Instructions for Use

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LH Urine ELISA

Enzyme immunoassay for the quantitative determination of Luteinizing Hormone in human urine.

REF **RE52111**

Σ **96**

2°C 8°C

EU: IVD CE

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Flughafenstrasse 52a
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Please use only the valid version of the Instructions for Use provided with the kit.

1 INTRODUCTION

1.1 Intended Use

The LH Urine ELISA is an enzyme immunoassay for the quantitative *in vitro* diagnostic measurement of Luteinizing hormone (LH) in urine.

This test is used to detect the midcycle LH surge in urine, which is an aid in predicting the time of ovulation.

1.2 Summary and Explanation

Luteinizing hormone (LH) is produced in both men and women by gonadotropic cells in the anterior pituitary gland in response to luteinizing hormone-releasing hormone (LH-RH or Gn-RH), which is released by the hypothalamus (1,2).

LH is also called interstitial cell-stimulating hormone (ICSH) in men. LH is a heterodimeric glycoprotein with a molecular weight of approximately 30 kDa. The protein dimer contains 2 glycopeptidic subunits, labeled alpha and beta subunits that are non-covalently associated (4). While the LH alpha subunit is identical to that found in human thyroid-stimulating hormone (TSH), follicle stimulating hormone (FSH), and human chorionic gonadotropin (hCG), the beta subunit differs between these hormones (2,4).

The basal secretion of LH in men is episodic and has the primary function of stimulating the interstitial cells (Leydig cells) to produce testosterone. The variation in LH concentrations in women is subject to the complex ovulatory cycle of healthy menstruating women, and depends upon a sequence of hormonal events along the gonado-hypothalamic-pituitary axis. The decrease in progesterone and estradiol levels from the preceeding ovulation initiates each menstrual cycle (5). As a result of the decrease in hormone levels, the hypothalamus increases the secretion of gonadotropin-releasing factors (GnRF), which in turn stimulates the pituitary to increase FSH production and secretion (4). The rising FSH levels stimulate several follicles during the follicular phase, one of these will mature to contain the egg. As the follicle develops, estradiol is secreted, peaking by day 12 or 13 of a normal cycle. LH is released as a result of this rapid increase of estradiol because of direct stimulation of the pituitary and increasing GnRF and FSH levels (2,5). This "LH surge" triggers ovulation approximately 12 to 18 hours after LH reaches a maximum level. This not only releases the egg from the follicle, but also initiates the conversion of the residual follicle into the corpus luteum which secretes progesterone and estrogen - two negative feedback regulators of LH on the hypotalamic-pituitary axis (3-8). The corpus luteum regresses if pregnancy does not occur, and the corresponding drop in progesterone and estradiol levels results in menstruation.

If pregnancy occurs, LH levels will decrease, and luteal function will instead be maintained by the action of hCG, a hormone very similar to LH but secreted from the new placenta. hCG causes the corpus luteum to continue producing progesterone and estradiol.

In the differential diagnosis of hypothalamic, pituitary, or gonadal dysfunction, assays of LH concentration are routinely performed in conjunction with FSH assays since their roles are closely interrelated. Furthermore, the hormone levels are used to determine menopause, pinpoint ovulation, and monitor endocrine therapy.

2 PRINCIPLE OF THE TEST

The LH Urine ELISA is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the **sandwich principle.**

The microtiter wells are coated with a monoclonal (mouse) antibody directed towards a unique antigenic site of the β-subunit of the LH molecule.

During the first incubation, the β-subunit of the LH molecule in the added sample binds to the immobilized antibody. After incubation, the added conjugate solution, which contains an anti-LH antibody conjugated to horseradish peroxidase, binds to the LH forming a sandwich complex.

After a washing step, to remove all unbound substances, the solid phase is incubated with the substrate solution. The colorimetric reaction is abruptly stopped by addition of stop solution and optical density (OD) of the resulting yellow product is measured. The intensity of color is proportional to the concentration of the analyte in the sample.

A standard curve is constructed by plotting OD values against concentrations of standards, and concentrations of unknown samples are determined using this standard curve.

