The MP DIAGNOSTICS (MPD) HTLV I/II ELISA 3.0 is an enzyme-linked immunosorbent assay intended for the detection of antibodies to HTLV-I and HTLV-II in human serum or plasma. It is intended as a screening test, requiring repeat testing of initially reactive specimens.

The wells of the polystyrene microplate strips are coated with a mixture of recombinant HTLV-I and HTLV-II antigens which correspond to the highly antigenic segments of HTLV-I and HTLV-II viruses. Human serum or plasma, diluted in diluent buffer, is incubated in these coated wells. HTLV-I/II specific antibodies, if present, will bind to the antigens immobilised on the solid phase. The wells are thoroughly washed to remove unbound materials and an affinity purified goat antibody anti-human IgG labeled with horseradish peroxidase is added to the wells. This labeled antibody will bind to any antigen-antibody complexes previously formed and excess unbound labeled antibodies are removed by washing. A substrate solution containing 3,3',5,5'-tetramethylbenzidine (TMB) is then added to each well. The presence of specific antibodies is indicated by the presence of a blue colour after substrate addition. Reaction is terminated by addition of hydrochloric acid. The intensity of the resulting yellow reaction product is measured spectrophotometrically at 450nm and is proportional to the amount of antibodies present in the specimen.
## COMPONENT DESCRIPTIONS

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Quantity Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MICROPLATE</strong></td>
<td></td>
</tr>
<tr>
<td>HTLV MICROPLATE</td>
<td></td>
</tr>
<tr>
<td>Twelve 8-well strips per plate.</td>
<td></td>
</tr>
<tr>
<td>Each microplate well contains adsorbed HTLV-I and HTLV-II recombinant proteins. Store at 2°C to 8°C.</td>
<td></td>
</tr>
<tr>
<td><strong>CONTROL</strong></td>
<td></td>
</tr>
<tr>
<td>NON-REACTIVE CONTROL</td>
<td>1 vial 2 vials 3 vials</td>
</tr>
<tr>
<td>Normal human serum, non-reactive for anti-HCV, anti-HIV-1/2, anti-HTLV-I/II and HBsAg. Contains thimerosal and sodium azide as preservatives. Contents: 280 µl per vial. Store at 2°C to 8°C.</td>
<td></td>
</tr>
<tr>
<td>REACTIVE CONTROL</td>
<td>1 vial 2 vials 4 vials</td>
</tr>
<tr>
<td>Inactivated human serum containing a high titer of antibodies specific for HTLV-I/II and non-reactive for anti-HCV, anti-HIV-1/2 and HBsAg. Contains thimerosal and sodium azide as preservatives. Contents: 300 µl per vial. Store at 2°C to 8°C.</td>
<td></td>
</tr>
<tr>
<td><strong>DILUENT</strong></td>
<td>1 bottle 2 bottles</td>
</tr>
<tr>
<td>Tris based saline solution containing heat treated normal goat serum, bovine serum albumin and stabilizers. Contains Bronidox™ as preservative. Contents: 100 ml per bottle. Store at 2°C to 8°C.</td>
<td></td>
</tr>
<tr>
<td><strong>PLATE WASH CONCENTRATE (20X)</strong></td>
<td>1 bottle 2 bottles</td>
</tr>
<tr>
<td>Phosphate buffered saline with Tween-20. Contains chloracetamide as preservative. Contents: 120 ml per bottle. Store at 2°C to 8°C.</td>
<td></td>
</tr>
<tr>
<td><strong>CONJUGATE</strong></td>
<td>1 vial 2 vials 3 vials</td>
</tr>
<tr>
<td>Goat antibody anti-human IgG labeled with horseradish peroxidase. Contents: 70 µl per vial. Store at 2°C to 8°C.</td>
<td></td>
</tr>
<tr>
<td><strong>SUBSTRATE</strong></td>
<td>1 bottle 2 bottles 5 bottles</td>
</tr>
<tr>
<td>Buffer containing 3,3',5,5'-tetramethylbenzidine (TMB). Store in the dark at 2°C to 8°C. Contents: 12.5 ml per bottle</td>
<td></td>
</tr>
</tbody>
</table>

### STOP SOLUTION

1N hydrochloric acid solution. Store in the dark at 2°C to 8°C. Contents: 30 ml per bottle

### PLATE COVERS

Adhesive covers for microplate during incubation

### INSTRUCTION MANUAL

1. For *in vitro* diagnostic use only.
2. For Professional use only
3. Please refer to the product labelling for information on potentially hazardous components

### WARNINGS AND PRECAUTIONS

1. **For in vitro** diagnostic use only.
2. **For Professional use only**
3. Please refer to the product labelling for information on potentially hazardous components

### HEALTH AND SAFETY INFORMATION

**CAUTION:** This kit contains materials of human origin. No test method can offer complete assurance that human blood products will not transmit infection.

