HCG+beta ELISA

Enzyme immunoassay (microtiter strips) for the quantitative determination of HCG and HCG-β in human serum.

REF RE52141

Σ 96

2-8 °C

For research use only. Not for use in diagnostic procedures.
1 INTRODUCTION

1.1 Intended Use
The β-HCG ELISA Kit is an enzyme immunoassay for the quantitative in vitro diagnostic measurement of total human chorionic gonadotropin (hCG and β-hCG) in serum.

1.2 Summary and Explanation
Chorionic Gonadotropin (hCG) is a glycoprotein hormone which is normally produced by the placenta during pregnancy. After conception, the hCG concentration increases rapidly to reach a peak near the end of the first trimester. Higher concentrations are observed throughout pregnancy. After delivery, hCG levels fall rapidly and become undetectable after a few days.

Structurally intact hCG molecules are composed of an alpha and a beta subunit. The alpha subunit is nearly identical to the alpha subunits of other glycoprotein hormones, such as Thyroid Stimulating Hormone (TSH), Luteinizing Hormone (LH), and Follicle Stimulating Hormone (FSH): The differences in the beta subunit of the respective hormones account for their biological specificity and immunochemical distinctiveness.

Monoclonal antibodies recognizing unique sites on the beta chain of the β-hCG/hCG molecule are essential for differentiation between hCG and LH, FSH and TSH.

Specific assays for beta-hCG permit the early detection of pregnancy. In addition to the elevated hCG levels during pregnancy, high concentrations of βhCG/hCG may be associated with neoplasms of trophoblastic and nontrophoblastic origin such as hydatidiform mole, choriocarcinoma, embryonal cell carcinoma, seminoma and many others.

2 PRINCIPLE OF THE TEST
The β-HCG ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle. The microtiter wells are coated with a monoclonal antibody [mouse] directed towards a unique antigenic site on a β-HCG molecule. An aliquot of patient sample containing endogenous β-HCG and/or HCG is incubated in the coated well with enzyme conjugate, which is an anti- β-HCG antibody conjugated with horseradish peroxidase. After incubation the unbound conjugate is washed off.

The amount of bound peroxidase is proportional to the concentration of β-HCG/HCG in the sample. Having added the substrate solution, the intensity of color developed is proportional to the concentration of β-HCG/HCG in the patient sample.

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 the package insert 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 (21-26°C) before starting the test. Temperature will affect the absorbance readings of the assay. However, values for the patient 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 microtiterplate 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 H₂SO₄. 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 Material Safety Data Sheets. Material Safety Data Sheets for this product are available upon request directly from IBL.

4 REAGENTS

4.1 Reagents provided

1. **Microtiterwells.** 12x8 (break apart) strips, 96 wells;
   Wells coated with anti-β-HCG antibody (monoclonal).

2. **Standard (Standard 0-5).** 6 vials (lyophilized), 1 mL;
   Concentrations: 0, 5; 25; 50; 100; 200 mIU/mL
   Conversion: 1pg/mL = 0.00916 mIU/mL
   The standards are calibrated against WHO approved Reference material IRR β-HCG, code 75/537
   See „Preparation of Reagents“;
   Contain non-mercury preservative.

3. **Sample Diluent,** 1 vial, 10 mL, ready to use,
   Contain non-mercury preservative.

4. **Enzyme Conjugate,** 1 vial, 11 mL, ready to use,
   Anti-β-HCG antibody conjugated to horseradish peroxidase;
   Contain non-mercury preservative.

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

6. **Stop Solution,** 1 vial, 14 mL, ready to use,
   contains 0.5M H$_2$SO$_4$,
   Avoid contact with the stop solution. It may cause skin irritations and burns.

   **Note:** Additional **Sample Diluent** for sample dilution is available upon request.

4.2 Materials required but not provided

- A microtiter plate calibrated reader (450±10 nm).
- Calibrated variable precision micropipettes.
- Distilled or deionized water
- Timer
- Graph paper or software for data reduction

4.3 Storage Conditions

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 foil bag has been opened, care should be taken to close it tightly again.

4.4 Reagent Preparation

Allow all reagents and required number of strips to reach room temperature prior to use.

**Standards**

Reconstitute the lyophilized contents of the standard vial with 1.0 mL Aqua dest.

**Note:** The reconstituted standards are stable for 2 months at 2-8°C. For longer storage freeze at -20°C.

4.5 Disposal of the Kit

The disposal of the kit must be made according to the national regulations. Special information for this product is given in the Material Safety Data Sheets.

