*Instructions for Use*

# Melatonin direct Serum/Plasma/Saliva RIA

**Radio immunoassay for the quantitative determination of melatonin in human serum and plasma.**
**Detection in saliva for research use only.**

REF **RE29301**

Σ **100**


EU: IVD CE


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## 1. INTENDED USE

Radio immunoassay for the quantitative determination of melatonin in human serum and plasma. Further the test can be used for research of saliva samples.

## 2. SUMMARY AND EXPLANATION

The pineal gland (corpus pineale) has been called a neuroendocrine transducer because of its important role in photoperiodism. The major hormone of the pineal gland is N-acetyl-5-methoxy-tryptamine or melatonin which is synthezised from the amino acid tryptophane. Melatonin has its highest levels in plasma during nighttime. Its characteristic nocturnal surge appears to encode temporal information such as length of night. Regulation of the melatonin secretion is under neural control. Sympathetic innervation seems to play a major role via its release of noradrenaline. Altered patterns and/or levels of melatonin secretion have been reported to coincide with sleep disorders, jet lag, depression, stress, schizophrenia, hypothalamic amenorrhea, pregnancy, anorexia nervosa, some forms of cancer, immunological disorders as well as control of sexual maturation during puberty.
Most of the circulating melatonin is metabolized in the liver to 6-hydroxymelatonin and subsequently to 6-sulfatoxymelatonin which is excreted into the urine.
The concentration of 6-hydroxymelatonin sulfate in urine correlates well with the total level of melatonin in the blood during the collection period.

## 3. TEST PRINCIPLE

Radio immunoassay (RIA) based on the competition principle. A limited amount of specific antibody (Ab) reacts with the corresponding antigen (*Ag) labelled with the $^{125}$I-radioisotope. Upon addition of an increasing amount of the Ag (sample), a correspondingly decreasing fraction of *Ag added is bound to the antibody. After separation of the bound from the free *Ag by precipitation and centrifugation, the amount of bound radioactivity of the precipitates is measured in a Gamma counter. Results of samples can be determined directly using the standard curve.

## 4. WARNINGS AND PRECAUTIONS

1. For *in-vitro diagnostic* use only. For professional use only.
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. Obey lot number and expiry date. Do not mix reagents of different lots. Do not use expired reagents.
5. Follow good laboratory practice and safety guidelines. Wear lab coats, disposable latex gloves and protective glasses where necessary.
6. Reagents of this kit containing hazardous material may cause eye and skin irritations. See MATERIALS SUPPLIED and labels for details. Material Safety Data Sheets for this product are available on the IBL-Homepage or upon request directly from IBL.
7. Chemicals and prepared or used reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
8. The cleaning staff should be guided by the professionals regarding potential hazards and handling.
9. This kit contains radioactive material, to be received, acquired, possessed and used by physicians, laboratories or hospitals only according to regulations and a specific license issued by the Nuclear Regulatory Commission or issued by a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.
10. Radioactive materials should be confined to specifically designated, regularly monitored areas in the laboratory, restricted to authorised personnel. Use disposable labware and disposable absorbent bench covers. Always wear film budges, lab coats and disposable gloves. Wipe up all spills immediately, cleaning the contaminated area with a decontaminant and dispose the contaminated materials as radioactive waste.

11. All reagents of this kit containing human serum or plasma have been tested and were found negative for anti-HIV I/II, HBsAg and anti-HCV. However, a presence of these or other infectious agents cannot be excluded absolutely. For this reason reagents should be treated as potential biohazards in use and for disposal.

## 5. 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.

## 6. SPECIMEN COLLECTION AND STORAGE

**Serum, Plasma (EDTA, Heparin)**

The usual precautions for venipuncture should be observed. It is important to preserve the chemical integrity of a blood specimen from the moment it is collected until it is assayed. Do not use grossly hemolytic, icteric or grossly lipemic specimens. Samples appearing turbid should be centrifuged before testing to remove any particulate material.

**Saliva**

The patient should not eat, drink, chew gums or brush teeth for 30 min before sampling. Otherwise rinse mouth thoroughly with cold water 5 min prior to sample collection. Do not collect samples when oral diseases, inflammation or lesions exist (blood contamination).

Saliva can be collected in a suitable sampling device (using a straw). Due to the high adsorption characteristics of some steroids at certain material we strongly recommend the use of the special IBL SaliCap® Set. 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 min at 2000 – 3000 x g to remove particulate material.