**HANDLE ASSAY SPECIMENS, REACTIVE AND NON-REACTIVE CONTROLS AS POTENTIALLY INFECTIOUS AGENTS.** It is recommended that the components and test specimens be handled using good laboratory working practices. They should be disposed of in accordance with established safety procedures.

The **Reactive Control** and **Non-Reactive Control** contain Thimerosal and Sodium Azide. Sodium azide can react with copper and lead used in some plumbing systems to form explosive salts. The quantities used in this kit are small, nevertheless when disposing of azide-containing materials they should be flushed away with relatively large quantities of water to prevent metal azide buildup in plumbing system. The following are the appropriate Risk (R) and Safety (S) phrases.

- **R20/21/22** Harmful by inhalation, in contact with skin and if swallowed.
- **R32** Contact with acids liberates very toxic gas.
- **S26/28** In case of contact with eyes, rinse immediately with plenty of water. After contact with skin, wash immediately with plenty of water.

The **Diluent** contains Bronidox and Tris which is classified per applicable European Economic Community (EEC) Directives as Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.

- **R36/38** Irritating to eyes and skin.
- **S36** Wear suitable protective clothing.
- **S46** If swallowed, seek medical advice immediately and show this container or label.
The Plate Wash Concentrate (20X) contains 2% Chloroacetamide which is classified per applicable European Economic Community (EEC) Directives as Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.

R22-43 Harmful if swallowed. May cause sensitization by skin contact.

S22-36/37-45 Do not breathe dust. Wear suitable protective clothing and gloves. In case of accident or if you feel unwell, seek medical advice immediately (Show label where possible).

1. Avoid microbial contamination of reagents when opening and removing aliquots from the original vials or bottles.
2. Do not pipette by mouth.
3. Handle assay specimens, microplates, Reactive and Non-Reactive Controls as potentially infectious agents.
4. Wear laboratory coats and disposable gloves while performing the assay. Discard gloves in bio-hazard waste-bags. Wash hands thoroughly afterwards.
5. It is highly recommended that this assay be performed in a biohazard cabinet.
6. Keep materials away from food and drink.
7. In case of an accident or contact with eyes rinse immediately with plenty of water and seek medical advice.
8. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, or other breaks in the skin.
9. Hydrochloric acid can cause burns. AVOID CONTACT. If it comes into contact with skin, wash thoroughly with water.
10. Avoid contact of hydrochloric acid with any oxidizing agent or metal.
11. Do not expose substrate to strong light.
12. Never add water to Stop Solution.
13. Wipe spills of potentially infectious materials immediately with absorbent paper and swab the contaminated area with 1% sodium hypochlorite solution before work is resumed. Sodium hypochlorite should not be used on acid contaminating spills unless the area is wiped dry with absorbent paper first. Material used (including disposable gloves) should be disposed of as potentially biohazardous material. Do not autoclave material containing sodium hypochlorite.
14. Autoclave all used and contaminated materials at 121°C, 15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste-bags.
15. Decontaminate all used chemicals and reagents by adding sufficient volume of sodium hypochlorite to make a final concentration of at least 1%. Leave for 30 minutes to ensure effective decontamination.

