Treponema pallidum IgM ELISA

Enzyme immunoassay for the qualitative determination of IgM-class antibodies to Treponema pallidum in human serum and plasma.

REF RE58861

∑ 96

2-8°C

EU: IVD
1 **INTENDED USE**
Enzyme immunoassay for the qualitative determination of IgM-class antibodies to Treponema pallidum in human serum and plasma. Results can also be expressed in cutoff-values (Units).

2 **SUMMARY AND EXPLANATION**
Spirochetes are motile bacteria with a periplasmatic axial filament. All pathogenic species belong to the family Treponemataceae, which includes the three genera: Treponema, Borrelia, and Leptospira. The Treponema are motile bacteria, 5-15 µm in length and 0.2 µm in width, containing about 10 flexible, undulating, spiral shaped rods. Treponema pallidum, the causative agent of Syphilis, is transmitted by direct contact, usually through sexual intercourse. Syphilis along with Gonorrhoea, Chancroid and Lymphogranuloma venereum, designated as a venereal disease, or VD, is an acute and chronic infectious disease. After an incubation period of 12-30 days, the first symptoms to appear are chancres, soon followed by syphilitic ulcers which then spontaneously disappear in a few weeks. During this first stage (primary syphilis) the Treponema pallidum propagates in related lymph nodes to be distributed to the whole body stream. Three further stages of disease follow which are classified as secondary, tertiary, and quaternary syphilis. Treatment with antibiotics at the earliest disease stage and prophylactic measures are ways to prevent epidemics. For this purpose, antenatal and donor blood screenings are mandatory in most of countries around the world.

3 **PRINCIPLE OF THE TEST**
The **Treponema pallidum IgM ELISA Kit** is a solid phase enzyme-linked immunosorbent assay (ELISA). Patient samples are diluted with **Sample Diluent** and additionally incubated with **IgG-RF-Sorbent**, containing hyper-immune anti-human IgG-class antibody to eliminate competitive inhibition from specific IgG and to remove rheumatoid factors. This pretreatment avoids false negative or false positive results. Microtiter wells as a solid phase are coated with Treponema pallidum antigen.

**Pretreated patient** specimens and **ready-for-use controls** are pipetted into these wells. During incubation Treponema pallidum-specific antibodies of positive specimens and controls are bound to the immobilized antigens. After a washing step to remove unbound sample and control material horseradish peroxidase conjugated anti-human IgM antibodies are dispensed into the wells. During a second incubation this anti-IgM conjugate binds specifically to IgM antibodies resulting in the formation of enzyme-linked immune complexes. After a second washing step to remove unbound conjugate the immune complexes formed (in case of positive results) are detected by incubation with TMB substrate and development of a blue color. The blue color turns into yellow by stopping the enzymatic indicator reaction with sulfuric acid. The intensity of this color is directly proportional to the amount of Treponema pallidum-specific IgM antibody in the patient specimen. Absorbance at 450 nm is read using an ELISA microtiter plate reader.

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. Avoid contact with Stop solution. It may cause skin irritations and burns.
9. 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 and therefore reagents should be treated as potential biohazards in use and for disposal.
5 STORAGE AND STABILITY
When stored at 2 °C to 8 °C unopened reagents will retain reactivity until expiration date. Do not use reagents beyond this date.
Opened reagents must be stored at 2 °C to 8 °C. Microtiter wells must be stored at 2 °C to 8 °C. Once the foil bag has been opened, care should be taken to close it tightly again.
Opened kits retain activity for two months if stored as described above.