⚠ **Take care that the saliva samples are visually okay (no reddish color indicating blood contamination).**

The use of Salivettes from Sarstedt (REF 51.1534) without additives is also appropriate.

| | | | | |
|---|---|---|---|---|
| Storage: | 2-8°C | ≤ -20°C (Aliquots) | ≤ -70°C (Aliquots) | Keep away from heat or direct sunlight. Avoid repeated freeze-thaw cycles. |
| Stability: | 24 h | 3 months | 12 months | |

## 7. MATERIALS SUPPLIED

### 7.1. Common materials for serum, plasma and saliva

| Quantity | Symbol | Component |
|---|---|---|
| 1 x 5.5 mL | TRACER LYO | **Melatonin $^{125}$I-Tracer** lyophilized<br>Activity: < 200 kBq |
| 2 x | ANTISERUM LYO | **Melatonin Antiserum** lyophilized<br>Contains: anti-Melatonin Antiserum (rabbit, polyclonal). |
| 1 x 50 mL | PREC ANTISERUM | **Precipitating Antiserum**<br>Ready to use. Contains: anti-rabbit IgG (goat), PEG, phosphate buffer. |
| 1 x 2.5 mL | CAL A | **Standard A**<br>Ready to use.<br>Contains: Melatonin. For exact concentrations see labels or QC certificate. |
| 1 x 6 x 0.25 mL | CAL B-G | **Standard B-G**<br>Ready to use.<br>Contains: Melatonin. For exact concentrations see labels or QC certificate. |
| 1 x 2 x 0.25 mL | CONTROL 1+2 | **Control 1+2**<br>Ready to use.<br>Contains: Melatonin, Concentrations / acceptable ranges see QC certificate. |
| 1 x 10 mL | ASSAYBUF | **Assay Buffer**<br>Ready to use. **Caution! Irritant.** |

### 7.2. Materials for serum and plasma ( do not use for saliva)

| Quantity | Symbol | Component |
|---|---|---|
| 2 x 3 mL | ENZ LYO | **Enzyme** lyophilized |
| 1 x 6 mL | ENZBUF | **Enzyme Buffer**<br>Ready to use. **Caution! Corrosive.** |
| 2 x 5 mL | DILUENT LYO | **Diluent** lyophilized<br>Contains: Plasma-serummatrix |

## 8. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipettes (Multipette Eppendorf or similar devices, < 3 % CV). Volume: 50; 200; 500; 1000 µL
2. Round-bottom polystyrene test tubes (12 x 75 mm)
3. Rack for test tubes
4. A suitable sampling device should be used.
5. Vortex mixer
6. Water bath, 37 °C
7. Centrifuge (preferably refrigerated); ≥ 3000 x g
8. Gamma Counter
9. Bidistilled or deionised water
10. Paper towels, pipette tips and timer

## 9. 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 pretreatment 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 determine samples in duplicate to be able to identify potential pipetting errors.
5. Labelling of all tubes is recommended.
6. The relative centrifugal force (g) is not equivalent to rounds per minute (rpm) but it has to be calculated depending on the radius of the centrifuge.

## 10. PRE-TEST SETUP INSTRUCTIONS

### 10.1. Preparation of lyophilized or concentrated components

| Dilute / dissolve Component | with | Diluent | Remarks | Storage | Stability |
|---|---|---|---|---|---|
| ENZ LYO<br>**(Serum/Plasma) only!** | 3 mL | ENZBUF | Mix 30 min on a roller mixer. | Prepare freshly and use only once. | |
| DILUENT LYO<br>**(Serum/Plasma) only!** | 5 mL | bidist. water | Mix 30 min on a roller mixer. | Prepare freshly and use only once. | |
| TRACER LYO | 5.5 mL | bidist. water | Let stand for 15 min. Mix without foaming. | ≤ -20°C (Aliquots) Avoid repeated freeze-thaw cycles. | until Exp. date |
| ANTISERUM<br>**(be sure to use the right volume of bidist. water)** | Saliva: 6 mL<br>Serum/Plasma: 2.75 mL | bidist. water | Let stand for 15 min. Mix without foaming. | | |

### 10.2. Dilution of Samples

#### 10.2.1. Serum/Plasma

Samples suspected to contain concentrations higher than the highest standard have to be diluted with diluent.

