Instructions for Use

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Estriol high sensitive Saliva ELISA

Enzyme immunoassay for the quantitative determination of Estriol in human saliva.

REF **30121046**

Σ **96**

2°C 8°C

EU: IVD CE 2797

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REVISION HISTORY OF INSTRUCTIONS FOR USE

Changes from the previous version 2019-09 to actual version 2023-04	
Cover page	Layout change
Chapter 2	Additional chapter
Chapter 3	Update to scientific validity
Chapter 5	Additional information
Chapter 6	Update
Chapter 7	Update and additional data
Chapter 8	Additional information
Chapter 11	Update
Chapter 13	Additional information
Chapter 15	Update and additional data
Chapter 16	Update and additional data
Chapter 17	Layout change and additional data
Chapter 18	Update
Chapter 19	Update
Symbol page	Layout change

1. INTENDED USE

Enzyme immunoassay for the quantitative determination of Estriol in human saliva.

2. INTENDED PURPOSE

The Estriol high sensitive Saliva ELISA is intended for the quantitative measurement of Estriol in human saliva.
Estriol is an estrogen typically produced during pregnancy. Estriol level found in non-pregnant women are similar to level both during pre- and post-menopause and are similar to the level in men. The estriol saliva assay is commonly applied to monitor estriol level in women who take supplements as part of a hormone replacement therapy and as an indicator of premature delivery in pregnant women. However, this assay is not intended to be used in the context of screening for congenital disorders of the fetus (such as Down Syndrome). Additonal hormone assays are recommended for an interpretation of the level of estriol.
The Estriol high sensitive Saliva ELISA is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding and measured on an absorbance reader. The assay is semi-automated requiring general purpose laboratory instruments and consumables such as absorbance microplate reader/washer, vortexer and pipettes to execute the test. The assay is adaptable by laboratory personnel to automate on open ELISA based liquid handler platforms; however, the programming of the steps and timing required must be verified by the laboratory. Test results are calculated from a standard curve and compared to laboratory established reference ranges from healthy adults (i.e. normal ranges).
The test kit is intended for professional laboratory use by trained personnel. The test kit is not for self-testing. The Estriol high sensitive Saliva ELISA is not intended for near-patient testing.

3. SUMMARY AND EXPLANATION

Estriol (E3) is the one of the ovarian estrogens in women (estriol, estradiol, estrone) and produced in placenta and then secreted into maternal circulation. A small portion (10 %) of estriol is not conjugated and remains as unconjugated estriol, which corresponds to the biological active fraction. Diurnal variation has been reported in both total estriol and unconjugated estriol with levels 15 % lower in the morning.[1]
During pregnancy, estriol is produced in the placenta. Placental steroidogenesis has been established as an indicator for health problems of the placenta.[2].
Low levels of unconjugated estriol in pregnancy may be indicative for congenital disorders of the fetus. The Estriol High Sensitive ELISA is NOT intended to be used in the context of screening for congenital disorders of the fetus (such as Down Syndrome).
In non-pregnant women, Estriol levels are very low [3] and similar in both pre- and post-menopause, and are also similar to levels in men.[4; 5]
The saliva test for estriol is most commonly used for monitoring of levels in women who use estriol containing supplements as part of hormone replacement therapy in menopausal women. Additional hormone assays are recommended for an interpretation of the level of estriol e.g. estrogens and androgens.[6; 7]
The lack of the production of estrogens leads to a variety of symptoms during menopause e.g. hot flashes, decreased energy, sleep disruption, night sweats, mood-related symptoms, vaginal atrophy, dysuria, urinary urgency and sexual dysfunction, which can be treated with a hormone replacement therapy, which was shown to be beneficial for women in relieving the signs and symptoms.[8]

Estriol can be measured in serum and saliva, however, measurement in saliva is advantageous because it is non-invasive, multiple samples can be collected, it is less stressful for the patient and can be collected by a layperson.[9] Additionally, the estriol present in saliva is unbound and bioactive and correlates with the unbound fraction in serum.[10]

4. TEST PRINCIPLE

The Estriol high sensitive Saliva ELISA is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding.
The microtiter wells are coated with a monoclonal antibody directed towards an antigenic site on the Estriol molecule. Endogenous Estriol of a patient sample competes with a Estriol-horseradish peroxidase conjugate for binding to the coated antibody. After incubation the unbound conjugate is washed off.
The amount of bound peroxidase conjugate is inversely proportional to the concentration of Estriol in the sample. After addition of the substrate solution, the intensity of colour developed is inversely proportional to the concentration of Estriol in the patient sample.

