CE 0123 IVD

MICROPOINT

qLabs® PT-INR Test Strips

REF	QS-1-12	Contains: 12 test strips	REF	Q-1	qLabs® ElectroMeter
REF	QS-1-24	Contains: 24 test strips			
REF	QS-1-48	Contains: 48 test strips			

For Self-Testing Use Only

INTENDED USE

The qLabs® PT-INR test system consists of an ElectroMeter and PT-INR test strips. The qLabs® test system is designed to provide quantitative measurements of Prothrombin Time (PT) and International Normalized Ratio (INR) in fresh capillary whole blood.

The qLabs® PT/INR test strips are intended for in vitro diagnostic use by patients taking oral anticoagulants (blood thinners) who need to monitor the clotting time of their blood.

For self-testing use only.

INTRODUCTION

PT-INR tests measure the blood's ability to clot. Blood normally clots to slow down it's flow in response to the damage of blood vessels, in order to prevent excessive bleeding. A clot formed inappropriately in the areas of heart, lung and brain, however, can hinder normal blood flow and may result in life-threatening events such as stroke and heart attack. For patients who lose their ability to properly reabsorb clots and patients who have low tolerance to clots, anticoagulation medicine (blood thinner) is prescribed. Because these medications may have narrow therapeutic windows and be sensitive to diet and lifestyle, it may be necessary for patients to adjust their dosage regularly. In order to make good decisions regarding the need for such an adjustment, it is important for the patient to know the clotting status of their blood. PT or INR value from the PT-INR tests helps patients or healthcare professionals make these decisions. A quick and accurate measurement of PT or INR value is critical for the safety and effectiveness of the anticoagulation therapy.

The clotting capacity of the blood is reported as a Prothrombin Time (PT) or an International Normalized Ratio (INR) value.

While PT times may vary depending on the test method used, INR values should be the same regardless of the method used. International Normalized Ratio (INR) is recommended by WHO to remove dependence on reagent and test method. The qLabs® ElectroMeter calculates the PT value based on an analysis of the test data, and then converts this to the correct INR value.

TEST PRINCIPLE

qLabs® PT/INR test strips are used together with qLabs® ElectroMeter. qLabs® ElectroMeter automatically detects the insertion of a qLabs® PT/INR test strip and heats the strip to a preset operating temperature. After a drop of blood is applied to the strip, the capillary channels carry the blood to the reaction zones, where the blood mixes with pre-printed reagents and starts to coagulate. Each strip contains two reaction zones: test zone and control zone. Each reaction zone contains a pair of metallic electrodes, to which a constant voltage is applied by the qLabs® ElectroMeter. As the coagulation of the blood proceeds, the current monitored across the two electrodes changes. The qLabs® ElectroMeter detects the change of the current in the test zone and determines the PT and INR results. qLabs® ElectroMeter and test strips provide both PT and INR results.

QUALITY CONTROL

The qLabs® ElectroMeter also monitors the current change in the control reaction zone. If the control zone result fails to fall within a predetermined range, the ElectroMeter will display an error message rather than give a possible erroneous PT/INR result. This safety measure guards the user against situations in which the qLabs® PT/INR test strip may have been subjected to very high temperatures or humidity (which could happen if the foil pouch is torn or punctured).

REAGENTS

Each test strip contains:

- Reagent channel: Recombinant human thromboplastin
- Control channel: Thrombin to yield pre-determined clotting times for the control
- Both channels: Heparin neutralizing reagent

PRECAUTIONS & WARNINGS

- For in vitro diagnostic use only. Do not take internally.
- Follow proper infection control guidelines for handling all blood specimens and related items.
- Use only fresh capillary blood.
- Never add blood to a test strip after the test has begun.
- Do not use strong repetitive pressure to collect the sample.
- Do not move the meter during a test.

The health status of the patient may affect the test. Please take this into consideration before making a therapeutic judgment based on the test results. Failure to do so may have serious consequences. See the results section below for more information.

STORAGE & HANDLING

qLabs® PT/INR test strips can be stored at room temperature (below 32° C) or in the refrigerator at 2°C to 8°C until the expiration date. Do not freeze.

Store strips in their original foil pouch until ready to use.

If refrigerated, allow the sealed pouch to equilibrate to room temperature for 5 minutes before opening it for testing.

Use the test strip within 10 minutes of opening the foil pouch.

SAMPLE PREPARATION

1. Gather the necessary materials:
   - qLabs® ElectroMeter
   - qLabs® Test Strips
   - Alcohol Pads and Gauze
   - Lancet Device
   - Puncture Resistant Waste Container
2. Make sure the hand is warm. If not, warm the hand by washing in warm water or using a heating pad.

TEST PROCEDURE

When powered on, the qLabs® ElectroMeter will automatically enter the **Test Mode** and prompt you to insert a test strip.

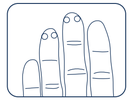
1. **Insert a test strip into the test strip guide on the meter.** Remove a fresh test strip from its foil pouch. Insert it into the test strip guide so that the electrode end goes in first. On the light blue end of the strip you should be able to read the word "PT-INR" appearing from left to right.
2. **Enter the strip code.** When you insert a fresh test strip, the meter will prompt you to enter a 7-digit numerical **Strip Code**. If the code matches with the strip code on the test strip pouch, simply press the "OK" button. If the code does not match, change each digit using the functional "+" and "-" buttons, then press the functional "NEXT" button to accept each value and move to the next digit. To index more quickly through numbers while making changes, hold down the functional "+" and "-" buttons.
3. **Confirm strip code.** After the 7-digit numerical strip code has been set, press "OK" button to confirm the code. If the code is correct, simply press the "OK" button.To edit the strip code, press the functional "BACK" button to go back to the first digit and repeat step 2 until all numbers are correctly entered.

⚠ **Always match the code on the display with the strip code on the strip pouch. Failure to do so may yield inaccurate results.**

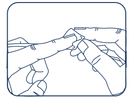
4. **Wait for the meter to warm up.** After confirming the code, the ElectroMeter will warm up automatically for the test. When it is ready to perform a test, the ElectroMeter will beep and prompt the user to apply a blood sample.
5. **Obtain a fingerstick blood sample.** It is important that you use the correct technique to obtain the right type and amount of blood sample. If the procedure is not followed, it can cause inaccurate results.

   5.1 Increase blood circulation by:
   - Warming the hand by washing in warm water
   - Warming the hand with a heating pad or hand warmer
   - Gently massaging the finger
   - Holding the hand below the heart

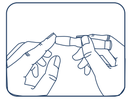
   5.2 Identify a site on the finger to puncture:
   - On one of the middle fingers of either hand
   - Near the top of the finger on either side
   - Away from any calluses or scars



5.3 Clean the selected area with 70% isopropyl alcohol, or an alcohol pad. Dry thoroughly with cotton or gauze.



5.4 Puncture the finger following the instructions for the lancet that you are using.



5.5 Apply gentle, continuous pressure until a large, hanging drop of blood forms.

6. **Add blood sample.** Apply the blood directly on the sample well of the strip. The minimum sample volume is 10 µL.

7. **Perform PT test.** After adding blood sample, the system will start test automatically.The test results will appear as PT value, QC value, and INR value, along with the date and time.
8. **Finish the test.** Discard the used lancet and test strip into an puncture resistant waste container. All blood samples should be regarded as potentially hazardous. The ElectroMeter will turn itself off after 5 minutes if no buttons are pressed.

RESULTS

Since PT results are expected to vary with the test method, it is recommended that the same method be used whenever doing routine patient monitoring.

Normal Range:

Results for normal blood were determined by testing 120 subjects who were not taking anticoagulant medication. The ranges found were:

INR: 0.7-1.4

Therapeutic Range:

Therapeutic ranges are determined for each patient individually by their clinical professional. While most recommendations are to be within an INR range of 2 to 4.5, values well below or well above that may be encountered.

Unexpected Results:

When the ElectroMeter displays a PT-INR result outside of the expected therapeutic range, it may or may not be due to an unusual clinical situation.

What causes unexpected results:

Hematocrit: The qLabs® system is validated to work reliably with blood having hematocrit values between 30% and 55%. Blood samples outside of this range may give unusual PT values.

Interfering antibodies: Conditions (such as Lupus) that produce antiphospholipid antibodies may interfere with the ability of blood to clot through the normal means.

Interfering metabolites: The qLabs® system is validated to work in the presence of unusually high concentrations of hemoglobin, bilirubin, or triglycerides (see Limitations Section below). Presence of these metabolites at concentrations above these limits may lead to long clot times.

Medications: Certain medications, including both prescription and over the counter, may interfere with oral anticoagulants, and may lead to an anomalous INR result.

Disease state: Certain medical conditions may interfere with anticoagulant therapy.

Diet: Oral anticoagulants may be sensitive to food, alcohol, and nutritional supplements.

What to do:

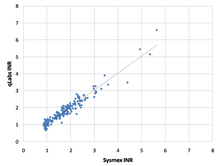
Whenever you encounter an unexpected result, please repeat the test with a fresh qLabs® test strip. If the result is seen a second time, please consult immediately with your medical professional.

LIMITATIONS

- The qLabs® system is designed to use fresh capillary whole blood. Plasma or anticoagulated whole blood should not be used.
- The qLabs® system is not affected by Heparin concentrations up to 3 anti-Xa units per mL of blood. This is true for both unfractionated heparin and low molecular weight Heparin.
- Hematocrit ranges between 30% and 55% will not affect test results.
- In vitro studies show no significant effect in blood samples containing up to 20 mg/dL of bilirubin, 500 mg/dL of hemoglobin, or 1500 mg/dL of triglycerides.
- The qLabs® PT/INR test strips are validated to perform at temperatures in the range 10 to 35°C, and 10 to 90% RH (relative humidity). This includes a 10 minute out of pouch exposure of the strips at these conditions.

ACCURACY

Regression analysis of the qLabs® system Compared to the Sysmex® CA-7000 Analyzer (y=1.002x+0.04, n=233, r=0.97)



PERFORMANCE CHARACTERISTICS

Category	Performance Specification
Intended sample	Fresh fingerstick
Operating temperature range	10 to 35°C
Operating humidity range	10 to 90% RH
Out-of-pouch stability	10 minutes
Shelf life (room temp, in pouch with desiccant)	18 months
Measurable range	INR between 0.5-7.5
Accuracy	Regression analysis vs. Sysmex: Slope = 1.002 Intercept = 0.04 Correlation = R =0.97
Precision	CV ≤ 5%
Factor II sensitivity	13%
Factor V sensitivity	48%
Factor VII sensitivity	45%
Factor X sensitivity	57%
Hematocrit range	30 to 55%
Interference by bilirubin	No significant effect up to 20 mg/dL
Interference by hemoglobin	No significant effect up to 500 mg/dL
Interference by triglycerides	No significant effect up to 1500 mg/dL
Sensitivity to heparin	Insensitive up to 3U/mL for both unfractionated and low molecular weight heparins

ADDITIONAL INFORMATION

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

Symbols	Explanation
IVD	In vitro diagnostics
	Name and Address of Manufacturer
EC REP	European Authorized Representative
CE 0123	CE Mark
	Temperature limitation
LOT	Lot number
	Expiry Date
	Do not reuse
REF	Catalogue number
Σ=n	Contains sufficient for n tests
	Caution. Read Carefully.

MICROPOINT

Micropoint Biotechnologies, Inc.
6F, No. 3, Industry 5 Road
Shekou, Shenzhen, Guangdong
China, 518067

www.micropointbio.com
Tel +86 755 86296766
Fax +86 755 86673903

EC REP Obelis SA
Bd. General Wahis, 53
1030 Brussels
Belgium

www.obelis.net
Tel +32 2 732 59 54
Fax +32 2 732 60 03

P/N 99030505409 Rev. A8