4.6 Damaged Test Kits

In case of any severe damage to the test kit or components, IBL has to be informed in writing, at the 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 COLLECTION AND PREPARATION
Serum should 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.

5.2 Specimen Storage and Preparation
Specimens should be capped and may be stored for up to 5 days 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 with Sample Diluent 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 Sample Diluent (mix thoroughly).
   b) dilution 1:100: 10 µL dilution a) 1:10 + 90 µL Sample Diluent (mix thoroughly).
   c) dilution 1:1000 10 µL dilution b) 1:100 + 90 µL Sample Diluent (mix thoroughly).

Note:
Sera of pregnant women must be diluted 1/100 in Sample Diluent before starting the assay.

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 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 Test Procedure (quantitative method)
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, Control and samples with new disposable tips into appropriate wells.
3. Dispense 100 µL Enzyme Conjugate into each well.
4. 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 5 times with distilled water (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 100 µL of Substrate Solution to each well.
8. Incubate for 15 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 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 (quantitative)
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 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.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Optical Units (450 nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard 0 (0 mIU/mL)</td>
<td>0.04</td>
</tr>
<tr>
<td>Standard 1 (5 mIU/mL)</td>
<td>0.15</td>
</tr>
<tr>
<td>Standard 2 (25 mIU/mL)</td>
<td>0.28</td>
</tr>
<tr>
<td>Standard 3 (50 mIU/mL)</td>
<td>0.53</td>
</tr>
<tr>
<td>Standard 4 (100 mIU/mL)</td>
<td>0.94</td>
</tr>
<tr>
<td>Standard 5 (200 mIU/mL)</td>
<td>1.50</td>
</tr>
</tbody>
</table>

6.4 Assay Procedure (qualitative method)
This procedure differentiates positive (pregnant) from negative samples by comparing the sample beta hCG levels with the Standard 0 (0 mIU/mL) and Standard 3 (50 mIU/mL).
Patient samples are run with the Standard 0 and the 50 mIU/mL Standard. The assay procedure is identical with the Quantitative Method, but step 9 and 10 is omitted.

6.5 Calculation of Results (qualitative)
For a qualitative analysis of the β-hCG level the color development of the specimen is compared with the color of the 0 mIU/mL and 50 mIU/mL standards.
If the blue color is less intense than the color of the 50 mIU/mL standard, the sample is considered as negative.
If the blue color is more intense than or equal to the color of the 50 mIU/mL standard the sample is considered as positive.

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

7.1 Normal healthy adults, non-pregnant
In a study conducted with apparently normal healthy adults, using the IBL β-HCG ELISA the following values are observed:

<table>
<thead>
<tr>
<th>Population</th>
<th>Age (years)</th>
<th>Valid N</th>
<th>β-hCG [mIU/ml]</th>
</tr>
</thead>
<tbody>
<tr>
<td>men</td>
<td>&lt; 50</td>
<td>40</td>
<td>&lt; 5</td>
</tr>
<tr>
<td></td>
<td>&gt; 50</td>
<td>10</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>women</td>
<td>&lt; 50</td>
<td>42</td>
<td>&lt; 5</td>
</tr>
<tr>
<td></td>
<td>&gt; 50</td>
<td>7</td>
<td>&lt; 5</td>
</tr>
</tbody>
</table>

7.2 Pregnant women in the 2nd trimester

<table>
<thead>
<tr>
<th>Week of pregnancy</th>
<th>Valid samples</th>
<th>5% Percentile [mIU/ml]</th>
<th>95% Percentile [mIU/ml]</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>103</td>
<td>10303</td>
<td>71980</td>
</tr>
<tr>
<td>15</td>
<td>96</td>
<td>9246</td>
<td>51666</td>
</tr>
<tr>
<td>16</td>
<td>91</td>
<td>5266</td>
<td>36947</td>
</tr>
<tr>
<td>17</td>
<td>14</td>
<td>4632</td>
<td>24033</td>
</tr>
</tbody>
</table>
CAUTION:
1. For the detection of pregnancy in serum, a qualitative assay is used with a cut-off point of 50 mIU/mL. Negative or borderline results should be repeated on a fresh specimen obtained at least 48 hours after the first specimen.
2. It has been shown that immunological pregnancy tests may yield false results in cases of several medications and diseases such as rheumatoid arthritis. In such cases, the interpretation of the pregnancy test should be done carefully.