#### 10.2.2. Saliva

Samples suspected to contain concentrations higher than the highest standard have to be diluted with bidistilled or deionised water.

## 11. TEST PROCEDURE

### 11.1. Procedure for serum and plasma

#### 11.1.1. Enzymatic Pretreatment of Standards, Controls and samples

| | |
|---|---|
| **1.** | Pipette **20 µL** of **Standard A** into the $B_0$ and NSB tubes and tubes for patient samples.<br>Pipette **20 µL** of each **Standard B - G and Control** into the respective tubes. |
| **2.** | Pipette **200 µL** of Diluent into the $B_0$ tubes, NSB tubes, Standard B-G tubes and control tubes.<br>Pipette **200 µL** of **patient samples** into the respective tubes. |
| **3.** | Pipette **50 µL** of freshly prepared **Enzyme Solution** into each tube. (Except Total activity.) Vortex. |
| **4.** | **Centrifuge** all tubes for **1 min** at 500 x g. |
| **5.** | **Incubate 2 h** at **37°C** or for 3 h at RT (18-25°C). |

#### 11.1.2. Assay

| | |
|---|---|
| **1.** | Pipette **100 µL** of **Assay Buffer** into each tube. Vortex. |
| **2.** | Pipette **50 µL** of **$^{125}$I-Tracer** into each tube. Include two tubes for Total Activity (T). |
| **3.** | Pipette **50 µL** of dissolved **Antiserum** into each tube. (Except T, except NSB). Vortex. |
| **4.** | **Centrifuge** all tubes for **1 min** at 500 x g. |
| **5.** | Cover tubes. **Incubate 16-24 h** at **RT (18-25°C).** |
| **6.** | Pipette **500 µL** of **Precipitating Antiserum** into each tube. (Except T). Vortex. |
| **7.** | **Incubate 15 min** at **RT (18-25°C).** |
| **8.** | **Centrifuge** all tubes for **15 min** at 3000 x g. The temperature of the rotor should not exceed 25°C. |
| **9.** | **Decant** all tubes in overhead position for **3-5 min** (except T). |
| **10.** | **Count** the tubes in a Gamma counter for **1 min**. |

### 11.2. Procedure for Saliva (enzymatic pretreatment (11.1.1.) not necessary)

| | |
|---|---|
| **1.** | Pipette **20 µL** of **Standard A** into the $B_0$ tubes, NSB tubes and tubes for patient samples.<br>Pipette **20 µL** of each **Standard B – G** and each **Control** into the respective tubes. |
| **2.** | Pipette **500 µL** of **bidistilled or deionised water** into the $B_0$ tubes, NSB tubes, standard B – G tubes and control tubes.<br>Pipette **500 µL** of **Patient Samples** into the respective tubes. |
| **3.** | Pipette **50 µL** of **Assay Buffer** into each tube (except Total Activity). Vortex. |
| **4.** | Pipette **50 µL** of **$^{125}$I-Tracer** into each tube. Include two tubes for Total Activity (T). |
| **5.** | Pipette **50 µL** of dissolved **Antiserum** into each tube. (Except T, except NSB). Vortex. |
| **6.** | **Centrifuge** all tubes for **1 min** at 500 x g. |
| **7.** | Cover tubes. **Incubate 16-24 h** at **RT (18-25°C).** |
| **8.** | Pipette **500 µL** of **Precipitating Antiserum** into each tube. (Except T). Vortex. |
| **9.** | **Incubate 15 min** at **RT (18-25°C).** |
| **10.** | **Centrifuge** all tubes for **15 min** at 3000 x g. The temperature of the rotor should not exceed 25°C. |
| **11.** | Carefully **aspirate** all tubes (except T). |
| **12.** | **Count** the tubes in a Gamma counter for **1 min**. |

## 12. 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. It is recommended to participate at appropriate quality assessment trials.

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.

## 13. CALCULATION OF RESULTS

Calculate the $B/B_0$% for each standard, control and sample as follows:

$$B/B_0\% = \frac{CPM(calibrator/sample) - CPM(NSB)}{CPM(Bo) - CPM(NSB)} \times 100$$

Calculate: $$B_0/T\% = \frac{CPM(Bo) - CPM(NSB)}{CPM(TotalCount(T))} \times 100 \qquad NSB/T\% = \frac{CPM(NSB)}{CPM(TotalCount(T))} \times 100$$

The obtained $\%B/B_0$ 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 Logisitcs or Logit-Log.