6 KIT COMPONENTS
6.1 Contents of the Kit
1. **MTP**  
   *Microtiterwells*
   12 x 8 (break apart) strips, 96 wells; Wells coated with Treponema pallidum antigen.  
   (incl. 1 strip holder and 1 cover foil)
2. **SAMPLEDIL**  
   *Sample Diluent*
   1 vial, 100 mL, ready to use, colored yellow; pH 7.2 ± 0.2.
3. **RF-AB**  
   *IgG-RF-Sorbent*
   1 vial, 6.5 mL, ready to use, colored yellow; Contains anti-human IgG-class antibody.
4. **CONTROL +**  
   *Pos. Control*
   1 vial, 2.0 mL, ready to use, colored yellow, red cap.
5. **CONTROL -**  
   *Neg. Control*
   1 vial, 2.0 mL, ready to use, colored yellow, yellow cap.
6. **CUT OFF ±**  
   *Cut-off Control*
   1 vial, 2.0 mL, ready to use, colored yellow, black cap.
7. **ENZCONJ**  
   *Enzyme Conjugate*
   1 vial, 20 mL, ready to use, Antibody to human IgM conjugated to horseradish peroxidase.
8. **TMB SUBS**  
   *Substrate Solution*
   1 vial, 14 mL, ready to use, Tetramethylbenzidine (TMB).
9. **TMB STOP**  
   *Stop Solution*
   1 vial, 14 mL, ready to use, contains 0.2 mol/L H₂SO₄.
   Avoid contact with the stop solution. It may cause skin irritations and burns.
10. **WASHBUF CONC**  
    *Wash Solution*
    1 vial, 30 mL (20X concentrated for 600 mL), pH 6.5 ± 0.1 see „Preparation of Reagents“.
    *contain non-mercury preservative

6.2 Equipment and material required but not provided
- A microtiter plate calibrated reader (450/620nm ±10 nm)
- Calibrated variable precision micropipettes
- Incubator 37 °C
- Manual or automatic equipment for rinsing wells
- Vortex tube mixer
- Deionised or (freshly) distilled water
- Timer
- Absorbent paper

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

**Wash Solution**
Dilute **Wash Solution 1+19** (e.g. 10 mL + 190 mL) with fresh and germ free redistilled water. This diluted wash solution has a pH value of 7.2 ± 0.2.
Consumption: ~ 5 mL per determination.
Crystals in the solution disappear by warming up to 37 °C in a water bath. **Be sure that the crystals are completely dissolved before use.**

*The diluted Wash Solution is stable for 4 weeks at 2 °C to 8 °C.*
6.4 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 Safety Data Sheet.

6.5 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.

7 SPECIMEN
Serum or plasma can be used in this assay.
Do not use haemolytic, icteric or lipaemic specimens.

7.1 Specimen Collection
Serum:
Collect blood by venipuncture (e.g. Sarstedt Monovette for serum), 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 anti-coagulant (e.g. Sarstedt Monovette with the appropriate plasma preparation) and centrifuged immediately after collection.

7.2 Specimen Storage and Preparation
Specimens should be capped and may be stored for up to 5 days at 2 °C to 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.

7.3 Specimen Dilution
Prior to assaying each patient specimen is first to be diluted with Sample Diluent. For the absorption of rheumatoid factor these prediluted samples then have to be incubated with IgG-RF-Sorbent.

1. Dilute each patient specimen 1+50 with Sample Diluent;
e.g. 10 µL of specimen + 0.5 mL of Sample Diluent. Mix well.
2. Mix well the IgG-RF-Sorbent before use.
3. Dilute this prediluted sample 1+1 with IgG-RF-Sorbent
e.g. 60 µL prediluted sample + 60 µL IgG-RF-Sorbent. Mix well.
4. Let stand for at least 15 minutes at room temperature or overnight at 2 °C – 8 °C and mix well again.
5. Take 100 µL of these pretreated samples for the ELISA.
Please note: Controls are ready for use and must not be diluted!

8 TEST PROCEDURE

8.1 General Remarks
− It is very important to bring all reagents, samples and controls to room temperature before starting the test run!
− Once the test has been started, all steps should be completed without interruption.
− Use new disposal plastic pipette tips for each standard, control or sample in order to avoid cross contamination
− Absorbance is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
− As a general rule the enzymatic reaction is linearly proportional to time and temperature.
− Close reagent vials tightly immediately after use to avoid evaporation and microbial contamination.
− To avoid cross-contamination and falsely elevated results pipette patient samples and dispense conjugate without splashing accurately to the bottom of wells.
− During 37°C incubation cover microtiter strips with foil to avoid evaporation.

8.2 Assay Procedure
Prior to commencing the assay, dilute Wash Solution, prepare patient samples as described in point 7.3.

1. Select the required number of microtiter strips or wells and insert them into the holder.

   Please allocate at least:
   
   1 well (e.g. A1) for the substrate blank,
   1 well (e.g. B1) for the Neg. Control,
   2 wells (e.g. C1+D1) for the Cut-off Control
   1 well (e.g. E1) for the Pos. Control.

   It is left to the user to determine controls and patient samples in duplicate.

2. Dispense
   100 µL of Neg. Control into well B1
   100 µL of Cut-off Control into wells C1 and D1
   100 µL of Pos. Control into well E1 and
   100 µL of each preatreated sample with new disposable tips into appropriate wells.

   Leave well A1 for substrate blank!

3. Cover wells with foil supplied in the kit. Incubate for 60 minutes at 37 °C.

4. Briskly shake out the contents of the wells.
   Rinse the wells 5 times with diluted Wash Solution (300 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!

5. Dispense 100 µL Enzyme Conjugate into each well, except A1.

6. Incubate for 30 minutes at room temperature (20 °C to 25 °C).
   *Do not expose to direct sun light!*

7. Briskly shake out the contents of the wells.
   Rinse the wells 5 times with diluted Wash Solution (300 µL per well). Strike the wells sharply on absorbent paper to remove residual droplets.

8. Add 100 µL of Substrate Solution into all wells.

9. Incubate for exactly 15 minutes at room temperature (20 °C to 25 °C) in the dark.

10. Stop the enzymatic reaction by adding 100 µL of Stop Solution to each well.
   Any blue color developed during the incubation turns into yellow.

   Note: Highly positive patient samples can cause dark precipitates of the chromogen!

11. Read the optical density at 450/620 nm with a microtiter plate reader within 30 minutes after adding the Stop Solution.

8.3 Measurement
Adjust the ELISA microplate or microstrip reader to zero using the substrate blank in well A1.

If - due to technical reasons - the ELISA reader cannot be adjusted to zero using the substrate blank in well A1, subtract the absorbance value of well A1 from all other absorbance values measured in order to obtain reliable results!

Measure the absorbance of all wells at 450 nm and record the absorbance values for each control and patient sample in the distribution and identification plan.

Dual wavelength reading using 620 nm as reference wavelength is recommended.

Where applicable calculate the mean absorbance values of all duplicates.
9 RESULTS

9.1 Validation of the Test Run

The test run may be considered valid provided the following criteria are met:

- **Substrate blank in A1:** Absorbance value lower than 0.100
- **Neg. Control in B1:** Absorbance value lower than 0.200
- **Cut-off Control in C1/D1:** Absorbance value between 0.350 – 0.800
- **Pos. Control in E1:** Absorbance value between 0.650 – 3.000

9.2 Calculation

**Mean absorbance value of Cut-off Control [CO]**

Calculate the mean absorbance value of the two (2) Cut-off Control determinations (e.g. in C1/D1).

**Example:** \( \frac{0.44 + 0.46}{2} = 0.45 = CO \)

9.3 Interpretation

**POSITIVE** Patient (mean) absorbance values more than 10 % above CO

\( \text{Mean OD patient} > 1.1 \times CO \)

**GREY ZONE** Patient (mean) absorbance values from 10 % above to 10 % below CO

\( 0.9 \times CO \leq \text{Mean OD patient} \leq 1.1 \times CO \)

Repeat test 2 - 4 weeks later - with new patient samples

If results in the second test again in the grey zone ⇒ **NEGATIVE**

**NEGATIVE** Patient (mean) absorbance values more than 10 % below CO

\( \text{Mean OD patient} < 0.9 \times CO \)

9.3.1 Results in Units [U]

Patient (mean) absorbance value \( \times 10 \) = [U]

\( \frac{1.580 \times 10}{0.45} = 35 \text{ U} \)

Interpretation of Results

- **Cut-off value:** 10 U
- **Grey zone:** 9 - 11 U
- **Negative:** < 9 U
- **Positive:** > 11 U

10 QUALITY CONTROL

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.

It is also recommended to make use of national or international Quality Assessment programs in order to ensure the accuracy of the results.

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.
11 ASSAY CHARACTERISTICS

11.1 Assay Dynamic Range
The range of the assay is between 0.52 - 60 DU/mL.

11.2 Specificity of Antigen (Cross Reactivity)
The antigen used for the Treponema pallidum IgM ELISA shows no cross-reactivity to Epstein Barr Virus (VCA), Mycoplasma pneumonia, and Borrelia burgdorferi IgM antibodies.