5. WARNINGS AND PRECAUTIONS

1. For *in-vitro diagnostic* use only. For professional use only by GLP trained professionals.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. In case of severe damage of the kit package please contact IBL or your supplier in written form, latest one week after receiving the kit. Do not use damaged components in test runs, but keep safe for complaint related issues.
4. Broken glass may cause injury. Handle glass vessels with caution.
5. Obey lot number and expiry date. Do not mix reagents of different lots. Do not use expired reagents.
6. Follow good laboratory practice and safety guidelines. Wear lab coats, disposable latex gloves and protective glasses where necessary.
7. Reagents of this kit containing hazardous material may cause eye and skin irritations. See MATERIALS SUPPLIED and labels for details. Safety Data Sheets for this product are available on the IBL-Homepage or upon request directly from IBL.
8. Chemicals and prepared, used, unused or expired reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
9. The cleaning staff should be guided by the professionals regarding potential hazards and handling.
10. All serious incidents that have occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
11. The device contains material of animal origin, which is certified apparently free of infectious or contagious diseases and injurious parasites. Still the material should be handled with extreme caution.
12. Avoid contact with Stop solution. It may cause skin irritations and burns.
13. Some reagents contain ProClin 300 as preservative. In case of contact with eyes or skin, flush immediately with water. When disposing reagents, flush with a large volume of water to avoid built-up.

6. STORAGE AND STABILITY

The kit is shipped at ambient temperature and should be stored at 2 - 8°C. Keep away from heat or direct sunlight. The storage and stability of specimens and prepared reagents is stated in the corresponding chapters.

The unopened reagents are stable until the expiry date indicated. The kit is stable up to 6 months after the first opening (not exceeding the expiry date) when the Microtiterplate is packed in a tightly closed bag, the bottles are closed with their screw caps and the kit is stored at indicated storage temperature.

7. SPECIMEN COLLECTION AND STORAGE

Specimen collection

The patient should not eat, drink, chew gums or brush teeth for 30 minutes before sampling. Rinse mouth thoroughly with cold water 5 minutes prior to sample collection.
Do not collect samples when oral diseases, inflammation or lesions exist (blood contamination). Reddish colour is indicating blood contamination and leading to wrong results.
A minimum of 0.5 mL liquid should be collected. Saliva flow can be stimulated by chewing on a piece of Parafilm®.
It is recommended to freeze samples at -20°C prior to laboratory testing. After thawing, mix and centrifuge 10 minutes at 2000 – 3000 x g to remove particulate material.
Due to the pulsatile dynamics of steroid secretion, repeated saliva sampling is recommended.* IBL recommends collecting 3 to 5 saliva samples within 2 hours. In the laboratory, equal volumes of the individual saliva samples can be mixed. This mixed sample results in a mean value, which represents the active hormone concentration in a reproducible way.

* Lightman, S. L., & Conway-Campbell, B. L. (2010). The crucial role of pulsatile activity of the HPA axis for continuous dynamic equilibration. *Nature Reviews Neuroscience*, *11*(10), 710-718.

Sample Collection Device

Saliva needs to be collected in polypropylene or glass tubes.
Salivette tubes should not be used as leading to wrong results.

Specimen storage

Saliva samples can be stored at 2°C to 8°C for ≤ 7 days.
It is recommended to freeze samples and store at -20°C for long time storage (< 6 months).
It is recommended to limit the number of freeze /thaw cycles to a maximum of 5.
Keep away from heat or direct sunlight.

8. MATERIALS SUPPLIED

Quantity	Symbol	Origin	Component
1 x 12 x 8	**MTP**	BIO	**Microtiter Plate** Break apart strips. MTP (12 strips of 8 wells each) Coated with anti-Estriol antibody (monoclonal) and coated with goat anti-rabbit antibody in solution containing bovine serum albumin. Vacuum dried.
1 x 9 mL	**ENZCONJ**	BIO	**Enzyme Conjugate** Ready to use. Contains estriol conjugated to peroxidase in MOPS buffer solution containing bovine serum albumin and Thimerosal <0.1 % (w/w).
1 x 6 x 1 mL	**CAL A-F**	BIO	**Standard A-F** Ready to use. 0; 2; 8; 24; 96; 288 pg/mL Contains: Estriol, bovine serum albumin and ≤ 0.1% ProClin (w/w).
1 x 2 x 1 mL	**CONTROL 1+2**	BIO	**Control 1+2** Ready to use. Contains: Estriol, bovine serum albumin and ≤ 0.1% ProClin (w/w). Exact concentrations see vial labels or QC certificate.
1 x 15 mL	**TMB SUBS**		**TMB Substrat Solution** Ready to use. Contains 3,3',5,5' Tetramethylbenzidine solution.
1 x 15 mL	**TMB STOP**		**TMB Stop Solution** Ready to use. Contains 1 M sulfuric acid
1 x 100 mL	**WASHBUF** **CONC**		**Wash Buffer Concentrate** (10x) Phosphate buffer containing 1 % Tween 20 (w/w).
3 x	**FOIL**		**Adhesive Foil**

9. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipettes (Multipette Eppendorf or similar devices, < 3 % CV). Volume: 50; 100; 250 µL
2. Vortex mixer
3. Sample Diluent (can be ordered separately from IBL under REF KLZZ731).
4. A suitable sampling device should be used.
5. 8-Channel Micropipette with reagent reservoirs
6. Wash bottle, automated or semi-automated microtiter plate washing system
7. Microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength 600 - 650 nm)
8. Bidistilled or deionised water
9. Paper towels, pipette tips and timer

10. PROCEDURE NOTES

1. Any improper handling of samples or modification of the test procedure may influence the results. The indicated pipetting volumes, incubation times, temperatures and pre-treatment steps have to be performed strictly according to the instructions. Use calibrated pipettes and devices only.
2. Once the test has been started, all steps should be completed without interruption. Make sure that required reagents, materials and devices are prepared ready at the appropriate time. Allow all reagents and specimens to reach room temperature (18 - 25°C) and gently swirl each vial of liquid reagent and sample before use. Mix reagents without foaming.
3. Avoid contamination of reagents, pipettes and wells/tubes. Use new disposable plastic pipette tips for each component and specimen. Do not interchange caps. Always cap not used vials. Do not reuse wells/tubes or reagents.
4. It is advised to perform duplicate measurements to be able to identify potential pipetting errors.
5. Use a pipetting scheme to verify an appropriate plate layout.
6. Incubation time affects results. All wells should be handled in the same order and time sequences. It is recommended to use an 8-channel Micropipettor for pipetting of solutions in all wells.
7. Microtiter plate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multichannel pipette or an automatic microtiter plate washing system. Do not allow the wells to dry between incubations. Do not scratch coated wells during rinsing and aspiration. Rinse and fill all reagents with care. While rinsing, check that all wells are filled precisely with Wash Buffer, and that there are no residues in the wells.
8. Humidity affects the coated wells/tubes. Do not open the pouch until it reaches room temperature. Unused wells/tubes should be returned immediately to the resealed pouch including the desiccant.

11. PRE-TEST SETUP INSTRUCTIONS

11.1. Preparation of concentrated components

The contents of the kit for 96 determinations can be divided into 3 separate runs.

The volumes stated below are for one run with all strips (96 determinations).

Dilute / dissolve	Component		Diluent	Relation	Remarks	Storage	Stability
100 mL	**WASHBUF** **CONC**	ad 1000 mL	bidist. water	1:10	Mix vigorously	2 - 8°C	8 weeks

11.2. Dilution of Samples

Samples suspected to contain concentrations higher than the highest standard have to be diluted with Sample Diluent (REF KLZZ731). Dilution has to be made in glass tubes. Measured results must be multiplied with the dilution factor to obtain corrected results.

12. TEST PROCEDURE

1.	Pipette **100 µL** of each **Standard, Control and sample** into the respective wells of the Microtiter Plate.
2.	Pipette **50 µL** of **Enzyme Conjugate** into each well.
3.	Thoroughly mix for 10 seconds.
4.	Cover plate with adhesive foil. **Incubate 120 minutes** at **18 - 25°C** (room temperature)**.**
5.	Remove adhesive foil. Discard incubation solution. Wash plate **4 x** with **250 µL** of diluted **Wash Buffer.** Remove excess solution by tapping the inverted plate on a paper towel.
6.	Pipette **100 µL** of **TMB Substrate Solution** into each well.
7.	**Incubate 30 minutes** at **18 - 25°C** (manual). In case of automation of the assay the incubation time can be reduced to 25 minutes.
8.	Stop the substrate reaction by adding **100 µL** of **TMB Stop Solution** into each well. Briefly mix contents by gently shaking the plate. Colour changes from blue to yellow.
9.	**Measure** optical density with a photometer at **450 nm** (Reference-wavelength: 600 - 650 nm) within **15 minutes** after pipetting of the Stop Solution.

13. AUTOMATION

Automated protocols can be provided for open ELISA systems: Freedom EVOlyzer®, ThunderBolt® and DSX®. For further information please contact: ProductSupport.IBL@tecan.com

For the use of products on automated instruments it is absolutely necessary to perform and maintain a validation according to legal requirements. A successful validation of the process is a prerequisite for diagnostic use. The responsibility for the implementation and documentation of validation in accordance with the country-specific requirements is assumed by the organization or institution.

