Progesterone ELISA

Enzyme immunoassay for the quantitative determination of Progesterone in human serum and plasma.

REF RE52231

Σ 96

2-8°C

EU: IVD CE

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1 INTRODUCTION

The Progesterone Enzyme Immunoassay Kit provides materials for the quantitative determination of Progesterone in serum and plasma. This assay is intended for in vitro diagnostic use only.

Progesterone (pregn-4-ene-3, 20-dione) is a C21 steroid hormone containing a keto-group (at C-3) and a double bond between C-4 and C-5 (Δ4). This steroid hormone is a female sex hormone which, in conjunction with estrogens, regulates the accessory organs during the menstrual cycle and it is particularly important in preparing the endometrium for the implantation of the blastocyte and in maintaining pregnancy.

In non-pregnant women progesterone is mainly secreted by the corpus luteum whereas in pregnancy the placenta becomes the major source. Minor sources are the adrenal cortex for both sexes and the testes for males.

Progesterone circulates in blood mainly bound to Corticosteroid Binding Globulin (CBG), Sex Hormone Binding Globulin (SHBG) and Albumin. Only 2-10% of the total concentration circulates as free hormone. Blood progesterone concentrations vary widely according to the phases of menstrual cycle; they are lower than 1 ng/mL (3.2 nmol/L) in the follicular phase and around 10-20 ng/mL (32-64 nmol/L) in the luteal phase. The maximal levels are achieved 4-7 days after ovulation and remain elevated for 4-6 additional days prior to falling to the preovulatory levels 24 hours before the onset of menstruation.

Since the rise and fall of progesterone parallel the activity of ovarian follicle and corpus luteum, measurements of plasma progesterone are clinically used to confirm ovulation and normal function of the corpus luteum in non-pregnant women. If ovulation does not occur the corpus luteum is not formed and no cyclical rise of progesterone in plasma is observed. Abnormal progesterone secretion has been implicated in premenstrual tension, irregular shedding of endometrium, dysmenorrhoea, and luteal insufficiency.

Progesterone concentration can vary not only from subject to subject but also in the same person from day to day or even from hour to hour. Consequently, in gynecological disorders or abnormal pregnancies serial measurements rather than single ones are recommended for a proper interpretation of results. During pregnancy progesterone is widely produced by placenta, and plasma levels rise steadily achieving values as high as 200 ng/mL at term.

2 PRINCIPLE OF THE TEST

The Progesterone ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding. The microtiter wells are coated with a polyclonal antibody directed towards an antigenic site on the Progesterone molecule. Endogenous Progesterone of a patient sample competes with a Progesterone horseradish peroxidase conjugate for binding to the coated antibody. After incubation the unbound conjugate is washed off.

The amount of bound peroxidase conjugate is reverse proportional to the concentration of Progesterone in the sample. After addition of the substrate solution, the intensity of colour developed is reverse proportional to the concentration of Progesterone in the patient sample.

3 PRECAUTIONS

- This kit is for in vitro diagnostic use only.
- For information on hazardous substances included in the kit please refer to Material Safety Data Sheets.
- 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.
- Avoid contact with Stop Solution containing 0.5 M H₂SO₄. It may cause skin irritation and burns.
- Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
- Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
- Wear disposable latex gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may give false results.
Handling should be in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.

• Do not use reagents beyond expiry date as shown on the kit labels.

• 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.

• 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.

• Chemicals and prepared or used reagents have to be treated as hazardous waste according the national biohazard safety guideline or regulation.

• Safety Data Sheets for this product are available upon request directly from IBL.

• The Safety Data Sheets fit the demands of: EU-Guideline 91/155 EC.

4 KIT COMPONENTS

4.1 Contents of the Kit

1. **MTP**  
   Microtiterwells, 12x8 (break apart) strips, 96 wells Wells coated with anti-Progesterone antibody (polyclonal)

2. **CAL**  
   Standard (Standard 0-6), 7 vials, 1 mL, ready to use
   Concentrations: 0; 0.3; 1.25; 2.5; 5; 15; 40 ng/mL
   Conversion: 1 ng/mL = 3.18 nmol/L
   Contains: 0.03% Proclin 300 + 0.005% gentamicin sulfate as preservative.