Analytical Precautions

1. Serum or plasma samples collected in EDTA, heparin or sodium citrate may be used. Before storage, ensure that blood clot or blood cells have been separated by centrifugation.
2. Optimal assay performance requires STRICT ADHERENCE to the assay procedure described in this Instruction Manual. Deviations from the procedure may lead to aberrant results.
3. DO NOT MODIFY OR SUBSTITUTE REAGENTS FROM ONE KIT LOT TO ANOTHER. Controls, conjugate and microplates are matched for optimal performance. Use only the reagents supplied with the kit.
4. Do not use kit components beyond the expiry date printed on the kit box.
5. Avoid microbial contamination of the reagents, when opening and removing aliquots from the original vials or bottles. As this will prematurely reduce the shelf life of the kits and give erroneous results. Use aseptic techniques including pipettes or disposable pipette tips when drawing aliquots from vials.
6. To prevent cross contamination, use a new pipette tip for each specimen aliquoted to, and do not touch the top or the bottom of the strips, the edge of the wells or the liquid in the wells with fingers or pipette tips.
7. It is recommended that glassware to be used with the reagents should be washed with 2M hydrochloric acid and rinsed thoroughly with distilled or deionised water prior to use.
8. For best results allow all reagents and samples to reach room temperature (25°C ± 3°C) before use. Immediately after use return to 2°C to 8°C storage.
9. Use only reagent grade quality, deionised or distilled water to dilute reagents.
10. All reagents must be mixed well before use.
11. Working Conjugate solution, Substrate solution and Diluted Wash Buffer should be prepared fresh prior to use.
12. Do not expose reagents or perform test in an area containing a high level of chemical disinfectant fumes (e.g. hypochlorite fumes) during storage or during incubation steps. Contact inhibits colour reaction. Also do not expose reagents to strong light.
13. Do not remove microplates from the storage bag until immediately before use. Opened, unused strips should be stored at 2°C to 8°C in its storage bag with the desiccant provided.
14. The kit controls should be assayed concurrently with patients’ samples for each test run.
15. Care should be taken to avoid touching or splashing the rim of the well with conjugate. Do not “blow out” from the micropipette. It is recommended to use reverse pipetting whenever possible.

16. Use of highly haemolyzed samples, incomplete clotted sera, plasma samples containing fibrin or samples with microbial contamination may give rise to erroneous results.

17. **DO NOT USE A WATER BATH TO INCUBATE PLATES.**

18. CO₂ incubators must not be used.

19. During 37°C incubation, evaporation must be prevented. Cover plates with adhesive covers provided.

20. Avoid repeatedly opening and closing the incubator door during incubation steps.

21. Do not store the stop solution in a shallow dish or return it to a stock bottle after use.

22. Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate. Remove any bubbles in the well, e.g. by gentle tapping.

23. Ensure that automated equipment if used is validated before use.

24. Routine maintenance of aspiration / wash system is strongly recommended to prevent carryover from highly reactive specimens to non-reactive specimens.

### STORAGE INSTRUCTIONS

1. Store MPD HTLV I/II ELISA 3.0 kit and its components at 2°C to 8°C when not in use.

2. All test reagents and strips in the Closed or unopened condition, when stored at 2°C to 8°C, are stable until the expiry date given on the kit. Do not freeze the reagents.

3. The stability of the kit after first opening is 12 months. Kit expiry will be the earliest expiry date either in the Closed or Opened condition.

4. Opened, unused microplate strips must be stored with the desiccant provided at 2°C to 8°C in a closed pouch.

5. Crystals may form when Plate Wash Concentrate (20x) is stored at 2°C to 8°C. These must be dissolved by warming at 37°C prior to use.

6. Precipitate may form when the Diluent is stored at 2°C to 8°C. This will not affect the performance of the kit.

### SPECIMEN COLLECTION, TRANSPORT AND STORAGE

Serum or plasma samples collected in EDTA, heparin or sodium citrate may be used. Before storage, ensure that blood clot or blood cells have been separated by centrifugation.

Samples should be stored 2°C to 8°C if the test is to be run within 7 days of collection or frozen at -20°C or colder if the test is to be delayed for more than 7 days. Clear, non-haemolysed samples are preferred. Lipemic, icteric or contaminated (particulate) samples should be filtered (0.45µm) or centrifuged before testing.

Patients’ sera can be inactivated but this is not a requirement for optimal test performance. Inactivate as follows:

1. Loosen caps of serum containers.
2. Heat serum to 56°C for 30 minutes in a water bath.
3. Allow serum to cool before retightening caps.
4. Serum can be stored frozen until analysis.

We recommend that the patients’ sera should not undergo repeated freeze-thaw cycles.

### ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED

1. Disposable absorbent bench top paper and paper towels.
2. Polypropylene tubes or containers.
3. Graduated pipettes: 5 ml, 10 ml.
4. Multichannel pipettor capable of delivering 50 µl, 100 µl, and 200 µl.
5. Pipettor capable of delivering 1-1000 µl.
6. Disposable pipette tips.
7. Reagent reservoirs (troughs) with a capacity of 25 ml.
8. Deionised or distilled water, reagent grade quality.
9. Flasks: 500 ml, 1 litre.
10. ELISA Microplate Washer. Alternatively, washing can be performed manually by using a multichannel pipettor delivering 0.3 ml volumes and an aspirator device.
11. A 37 ± 1°C incubator.
12. A dual (A₄₅₀-A₆₂₀) or single (A₄₅₀) wavelength microassay plate reader.
13. Sodium hypochlorite (5%) solution or liquid household bleach.
1. WORKING CONJUGATE
   a. WORKING CONJUGATE should be prepared fresh prior to use.
   b. To prepare diluted conjugate, make a 1:500 dilution of conjugate with diluent provided in the kit, for example, 10 µl conjugate to 5 ml diluent.
   c. Use only polypropylene containers or tubes.
   d. 12.0 ml of WORKING CONJUGATE is required for one microplate.

