relative to the Code chip installation. Abbreviated instructions are as follows:

(1) Connect the power cord of FREND™ System into an appropriate outlet.

(2) Insert the Code chip into the Code chip slot on the rear of instrument in the direction of the arrow.

(3) Press the ‘Setup’ button on the ‘Main’ screen.

(4) Press the ‘Code chip’ button on the ‘Setup’ screen.

(5) The information embedded on the FREND™ Thyroid Duo Code chip is automatically saved on the FREND™ System.

(6) When the Code chip installation is completed, press the ‘OK’ button to go to the ‘Setup’ screen.

(7) Press the ‘Item’ button on the ‘Setup’ screen.

(8) Check if the lot numbers of the cartridge and Code chip are the same.

(9) Press the ‘Home’ button to go to the ‘Main’ screen to begin running external quality control and patient samples.

Quality control

- **FREND™ System QC cartridge**

The FREND™ QC cartridge contains multiple controls to check the optics of the system. By testing with the QC cartridge, the analytical components of the system; (1) laser power (2) alignment, and (3) mechanical integrity are confirmed.

For each day of patient testing, perform QC Cartridge testing. Refer to the quality control procedures section in the User manual of FREND™ System. In brief, perform QC Cartridge testing for the following conditions:

(1) Upon initial setup of the system
(2) Each day of patient testing
(3) When the system has been transported or moved
(4) Whenever there is uncertainty about the performance of the system
(5) Whenever required by your laboratory's quality control requirements

- **Internal procedural controls**

The FREND™ Thyroid Duo test cartridge contains built in control features. Fluorescence signal in the Reference Zone of each cartridge shows: (1) that enough sample volume is added, (2) that proper flow is obtained, and (3) that the antibody is reactive. If this Reference Zone signal is missing or lower than the threshold, the FREND™ System considers it as an incorrect or failed test, and produces an error message instead of a test result. In addition, with each cartridge run, the system monitors, in part, for (1) flow of sample, (2) speed of sample flow, (3) shelf-life of cartridge components, (4) function of internal barcode scanner, and (5) function of scanner's mechanical components.

- **External quality control testing**

Commercially available controls that contain FT4/TSH as a measured analyte are available from a variety of manufacturers. It is recommended that a minimum of two (2) levels of controls be run at least once per month or once for each new lot, whichever comes earlier. However, Controls should be run with a minimum frequency, depending on number of tests run in the laboratory. Each laboratory should establish its own criteria based on the following parameters.

(1) Each new lot
(2) Each new shipment (even if from the same lot previously received)
(3) Each new operator (an individual who has not run the tests for at least two weeks)
(4) Monthly, as a continued check on storage conditions
(5) Whenever problems (storage, operator, or other) are identified
(6) Or other times as required by your laboratory's standard QC procedures

Individual laboratory policy will dictate exactly which control materials and lot numbers should be run, the frequency with which controls are to be tested, criteria for acceptance of the results and required corrective action to be taken if results do not meet laboratory criteria. If any external quality control sample values are out of the acceptable range, it will be necessary to investigate the problem before reporting patient results to assure there is not an instrument or software malfunction. Do not assay patient samples on the FREND™ System using the FREND™ Thyroid Duo if quality control results do not give expected values. Refer to your laboratory policies on how to determine acceptability of external control material results. Each laboratory operates under a different set of regulations. Every laboratory must follow the standardized procedures acceptable to the regulatory agencies to whom the laboratory is responsible.

Specimen processing

- **Preparation**

  Remove sufficient FREND™ Thyroid Duo cartridges and pretreatment tubes from the refrigerator to test the number of patient samples and required external quality control materials. Allow the tubes and the sealed pouches containing the cartridges to come to room temperature for 15-30 minutes prior to the start of the testing sequence.
  If using refrigerated patient samples, remove those from the refrigerator and allow them to come to room temperature prior to testing. If frozen samples will be utilized, be sure these are removed from the freezer, thawed naturally and then mixed gently but thoroughly prior to testing. Testing should not begin on previously frozen samples until they have reached room temperature. There are no other reagent or sample preparations necessary.

- **Assay Procedure**

  ⚠ ***Caution:*** *When processing samples, rinse the pipette several times with the sample* and dispense 70 µL into the pretreatment tube.

  (1) Prepare the FREND™ Thyroid Duo cartridge, pretreatment tube and specimen.