3. **ENZCONJ**  
   Enzyme Conjugate, 1 vial, 25 mL, ready to use
   Progesterone conjugated to horseradish Peroxidase
   Contains: 0.03% Proclin 300, 0.015% BND and 0.010% MIT* as preservative.

4. **TMB SUBS**  
   Substrate Solution, 1 vial, 25 mL, ready to use
   TMB

5. **TMB STOP**  
   Stop Solution, 1 vial, 14 mL, ready to use
   Contains: 0.5M H₂SO₄
   Avoid contact with the stop solution. It may cause skin irritations and burns.

6. **WASHBUF CONC**  
   Wash Solution, 1 vial, 30 mL (40X concentrated)
   see „Preparation of Reagents“

* BND  = 5-bromo-5-nitro-1,3-dioxane
   MIT  = 2-methyl-2H-isothiazol-3-one

**Note:** Additional Standard 0 for sample dilution is available on request.

4.1.1 Equipment and material required but not provided

− A microtiter plate calibrated reader (450±10 nm)
− Calibrated variable precision micropipettes.
− Absorbent paper.
− Aqua dest.

4.2 Storage and stability of the Kit

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

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

Opened kits retain activity for two months if stored as described above.
4.3 Preparation of Reagents
Allow all reagents and required number of strips to reach room temperature prior to use.

Wash Solution
Add deionized water to the 40X concentrated Wash Solution. Dilute 30 mL of concentrated Wash Solution with 1170 mL deionized water to a final volume of 1200 mL. The diluted Wash Solution is stable for 2 weeks at room temperature.

4.4 Disposal of the Kit
The disposal of the kit must be made according to the national official regulations.

4.5 Damaged Test Kits
In case of any severe damage of the test kit or components, IBL have to be informed written, latest one week after receiving the kit. Severely damaged single components should not be used for a test run. They have to be stored until a final solution has been found. After this, they should be disposed according to the official regulations.

5 SPECIMEN
Serum or plasma (EDTA-, Heparin- or citrate plasma) can be used in this assay.
Do not use haemolytic, icteric or lipaemic specimens.
Please note: Samples containing sodium azide should not be used in the assay.

5.1 Specimen Collection
Serum:
Collect blood by venipuncture (e.g. Sarstedt Monovette # 02.1388.001), allow to clot, and separate serum by centrifugation at room temperature. Do not centrifuge before complete clotting has occurred. Patients receiving anticoagulant therapy may require increased clotting time.

Plasma:
Whole blood should be collected into centrifuge tubes containing anticoagulant and centrifuged immediately after collection.
(E.g. for EDTA plasma Sarstedt Monovette – red cap - # 02.166.001
    for Heparin plasma Sarstedt Monovette – orange cap - # 02.165.001
    for Citrate plasma Sarstedt Monovette – green cap - # 02.167.001.)

5.2 Specimen Storage
Specimens should be capped and may be stored for up to 24 hours at 2-8°C prior to assaying. Specimens held for a longer time should be frozen only once at -20°C prior to assay. Thawed samples should be inverted several times prior to testing.

5.3 Specimen Dilution
If in an initial assay, a specimen is found to contain more than the highest standard, the specimens can be diluted 10-fold or 100 fold with Standard 0 and reassayed as described in Assay Procedure. For the calculation of the concentrations this dilution factor has to be taken into account.

Example:
    a) Dilution 1:10: 10 µL Serum + 90 µL Standard 0 (mix thoroughly)
    b) Dilution 1:100: 10 µL dilution a) 1:10 + 90 µL Standard 0 (mix thoroughly).
6 TEST 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 disposable 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 Assay Procedure
Each run must include a standard curve.