3 WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only. For professional use only.
2. All reagents of this test kit which contain human serum or plasma have been tested and confirmed negative for HIV I/II, HBsAg and HCV by FDA approved procedures. All reagents, however, should be treated as potential biohazards in use and for disposal.
3. Before starting the assay, read the instructions completely and carefully. Use the valid version of instructions for use provided with the kit. Be sure that everything is understood.
4. The microplate contains snap-off strips. Unused wells must be stored at 2°C to 8°C in the sealed foil pouch and used in the frame provided.
5. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
6. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
7. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
8. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
9. Allow the reagents to reach room temperature (20°C to 26°C) before starting the test. Temperature will affect the absorbance readings of the assay. However, values for the samples will not be affected.
10. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
11. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
12. Wear disposable latex gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may give false results.
13. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
14. Do not use reagents beyond expiry date as shown on the kit labels.
15. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiter plate readers.
16. Do not mix or use components from kits with different lot numbers. It is advised not to exchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may result slightly different.
17. Avoid contact with Stop Solution containing 0.5 M H_2SO_4. It may cause skin irritation and burns.
18. Some reagents contain Proclin 300, BND and/or MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
19. TMB substrate has an irritant effect on skin and mucosa. In case of possible contact, wash eyes with an abundant volume of water and skin with soap and abundant water. Wash contaminated objects before reusing them. If inhaled, take the person to open air.
20. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
21. For information on hazardous substances included in the kit please refer to Safety Data Sheets. Safety Data Sheets for this product are available upon request.

4 REAGENTS

4.1 Reagents provided

1. **MTP** ***Microtiter Plate***, 12 x 8 (break apart) strips, 96 wells;
   Wells coated with anti-β-subunit LH antibody (monoclonal).

2. **ENZCONJ** ***Enzyme Conjugate***, 1 vial, 11 mL, ready to use;
   Anti-LH antibody conjugated with horseradish peroxidase;
   Contains non-mercury preservative.

3. **CAL** **LYO** ***Standard (Standard 0 - 5)***, 6 vials, 1 mL each, lyophilized;
   Concentrations: 0 – 10 – 20 – 40 – 100 – 200 mIU/mL
   The standards are calibrated against the following reference material: WHO International Standard Luteinizing Hormone, Human, Pituitary, NIBSC code: 80/552;
   See “Reagent Preparation“.
   Contain non-mercury preservative.

4. **WASHBUF** **CONC** ***Wash Solution***, 1 vial, 30 mL (40X concentrated);
   See “Reagent Preparation“.

5. **SUBS** ***Substrate Solution***, 1 vial, 14 mL, ready to use;
   Tetramethylbenzidine (TMB).

6. **STOP** ***Stop Solution***, 1 vial, 14 mL, ready to use;
   Contains 0.5 M H_2SO_4,
   Avoid contact with the stop solution. It may cause skin irritations and burns.

4.2 Materials required but not provided

- A calibrated microtiter plate reader (450 nm, with reference wavelength at 620 nm to 630 nm)
- Calibrated variable precision micropipettes
- Absorbent paper
- Distilled water
- Timer
- Graph paper or software for data reduction

4.3 Storage Conditions

When stored at 2°C to 8°C unopened reagents will retain reactivity until expiration date. Do not use reagents beyond this date.

Opened reagents must be stored at 2°C to 8°C. Microtiter wells must be stored at 2°C to 8°C. Once the foil bag has been opened, care should be taken to close it tightly again.

Opened kits retain activity for 4 weeks if stored as described above.

4.4 Reagent Preparation

Standards: The reconstituted standards are stable for 4 weeks at 2°C to 8°C.

For longer storage (up to 18 months), aliquot and freeze at -20°C.

Wash Solution: Add distilled water to the 40X concentrated Wash Solution.
Dilute 30 mL of concentrated *Wash Solution* with 1170 mL distilled water to a final volume of 1200 mL.

The diluted *Wash Solution* is stable for 1 week at room temperature.

4.5 Disposal of the Kit

The disposal of the kit and all used materials/reagents must be performed according to the national regulations. Special information for this product is given in the Safety Data Sheet.

4.6 Damaged Test Kits

In case of any damage to the test kit or components, IBL must be informed in writing, at the latest one week after receiving the kit. Damaged single components should not be used for a test run. They must be stored until a final solution has been found. After this, they should be disposed of according to the official regulations.

5 SPECIMEN COLLECTION AND PREPARATION

Urine must be used in this assay. **ATTENTION!** This kit is for use with samples without additives only.

5.1 Specimen Collection

It is recommended to collect the first morning urine (after fasting).

First clean genital area with mild disinfectant to prevent contamination. Then collect clean-catch midstream urine in an appropriate sterile container without preservatives.

Directly after collection, the urine should be centrifuged for 5 to 10 minutes (e.g. at 2,000 g) to remove cellular debris.

Use supernatant for analyte quantification.

