



IVD

MICROPOINT

qLabs® PT-INR Liquid Control

qLabs® PT-INR Liquid Control Kit Specification / Order Information

| REF | Quantity | Name | Storage |
|-------------|----------|--|----------|
| QS-1-CL Pro | 2 x 1 ml | qLabs® PT-INR Liquid Control Level 1 (For Professional Use Only) | 18-30 °C |
| | 2 x 1 ml | qLabs® PT-INR Liquid Control Level 2 (For Professional Use Only) | 18-30 °C |

For Health Care Professional Use Only

INTENDED USE

Micropoint Biotechnologies, Inc. has optional liquid controls for qLabs® PT-INR system. The qLabs® PT-INR liquid controls are used with qLabs® PT-INR test strips to verify the qLabs® PT-INR system performance. It is recommended that two levels of liquid controls are used to perform the test.

WARNING AND PRECAUTIONS

- For in vitro diagnostics use only. Do not take internally.
- Carefully read instructions before using. Deviations from the described procedure may alter performance.
- Take all necessary precautions required when handling laboratory reagents.
- Do not freeze liquid controls.
- Do not use expired liquid controls.
- Do not use for any purpose other than

described in the “Intended Use” section.

- Do not interchange caps as contamination may occur and compromise results.
- Refer to local biohazard procedures for safe waste disposal.

REAGENTS

Each control contains varied levels of electrolytes, coagulation factors, stabilizers and preservatives. The INR values of qLabs® liquid controls are lot-specific.

Please ensure that strip code entered into meter for the test is the same as that printed on the label of the control vials.

CONTROL STORAGE AND STABILITY

- Unopened controls are stable at 18-30 °C until expiration date stated on the label.
- Once opened, controls are stable for 15 days if capped tightly at 18-30 °C.
- Before sampling, gently swirl the vial several times to ensure homogeneity.

Do not freeze. Do not expose to excessive heat.

QUALITY CONTROL TESTING PROCEDURES

- Gather materials
 - qLabs® ElectroMeter
 - qLabs® ElectroMeter User’s Manual

- qLabs® PT-INR test strip
- qLabs® PT-INR liquid control: level 1 and level 2

Note: Please refer to the user’s manual for appropriate operation instructions about the test strip and the meter.

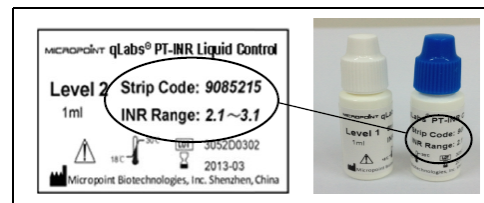
2. Insert the strip

- Turn on the qLabs® ElectroMeter.
- Remove a new qLabs® PT-INR test strip from foil pouch.
- Insert the strip, electrode end first, into the test strip guide.

Notes:

- When the meter displays “QC STATUS”, a QC test must be performed before starting the test. The QC test can be started simply by pressing the “OK” button.
- If the meter prompts the user to input a PID to continue the QC test, please do as needed.

3. Enter the strip code and the lot number



Please refer to the user’s manual for detailed operation instructions about

entering the strip code and the lot number of the liquid control that printed on the label of the package box and vials. If a new, unopened liquid control is being used, the user should change the strip code and lot number before conducting the test.

Notes:

- The entered control code and lot number must match with those on the label of control package box and vials.
- If the meter does not prompt to enter a lot number, then the user can skip the lot number entering.
- If the code keeps flashing or the test can not be continued, the user should confirm the entered code matches the one on the label.

4. Confirm the control code and the lot number.

Press “OK” button to confirm the control code and lot number. Once the control’s lot number is entered, the meter will automatically check whether the control is expired. If the control is expired, the user need to change to another control within the expiration period to perform the test.

Note: Always match the strip code, lot number and test item name on the display with those on the control vials. Failure to do so may cause inaccurate results.

5. Wait for the meter to warm up.

After confirming the code and lot number,

the meter will warm up automatically for the test. When it is ready to perform a test, the meter will beep and prompt the user to apply control sample.

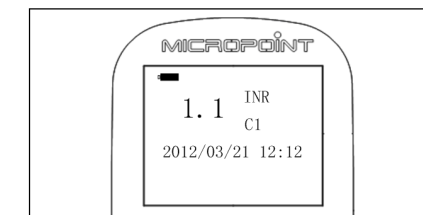
6. Perform the control test.

Before using, slightly swirl the target control at least 10 times and then apply one drop of the liquid control to the sample well, the system will start test automatically.

Do not add more than one drop of liquid control.



The QC test result will appear as INR value, along with test date, name and time in approximately 1 minute.



Note: The result interface may be different, depending on the software configuration.

7. Finish the test.

Remove the used test strip after the test is completed. Dispose of the used test strip in compliance with the local biohazard regulations.

Insert a new test strip and repeat the above procedures to perform the next level liquid control test.

EXPECTED RESULTS

The system is working properly and all testing procedure has been done correctly when the test results obtained fall within the assigned control INR range on the vial.

Note: Please refer to the strip code and the assigned INR control range printed on the label of the vial.

UNEXPECTED RESULTS

If the test results fall outside of the assigned range or qLabs® ElectroMeter displays error code “E XXX”, check for the following:

- 1. Controls may be expired and stored improperly.
- 2. The user may not be doing the test correctly. Insert a new test strip and repeat the test procedure to perform a new test.

- 3. If the user follow all guidelines and the results are still unacceptable, please contact the local distributor or call Micropoint Biotechnologies, Inc. technical support at +86 755 86296766.

PERFORMANCE CHARACTERISTICS

| Within-Run (N=20) | INR Value Mean | S.D. | %CV |
|-------------------|----------------|------|------|
| Level 1 | 1.11 | 0.02 | 2.00 |
| Level 2 | 2.64 | 0.09 | 3.28 |

| Between-Run (N=40) | INR Value Mean | S.D. | %CV |
|--------------------|----------------|------|------|
| Level 1 | 1.10 | 0.02 | 2.02 |
| Level 2 | 2.56 | 0.10 | 3.85 |

ADDITIONAL INFORMATION

For additional information about this product, please call your local distributor or call our customer service at +86 755 86296766.

| Symbols | Explanation |
|---------|------------------------------------|
| IVD | In Vitro Diagnostics |
| | Name and Address of Manufacturer |
| EC REP | European Authorized Representative |
| CE | CE Mark |
| | Temperature Limitation |
| LOT | Lot Number |
| | Expiry Date |
| | Do Not Reuse |
| REF | Catalogue Number |
| | Contains Sufficient for n Tests |
| | Caution. Read Carefully. |

MICROPOINT



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