2. DILUTED WASH BUFFER
   a. DILUTED WASH BUFFER should be prepared fresh prior to use.
   b. Dilute 1 volume of PLATE WASH CONCENTRATE with 19 volumes of distilled water (reagent grade quality). Mix well. Approximately 400 ml of wash buffer is required to wash 1 plate.

CONJUGATE PREPARATION CHART

<table>
<thead>
<tr>
<th>Number of tests</th>
<th>Vol. of Conjugate (µl)</th>
<th>Vol. of Diluent (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>10.0</td>
<td>5.0</td>
</tr>
<tr>
<td>48</td>
<td>15.0</td>
<td>7.5</td>
</tr>
<tr>
<td>72</td>
<td>20.0</td>
<td>10.0</td>
</tr>
<tr>
<td>96</td>
<td>24.0</td>
<td>12.0</td>
</tr>
</tbody>
</table>

3. Incubate for 60 minutes at 37°C (Do not use a 37°C water bath for incubation).

4. Prepare WORKING CONJUGATE as described in the PREPARATION OF REAGENTS prior to washing the microplate.

5. Remove and discard the plate cover and wash the microplate with DILUTED WASH BUFFER using one of the two recommended methods.
   A. Automated or Semi-automatic Microplate Washer - Wash six (6) times with at least 300 µl per well per wash.
   B. Manual Microplate Washer - Aspirate completely the contents of all wells by lowering the aspirator tip gently to the bottom of each well. BE CAREFUL NOT TO SCRATCH THE INSIDE OF THE WELL SURFACE. Fill the entire plate with at least 300 µl/well, then aspirate immediately in the same order. Perform this cycle six (6) times.

6. Blot dry by inverting the microplate and tapping firmly onto absorbent paper. All residual plate wash buffer should be blotted dry. Colour formation can be inhibited during the substrate incubation by residual plate wash buffer.

ASSAY PROCEDURE

IMPORTANT: - Immunoassays of this nature are temperature-sensitive and time-dependent. Strict adherence to the assay procedure will ensure optimal assay performance. Deviations from the recommended procedure may lead to aberrant results.

1. Remove microplate from the aluminum bag.
2. Shake specimen and control vials before use.
3. Fill a reagent reservoir with DILUENT. Using a multichannel pipettor, add 200 µl of DILUENT to all wells.
4. Wells A1 and B1 are 'BLANKS'. DO NOT ADD SPECIMEN TO THESE WELLS. Add an additional 20 µl of diluent to these wells.
5. Add 20 µl of specimen to the assigned well, starting at well H1. This will give a final specimen dilution of 1:11. DO NOT PLACE SPECIMEN IN AN EMPTY WELL.
6. After the test specimen have been added, add 20 µl of NON-REACTIVE CONTROL per well to wells C1, D1.
7. Add 20 µl of REACTIVE CONTROL per well to wells E1 and F1 and G1. Mix thoroughly by tapping gently on all sides of microplate, taking care to keep the plate flat on the bench-top.
8. Carefully cover the microplate with a plate cover provided to prevent evaporation during incubation.
9. Incubate for 30 minutes at 37°C (Do not use a 37°C water bath for incubation).
10. Remove and discard the plate cover. Repeat the wash procedure as in Step 11 and Step 12.
11. Fill a reagent reservoir with the WORKING CONJUGATE. Using a multichannel pipettor, add 100 µl of WORKING CONJUGATE to each well. Apply another plate cover.
12. Incubate the microplate for 30 minutes at 37°C (Do not use a 37°C water bath for incubation).
13. Fill a reagent reservoir with the SUBSTRATE. Using a multichannel pipettor, add 100 µl of SUBSTRATE to each well. Apply a plate cover.
17. Incubate for 15 minutes in the dark at 37°C. (Do Not use a 37°C water bath for incubation).
18. Remove and discard the plate cover.
19. Using a multichannel pipettor, add 100 µl of STOP SOLUTION to each well. Mix gently by tapping the plate.
20. Determine the Absorbance for each well at 450nm. If a dual filter instrument is used, the reference wavelength should be 620 nm.