1. Secure the desired number of Microtiter wells in the holder.
2. Dispense 25 µL of each Standard, controls and samples with new disposable tips into appropriate wells.
3. Incubate for 5 minutes at room temperature.
4. Dispense 200 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 60 minutes at room temperature.
6. Briskly shake out the contents of the wells.
   Rinse the wells 3 times with diluted Wash Solution (400 µL per well). 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 200 µL of Substrate Solution to each well.
8. Incubate for 15 minutes at room temperature.
9. Stop the enzymatic reaction by adding 100 µL of Stop Solution to each well.
10. Determine the absorbance (OD) of each well at 450±10 nm 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 patient samples.
2. 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 IFU have been calculated automatically using a 4 PL (4 Parameter Logistics) curve fit. 4 Parameter Logistics is the preferred method. 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. 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.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Optical Units (450 nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard 0 (0 ng/mL)</td>
<td>1.52</td>
</tr>
<tr>
<td>Standard 1 (0.3 ng/mL)</td>
<td>1.17</td>
</tr>
<tr>
<td>Standard 2 (1.25 ng/mL)</td>
<td>0.88</td>
</tr>
<tr>
<td>Standard 3 (2.5 ng/mL)</td>
<td>0.69</td>
</tr>
<tr>
<td>Standard 4 (5.0 ng/mL)</td>
<td>0.55</td>
</tr>
<tr>
<td>Standard 5 (15 ng/mL)</td>
<td>0.35</td>
</tr>
<tr>
<td>Standard 6 (40 ng/mL)</td>
<td>0.13</td>
</tr>
</tbody>
</table>

7 EXPECTED VALUES
It is strongly recommended that each laboratory should determine its own normal and abnormal values.

In a study conducted with apparently normal healthy adults, using the Progesterone ELISA the following values are observed:

**Normal Women**
- Follicular phase: 0.2 – 1.4 ng/mL
- Luteal phase: 4 - 25 ng/mL
- Menopause: 0.1 – 1 ng/mL

**Normal men**
- 0.1 – 1 ng/mL

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 in order 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 patient 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 ASSAY CHARACTERISTICS

9.1 Assay Dynamic Range
The range of the assay is between 0–40 ng/mL.

9.2 Specificity of Antibodies (Cross Reactivity)
The following substances were tested for cross reactivity of the assay:

<table>
<thead>
<tr>
<th>Steroid</th>
<th>Cross Reaction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>100.00</td>
</tr>
<tr>
<td>17α OH Progesterone</td>
<td>0.30</td>
</tr>
<tr>
<td>Estriol</td>
<td>&lt; 0.10</td>
</tr>
<tr>
<td>Estradiol 17β</td>
<td>&lt; 0.10</td>
</tr>
<tr>
<td>Testosterone</td>
<td>&lt; 0.10</td>
</tr>
<tr>
<td>11-Desoxycorticosterone</td>
<td>1.10</td>
</tr>
<tr>
<td>DHEA-S</td>
<td>&lt; 0.02</td>
</tr>
<tr>
<td>Cortisol</td>
<td>&lt; 0.02</td>
</tr>
<tr>
<td>Corticosterone</td>
<td>0.20</td>
</tr>
<tr>
<td>Pregnenolone</td>
<td>0.35</td>
</tr>
<tr>
<td>Cortison</td>
<td>&lt; 0.10</td>
</tr>
<tr>
<td>11-Desoxycortisol</td>
<td>0.10</td>
</tr>
</tbody>
</table>

9.3 Analytical Sensitivity
The analytical sensitivity was calculated from the mean minus two standard deviations of twenty (20) replicate analyses of Standard 0 and was found to be 0.045 ng/mL.

9.4 Precision
9.4.1 Intra Assay Variation
The within assay variability is shown below:

<table>
<thead>
<tr>
<th>Sample</th>
<th>n</th>
<th>Mean (ng/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20</td>
<td>0.62</td>
<td>5.4</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>4.67</td>
<td>6.99</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>10.80</td>
<td>6.86</td>
</tr>
</tbody>
</table>