For the calculation of the standard curve, apply each signal of the standards (one obvious outlier of duplicates might be omitted and the more plausible single value might be used).

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

In case of diluted samples the values have to be multiplied with the corresponding dilution factor.

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

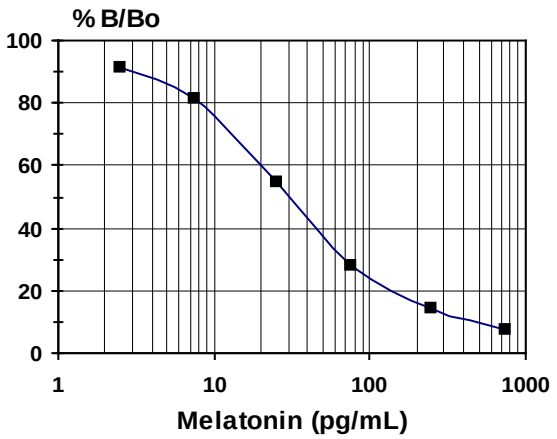
Conversion:

Melatonin (pg/mL) x 4.30 = pmol/L

### Typical Calibration Curve (Serum/Plasma)

(Example. Do not use for calculation!)

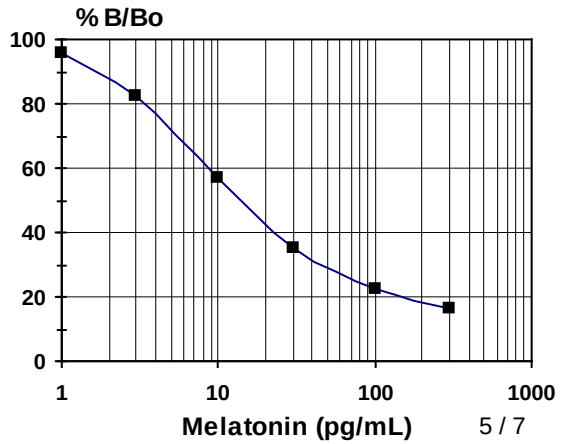
| Standard | Melatonin (pg/mL) | Mean cpm | B/T (%) | $B/B_0$ (%) |
|---|---|---|---|---|
| T | | 73861 | | |
| NSB | | 1571 | 2.1 | |
| A | 0 | 25917 | 33.0 | 100 |
| B | 2.5 | 23883 | | 91.6 |
| C | 7.5 | 21441 | | 81.6 |
| D | 25 | 14885 | | 54.7 |
| E | 75 | 8408 | | 28.1 |
| F | 250 | 5037 | | 14.2 |
| G | 750 | 3410 | | 7.6 |




### Typical Calibration Curve Saliva

(Example. Do not use for calculation!)

| Standard | Melatonin (pg/mL) | Mean cpm | B/T (%) | $B/B_0$ (%) |
|---|---|---|---|---|
| T | | 41379 | | |
| NSB | | 976 | 2.4 | |
| A | 0 | 13878 | 31.2 | 100 |
| B | 1 | 13304 | | 95.9 |
| C | 3 | 11405 | | 82.2 |
| D | 10 | 7899 | | 56.8 |
| E | 30 | 4842 | | 34.9 |
| F | 100 | 3084 | | 22.2 |
| G | 300 | 2248 | | 16.2 |



## 14. EXPECTED VALUES

The results themselves should not be the only reason for any therapeutical consequences. They have to be correlated to other clinical observations and diagnostic tests.

Apparently healthy subjects show the following values:

The serum, plasma and saliva melatonin levels in humans show a marked circadian rhythm characterized by very low levels during day-time (up to 30 pg/mL for serum/plasma and < 5 pg/mL for saliva) and high levels during night-time (up to 150 pg/mL for serum/plasma and > 10 pg/mL for saliva).
Furthermore, the melatonin concentration is age dependent. The highest concentrations were found in samples of infants (up to 3 years).
The nocturnal melatonin peak among healthy individuals varies significantly.
It is recommended that each laboratory establishes its own range of normal values.

