



qLabs® PT-INR Liquid Control

| REF | Quantity | Name | Storage |
|-------------|----------|---|-----------|
| QS-1-CL Pro | 2 x 1 ml | qLabs® PT-INR Liquid Control Level 1 (For Professional Use Only) | 2 - 32 °C |
| | 2 x 1 ml | qLabs® PT-INR Liquid Control Level 2 (For Professional Use Only) | 2 - 32 °C |

For Health Care Professional Use Only

INTENDED USE

Micropoint Biotechnologies Co., Ltd. has optional liquid controls for qLabs® PT-INR system. The qLabs® PT-INR liquid controls are used with qLabs® PT-INR Test Strips/qLabs® PT-INR Owren (Dry) 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 Control are lot-specific.

CONTROL STORAGE AND STABILITY

- Unopened controls are stable at 2 - 32 °C until expiration date stated on the label.
- Once opened, controls are stable for 15 days if capped tightly at 2 - 32 °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

⚠ Read this part together with the User's Manual of qLabs® ElectroMeter, please refer the manual if need more detailed meter operation instruction.

1. Gather materials

Materials provided

- qLabs® PT-INR Liquid Control: Level 1 and Level 2

Materials required (but not provided)

- qLabs® ElectroMeter
- qLabs® PT-INR Test Strips or qLabs® PT-INR Owren (Dry) Test Strips
- Puncture-resistant container for medical sharps

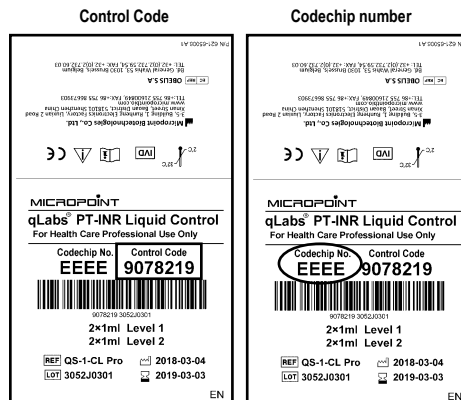
2. Insert the strip

- Turn on the qLabs® ElectroMeter, refer to the User's Manual to enter the QC Mode, then the meter will prompt you to insert a test strip
- Remove a new test strip from the foil pouch.
- Insert the strip, electrode end first, into the test strip guide.

3. Input the Control and Strip information.

Please follow the User's Manual of qLabs® ElectroMeter to input the Control and Strip information then continue the next step.

⚠ Always match the Control and Strip information on the display with those on the package.



4. Wait for the meter to warm up.

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

5. Perform the control test.

5.1 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.

5.2 The QC test result will appear on the screen in approximately 1 minute (The result interface may be different, depending on the software configuration).

6. 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 regulation.
- 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.

⚠ Please refer to the assigned INR control range printed on the label of the vial.

UNEXPECTED RESULTS

If the test results fall outside of the assigned range, qLabs® ElectroMeter will display error code "E XXX", check for the following:

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

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 contact the local distributor or Micropoint Technical Support by emailing customerservice@micropointbio.com or calling +86 755 21600849.


SYMBOLS EXPLANATION

| Symbols | Explanation |
|---|------------------------------------|
|  | In vitro diagnostics |
|  | Name and Address of Manufacturer |
|  | European Authorized Representative |
|  | CE Marking |
|  | Temperature limitation |
|  | Lot number |
|  | Date of Manufacture |
|  | Expiry Date |
|  | Catalogue number |
|  | Caution! Read Carefully. |
|  | Consult instructions for use |


REVISION HISTORY

| Rev. No | Description of Change | Revision Date |
|---------|-----------------------|---------------|
| A1 | New Release. | 2020-06-30 |

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P/N 631-62006 Rev.A1 EN 2020-06-30