The variation in LH concentrations in women is subject to the complex ovulatory cycle of healthy menstruating women.

5.2 Specimen Storage and Preparation

The urine supernatant should be capped and may be stored for up to 7 days at 2°C to 8°C prior to assaying.

The supernatants cannot be stored frozen.

6 ASSAY PROCEDURE

6.1 General Remarks

- All reagents and specimens must be allowed to come to room temperature before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps should be completed without interruption.
- Use new disposal plastic pipette tips for each standard, control or sample in order to avoid cross contamination.
- Absorbance is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
- As a general rule the enzymatic reaction is linearly proportional to time and temperature.

6.2 Test Procedure

Each run must include a standard curve.

1. Secure the desired number of Microtiter wells in the frame holder.
2. Dispense **50 µL** of each ***Standard,*** control and sample with new disposable tips into appropriate wells.
3. Incubate for **30 minutes** at room temperature.
4. Dispense **100 µL** ***Enzyme Conjugate*** into each well.
   Thoroughly mix for 10 seconds. It is important to have a complete mixing in this step.
5. Incubate for **30 minutes** at room temperature.
6. Briskly shake out the contents of the wells.
   Rinse the wells **3 times** with **300 µL** diluted *Wash Solution* per well for manual washing. Strike the wells sharply on absorbent paper to remove residual droplets.
   Important note:
   The sensitivity and precision of this assay is markedly influenced by the correct performance of the washing procedure!
7. Add **100 µL** of ***Substrate Solution*** to each well.
8. Incubate for **10 minutes** at room temperature.
9. Stop the enzymatic reaction by adding **50 µL** of ***Stop Solution*** to each well.
10. Determine the absorbance (OD) of the solution in each well at **450 nm (reading) and at 620 nm to 630 nm (background subtraction, recommended)** with a microtiter plate reader.
    It is recommended that the wells be read **within 10 minutes** after adding the *Stop Solution*.

6.3 Calculation of Results

1. Calculate the average absorbance values for each set of standards, controls and samples.
2. Using semi-logarithmic graph paper, construct a standard curve by plotting the mean absorbance obtained from each standard against its concentration with absorbance value on the vertical (Y) axis and concentration on the horizontal (X) axis.
3. Using the mean absorbance value for each sample determine the corresponding concentration from the standard curve.
4. Automated method: The results in the Instructions for Use have been calculated automatically using a 4-Parameter curve fit. (4 Parameter Rodbard or 4 Parameter Marquardt are the preferred methods.) Other data reduction functions may give slightly different results.
5. The concentration of the samples can be read directly from this standard curve. Samples with concentrations higher than that of the highest standard have to be further diluted or reported as > 200 mIU/mL. For the calculation of the concentrations this dilution factor has to be taken into account.

6.3.1 Example of Typical Standard Curve

The following data is for demonstration only and **cannot** be used in place of data generations at the time of assay.

Standard	Optical Units (450 nm)
Standard 0 (0 mIU/mL)	0.02
Standard 1 (10 mIU/mL)	0.16
Standard 2 (20 mIU/mL)	0.30
Standard 3 (40 mIU/mL)	0.50
Standard 4 (100 mIU/mL)	1.22
Standard 5 (200 mIU/mL)	2.30

7 EXPECTED NORMAL VALUES

It is strongly recommended that each laboratory should determine its own normal and abnormal values.
Using the LH Urine ELISA the following values are observed:

Population		Age	n	Mean	Range
Males:	pre-pubescent	< 10 years	10	1.1 mIU/mL	0 - 2.9 mIU/mL
	adult	18 - 65 years	30	4.6 mIU/mL	1.0 - 13.8 mIU/mL
Females:	pre-pubescent	< 10 years	8	0.8 mIU/mL	0 - 1.5 mIU/mL
	adult	20 - 36 years	47	14.8 mIU/mL	0.6 - 96.2 mIU/mL
	follicular and luteal phase				< 20 mIU/mL
	LH surge				40 - 200 mIU/mL
	post-menopausal	46 - 60 years	23	36.3 mIU/mL	8.4 - 102.0 mIU/mL

The results alone should not be the only reason for any therapeutic consequences. The results should be correlated to other clinical observations and diagnostic tests.