9.4.2 Inter Assay Variation
The between assay variability is shown below:

<table>
<thead>
<tr>
<th>Sample</th>
<th>n</th>
<th>Mean (ng/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>0.56</td>
<td>9.96</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
<td>4.55</td>
<td>4.34</td>
</tr>
<tr>
<td>3</td>
<td>12</td>
<td>10.65</td>
<td>5.59</td>
</tr>
</tbody>
</table>
9.5 Recovery
Samples have been spiked by adding Progesterone solutions with known concentrations in a 1:1 ratio. The expected values were calculated by addition of half of the values determined for the undiluted samples and half of the values of the known solutions. The % Recovery has been calculated by multiplication of the ratio of the measurements and the expected values with 100.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Added Concentration 1:1 (v/v) (ng/mL)</th>
<th>Measured Conc. (ng/mL)</th>
<th>Expected Conc. (ng/mL)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>40.0</td>
<td>1.63</td>
<td>20.35</td>
<td>20.82</td>
</tr>
<tr>
<td></td>
<td>15.0</td>
<td>8.45</td>
<td>3.52</td>
<td>3.32</td>
</tr>
<tr>
<td></td>
<td>5.0</td>
<td>2.31</td>
<td>2.07</td>
<td>112.0</td>
</tr>
<tr>
<td></td>
<td>2.5</td>
<td>4.17</td>
<td>22.69</td>
<td>22.09</td>
</tr>
<tr>
<td>2</td>
<td>40.0</td>
<td>10.45</td>
<td>4.42</td>
<td>4.59</td>
</tr>
<tr>
<td></td>
<td>5.0</td>
<td>3.62</td>
<td>3.34</td>
<td>108.3</td>
</tr>
<tr>
<td></td>
<td>2.5</td>
<td>11.03</td>
<td>26.94</td>
<td>25.52</td>
</tr>
<tr>
<td>3</td>
<td>40.0</td>
<td>12.44</td>
<td>7.70</td>
<td>8.02</td>
</tr>
<tr>
<td></td>
<td>5.0</td>
<td>6.15</td>
<td>6.77</td>
<td>90.9</td>
</tr>
</tbody>
</table>

9.6 Linearity

<table>
<thead>
<tr>
<th>Sample</th>
<th>Dilution</th>
<th>Measured Conc. (ng/mL)</th>
<th>Expected Conc. (ng/mL)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>None</td>
<td>1.63</td>
<td>1.63</td>
<td>92.0</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>0.75</td>
<td>0.82</td>
<td>111.9</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>0.46</td>
<td>0.41</td>
<td>107.0</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>0.20</td>
<td>0.20</td>
<td>99.1</td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>0.11</td>
<td>0.10</td>
<td>107.0</td>
</tr>
<tr>
<td>2</td>
<td>None</td>
<td>4.17</td>
<td>4.17</td>
<td>110.3</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>2.30</td>
<td>2.09</td>
<td>104.8</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>1.09</td>
<td>1.04</td>
<td>93.3</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>0.49</td>
<td>0.52</td>
<td>87.8</td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>0.23</td>
<td>0.26</td>
<td>105.4</td>
</tr>
<tr>
<td>3</td>
<td>None</td>
<td>11.03</td>
<td>11.03</td>
<td>107.2</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>5.81</td>
<td>5.52</td>
<td>108.6</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>2.96</td>
<td>2.76</td>
<td>104.7</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>1.50</td>
<td>1.38</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>0.72</td>
<td>0.69</td>
<td></td>
</tr>
</tbody>
</table>

10 LIMITATIONS OF USE

10.1 Interfering Substances
Any improper handling of samples or modification of this test might influence the results. Haemoglobin (up to 4 mg/mL), Bilirubin (up to 0.5 mg/mL) and Triglyceride (up to 1.8 mg/mL) have no influence on the assay results.

10.2 Drug Interferences
Until today no substances (drugs) are known to us, which have an influence to the measurement of Progesterone in a sample.
10.3 High-Dose-Hook Effect
No hook effect was observed in this test.

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, within the test procedure, 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
4. Thomas Labor und Diagnose
<table>
<thead>
<tr>
<th>REF</th>
<th>Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote n.: / Αριθμός-Κατ.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAT</td>
<td>Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Χρησιμοποιείται από:</td>
</tr>
<tr>
<td>NO.</td>
<td>No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests:</td>
</tr>
<tr>
<td>CONC</td>
<td>Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα</td>
</tr>
<tr>
<td>LYO</td>
<td>Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Λυοφιλιασμένο</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostic In vitro. / Ιατρική συσκευή για In-Vitro ∆ιάγνωση.</td>
</tr>
<tr>
<td>Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit de avaliação. / Kit di evaluzione.</td>
<td></td>
</tr>
<tr>
<td>Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Leggere le istruzioni prima dell’uso. / Διαβάστε τις οδηγίες πριν την χρήση.</td>
<td></td>
</tr>
<tr>
<td>Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:</td>
<td></td>
</tr>
<tr>
<td>Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:</td>
<td></td>
</tr>
</tbody>
</table>

**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.

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