



qLabs® Coag Panel 2 Liquid Control

REF	Quantity	Name	Storage
QS-4-CL Pro	2 x 1 ml	qLabs® Coag Panel 2 Liquid Control Level 1 (For Professional Use Only)	2 - 32 °C
	2 x 1 ml	qLabs® Coag Panel 2 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® Coag Panel 2 system. The qLabs® Coag Panel 2 liquid controls are used with qLabs® Coag Panel 2 Test Strips to verify the qLabs® Coag Panel 2 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 and APTT 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® Coag Panel 2 Liquid Control: Level 1 and Level 2

Materials required (but not provided)

- qLabs® ElectroMeter
- qLabs® Coag Panel 2 Test Strips
- Puncture-resistant container for medical sharps

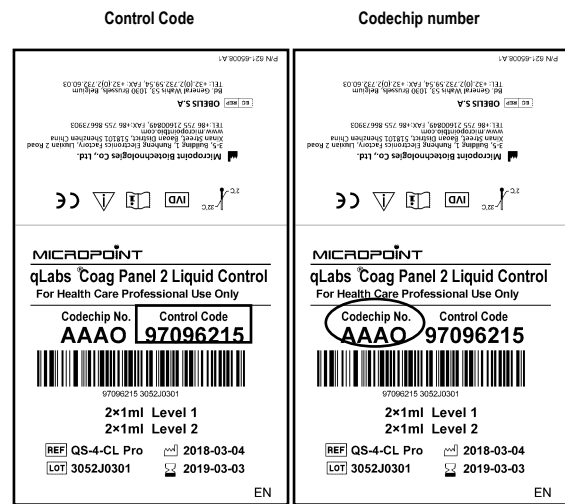
2. Insert the strip

- 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 foil pouch.
- Insert the strip, electrode end first, into the test strip guide.

3. Enter the Control and Strip information.

Please follow the User's Manual of qLabs® ElectroMeter to enter 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 7 minutes (The result interface may be different, depending on the software configuration).

6. Finish the test.

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

6.2 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 and APTT range on the vial.

⚠ Please refer to the assigned INR and APTT 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

Within-Run (N=20)	APTT Value Mean	S.D.	%CV
Level 1	33.03	1.27	3.85
Level 2	64.41	2.02	3.14












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

Between-Run (N=20)	APTT Value Mean	S.D.	%CV
Level 1	35.48	1.19	3.34
Level 2	63.80	3.13	4.89

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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