NOTE: Absorbance should be read within 10 minutes upon addition of the STOP SOLUTION.

QUALITY CONTROL

1. The BLANK and NON-REACTIVE CONTROL should be assayed in duplicate, whereas REACTIVE CONTROL in triplicate on each plate with each run of specimens.
2. Blank values must have an absorbance of ≤ 0.100.
3. Non-Reactive Control values must have an absorbance of ≤ 0.100 after subtracting the Blank value.
4. At least 2 of the 3 Reactive Control values must have absorbance ≥ 0.800 after subtraction of the Blank. Any values outside of this range should not be used for calculation of the Reactive Control Mean (RCx).
5. If 2 or more Reactive Control values deviate more than 30% of the MEAN, the run is INVALID and should be repeated.
6. For the assay to be valid, the difference between the mean absorbances of the Reactive Control and the Non-Reactive Control (RCx - NRCx) should be ≥ 0.700. If not, technique may be suspected and the assay must be repeated. If this MEAN absorbance difference (RCx - NRCx) is consistently low, deterioration of reagents may be suspected.

RESULTS

Each microplate must be considered separately when calculating and interpreting results of the assay, regardless of the number of plates concurrently processed.

The MEAN ABSORBANCE BLANK VALUES SHOULD BE SUBTRACTED FROM ALL ABSORBANCE VALUES ON THE PLATE BEFORE INTERPRETATION OF RESULTS.

The presence or absence of antibodies specific for HTLV-I/II is determined by relating the absorbance of the specimens to the CUT-OFF VALUE (COV) of the plate.

The CUT-OFF VALUE is calculated as (0.45 absorbance unit + NRC Mean Absorbance):

\[ \text{CUT-OFF VALUE} = 0.45 + \text{NRC} \]

CALCULATION OF RESULTS

1. Calculation of Non-Reactive Control Mean Absorbance (NRCx)
   
   Example:  
<table>
<thead>
<tr>
<th>Well No</th>
<th>Absorbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>0.020</td>
</tr>
<tr>
<td>D1</td>
<td>0.022</td>
</tr>
<tr>
<td>Total</td>
<td>0.042</td>
</tr>
<tr>
<td>Mean</td>
<td>0.042 / 2 = 0.021 (NRCx)</td>
</tr>
</tbody>
</table>

   Individual Non-Reactive Control values should be ≤ 0.100 unit.

   If one Non-Reactive Control value does not meet the above criteria, the assay is invalid and must be repeated.

2. Calculation of Reactive Control Mean Absorbance (RCx)
   
   Example:  
<table>
<thead>
<tr>
<th>Well No</th>
<th>Absorbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>1.221</td>
</tr>
<tr>
<td>F1</td>
<td>1.144</td>
</tr>
<tr>
<td>G1</td>
<td>1.298</td>
</tr>
<tr>
<td>Total</td>
<td>3.663</td>
</tr>
<tr>
<td>Mean</td>
<td>3.663 / 3 = 1.221 (RCx)</td>
</tr>
</tbody>
</table>

   Individual Reactive Control values must be ≥ 0.800 unit.

   If one Reactive Control value does not meet the above criteria, it must be excluded as aberrant. The Reactive Control Mean (RCx) should then be recalculated using the remaining individual Reactive Control values. All remaining individual Reactive Control values must meet the above criteria or the assay is invalid and must be repeated.
### INTERPRETATION OF RESULTS

1. Specimens with absorbance values less than the CUT - OFF value are considered **Non-Reactive** by the MPD HTLV I/II ELISA 3.0.
2. Specimens with absorbance values greater than or equal to the CUT - OFF value are considered **initially reactive** by the criteria of the MPD HTLV I/II ELISA 3.0 and should be retested in duplicate before interpretation.
3. Specimens found Reactive on retesting may be interpreted to be **repeatedly reactive** for antibodies to HTLV-I/II by the criteria of the MPD HTLV I/II ELISA 3.0.
4. Initially reactive specimens which are **Non-Reactive** on retesting are considered **negative** by the criteria of the MPD HTLV I/II ELISA 3.0.
5. Specimens which are repeatedly reactive in the MPD HTLV I/II ELISA 3.0 should be further tested by additional, more specific tests, such as MPD HTLV BLOT 2.4.

