IVD

MICROPOINT

qLabs® Coag Panel 2 Test Strips

REF QS-4 Pro Contains: 12 test strips

REF Q-2 Plus qLabs® ElectroMeter Plus

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 Plus instrument using fresh capillary whole blood.

NOTE: The qLabs® Coag Panel 2 test strip is intended for in vitro diagnostic use. It is suitable for professional use only.

INTRODUCTION

Blood normally clots to slow down the flow of the blood 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. A quick and accurate measurement of clotting capacity is critical for the safety and effectiveness of the anticoagulation therapy.

The PT is a test of the extrinsic coagulation pathway, which is commonly used for monitoring vitamin K antagonist therapy because of its sensitivity to variations in the concentration of the vitamin K dependent factors II, VII and X. 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 meter calculates the PT value based on an analysis of the test data, and then converts this to the correct INR value.

The 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.

Coag Panel 2 test strip measures the blood's ability to clot which derives 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 Plus. The meter automatically detects the insertion of a qLabs® Coag Panel 2 test strip and heats the strip up 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: one for PT testing, another for APTT testing. Each reaction zone contains one pair of metallic electrodes, to which a constant voltage is applied by the meter. As the coagulation of the blood proceeds, the current monitored across the two electrodes changes. The meter detects the change of the current in the reaction zone and identifies a clot endpoint for each of the two reaction zones. Based on analyses of the test data, the resultant clot endpoints for PT and APTT testing are converted to an INR value and an APTT value that is more familiar to the clinician, respectively.

REAGENTS

Each test strip contains a dual standardized amount of reagents on the test zones: recombinant human thromboplastin, heparin neutralizing reagent, and stabilizers on the PT test zone, and phospholipid, particulate activator, stabilizers and buffers on the APTT test zone. An individual test strip is packaged in a pouch with one desiccant bag.

PRECAUTIONS & WARNINGS

- For in vitro diagnostic use only. Do not take internally.
- Follow proper infection control guidelines when handling all blood specimens and related items.
- Use only fresh capillary blood.
- Never add more blood to a test strip after the test has begun.
- Do not use strong repetitive pressure to collect the specimens.
- Do not move the meter during a test.
- Do not use test strip that past their marked expiration date, or which has been improperly stored.

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 cause serious consequences.

STORAGE & HANDLING

qLabs® Coag Panel 2 test strips can be stored in the refrigerator at 2°C to 8°C or at room temperature (below 32° 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 come to room temperature for 5 minutes before opening it for testing.

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

TEST PROCEDURE

When powered on, the meter 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 foil pouch. Insert it into the test strip guide so that the electrode end goes in first. On the end of the strip you should be able to read the word "PT/APTT" appearing from left to right.
2. **Enter the patient ID.** The patient ID can be entered either via user's manual input or the built-in barcode scanner. Please refer to meter's user manual to correctly enter a patient ID.
3. **Enter the strip code and the lot number.** When you insert a fresh test strip, the meter will prompt you to enter a strip code and lot number. If the code and lot number already match with the code and lot on the test strip pouch, simply press the "OK" button. If it does not match, you can either use the left arrow button to select the "PEN" symbol to manually input the required information or use the right arrow button to select the "BarCode" symbol to input the required information with the built-in barcode scanner. Please follow the user's manual to ensure the code and lot number are entered correctly.
4. **Confirm the strip code and the lot number.** Once you have input the strip code and lot number, the meter will automatically check whether the strip is expired. If it is expired, an error will be reported. You will not be able to test with an expired strip.

⚠ **Always match the strip code, lot number and test item name on the display with those on the strip pouch.**

Failure to do so may cause inaccurate results.

5. **Wait for the meter to warm up.** Once the strip code and lot number have been confirmed, the meter will automatically warm up for the test. When it is ready to perform a test, the meter will beep and prompt the user to apply a blood sample.
6. **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.