11.3 Analytical Sensitivity
The analytical sensitivity of the ELISA was calculated by adding 2 standard deviations from the mean of 20 replicate analyses of the negative control and was found to be 0.52 DU/mL (OD\textsubscript{450} = 0.025).

11.4 Diagnostic Specificity
The diagnostic specificity is defined as the probability of the assay of scoring negative in the absence of the specific analyte. (Detected by method comparison with Mikrogen ELISA, with three lots of IBL ELISA. 77 samples, therefrom 57 negative samples are assayed with IBL ELISA lot 1-3.) It is 100% (for all three lots).

11.5 Diagnostic Sensitivity
The diagnostic sensitivity is defined as the probability of the assay of scoring positive in the presence of the specific analyte. (Detected by method comparison with Mikrogen ELISA, with three lots of IBL ELISA. 77 samples, therefrom 20 positive samples are assayed with IBL lot 1-3.) It is 100% (for all three lots).

11.6 Method Comparison
The Treponema pallidum IgM ELISA was compared with another Treponema pallidum IgM ELISA (Mikrogen). 77 serum samples are assayed.

<table>
<thead>
<tr>
<th></th>
<th>Other ELISA</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pos.</td>
<td>neg.</td>
</tr>
<tr>
<td>IBL ELISA Lot 1</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>57</td>
</tr>
</tbody>
</table>

Agreement: 100%
11.7 Reproducibility

11.7.1 Intra-assay
The intra-assay (within-run) precision of the Treponema pallidum IgM ELISA was determined by 20 x measurements of 12 serum samples covering the whole measuring range.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean OD_{450}</th>
<th>Intra-Assay CV (%)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.37</td>
<td>8.30</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>0.24</td>
<td>9.64</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>0.51</td>
<td>8.65</td>
<td>20</td>
</tr>
<tr>
<td>4</td>
<td>0.94</td>
<td>6.29</td>
<td>20</td>
</tr>
<tr>
<td>5</td>
<td>0.94</td>
<td>7.11</td>
<td>20</td>
</tr>
<tr>
<td>6</td>
<td>0.67</td>
<td>6.51</td>
<td>20</td>
</tr>
<tr>
<td>7</td>
<td>1.30</td>
<td>3.72</td>
<td>20</td>
</tr>
<tr>
<td>8</td>
<td>1.35</td>
<td>3.42</td>
<td>20</td>
</tr>
<tr>
<td>9</td>
<td>1.44</td>
<td>3.35</td>
<td>20</td>
</tr>
<tr>
<td>10</td>
<td>1.96</td>
<td>2.48</td>
<td>20</td>
</tr>
<tr>
<td>11</td>
<td>2.08</td>
<td>2.85</td>
<td>20</td>
</tr>
<tr>
<td>12</td>
<td>1.62</td>
<td>4.75</td>
<td>20</td>
</tr>
</tbody>
</table>

11.7.2 Inter-assay
The inter-assay variation of the Treponema pallidum IgM ELISA was determined with 3 samples with 2 production kits in 10 independent runs with 2 replicates per run.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean OD_{450}</th>
<th>Inter-Assay CV (%)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.86</td>
<td>2.75</td>
<td>40</td>
</tr>
<tr>
<td>2</td>
<td>1.20</td>
<td>3.31</td>
<td>40</td>
</tr>
<tr>
<td>3</td>
<td>1.44</td>
<td>2.69</td>
<td>40</td>
</tr>
</tbody>
</table>

11.8 Linearity
Three samples (serum) containing different amounts of analyte were serially diluted with sample diluent and assayed with the IBL ELISA. The percentage recovery was calculated by comparing the expected and measured values for the analyte.

<table>
<thead>
<tr>
<th>Serum 1</th>
<th>Serum 2</th>
<th>Serum 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration DU/mL</td>
<td>42.66</td>
<td>34.23</td>
</tr>
<tr>
<td>Average % Recovery</td>
<td>97.81</td>
<td>104.93</td>
</tr>
<tr>
<td>Min Recovery from</td>
<td>86.59</td>
<td>95.07</td>
</tr>
<tr>
<td>Max Recovery to</td>
<td>112.41</td>
<td>114.17</td>
</tr>
</tbody>
</table>

Status Linearity (100 +/-15%) passed passed passed

12 LIMITATIONS OF USE
Bacterial contamination or repeated freeze-thaw cycles of the specimen may affect the absorbance values. In immunocompromised patients and newborns serological data only have restricted value.

12.1 Interfering Substances
In general, haemolytic, icteric or lipaemic samples should be avoided, but can be tolerated up to at least 4 mg/mL haemoglobin, 0.5 mg/mL Bilirubin, and 30 mg/mL triglycerides.
None of the following samples with interference factors will interfere with the ELISA: samples with rheumatoid factor, samples with pregnancy hormones, samples with tumor marker (CYFRA, CA-72-4, CA-21-1, CA-15-3), samples with HAMA, samples with ANA and samples from elderly with high amount of proteins.
13 LEGAL ASPECTS

13.1 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 us.

13.2 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 13.1. Any laboratory result is only a part of the total clinical picture of a patient. Diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. 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.

13.3 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 13.2. 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.

14 REFERENCES
### SHORT INSTRUCTIONS FOR USE

<table>
<thead>
<tr>
<th>Step</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>All reagents and specimens must be allowed to come to room temperature (18-25°C) before use. Leave well A1 for substrate Blank. Dispense 100 µl of Controls into appropriate wells.</td>
</tr>
<tr>
<td>2.</td>
<td>Dispense 100 µl of sample into selected wells. <em>(Please note special sample treatment, point 5.3!)</em></td>
</tr>
<tr>
<td>3.</td>
<td>Cover wells with foil. Incubate for <strong>60 minutes</strong> at 37 °C.</td>
</tr>
<tr>
<td>4.</td>
<td>Briskly shake out the contents of the wells.</td>
</tr>
<tr>
<td>5.</td>
<td>Rinse the wells 5 times with diluted Wash Solution (300 µl per well).</td>
</tr>
<tr>
<td>6.</td>
<td>Strike the wells sharply on absorbent paper to remove residual droplets.</td>
</tr>
<tr>
<td>7.</td>
<td>Dispense 100 µl of Enzyme-Conjugate into each well.</td>
</tr>
<tr>
<td>8.</td>
<td>Incubate for <strong>30 minutes</strong> at room temperature.</td>
</tr>
<tr>
<td>9.</td>
<td>Briskly shake out the contents of the wells.</td>
</tr>
<tr>
<td>10.</td>
<td>Rinse the wells 5 times with diluted Wash Solution (300 µl per well).</td>
</tr>
<tr>
<td>11.</td>
<td>Strike the wells sharply on absorbent paper to remove residual droplets.</td>
</tr>
<tr>
<td>12.</td>
<td>Add 100 µl of Substrate Solution to each well.</td>
</tr>
<tr>
<td>13.</td>
<td>Incubate for <strong>15 minutes</strong> at room temperature.</td>
</tr>
<tr>
<td>14.</td>
<td>Stop the reaction by adding 100 µl of Stop Solution to each well.</td>
</tr>
<tr>
<td>15.</td>
<td>Determine the absorbance of each well at 450 nm.</td>
</tr>
</tbody>
</table>
Symbols / Symbole / Symbôles / Símbolos / Σύμβολα

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<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tr>
<td>REF</td>
<td>Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.° Cat.: / N.-Cat.: / Αριθμός-Κατ.:</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή:</td>
</tr>
<tr>
<td>Use by</td>
<td>/ Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από:</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 / Liofilizado / Liofilizzato / Λυοφιλιασμένο</td>
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<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Equipamiento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση.</td>
</tr>
<tr>
<td>E</td>
<td>Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit de evaluación. / Kit Αξιολόγησης.</td>
</tr>
<tr>
<td>Read</td>
<td>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.</td>
</tr>
<tr>
<td>Store</td>
<td>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. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου.</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:</td>
</tr>
<tr>
<td>CAUTION</td>
<td>Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!</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 συμβουλεύετε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

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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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IBL International GmbH
Flughafenstr. 52A, 22335 Hamburg, Germany
Tel.: + 49 (0) 40 532891 -0 Fax: -11
E-MAIL: IBL@IBL-International.com
WEB: http://www.IBL-International.com

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