Open the pouch and input the FREND™ Free T4 cartridge into the cartridge tray of the AP device. Press “NEXT” to close the cartridge tray and open the pretreatment tube tray.

(2) Transfer 70 µL of specimen to the Pretreatment tube. *(⚠**Caution:** once the sample is added to the pretreatment tube. Do not invert the tube.)* Insert the pretreatment tube into the tube hole in the FREND™ AP pretreatment tube tray. Refer to the FREND™ AP User manual for complete operating instructions.

(3) Press the “NEXT” button. The pretreatment tray will close and the first incubation step will begin.

(4) After the first incubation is complete, 35µL of mixed sample will be loaded onto the cartridge and the second incubation step will begin.

(5) When both incubation steps are completed, the cartridge tray will open and the cartridge will be ready to be inserted into the FREND™ System.

(6) Press the ‘Test’ button on the ‘Main’ screen of the FREND™ System.

(7) The system moves to the Patient ID screen automatically.

(8) Type the Patient ID and press the ‘Enter’ button to begin the test.

(9) Insert the loaded cartridge into the cartridge slot using the cartridge arrows as a guide.

⚠***Caution:*** *Please check the direction of the cartridge before insertion and assure that insertion is complete. For the best performance, leave the loaded cartridge into the FREND™ System within 5 minutes since incubation for 30 seconds.*

(10) When the reaction in the cartridge is completed, the FREND™ System will automatically begin the reading process.

(11) When the measurements are completed, the FREND™ System will automatically begin the reading process.

⚠***Caution:*** *Do not disconnect power cord or shut off power from the FREND™ System while a cartridge is in the reading chamber. This may cause a system error.*

(12) If the FREND™ System is connected to the optional printer, press the ‘Print’ button and the results will be printed on the printer paper.

For more detailed instructions, please refer to the FREND™ System User manual.

Procedural notes

Samples cannot be diluted for FT4/TSH determinations.
Samples which read FT4 > 6.00 ng/dL , TSH > 25.00 mIU/L should be reported as such.

Calculation of results

The FREND™ System performs all sample and reagent handling operations automatically within the cartridge once the sample has been manually loaded to the sample inlet in the cartridge and the cartridge placed into the FREND™ System. The rate of fluorescence produced by the reaction is read at various intervals during the analysis process. Blank readings are subtracted after which the net rate is automatically converted to FT4 concentration in ng/dL, TSH concentration in mIU/L based upon information stored on the Thyroid Duo Code chip. This result is then displayed on the screen and can be sent to the optional printer. It is also stored in memory on the FREND™ System.

Screen displayed for various concentration scenarios

Displayed result	Description
	FT4 concentration Less than 0.40 ng/dL TSH concentration Less than 0.06 mIU/L
	FT4 concentration Not less than 0.40 ng/dL and not higher than 6.00 ng/dL TSH concentration Not less than 0.06 mIU/L and not higher than 25.00 mIU/L
	FT4 concentration Higher than 6.00 ng/dL TSH concentration Higher than 25.00 mIU/L

Limitation of the procedure

1) When used for diagnostic purposes, the results obtained from this assay should be used in conjunction with other data (e.g., symptoms, results of other tests, clinical impressions, medical history, therapy, etc).

2) The FREND™ System paired with a FREND™ Thyroid Duo cartridge, is programmed to report 6.00 ng/dL as the highest concentration of FT4 and 0.06 mIU/L as the highest concentration of TSH measurable without dilution. The lowest measurable concentration is FT4 0.40 ng/dL, TSH 0.06 mIU/L – the assay limit of quantitation.
※ Measurement unit of TSH value: mIU/L = μIU/mL

3) Specimens from patients with heterophilic antibodies, such as anti-mouse (HAMA), anti-goat (HAGA), or anti-rabbit (HARA) antibodies, may show falsely elevated or depressed values or may result in the error message "Incomplete Test"[13, 14]. Patients routinely exposed to animals or animal serum products can be prone to these types of heterophilic interferences. If the FT4/TSH level is inconsistent with clinical evidence, additional FT4/TSH or other thyroid testing using a different method is suggested to confirm the results.

4) Certain medications may interfere with assay performance. All results should be interpreted with respect to the clinical picture of the patient.

5) Although hemolysis has an insignificant effect on the assay, hemolyzed samples may indicate mistreatment of a specimen prior to assay and results should be interpreted with caution.

6) Lipemia has an insignificant effect on the assay except in the case of gross lipemia where interference with the lateral flow of the sample in the cartridge may occur.