6.1 Increase blood circulation by:

- Warming the hand by soaking in warm water
- Warming the hand with a heating pad or hand warmer
- Massaging the finger gently
- Holding the hand below the heart

6.2 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

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

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

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

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

8. **Perform PT/APTT test.** After adding blood sample, the system will start test automatically. The test results will appear as PT, APTT along with the date and time.
9. **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 meter will turn itself off after 5 minutes if no buttons are pressed.

Material Provided

- qLabs® Coag Panel 2 Test Strips

Material Required, but Not Provided

- qLabs® ElectroMeter Plus
- Alcohol pads and gauze
- Lancet device
- Puncture resistant waste container

SAMPLE COLLECTION AND HANDLING

Follow the institutional and NCCLS (H21-A3, H47-A) guidelines to obtain blood samples for testing.

PT 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 ElectoMeter 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 local distributor.

APTT RESULTS

Since APTT 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 20 subjects who were not taking anticoagulant medication. The ranges found were 31 – 42 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 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 APTT therapeutic ranges for its respective patient population.

Unexpected Results:

When the ElectoMeter displays an APTT 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 APTT 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 prolonged clot times.

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

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	0.7-1.4	31-42

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

NOTE: the meter INR values greater than 7.5, APTT values greater than 420 will be reported as ">7.5, >420", respectively, and 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.

PT: normal donor

		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

INR: normal donor

		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	1.0	0.1	1.7
Day 2	Lot 2	6	1.0	0.1	3.7
Day 3	Lot 3	6	1.0	0.1	2.2

PT: therapeutic donor

		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

INR: therapeutic donor

		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	2.2	0.1	2.5
Day 2	Lot 2	6	2.1	0.1	4.5
Day 3	Lot 3	6	2.1	0.1	3.5

APTT: normal donor

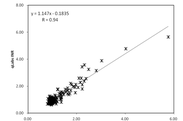
		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	33.3	1.4	4.1
Day 2	Lot 2	6	35.5	1.2	3.5
Day 3	Lot 3	6	35.2	0.7	2.1

APTT: heparinized normal donor

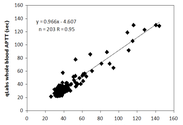
		N	Mean	S.D.	CV
			(sec)	(sec)	(%)
Day 1	Lot 1	6	87.9	6.1	6.9
Day 2	Lot 2	6	92.2	1.8	1.7
Day 3	Lot 3	6	78.8	3.8	4.8

Accuracy:

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

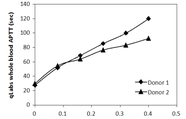


Regression analysis of the qLabs® Coag Panel APTT test compared to central laboratory analyzer (n=203).



Heparin sensitivity:

qLabs® APTT 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.



NOTE: 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. Plasma or anticoagulated whole blood should not be used.
2. The drop of blood must be a minimum of 10 µL.
3. Hematocrit ranges between 30% and 55% will not affect test results.
4. In vitro studies show no significant effect in blood samples containing up to 10 mg/dL of bilirubin, 100 mg/dL of hemoglobin.
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.

PERFORMANCE SPECIFICATIONS

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	12 months (2-32 °C , in pouch with desiccant)
Measurable Range	INR: 0.5-7.5 APTT: 20-420 sec
Accuracy	Regression analysis vs. central lab: Correlation: PT: r ≥ 0.90 APTT: r ≥ 0.90
Precision	PT/INR: CV ≤ 5% APTT: CV ≤ 7%
Hematocrit range	30% to 55%
Time to results	7 minutes
Interference by bilirubin	No significant effect up to 20 mg/dL for PT
Interference by hemoglobin	No significant effect up to 500 mg/dL for PT
Interference by triglycerides	No significant effect up to 1500mg/dl for PT
Sensitivity to heparin	PT test is insensitive up to 3 U/mL blood for both unfractionated and low molecular weight heparins; APTT test is sensitive up to 0.6 U/mL for unfractionated heparin

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

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

MICROPOINT

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