14. QUALITY CONTROL

The test results are only valid if the test has been performed following the instructions. Moreover, the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or comparable standards/laws. User and/or laboratory must have a validated system to get diagnosis according to GLP. All kit controls must be found within the acceptable ranges as stated on the labels and the QC certificate. If the criteria are not met, the run is not valid and should be repeated. Each laboratory should use known samples as further controls.

In case of any deviation the following technical issues should be proven: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, incubation conditions and washing methods.

It is recommended to participate at appropriate quality assessment trials.

15. CALCULATION OF RESULTS

15.1. Determining the standard curve

The obtained ODs of the standards (y-axis, linear) are plotted against their concentration (x-axis, logarithmic) either on semi-logarithmic graph paper or using an automated method. A good fit is provided with cubic spline, 4 Parameter Logistics or Logit-Log.
For the calculation of the standard curve, apply each signal of the standards (one obvious outlier of duplicates could be omitted and the more plausible single value used).

The concentration of the samples can be read directly from the standard curve.

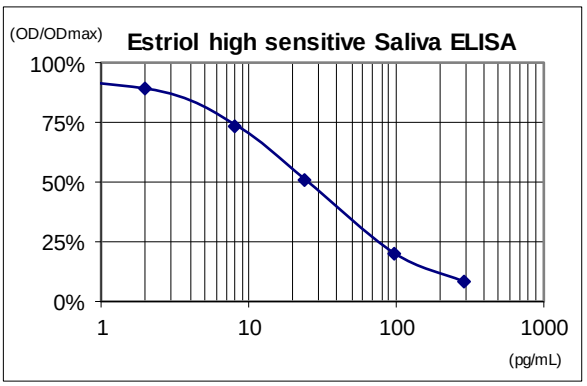
Samples showing concentrations above the highest standard have to be diluted as described in PRE-TEST SETUP INSTRUCTIONS and re-assayed.

Conversion: 1000 pg/mL = 1 ng/mL
Estriol (pg/mL) x 3.47 = pmol/L

Typical Calibration Curve

(Example. Do not use for calculation!)

Standard	Estriol	OD_{Mean}	OD/OD_{max}
A	0 pg/mL	2.273	100 %
B	2 pg/mL	2.025	89.1 %
C	8 pg/mL	1.682	74.0 %
D	24 pg/mL	1.159	51.0 %
E	96 pg/mL	0.460	20.2 %
F	288 pg/mL	0.186	8.18 %



Measuring Range: 3.2 pg/mL (LoQ as functional sensitivity) to 166.8 pg/mL (highest concentration tested in linearity studies)

16. EXPECTED VALUES

The results themselves should not be the only reason for any therapeutic consequences. They have to be correlated to other clinical observations and diagnostic tests.
In a clinical study, performed at IBL, the following expected values were obtained for apparently healthy subjects, which is in accordance with the values published in the literature. Measurements of normal values are in accordance to the published mean values of 5.7 pg/mL for premenopausal and 3.7 pg/mL for postmenopausal women. [12] This is in accordance with the following data measured at IBL.
Apparently healthy subjects show the following values:

	Age	n	5 % - 95 % percentile	Median
Females (Premenopausal)	15 - 54 years	103	2.1 - 13.3 pg/mL	4.8 pg/mL
Females (Postmenopausal)	55 - 81 years	115	2.5 - 17.0 pg/mL	4.2 pg/mL
Males	18 - 76 years	99	1.8 - 10.4 pg/mL	4.7 pg/mL

It is recommended that each laboratory establishes its own range of normal values.
Medical decision points ranging from 1.4 ng/mL up to 2.6 ng/mL (1400 - 2600 pg/mL) provide negative predictive values for preterm delivery. Salivary estriol assessment was accurate in predicting pregnancy outcome according to the literature. [13]

17. LIMITATIONS OF THE PROCEDURE

Specimen collection and storage have a significant effect on the test results. See SPECIMEN COLLECTION AND STORAGE for details. For cross-reactivities, see PERFORMANCE.

	Substance	Concentration
The following substances do not have a significant effect (+/- 20 % of expected value) on the test results up to the stated concentrations	Milk	10 %
	Whole blood	1 %
	Citric acid	0.01 %

18. PERFORMANCE

18.1. Analytical Specificity (Cross Reactivity)

The cross reactivity study was conducted with high and low kit controls. Standard A was spiked with potential interfering substance in six different concentrations. Each concentration was tested in duplicate using one reagent lot.