7) The concentration of FT4/TSH in a given sample determined using assays from different manufacturers can vary due to differences in assay methods, calibration, and antibody specificity.

8) Please refer to the Specimen Collection and Handling, Warnings and Precautions, Storage and Stability, and Procedural Notes sections in this insert sheet.

9) The FREND™ Thyroid Duo has not been validated in point-of-care settings.

10) Performance of this assay has not been established with neonatal specimens or specimens from pregnant patients.

11) The FREND™ Thyroid Duo is to be used in licensed clinical laboratories with trained technologists.

Performance Characteristics

Precision

A single lot imprecision study was performed at the NanoEntek laboratory as described in the *CLSI* protocol EP5-A3. Three serum pools were assayed for 20 days, 2 runs per day in duplicate using a single lot of Thyroid Duo reagent cartridge.
The results are summarized below:

FREND™ Thyroid Duo Single Site Single Lot Precision

(Free T4)

Sample ID	Mean (ng/dL)	Within-run		Between-run		Between-day		Between-laboratory	
		SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	0.80	0.062	7.8	0.014	1.7	0.008	1.0	0.064	8.0
2	1.82	0.115	6.3	0.028	1.5	0.030	1.7	0.122	6.7
3	2.49	0.132	5.3	0.009	0.4	0.021	0.9	0.134	5.4

(TSH)

Sample ID	Mean (ng/dL)	Within-run		Between-run		Between-day		Between-laboratory	
		SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	0.51	0.035	7.0	0.007	1.5	0.008	1.6	0.037	7.3
2	6.04	0.374	6.2	0.120	2.0	0.066	1.1	0.398	6.6
3	12.06	0.448	3.7	0.267	2.2	0.138	1.1	0.540	4.5

Linearity

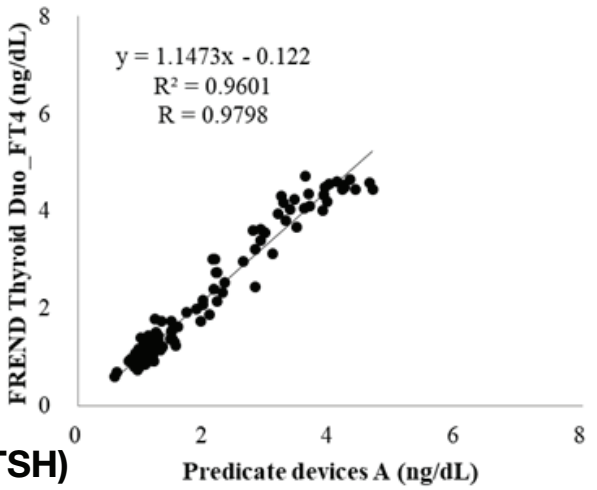
To demonstrate the linearity of the assay, a serum base pool with an elevated FT4 and TSH was prepared and diluted to a total of 11 levels according to the dilution protocol outlined in *CLSI-EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.*

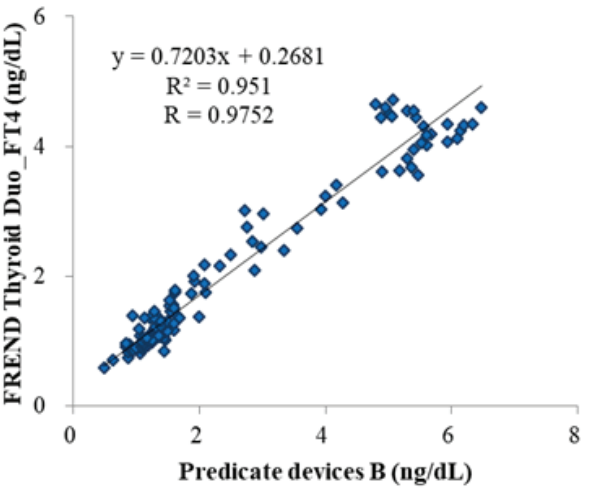
At each dilution level, the samples were tested in duplicate to determine the experimental value of FT4 and TSH. FT4 linearity was from <0.4 ng/dL to > 6.00 ng/dL, TSH linearity was demonstrated from <0.06 mIU/L to > 25.00 mIU/L. The measuring range for the FREND™ Thyroid Duo is FT4; 0.4 ~ 6.0 ng/dL, TSH; 0.06~25.00 mIU/L.

