



## Reflotron Plus 'QC User Guide'



### Running a Quality Control (QC)

The QC should be assayed in the same manner as patient samples

**As for clinical specimens, all QC samples should be handled as if capable of transmitting infection. Appropriate procedures should be used for their disposal.**

### The Reflotron<sup>®</sup> Quality Control (QC) Kit

The Reflotron<sup>®</sup> Quality Control should be used with the Reflotron<sup>®</sup> test strips to ensure that the strips are working correctly and giving accurate and reliable results.

Precinorm Hb QC kit should be used with the Hb test strips

- 4 x 2ml bottles for reconstitution with 2mls deionised/distilled water
- 4 x level 1

Precinorm HDL QC kit should be used with the HDL test strips

- 4 x 2ml bottles for reconstitution with 2mls deionised/distilled water
- 2 x level 1, 2 x level 2

Precinorm U QC kit should be used for all other test strips

- 4 x 2ml bottles for reconstitution with 2mls deionised/distilled water
- 4 x level 1

QC should be run:-

- With each new lot of test strips



- With each new shipment of test strips
- Whenever there is any concern that the test result may be wrong: test strips not stored correctly; there is concern that a user may not be performing the test correctly
- Every 30 days to ensure correct storage of test strips
- Use controls according to local quality standards

**Always check the pack insert with each box of controls to ensure correct preparation and usage**

### *Storage & Stability*

- Unopened control kit kept in fridge at 2-8°C can be kept till the expiry date on the box
- Once reconstituted Precinorm U & HDL is stable at room temperature for 8 hours, or 14 days when refrigerated at 2-8°C. Alternatively it can be stored for one month frozen at -20°C.
- Once reconstituted Precinorm Hb is stable at room temperature for 8 hours or 14 days refrigerated at 2-8°C. This control is unsuitable for freezing.

### *Preparing the Controls*

For the Precinorm U & Hb –

- Using a 2ml pipette and clean plastic tip, add 2mls of deionised /distilled water to one control bottle
- Place on a roller or gently mix and leave for 30 mins making sure that the contents are completely dissolved.

For the Precinorm HDL –

- Using a 2ml pipette and clean plastic tip, add 2mls of deionised /distilled water to each of one bottle of level 1 and one bottle of level 2
- Place on a roller or gently mix and leave for 30 mins making sure that the contents are completely dissolved.

The controls are now ready for use.

### *Running the controls*

#### *Preparing the Reflotron® test strip*

- Remove the appropriate strip from its container and replace lid
- Place strip on a clean dry surface

#### *Adding the control*

- Using the dedicated 32µl pipette and a clean dry tip, dispense 32µl of reconstituted control onto the appropriate test strip
- Check there are no bubbles in the tip
- Hold the pipette and tip vertically over the sample pad on the test strip
- Follow the steps as for patient sample

#### *Reviewing the results*

- Check the result against the values provided in the appropriate pack insert
- If the control is within the acceptable range, record the result and continue testing
- If the control is outside the acceptable range, record the result and repeat the test.



## What to do if the Reflotron® QC results are unacceptable:

