AFP ELISA

Enzyme immunoassay (microtiter strips) for the quantitative determination of Alpha-Fetoprotein in human serum.

REF RE52011

Σ 12x8

2-8°C

EU: IVD U.S.: For research use only.

Not for use in diagnostic procedures.
**Contents**

1. INTRODUCTION ............................................... 2
2. PRINCIPLE OF THE TEST ............................... 2
3. PRECAUTIONS................................................. 2
4. KIT COMPONENTS .......................................... 3
5. SPECIMEN........................................................ 4
6. TEST PROCEDURE.......................................... 4
7. EXPECTED VALUES ........................................ 6
8. QUALITY CONTROL......................................... 6
9. ASSAY CHARACTERISTICS............................ 7
10. LIMITATIONS OF USE...................................... 8
11. LEGAL ASPECTS ............................................. 8
12. REFERENCES .................................................. 9
1 INTRODUCTION

1.1 Intended Use
The IBL International AFP ELISA is an enzyme immunoassay for the quantitative in vitro diagnostic measurement of alpha fetoprotein (AFP) in serum.

1.2 Summary and Explanation
Alpha-fetoprotein (AFP) is a glycoprotein with a molecular weight of approximately 70 KD(1). AFP is normally produced during fetal and neonatal development by the liver, yolk sac, and in small concentrations by the gastrointestinal tract (2). After birth, serum AFP concentrations decrease rapidly, and by the second year of life and thereafter only trace amounts are normally detected in serum (3). Elevation of serum AFP to abnormally high values occurs in several malignant diseases (4-7), most notably nonseminomatous testicular cancer and primary hepatocellular carcinoma. In the case of nonseminomatous testicular cancer, a direct relationship has been observed between the incidence of elevated AFP levels and the stage of disease (8-9). Elevated AFP levels have also been observed in patients diagnosed with seminoma with nonseminomatous elements, but not in patients with pure seminoma (6,8,10-11). In addition, elevated serum AFP concentrations have been measured in patients with other noncancerous diseases, including ataxia telangiectasia, hereditary tyrosinemia, neonatal hyperbilirubinemia, acute viral hepatitis, chronic active hepatitis and cirrhosis (12-15). Elevated serum AFP concentrations are also observed in pregnant women (16-17). Therefore, AFP measurements are not recommended for use as a screening procedure to detect the presence of cancer in the general population.

2 PRINCIPLE OF THE TEST
The IBL International AFP ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle. The microtiter wells are coated with a monoclonal [mouse] antibody directed towards a unique antigenic site on an AFP molecule. An aliquot of patient sample containing endogenous AFP is incubated in the coated well with enzyme conjugate, which is an anti- AFP antibody conjugated with horseradish peroxidase. After incubation the unbound conjugate is washed off. The amount of bound peroxidase is proportional to the concentration of AFP in the sample. Having added the substrate solution, the intensity of colour developed is proportional to the concentration of AFP 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 International

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-AFP antibody (monoclonal).

2. **STD** *Standard (Standard 0-4)*, 5 vials (lyophilized), 0.5 mL; Concentrations: 0 - 10 - 40 - 80 - 160 IU/mL
   Conversion: 1IU/mL = 1.21ng/mL
   The standards are calibrated against NIBSC 1st International Standard for Alphaoetoprotein AFP (AFP 1st IRP 72/225)
   See „Preparation of Reagents“;
   * contain 0.03% Proclin 300, 0.015% BND and 0.010% MIT as preservatives.

3. **ENZY CONJ** *Enzyme Conjugate*, 1 vial, 11 mL, ready to use, Anti-AFP antibody conjugated to horseradish peroxidase;
   * contains 0.03% Proclin 300, 0.015% BND and 0.010% MIT as preservatives.

4. **TMB SUBS** *Substrate Solution*, 1 vial, 14 mL, ready to use, Tetramethylbenzidine (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.

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

**Note:** Additional *Standard 0* for sample dilution is available upon 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.
- Bidistilled water

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 foil bag has been opened, care should be taken to close it tightly again.
Opened kits retain activity for six weeks 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.

**Standards**
Reconstitute the lyophilized contents of the standard vial with 0.5 mL bidistilled water!
**Note:** The reconstituted standards are stable for 2 months at 2-8°C. For longer storage freeze at -20°C.

4.4 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 Material Safety Data Sheets (see chapter 13).

4.5 Damaged Test Kits
In case of any severe damage of the test kit or components, IBL International 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 should be used in this assay.
Do not use haemolytic, icteric or lipaemic specimens.
NOTE: Samples containing sodium azide should not be used in the assay.

NOTE: If an amniocentesis is necessary the specimen collection has to be done before the puncture. After the amniotic puncture increased AFP values are determined.

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
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 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 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.
6.2 Assay Procedure

Each run must include a standard curve.

1. Secure the desired number of Microtiter wells in the frame 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. Thoroughly mix for 10 seconds. It is important to have a complete mixing in this step.
4. Incubate for 30 minutes at room temperature.
5. 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!
6. Add 100 µL of Substrate Solution to each well.
7. Incubate for 10 minutes at room temperature.
8. Stop the enzymatic reaction by adding 50 µL of Stop Solution to each well.
9. 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 IU/mL)</td>
<td>0.07</td>
</tr>
<tr>
<td>Standard 1 (10 IU/mL)</td>
<td>0.21</td>
</tr>
<tr>
<td>Standard 2 (40 IU/mL)</td>
<td>0.69</td>
</tr>
<tr>
<td>Standard 3 (80 IU/mL)</td>
<td>1.29</td>
</tr>
<tr>
<td>Standard 4 (160 IU/mL)</td>
<td>1.97</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 using the IBL International ELISA the following values are observed:

7.1 Normal healthy adults, non-pregnant
The lower limit of AFP concentration in normal serum is less than 1 IU/mL; the upper limit is about 10 IU/mL.

7.2 Values during pregnancy

<table>
<thead>
<tr>
<th>Weeks of pregnancy</th>
<th>AFP [IU/mL]</th>
<th>Weeks of pregnancy</th>
<th>AFP [IU/mL]</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>9 - 24</td>
<td>19</td>
<td>32 - 103</td>
</tr>
<tr>
<td>11</td>
<td>10 - 27</td>
<td>20</td>
<td>42 - 121</td>
</tr>
<tr>
<td>12</td>
<td>10 - 30</td>
<td>21</td>
<td>48 - 139</td>
</tr>
<tr>
<td>13</td>
<td>10 - 34</td>
<td>22 - 24</td>
<td>56 - 224</td>
</tr>
<tr>
<td>14</td>
<td>11 - 45</td>
<td>25 - 27</td>
<td>95 - 357</td>
</tr>
<tr>
<td>15</td>
<td>14 - 60</td>
<td>28 - 30</td>
<td>135 - 435</td>
</tr>
<tr>
<td>16</td>
<td>16 - 69</td>
<td>31 - 33</td>
<td>141 - 423</td>
</tr>
<tr>
<td>17</td>
<td>17 - 78</td>
<td>34 - 36</td>
<td>121 - 380</td>
</tr>
<tr>
<td>18</td>
<td>22 - 93</td>
<td>37 - 40</td>
<td>93 - 321</td>
</tr>
</tbody>
</table>

CLINICAL IMPORTANCE
1. Maternal serum containing above 2.5 times the normal median for weeks 16 to 18 of pregnancy was detected in 88% of cases of anencephaly and in 79% of cases of open spina bifida.
2. The concentration of AFP in hepatocellular carcinoma and germ cell tumor varies from the normal range up to several million IU/ml. After surgical resection, the serum AFP may drop to normal range or somewhat above it.
3. AFP may occur in serum of patients with diseases other than hepatocarcinoma or embryonal carcinoma of the testes, such as neonatal hepatitis and nonhepatic neoplasms.

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 International directly.
9 ASSAY CHARACTERISTICS

9.1 Assay Dynamic Range
The range of the assay is between 0 – 160 IU/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>Produced Color Intensity Equivalent to AFP in serum (IU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSA</td>
<td>20 mg/ml 2</td>
</tr>
<tr>
<td>Prolaktin</td>
<td>200 ng/ml 2</td>
</tr>
<tr>
<td>hCG</td>
<td>2000 ng/ml 2</td>
</tr>
<tr>
<td>SP- 1</td>
<td>2000 ng/ml 2</td>
</tr>
<tr>
<td>hPL</td>
<td>2011 µg/ml 2</td>
</tr>
</tbody>
</table>

9.3 Analytical Sensitivity
The analytical sensitivity was calculated from the mean plus two standard deviations of twenty (20) replicate analyses of Standard 0 and was found to be 1.78 IU/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 (IU/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20</td>
<td>25.63</td>
<td>3.82</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>105.78</td>
<td>5.39</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>77.63</td>
<td>3.50</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Sample</th>
<th>n</th>
<th>Mean (IU/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>25.31</td>
<td>3.64</td>
</tr>
<tr>
<td>2</td>
<td>16</td>
<td>109.34</td>
<td>6.54</td>
</tr>
<tr>
<td>3</td>
<td>16</td>
<td>84.10</td>
<td>6.74</td>
</tr>
</tbody>
</table>

9.5 Recovery
Recovery of the IBL International ELISA was determined by adding increasing amounts of the analyte to three sera of pregnant women. The percentage recoveries were determined by comparing expected and measured values of the samples.

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration [IU/mL]</td>
<td>30.86</td>
<td>115.20</td>
</tr>
<tr>
<td>Average Recovery</td>
<td>92.9</td>
<td>94.0</td>
</tr>
<tr>
<td>Range of Recovery [%]</td>
<td>from 86.7</td>
<td>93.4</td>
</tr>
</tbody>
</table>
9.6 Linearity
Three samples (serum) containing different amounts of analyt were serially diluted (up to 1:16) with zero standard and assayed with the IBL International ELISA. The percentage recovery was calculated by comparing the expected and measured values for the analyt.

<table>
<thead>
<tr>
<th></th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration [IU/mL]</td>
<td>39.7</td>
<td>75.6</td>
<td>128.4</td>
</tr>
<tr>
<td>Average Recovery</td>
<td>102.0</td>
<td>95.5</td>
<td>96.8</td>
</tr>
<tr>
<td>Range of Recovery [%]</td>
<td>from 90.9 to 115.0</td>
<td>86.2 to 109.3</td>
<td>92.9 to 101.3</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 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 AFP in a sample.

10.3 High-Dose-Hook Effect
No hook effect was observed in this test up to 1600 IU/mL of AFP.

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 International.

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


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

<table>
<thead>
<tr>
<th>REF</th>
<th>Cat.-No.: / Kat.-Nr.: / No.-</th>
<th>Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Lot-No.: / Chargen-Bez.: / No. Lot.: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από:</td>
<td></td>
</tr>
<tr>
<td>CONC</td>
<td>Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Λυοφιλιασµένο</td>
<td></td>
</tr>
<tr>
<td></td>
<td>In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης.</td>
<td></td>
</tr>
<tr>
<td></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>
<td></td>
</tr>
<tr>
<td></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. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!</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 veja 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.

### IBL AFFILIATES WORLDWIDE

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</thead>
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</tr>
<tr>
<td></td>
<td>WEB: <a href="http://www.IBL-International.com">http://www.IBL-International.com</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IBL International Corp.</th>
<th>Tel.: +1 (416) 645-1703  Fax: -1704</th>
</tr>
</thead>
<tbody>
<tr>
<td>194 Wildcat Road, Toronto, Ontario M3J 2N5, Canada</td>
<td>E-MAIL: <a href="mailto:Sales@IBL-International.com">Sales@IBL-International.com</a></td>
</tr>
<tr>
<td></td>
<td>WEB: <a href="http://www.IBL-International.com">http://www.IBL-International.com</a></td>
</tr>
</tbody>
</table>

### 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 / 2012-01-20