CE IVD MICROPOINT

qLabs® Coag Panel 2 Test Strips

REF QS-4 Pro Contains: 12 test strips Σ=12

REF Q-2 Plus qLabs® ElectroMeter Plus
REF Q-3 Plus qLabs® ElectroMeter
REF Q-3 Pro qLabs® ElectroMeter

For Health Care Professional Use Only

INTENDED USE

The qLabs® Coag Panel 2 Test Strip is designed to provide quantitative determination of Prothrombin Time (PT)/International Normalized Ratio (INR) and Activated Partial Thromboplastin Time (APTT).
The qLabs® Coag Panel 2 test is performed on the qLabs® ElectroMeter instrument using fresh capillary whole blood and venous whole blood. Plasma or anticoagulated whole blood shall not be used.
The qLabs® Coag Panel 2 Test Strip is intended for in vitro diagnostic use. It is suitable for health care professional use only.

QUALITY CONTROL

The qLabs® system utilizes a number of internal quality methods to ensure proper operation. The built-in quality control of instrument automatically monitors critical conditions before and during the testing period. The onboard quality control of strip detects the signal characteristics of two channels. By identifying possible problems such as test strip defects and operational issues, to ensure the accuracy of the test results.
Failure of Quality Control test will result in the instrument displaying an error code. Please repeat the test utilizing a new test strip.

INTRODUCTION

Prothrombin time (PT) is the test of choice for monitoring patients who are receiving oral Warfarin therapy. The international normalized ratio (INR) is the recommended method for reporting PT results that are independent of PT methods. INR plays a critical role in maintaining the Warfarin response within a therapeutic range such that it provides the efficacy of anticoagulation (blood thinning) while avoiding the risks of hemorrhage. The qLabs® PT-INR system can be used to monitor the INR levels of patients undergoing Warfarin therapy.
Partial thromboplastin time (APTT) is a general coagulation test used for screening and measuring the functionality of the intrinsic coagulation pathway, which involves the coagulation factor XII, XI, IX, VIII, X, V, II and fibrinogen. It is also used to monitor the effectiveness of heparin therapy. The APTT is a modification of the Partial Thromboplastin Time (PTT); it can provide a more precise and sensitive assay.
qLabs® Coag Panel 2 Test Strip measures the blood's ability to clot which determines Prothrombin Time (PT)/International Normalized Ratio (INR) and Activated Partial Thromboplastin Time (APTT) on whole blood.

TEST PRINCIPLE

qLabs® Coag Panel 2 Test Strips are used together with qLabs® ElectroMeter. After a drop of blood is added to the strip, the blood flows to the test zones where it reacts with reagents, initiating clot formation. As clotting proceeds, the qLabs® ElectroMeter detects the change of electric current across the clot, which is used to determine PT-INR and APTT results.

REAGENTS

Each test strip contains:
- PT channel: Recombinant human thromboplastin, heparin neutralizing reagent
- APTT channel: Phospholipid, particulate activator

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 fresh capillary blood or venous whole 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® Coag Panel 2 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

Materials provided
- qLabs® Coag Panel 2 Test Strips
- CodeChip (for Q-3 Pro and Q-3 Plus instrument only)

Materials required (but not provided)
- qLabs® ElectroMeter
- Puncture-resistant container for medical sharps

1. Testing fingerstick blood sample.
- Alcohol Pads and Gauze
- 23-gauge or larger Lancet Device

⚠ **Make sure the hand is warm.** If not, warm the hand by washing in warm water or using a heating pad.

2. Testing fresh venous whole blood sample
- 21-gauge needle or larger with 1.0 mL syringe
- Sterile alcohol
- Disposable glove
- Sterile band aid

TEST PROCEDURE

⚠ **When the meter is powered on, refer to the User's Manual of qLabs® ElectroMeter to enter the Test Mode and which prompts 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 the strip into the test strip guide so that the electrode end goes in first. On the light purple end of the strip you should be able to read the word "PT/aPTT" appearing from left to right.

2. Input the Strip Code / strip Codechip number.

2.1 For Q-2 Plus meter, input the **Strip Code** information. The **Strip Code** is inputted manually, or by scanning the barcode labeled on the pouch. Then check the **Strip Code** to see if it is the same as the code on the pouch, correct once the code is wrong.

2.2 For Q-3 Pro and Q-3 Plus meter, input the **Codechip number** of the test strip. The **Codechip number** is inputted manually, or by scanning the barcode labeled on the pouch. Insert the **Codechip** of the strip into the chip slot. The qLabs® ElectroMeter will automatically confirm the entered **Codechip number.** If not correct, meter will display an error, and user needs to re-test by inputting the correct strip **Codechip number** or inserting the correct **strip Codechip** to continue the test.

⚠ **Always match the Strip Code or Codechip number on the display with these on the strip pouch. Failure to do so may yield inaccurate results.**

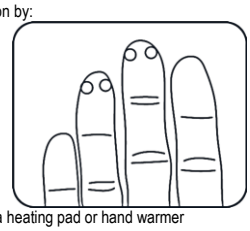
Strip Code

Codechip Number

3. Wait for the meter to warm up. The ElectroMeter will warm up automatically for the test. When it is ready to perform a test, the ElectroMeter will beep and prompt user to apply a blood sample.

4. 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 may occur.

4.1 Increase blood circulation by:



- Warming the hand with a heating pad or hand warmer
- Gently massaging the finger
- Holding the hand below the heart

4.2 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

4.3 Clean the selected area with 70% isopropyl alcohol, or an alcohol pad. Dry thoroughly with cotton or gauze.
4.4 Puncture the finger following the instructions for the lancet that you are using.
4.5 Apply gentle, continuous pressure until a large, hanging drop of blood (at least 10µL) forms. Do not use strong repetitive pressure to collect the sample.
4.6 Add the hanging drop of blood to the sample well of the test strip.

5. Obtain fresh venous whole blood samples.

5.1 Clean the venipuncture site with alcohol and allow it to air-dry completely.
5.2 Collect >0.1 mL of venous blood into 1.0mL syringe.
5.3 Add one large, hanging drop of blood (at least 10µL) to the sample well of the strip.

⚠ **Do not exceed 30 seconds from venipuncture to adding blood sample. The first four drops of blood must be discarded.**
Plasma or anticoagulated whole blood shall not be used

⚠ **Follow the institutional and CLIA (H21-A5, H47-A2) guidelines to obtain blood samples for testing.**

6. Perform PT/APTT test. After adding the blood sample, the system will start the test automatically. The test results will appear on the screen.

7. Finish the test. Discard the used lancet and test strip into a puncture resistant waste container. All blood samples should be regarded as potentially hazardous.

RESULTS

Since PT and APTT results are expected to vary with the test method, it is recommended that the same method must 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: 0.70 -1.40, APTT: 31.0 - 42.0 sec. Due to many variables that affect clotting times, each individual laboratory should establish relevant normal range for its respective patient population.

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 2.00 to 4.50, values well below or well above that may be encountered.
Therapeutic heparin levels of 0.2 - 0.4 U/mL should give 1.5 - 2.5 times the mean normal APTT values.
Due to many variables that affect clotting times, each individual laboratory should establish relevant normal range for its respective patient population

Unexpected Results:

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

What may cause 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 or APTT values and the meter will display an error code instead of INR or APTT value.
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 prolonged clot times.
Medications: Certain medications, including both prescription and over the counter, may interfere with oral anticoagulants, and may lead to an anomalous INR or APTT 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 health care professional and local distributor. If any serious incident related to the instrument has occurred, please report it to us and the competent authority of the Member State in which you are established.

PERFORMANCE CHARACTERISTICS

Normal Range:

According to CLSI C28-A2, the normal range of qLabs® Coag Panel 2 tests were evaluated using fresh

fingerstick whole blood from normal volunteer donors (n=20).

Test	INR	APTT (sec)
Normal range	0.70 -1.40	31.0 - 42.0

⚠ Each institution should establish its own normal range and target range of therapeutic anticoagulation based on its patient population.

⚠ The meter INR or APTT values out of range may indicate excessive blood coagulation activation, possibly due to specimen contamination upon sample collection or processing and should be repeated.

Precision:

The precision of the PT-INR test was evaluated using fresh fingerstick whole blood from normal and therapeutic volunteer donors. The precision of the APTT test was evaluated using fresh fingerstick whole blood from normal volunteer donor and heparinized fresh venous whole blood from normal volunteer donor.

Normal donor

PT		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	12.7	0.2	1.4
Day 2	Lot 2	6	12.2	0.4	3.2
Day 3	Lot 3	6	12.8	0.2	1.8

Heparinized normal donor

PT		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	24.5	0.5	2.1
Day 2	Lot 2	6	23.5	0.9	3.8
Day 3	Lot 3	6	23.3	0.7	3.0

Normal donor

INR		N	Mean	S.D.	CV
					(%)
Day 1	Lot 1	6	1.00	0.10	1.7
Day 2	Lot 2	6	1.00	0.10	3.7
Day 3	Lot 3	6	1.00	0.10	2.2

Heparinized normal donor

INR		N	Mean	S.D.	CV
					(%)
Day 1	Lot 1	6	2.20	0.10	2.5
Day 2	Lot 2	6	2.10	0.10	4.5
Day 3	Lot 3	6	2.10	0.10	3.5

Normal donor

APTT		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	33.3	1.4	4.1
Day 2	Lot 2	6	35.5	1.2	3.5
Day 3	Lot 3	6	35.2	0.7	2.1

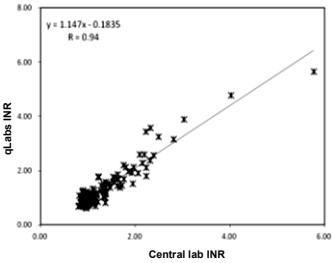
Heparinized normal donor

APTT		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	87.9	6.1	6.9
Day 2	Lot 2	6	92.2	1.6	1.7
Day 3	Lot 3	6	78.8	3.8	4.8

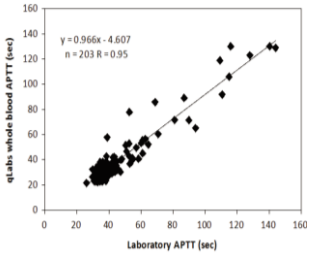
ACCURACY

1. Fresh fingerstick whole blood

Regression analysis of the qLabs® Coag Panel 2 Test Strips PT-INR test compared to the central laboratory analyzer (n=200).

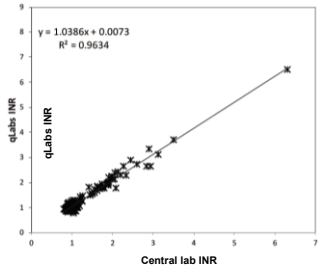


Regression analysis of the qLabs® Coag Panel 2 Test Strips APTT test compared to central laboratory analyzer (n=203).

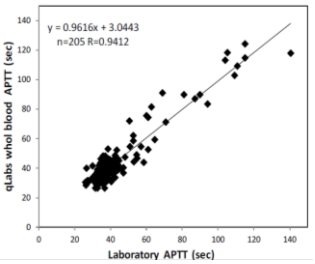


2. Fresh venous whole blood

Regression analysis of the qLabs® Coag Panel 2 Test Strips PT-INR test compared to the central laboratory analyzer (n=249).

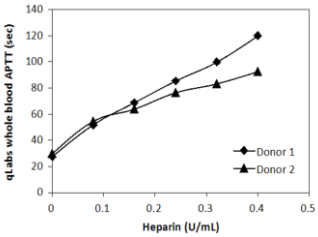


Regression analysis of the qLabs® Coag Panel 2 Test Strips APTT test compared to central laboratory analyzer (n=205)



Heparin sensitivity:

qLabs® Coag Panel 2 Test Strips are sensitive to the presence of therapeutic levels (0.2 - 0.4 U/mL by protamine titration) of heparin in the sample. The sensitivity curves below are obtained by adding increasing quantities of unfractionated porcine heparin to aliquots of normal donor blood.



⚠ The heparin sensitivity curve is unique to each patient and can vary due to many variables (e.g. different source of heparin being used). The curves are intended to serve as examples only.

LIMITATIONS

1. The qLabs® system is designed to use fresh capillary whole blood and venous blood. Plasma or anticoagulated whole blood should not be used.
2. The qLabs PT is not affected by Heparin concentrations up to 1 anti-Xa units per mL of blood. This is true for both unfractionated heparin and low molecular weight Heparin. The qLabs APTT is not affected by Heparin concentrations up to 0.6 anti-Xa units per mL of blood for unfractionated heparin.
3. The drop of blood drop must be at least 10 µL in volume or a large hanging blood drop. Low sample volume will cause an error message.
4. In vitro studies show no significant effect for PT in blood samples containing up to 20 mg/dL of bilirubin, 500 mg/dL of hemoglobin (hemolysis), or 1500 mg/dL of triglycerides (lipemia). And no significant effect for APTT in blood samples containing up to 10 mg/dL of bilirubin, 100 mg/dL of hemoglobin (hemolysis).
5. The qLabs® Coag Panel 2 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.
6. As with all diagnostic tests, qLabs® Coag Panel 2 test results should be scrutinized in light of a specific patient's condition and anticoagulant therapy. Any results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional test data or repeated with other testing methods.

ADDITIONAL INFORMATION

If you have any questions regarding the use of this product, please contact the local distributor or Micropoint Technical Support by emailing customerservice@micropointbio.com or calling +86 755 21600849.

PERFORMANCE SPECIFICATIONS

Category	Performance Specification
Intended sample	Fresh fingerstick whole blood/Fresh venous whole blood
Operating temperature range	10 - 35°C
Operating humidity range	10 - 90% RH
Out-of-pouch stability	10 minutes
Shelf life	12 months (2 - 32 °C, in pouch with desiccant)
Measurable range	INR: 0.50 - 8.00 APTT: 20.0 - 130.0 sec
Accuracy	Reference to ACCURACY part
Precision	PT/INR: CV ⩽ 5% APTT: CV ⩽ 7%
Hematocrit range	30% - 55%
Time to results	3-7 minutes
Sample volume	10 - 15 µL

SYMBOLS EXPLANATION

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

REVISION HISTOTY

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

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