## 15. 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.

The following blood components do not have a significant effect (+/-20% of expected) on the test results up to the below stated concentrations:

| | |
|---|---|
| Hemoglobin | 8.0 mg/mL |
| Bilirubin | 0.36 mg/mL |
| Triglyceride | 3.8 mg/mL |

## 16. PERFORMANCE

| | | | | |
|---|---|---|---|---|
| **Analytical Specificity (Cross Reactivity)** | Substance | Cross-reactivity (%) | | Cross-reactivity of other substances tested < 0.01 % |
| | N-Acetyl-Serotonin | 1.2 | | |
| | 5-Methoxy-Tryptophole | 1.2 | | |
| | 5-Methoxy-Tryptamine | 2.5 | | |
| | Serotonin | 0.02 | | |
| **Analytical Sensitivity (Limit of Detection)** | Serum/Plasma: 0.9 pg/mL | | Mean signal (Zero-Standard) - 2SD | |
| | Saliva: 0.3 pg/mL | | | |
| **Precision** | Specimen | Range (pg/mL) | | CV (%) |
| Intra-Assay | Serum/Plasma | 28.8 - 266 | | 3.9 – 6.9 |
| | Saliva | 1.3 -52.5 | | 11 - 14 |
| Inter-Assay | Serum/Plasma | 3.5 - 281 | | 6.2 – 16 |
| | Saliva | 2.7 – 61.5 | | 14 - 17 |
| **Linearity** | Specimen | Range (pg/mL) | Serial dilution up to | Range (%) |
| | Serum/Plasma | 15.9 – 376 | 1:16 | 82 - 119 |
| | Saliva | 181.3 - 247 | 1:16 | 104 - 116 |
| **Recovery** | Specimen | Mean recovery after spiking (%) | | Range (%) |
| | Serum/Plasma | 102 | | 88 - 115 |
| | Saliva | 107 | | 107 - 120 |
| **Method Comparison versus RIA** | IBL-Assay = 0.97 x RIA -1.35 (commercially available RIA) | | | r = 0.97; n = 19 |

## 17. PRODUCT LITERATURE REFERENCES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2. Mann, K, Wagner, P, Hiemke, Ch, Frank C, Röschke J. Nocturnal Hormone Profiles in Healthy Humans under the Influence of Pulsed High-Frequency Electromagnetic Fields. In: The Pineal Gland and Cancer. Springer-Verlag, Eds. Bartsch C. et al. (2001). Address: J. Röschke. University of Mainz, Germany
3. Barriga C, Marchena JM, Ortega E, Martín MI, Rodríguez AB. Melatonin levels and exercise in adolescent boys and girls. Biogenic Amines, 15 (6): 643-653 (2000). Address: C. Barriga, University of Extremadura, Spain
4. Follenius M, Weibel L, Brandenberger G. Distinct modes of melatonin secretion in normal men. J. Pineal Res., 18: 135-140 (1995) Address: M. Follenius, Laboratoire de Physiologle et de Physiologie Environnementales, Strasbourg, France
5. Dubbels R, Reiter RJ, Klenke E, Goebel A, Schnakenberg E, Ehlers C, Schiwara HW, Schloot W. Melatonin in edible plants identified by radioimmunoassay chromatography-mass spectrometry. J. Pineal Res., 18: 28-31 (1995) Address:R. Dubbels, University of Bremen, Bremen, Germany
6. Czeisler CA, Shanahan TL, Klerman EB, Martens H, Brotman DJ, Emens JS, Klein T, Rizzo III JF. Supression of Melatonin secretion in some blind patients by exposure to bright light. New England J. of Medicine, 332: 6-11 (1995) Address: Ch. A. Czeisler, Harvard Medical School, Boston, U.S.A.

# Symbols / Symbole / Symbôles / Símbolos / Símbolos / Σύμβολα

| | |
|---|---|
| REF | Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.: |
| LOT | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή: |
|  | Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από: |
|  | No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests: / Αριθμός εξετάσεων: |
| CONC | Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα |
| LYO | Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο |
| IVD | In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Dispositivo Médico para Diagnóstico In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση. |
|  | Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluació. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης. |
|  | Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Ler as instruções antes de usar. / Leggere le istruzioni prima dell'uso. / 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. / Manter longe do calor ou luz solar directa. / Non esporre ai raggi solari. / 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: / Αποθήκευση στους: |
|  | Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός: |
|  | Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / 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.
Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.
Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.
Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

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.



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