Method comparison

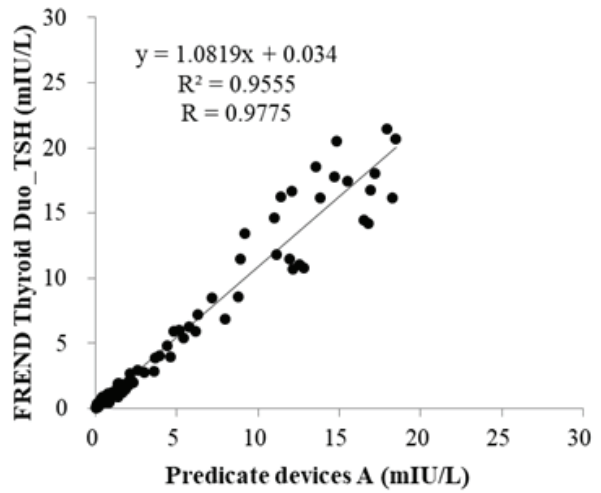
Comparison studies were performed using 120 serum samples with two predicate devices. Results generated using the FREND™ Thyroid Duo on the FREND™ System (y) were compared to those predicate device (x) by Ordinary least-square regression analysis.

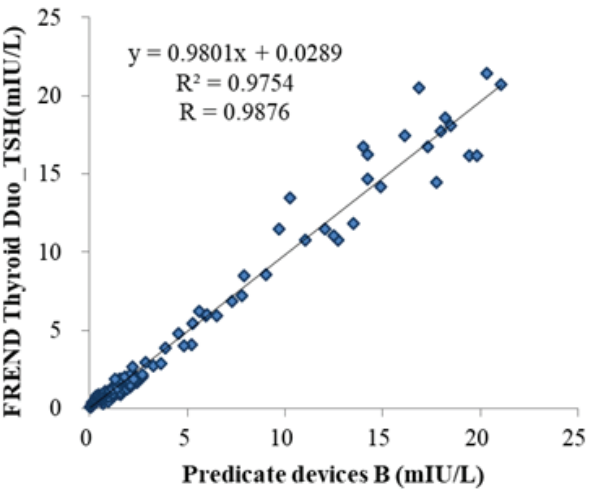
(Free T4)





(TSH)





Comparability using CLSI guideline EP09-A3 shows that the two methods compare favorably.

Sensitivity

The limit of blank (LoB) and limit of detection (LoD) was determined using guidelines found in CLSI document EP17-A. LoB was determined from 60 replicate measurements using a negative standard solution. LoD was determined using 12 replicates measurements of five low patient samples.

Analyte	LoB	LoD	LoQ
Free T4(ng/dL)	0.28	0.37	0.40
TSH (mIU/L)	0.03	0.05	0.06

Specificity

The interference study was performed as recommended in the CLSI EP7-A2 protocol using three concentrations of Thyroid Duo (Free T4 and TSH). Recovery within 90% to 110% of the expected Thyroid Duo was considered as lack of interference.
No interference by the substances below was found.

Potential interference	Concentration
Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL
Triglycerides	3 g/dL
Total protein	12 g/dL

The following substances were evaluated for potential cross-reactivity with the FREND™ Thyroid Duo at three concentrations. Testing was done according to the CLSI protocol EP07-A2. No significant cross-reactivity was found.

Cross-reactants	Concentration
Diiodothyronin, T2	5 µg/dL
Tetraiodothyroacetic Acid	10 µg/dL
Triiodothyroacetic Acid	1 µg/dL
Triiodothyropropionic Acid	5 µg/dL
Diiodotyrosine, DIT	1,000 µg/dL
L-Triiodothyronine, T3	1 µg/dL
Monoiodotyrosine	1,000 µg/dL
Reverse T3	10 µg/dL
Follicle-stimulating hormone (FSH)	500 mIU/mL
Luteinizing hormone (LH)	500 mIU/mL
Human chorionic gonadotropin (HCG)	200,000 mIU/mL

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Glossary of symbols

	Caution, warning, Consult accompanying documents
REF	Catalogue number/Reference number
LOT	Lot number/Batch number
	Use by YYYY-MM-DD or YYYY-MM
	Manufacturer
EC REP	Authorized representative in the European Community
CE	CE marking
IVD	diagnostic medical device
	Temperature limitation
	Contains sufficient for <n> tests
	Do not reuse
	Do not use if package is damaged
	For prescription use only
	Irritant

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