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 PERFORMANCE CHARACTERISTICS

9.1 Assay Dynamic Range
The range of the assay is between 1 – 200 mIU/mL.

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

<table>
<thead>
<tr>
<th>Protein</th>
<th>Concentration</th>
<th>Produced Colour Intensity Equivalent to β-HCG in serum (mIU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>hLH</td>
<td>300 mIU/mL</td>
<td>6</td>
</tr>
<tr>
<td>hLH</td>
<td>200 mIU/mL</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>hLH</td>
<td>80 mIU/mL</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>TSH</td>
<td>75 µIU/mL</td>
<td>8</td>
</tr>
<tr>
<td>TSH</td>
<td>50 µIU/mL</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>TSH</td>
<td>25 µIU/mL</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>FSH</td>
<td>200 mIU/mL</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>FSH</td>
<td>50 mIU/mL</td>
<td>&lt; 5</td>
</tr>
</tbody>
</table>

9.3 Sensitivity
The analytical sensitivity was calculated from the mean plus two standard deviations of twenty (20) replicate analyses of the Standard 0 and was found to be < 1 mIU/mL.
9.4 Reproducibility

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

<table>
<thead>
<tr>
<th>Sample</th>
<th>n</th>
<th>Mean (mIU/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20</td>
<td>5.9</td>
<td>8.9</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>18.5</td>
<td>4.0</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>148.1</td>
<td>3.4</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (mIU/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>9.9</td>
</tr>
<tr>
<td>2</td>
<td>17</td>
<td>7.3</td>
</tr>
<tr>
<td>3</td>
<td>140</td>
<td>6.6</td>
</tr>
</tbody>
</table>

9.5 Recovery
Samples have been spiked by adding β-hCG 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) (mIU/mL)</th>
<th>Measured Conc. (mIU/mL)</th>
<th>Expected Conc. (mIU/mL)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>148</td>
<td>148</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>113</td>
<td>124</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>75</td>
<td>110</td>
<td>111.5</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>91.6</td>
<td>99</td>
<td>93</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>53.9</td>
<td>53.9</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>36.6</td>
<td>39.45</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>46.9</td>
<td>51.95</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>68.5</td>
<td>76.95</td>
<td>89</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>23.9</td>
<td>23.9</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>23.1</td>
<td>24.45</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>33.7</td>
<td>36.95</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>54.9</td>
<td>61.95</td>
<td>89</td>
</tr>
</tbody>
</table>

9.6 Linearity

<table>
<thead>
<tr>
<th>Sample</th>
<th>Dilution</th>
<th>Mean Conc. (mIU/mL)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>None</td>
<td>109.8</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>56.6</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>28.2</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>14.4</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>7.41</td>
<td>108</td>
</tr>
<tr>
<td>2</td>
<td>None</td>
<td>117</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>54.7</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>30.1</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>15.8</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>7.69</td>
<td>105</td>
</tr>
<tr>
<td>3</td>
<td>None</td>
<td>94.9</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>42.9</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>25</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>12.8</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>6.5</td>
<td>110</td>
</tr>
</tbody>
</table>
10 LIMITATIONS OF USE
Any improper handling of samples or modification of this test might influence the results.

10.1 Interfering Substances
Haemoglobin (up to 4 mg/mL), Bilirubin (up to 0.5 mg/mL) and Triglyceride (up to 30 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 $\beta$-HCG in a sample.

10.3 High-Dose-Hook Effect
No hook effect was observed in this test up to 158600 mIU/mL of $\beta$-HCG.

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
<table>
<thead>
<tr>
<th>REF</th>
<th>Cat.-No.: / Kat.-Nr.: / No.-Cat.: / Cat.-No.: / N.° Cat.: / N.–Cat.:</th>
<th>Symbols / Symbole / Symbôles / Símbolos / Σύμβολα</th>
</tr>
</thead>
</table>
| LOT | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit di valutazione. / Κιτ Αξιολόγησης. | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Λυοφιλιασµένο | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit di valutazione. / Κιτ Αξιολόγησης. | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Λυοφιλιασµένο | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
| Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit di valutazione. / Κιτ Αξιολόγησης. | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: | Σύµβολα / Αριθµός-Κατ.:
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**LIABILITY:** Complaints will be accepted in each mode –written or vocal. Preferred is that the complaint is accompanied with the test performance and results. 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. 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 kit during transportation is not subject to the liability of the manufacturer.

**Symbols Version 3.5 / 2011-07-01**