



IVD



## qLabs® APTT Liquid Control

### qLabs® APTT Liquid Control Kit Specification / Order Information

REF	Quantity	Name	Storage
QS-9-CL Pro	5 x 1 ml	qLabs® APTT Control Level 1 (For Professional Use Only)	2-8 °C
	5 x 1 ml	qLabs® APTT Control Level 2 (For Professional Use Only)	2-8 °C

### For Health Care Professional Use Only

#### INTENDED USE

The qLabs® APTT liquid control is intended for use as a quality control whole blood to verify and monitor performance of the qLabs® APTT system. It is recommended that two levels of the liquid control are used when performing quality control check.

#### WARNING AND PRECAUTIONS

- For in vitro diagnostics use only. Do not take internally.
- Carefully read instructions before use.

Deviations from the described procedure may alter performance.

- Take all necessary precautions required when handling laboratory reagents.
- Do not freeze controls.
- Do not use product that is past the expiration date stated on the vial.
- Do not use for any purpose other than described in the "Intended Use" section.
- Refer to local legal requirements for safe waste disposal.

#### REAGENTS

Level 1 and Level 2 quality control products are lyophilized preparations consisting of fixed human red whole blood cells and citrated human plasma with added purified chemicals and preservatives. Each control is provided in a glass ampoule which is contained in a plastic vial. Diluent is a liquid preparation of deionized water, antimicrobial agent and calcium chloride. Diluent is provided in the same plastic vial for reconstituting the control in-situ before use.

#### STORAGE AND HANDLING

When refrigerated (2-8°C), the vials are stable until expiration date stated on label. When stored at room temperature, the vials are stable up to 4 weeks and should be re-dated with appropriate label. Avoid exposing the vials to temperatures above 37°C. Once reconstituted, the vials should be used immediately. Used vials should be disposed of in a manner approved for bio-hazardous material.

**⚠ Potential Biohazard: The control is of human source material and should be treated as potentially infectious and handled with care.**

#### PROCEDURE

##### Materials required but not provided:

- qLabs® ElectroMeter Q-2 Plus
- qLabs® APTT Strips

#### PREPARATION OF CONTROL MATERIALS

- Gather all the required materials and have them ready to perform the control testing.
- Remove the control vials from refrigerator and allow them to equilibrate to room temperature (18-25°C) before use. This equilibration process may take up to 30 minutes.
- For APTT test strip instructions, refer to the APTT package insert.

#### PERFORMING QUALITY CONTROL TEST

- Insert the test strip into the strip guide of the meter.
- Select **QC testing** mode.
- Enter an 8-digit numerical **Strip Code** as prompted by the meter.
- Reconstitute the control as follows:
  - Remove the label from the vial.
  - Place the vial into the protective sleeve.
  - Hold the sleeved vial upright and bend the vial firmly over the edge of a table top for two or three times until the inner glass ampoule is broken and completely crushed.
  - Invert the vial end to end vigorously for 5 times.

**Note:** The 8-digit Strip Code entered into the meter should match the code on the vial label.

- Depress the "OK" key of the meter to confirm Strip Code which initiates warming-up of the meter. While warming up, keep inverting the vial end to end until reader prompts to add control.
- When prompted, remove the vial cap and squeeze the vial to discard the first drop of the reconstituted control, followed by adding one drop of the control to the sample well of the test strip.
- Sample addition automatically initiates the testing. Results will be displayed in 7 minutes.
- Remove the used test strip from the meter and the sleeve from the control vial. Dispose of the used strip and the used control vial appropriately while retaining the protective sleeve for reuse.
- Record the results.

#### INTERPRETATION OF QUALITY CONTROL RESULTS

For quality control check, the expected value ranges for each quality control product are provided and printed on back of this package insert. These values are derived from replicate analyses at the manufacturer's facility and are lot specific. User should establish its own means and acceptable ranges and use those provided as guides only.

#### EXPECTED RESULTS

If the test results fall within the value ranges

provided, it indicates that the system is working properly and all handling has been done correctly.

#### UNEXPECTED RESULTS












If the results fail to fall within the value ranges provided, verify that all the materials were chosen correctly and repeat with a new control vial. If the results continue to fall outside of the value ranges provided, patient result should be considered suspect and check for the followings:

- Controls and/or strips may be expired or stored improperly.
- The instrument may not be functioning properly.
- You may not be performing the test, in particular, reconstituting the controls correctly.
- If you follow all the instructions correctly and your results are still unacceptable, contact your local distributor or call Micropoint Biotechnologies, Inc Technical Support at +86 755 86296766.

#### ADDITIONAL INFORMATION

If you have any questions regarding the use of this product, please call your local distributor, or our customer service at +86 755 86296766.



Symbols	Explanation
	In Vitro Diagnostics
	Name and Address of Manufacturer
	European Authorized Representative
	CE Mark
	Temperature Limitation
	Lot Number
	Expiry Date
	Do Not Reuse
	Catalogue Number
	Contents Sufficient for N Tests
	Caution. Read Carefully.

## MICROPOINT



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