8 QUALITY CONTROL

Good laboratory practice requires that controls be run with each calibration curve. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance.
It is recommended to use control samples according to state and federal regulations. The use of control samples is advised to assure the day to day validity of results. Use controls at both normal and pathological levels.
The controls and the corresponding results of the QC-Laboratory are stated in the QC certificate added to the kit. The values and ranges stated on the QC sheet always refer to the current kit lot and should be used for direct comparison of the results.
It is also recommended to make use of national or international Quality Assessment programs to ensure the accuracy of the results.
Employ appropriate statistical methods for analysing control values and trends. If the results of the assay do not fit to the established acceptable ranges of control materials, the results should be considered invalid.
In this case, please check the following technical areas: Pipetting and timing devices; photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods.
After checking the above mentioned items without finding any error contact your distributor or IBL directly.

9 PERFORMANCE CHARACTERISTICS

9.1 Assay Dynamic Range

The linear range of the assay is between 0.89 - 200 mIU/mL.

9.2 Specificity of Antibodies (Cross-Reactivity)

The following substances were tested for cross-reactivity of the assay:

Substance	Added Conc.	Measured Conc.	Cross-reactivity
hCG (WHO RR, NIBSC code: 99/688	20 - 20 000 mIU/mL	0.0 mIU/mL	0.0 %
βhCG (IRP, NIBSC code: 75/551)	20 - 20 000 mIU/mL	0.0 mIU/mL	0.0 %
FSH (WHO IS, NIBSC code: 92/510)	3 - 3000 mIU/mL	0.0 mIU/mL	0.0 %
TSH (WHO RR, NIBSC code: 94/674)	0.3 - 300 mIU/mL	0.0 mIU/mL	0.0 %

9.3 Detection Capability

The Limit of Blank (LoB) is 0.016 mIU/mL.
The Limit of Detection (LoD) is 0.287 mIU/mL.
The Limit of Quantification (LoQ) is 3.272 mIU/mL.

9.4 Repeatability and Reproducibility

9.4.1 Repeatability (within-run precision)

The within-assay variability was determined by measuring each sample 10 times per run (n = 10):

Sample	n	Mean	CV
1	10	5.3 mIU/mL	2.7 %
2	10	16.3 mIU/mL	2.7 %
3	10	39.5 mIU/mL	1.3 %
4	10	50.2 mIU/mL	2.3 %

9.4.2 Reproducibility (between run)

The between-assay variability was determined by measuring each sample 10 times per run for 3 days (n = 30):

Sample	n	Mean	CV
1	30	5.9 mIU/mL	9.8 %
2	30	16.8 mIU/mL	3.9 %
3	30	40.6 mIU/mL	2.8 %
4	30	50.4 mIU/mL	2.8 %

9.4.3 Reproducibility (between lot)

The between-lot variability was determined by 6 measurements of 4 samples with 3 different kit lots (n=18)

Sample	Mean Conc. Lot 1	Mean Conc. Lot 2	Mean Conc. Lot 3	Mean Conc.	Between- Lot CV	n
1	28.24 mIU/mL	35.10 mIU/mL	33.27 mIU/mL	32.20 mIU/mL	11.0 %	18
2	41.42 mIU/mL	38.14 mIU/mL	35.58 mIU/mL	38.38 mIU/mL	7.6 %	18
3	178.80 mIU/mL	171.98 mIU/mL	164.16 mIU/mL	171.65 mIU/mL	4.3 %	18
4	24.38 mIU/mL	22.98 mIU/mL	20.84 mIU/mL	22.74 mIU/mL	7.8 %	18

9.5 Recovery

Samples have been spiked by adding LH solutions with known concentrations.
The recovery (%) was calculated by multiplying the ratio of measured and expected values with 100.

		Sample 1	Sample 2	Sample 3	Sample 4
Concentration		1.6 mIU/mL	5.9 mIU/mL	8.5 mIU/mL	12.9 mIU/mL
Average Recovery		96.0 %	95.7 %	105.1 %	93.6 %
Range of Recovery	**from**	88.9 %	89.6 %	103.8 %	85.5 %
	to	102.1 %	100.9 %	105.8 %	98.8 %

9.6 Linearity

Samples were measured undiluted and in serial dilutions with standard 0. The recovery (%) was calculated by multiplying the ratio of expected and measured values with 100.

		Sample 1	Sample 2	Sample 3	Sample 4
Concentration		22.2 mlU/mL	24.1 mlU/mL	49.6 mlU/mL	59.6 mlU/mL
Average Recovery		96.9 %	104.2 %	109.7 %	103.7 %
Range of Recovery	**from**	93.5 %	101.5 %	106.1 %	86.9 %
	to	100.3 %	106.9 %	112.7 %	114.7 %

10 LIMITATIONS OF USE

Reliable and reproducible results will be obtained when the assay procedure is performed with a complete understanding of the package insert instruction and with adherence to good laboratory practice.

Any improper handling of samples or modification of this test might influence the results.

10.1 Drug Interferences

Until today no substances (drugs) are known to us, which have an influence on the measurement of LH in a sample.

10.2 High-Dose-Hook Effect

Hook effect was not observed in this test up to a concentration of 4000 mlU/mL of LH.

11 LEGAL ASPECTS

11.1 Reliability of Results

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, a sufficient number of controls for validating the accuracy and precision of the test.

The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact IBL.

11.2 Therapeutic Consequences

Therapeutic consequences should never be based on laboratory results alone even if all test results are in agreement with the items as stated under point 11.1. Any laboratory result is only a part of the total clinical picture of a patient.

Only in cases where the laboratory results are in acceptable agreement with the overall clinical picture of the patient should therapeutic consequences be derived.

The test result itself should never be the sole determinant for deriving any therapeutic consequences.

11.3 Liability

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement.

Claims submitted due to customer misinterpretation of laboratory results subject to point 11.2 are also invalid. Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

12 REFERENCES / LITERATURE

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Symbols / Symbole / Symboles / Símbolos / Simboli / Símbolos / Σύμβολα

REF	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.–Cat.: / N.º Cat.: / Αριθμός-Κατ.:
LOT	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lotto n.: / Lote N.º: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Da utilizzare entro:/ Usar até: / Χρησιμοποιείται από:
Σ	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / Quantità dei tests: / N.º de Testes: / Αριθμός εξετάσεων:
CONC	Concentrate / Konzentrat / Concentré / Concentrar / Concentrato / Concentrado / Συμπύκνωμα
LYO	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Liofilizado / Λυοφιλιασμένο
IVD	In Vitro Diagnostic Medical Device / In-vitro-Diagnostikum / Appareil Médical pour Diagnostics In Vitro / Dispositivo Médico para Diagnóstico In Vitro / Dispositivo Medico Diagnostico In vitro / Equipamento Médico de Diagnóstico In Vitro / Ιατρική συσκευή για In-Vitro Διάγνωση
BIO	Contains biological material of human origin / Enthält biologisches Material menschlichen Ursprungs / Contient une substance biologique d'origine humaine / Contiene material biológico de origen humano / Contiene materiale biologico di origine umana / Contém material biológico de origem humana / Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης
BIO	Contains biological material of animal origin / Enthält biologisches Material tierischen Ursprungs / Contient une substance biologique d'origine animale / Contiene material biológico de origen animal / Contiene materiale biologico di origine animale / Contém material biológico de origem animal / Περιέχει βιολογικό υλικό ζωικής προέλευσης
UDI	Unique Device Identification / Eindeutige Gerätekennung / Identifiant de dispositif unique / Identificación única de producto / Identificatore univoco del dispositivo / Identificador de dispositivo único / Μοναδικός αναγνωριστικός κωδικός προϊόντος
	Read instructions before use / Arbeitsanleitung lesen / Lire la fiche technique avant emploi / Lea las instrucciones antes de usar / Leggere le istruzioni prima dell'uso / Ler as instruções antes de usar / Διαβάστε τις οδηγίες πριν την χρήση
	Keep away from heat or direct sun light / Vor Hitze und direkter Sonneneinstrahlung schützen / Garder à l'abri de la chaleur et de toute exposition lumineuse / Manténgase alejado del calor o la luz solar directa / Non esporre ai raggi solari / Manter longe do calor ou luz solar directa / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Armazenar em: / Αποθήκευση στους:
2-8°C	Store at: 2 - 8°C / Lagern bei: 2 - 8°C / Stocker à: 2 - 8°C / Almacene a: 2 - 8°C / Armazenar a: 2 - 8°C / Conservare a: 2-8°C / Armazenar em: 2-8°C / Αποθήκευση στους: 2-8°C
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Distributor: / Distributor: / Distributeur: / Distributor: / Distributore: / Distribuidor: / Διανομέας:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Attenzione! / Cuidado! / Προσοχή!
	Symbols of the kit components see MATERIALS SUPPLIED. Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben. Voir MATERIEL FOURNI pour les symbôles des composants du kit. Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS. Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT. Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS. Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

Generic table, not all symbols are present in the product

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

The labelling of hazardous substances is according to European directive.
For further country-specific classifications, please refer to the corresponding safety data sheet.

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