### SPECIFIC PERFORMANCE CHARACTERISTICS

The MPD HTLV I/II ELISA 3.0 (TMB version) is equivalent to the MPD HTLV I/II ELISA 3.0 (OPD version). Technically and biologically they have similar:

- **conditions of use;**
- **specifications / properties;**
- **design;**
- **deployment methods;**
- **principles of operation; and**
- **same materials in contact with the same body fluids**

The assays differ with respect to:

- the substrate (OPD versus TMB) used;
- the type & volume of stop solution required (Sulphuric acid versus Hydrochloric acid); and
- the wavelength at which the assay was read (492 versus 450 nm).

Consequently the performance of MPD HTLV I/II ELISA 3.0 for the detection of antibodies to HTLV-I and HTLV-II was evaluated using the OPD version. The performance characteristics obtained as indicated below were extrapolated to the TMB version.

**NOTE**: The Australian study was performed with both OPD & TMB substrate systems and was found to be concordant [155/155] for both substrate types (≥ 99.9%).

### Sensitivity

420 reactive samples (ELISA and/or Western Blot positives) were studied in three separate evaluations conducted at three locations, in-house, Sweden and Australia. The Swedish (n=163) study indicates comparable sensitivity to a state-of-the-art test system of comparison. Whereas the Australian (n=155) evaluation showed sensitivity of 100%, the in-house evaluation yielded a sensitivity of 99% (105/106) based on commercial samples and Mixed Titre Performance Panel PRP206. The one sample that was detected negative with MPD HTLV I/II ELISA 3.0 in the in-house evaluation was also detected negative with a competitor ELISA and was found to be indeterminate on Western Blot, with a presence of weak GD21 and p19 band.

All the three evaluations indicate an overall sensitivity greater than 99.7%.

### Specificity

A total of 5300 samples comprising of random blood donor samples (5,000), Clinical samples (200) and potentially interfering samples (100) were tested. Diagnostic specificity in the random blood donor, clinical samples and potentially interfering samples groups was found to be 99.8%, 98% and 97% respectively. MPD HTLV I/II ELISA 3.0 showed a high specificity of over 99% for all the three sets of samples tested.

### Reproducibility

The inter-lot and intra-lot reproducibility of the MPD HTLV I/II ELISA 3.0 was evaluated in-house using the kit controls, a HTLV-I positive sample, a HTLV-I negative sample and ACCURUN 24, a multi-marker Confirmatory Control from BBI.

Inter-Lot: Two lots of microplates were assayed on four different occasions with 3 replicates of each kit control, and 8 replicates of the remaining samples on each occasion.

Intra-Lot: One lot of microplate was assayed twice in a day with 8 replicates of each sample including kit controls for each assay run over four separate days.

The results indicated that the Coefficient of Variation (CV) was between 3 - 8 % for the samples tested.

### LIMITATIONS OF THE METHOD

Repeatedly reactive results from the MPD HTLV I/II ELISA 3.0 is presumptive evidence of antibodies to HTLV-I/II in the specimen. A **NON-REACTIVE** result from the MPD HTLV I/II ELISA 3.0 indicates the likely absence of detectable antibodies to HTLV-I/II in the specimen. However, there is insufficient data to exclude the transmission of HTLV-I/II in blood samples determined to be non-reactive with the MPD HTLV I/II ELISA 3.0. A **NEGATIVE** result therefore does not exclude the possibility of exposure to or infection with HTLV-I/II.

Falsely reactive results can be suspected with a test kit of this nature. The proportions of false reactive will depend on the sensitivity and the specificity of the test kit. For most screening assays, the higher the prevalence of HTLV-I/II antibody in a population, the lower the proportion of falsely reactive samples.
The manufacturer makes no expressed warranty other than that the test kit will function as an in vitro diagnostic assay within the specifications and limitations described in the product Instruction Manual when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied, including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any other purposes. The manufacturer is limited to either replacement of the product or refund of the purchase price of the product. The manufacturer shall not be liable to the purchaser or third parties for any damage, injury or economic loss howsoever caused by the product in the use or in the application thereof.

Should there be a technical problem / complaint, please do the following:

1. Note the kit lot number and the expiry date.
2. Retain the kits and the results that were obtained.
3. Contact the nearest MP Biomedicals office or your local distributor.

BIBLIOGRAPHY


* Australian Patent 613350, 667189, 690540
* US Patent 5,066,579, 5,614,366
5,763,572, 5,814,441
5,871,933, 5,643,714
* Canadian Patent 1337799
* Europe Patent 0395634
* Japan Patent 2559482

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