Substance	Cross Reactivity	Substance	Cross Reactivity
Estriol 3 sulfate (sodium salt)	2.6 %	Prednisolone	≤ 0.01 %
16-Epistriol	2.1 %	Ethinylestradiol	≤ 0.01 %
Estetrol (E4)	2.0 %	Fulvestrant	≤ 0.01 %
Estradiol (E2)	0.4 %	Dehydroepiandrosterone	≤ 0.01 %
Estriol 16 alpha(ß-D-gluconide)	0.04 %	Estrone	≤ 0.01 %
21-Hydroxyprogesterone	≤ 0.01 %	Cortisol	≤ 0.01 %
Prednisone,	≤ 0.01 %	Estrone-3-sulfate	≤ 0.01 %
17-Hydroxyprogesterone	≤ 0.01 %	Testosterone	≤ 0.01 %
Pregnenolone	≤ 0.01 %	Progesterone	≤ 0.01 %
Androstenedione	≤ 0.01 %	17-Epiestriol	≤ 0.01 %
5A-Dihydrotestosterone	≤ 0.01 %		

18.2. Evaluation of Detection Capability

Limit of Blank (LoB)

The LoB study was conducted during three days of testing by one operator. Four different lots of Standard A were used as samples. Each sample was tested in duplicate with two different kit lots in 6 runs.
Limit of Blank = 1.6 pg/mL

Limit of Detection (LoD)

The LoD study was conducted during three days of testing by one operator. The runs were performed with 4 non- blank samples. Each sample was tested three times using two reagent lots.
Limit of Detection = 2.9 pg/mL.

Limit of Quantitation (LoQ as functional sensitivity)

In the LoQ study described as functional sensitivity the concentration of four non- blank samples was determined in 3 replicates in 6 runs and 2 different kits lots on 3 different days by 1 operator (= 72 observations).

The concentration of 3 higher concentrated samples was determined in 4 replicates, 6 runs and 2 kit lots on 3 different days by 1 operator (= 144 observations).

Limit of quantification as functional sensitivity = 3.2 pg/mL (with a precision of 20 %).

18.3. Linearity

Three Saliva samples with Estriol levels between 5.7 and 166.8 pg/mL were serially diluted with Sample Diluent. Each dilution was measured in duplicates using one kit lot. The mean recovery was 100 % (Range 94 - 106 %).

18.4. Recovery

The recovery study was performed measuring 3 different samples with concentrations between 2.3 - 88.5 pg/mL. Different amounts of Estriol were added.
The mean recovery for Estriol was 96 % (Range 89 - 106 %).

18.5. Method Comparison

A method comparison with LCMS reference method (ZRT) was performed. 62 saliva samples were measured with the following result: r = 0.9923.

18.6. Metrological Traceability

Values assigned to Standards and Controls are traceable to reference method LC-MS/MS with a mean uncertainty of 3.8 %.

18.7. Precision

The intra-assay study was conducted during 20 days using one reagent lot. Two runs were performed per day. Each sample was run in duplicate.

Intra-Assay			
Sample	**Mean conc.**	**SD**	**CV**
1	8.1 pg/mL	0.61 pg/mL	7.5 %
2	22.2 pg/mL	1.41 pg/mL	6.4 %
3	56.7 pg/mL	2.59 pg/mL	4.6 %
4	114.0 pg/mL	5.62 pg/mL	4.9 %

The intra-assay precision showed a mean CV from 5.9% (Range: 4.6 % - 7.5 %).

The inter-assay study was conducted during 20 days using one reagent lot. Two runs were performed per day. Each sample was run in duplicate.

Inter-Assay			
Sample	**Mean conc.**	**SD**	**CV**
1	8.1 pg/mL	0.79	9.8 %
2	22.2 pg/mL	1.55	7.0 %
3	56.7 pg/mL	3.11	5.5 %
4	114.0 pg/mL	8.13	7.1 %

The inter-assay precision showed a mean CV from 7.4 % (Range: 5.5 % - 9.8 %).

The between lot variation study was conducted during 5 days of testing. Each sample was tested in triplicate per run with 3 different reagent lots.

Inter-Lot			
Sample	**Mean conc.**	**SD**	**CV**
1	8.7 pg/mL	1.29 pg/mL	15.0 %
2	23.9 pg/mL	2.39 pg/mL	10.0 %
3	57.5 pg/mL	5.29 pg/mL	9.2 %
4	122.7 pg/mL	8.89 pg/mL	7.2 %

The between-lot precision showed a mean CV from 10.4 % (Range: 7.2 % - 15.0 %).

19. PRODUCT LITERATURE REFERENCES

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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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