**INTENDED USE**

The mLabs® Multi-level PCT controls are intended for use as quality control materials to assess the performance of mLabs® PCT test performed on mLabs® ImmunoMeter. It is recommended that two levels of controls are used to perform the test.

**WARNING AND PRECAUTIONS**

1. For in vitro diagnostics use only.
2. Carefully read instructions prior to use. Failure to follow the procedures may result in erroneous results.
3. Do not use expired controls.
4. Do not use for any purpose other than described in the “Intended Use” section.
5. Take all necessary precautions required when handling laboratory reagents.
6. Refer to local biohazard procedures for safe waste disposal.

**COMPOSITION**

- 2 vials of level I controls
  - P/N 99010555202
- 2 vials of level II controls
  - P/N 99010555203
- 1 Data Drive
- 1 Product insert
4. Performing Test and Reading Results

- Insert the test cartridge to the cartridge holder of the mLabs® ImmunoMeter.

**Note:** Make sure the cartridge barcode is face-up and the arrow is facing towards the meter when inserted.

- Start test by pressing “RUN QC TEST” from the main menu of the ImmunoMeter.
- Enter QC lot number on control vials and then press “OK”.
- Insert the cartridge with QC sample into the meter and click “START” to start quality control test.

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**SAFETY WARNING**

The controls have been prepared exclusively from the blood of donors tested individually and shown by official approved methods to be free from HbsAg and antibodies to HIV 1, HIV 2 and HCV. As the risk of infection cannot be ruled out with certainty, however, the product must be handled just as carefully as patient specimens.