CE IVD MICROPOINT

qLabs® APTT Test Strips

REF QS-9 Pro Contains: 12 test strips

Σ 2×12

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

For Health Care Professional Use Only

INTENDED USE

The qLabs® APTT Test Strip is designed to provide quantitative determination of Activated Partial Thromboplastin Time (APTT).

The qLabs® APTT test is performed on the qLabs® ElectroMeter instrument using fresh capillary whole blood or fresh venous whole blood. Plasma or anticoagulated whole blood shall not be used.

The qLabs® APTT Test Strip is intended for in vitro diagnostic use. It is suitable for professional use only.

INTRODUCTION

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.

The qLabs® APTT Test Strip measures the blood's ability to clot which determines the Activated Partial Thromboplastin Time (APTT) on whole blood.

TEST PRINCIPLE

qLabs® APTT 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 APTT results.

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.

REAGENTS

Each test strip contains:

- APTT channel: Phospholipid, particulate activator
- Control channel: Thrombin to yield predetermined clotting times for the control, 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 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® APTT 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® APTT 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 powered on, refer to the User's Manual of qLabs® ElectroMeter to 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 orange end of the strip you should be able to read the word "aPTT" appearing from left to right.

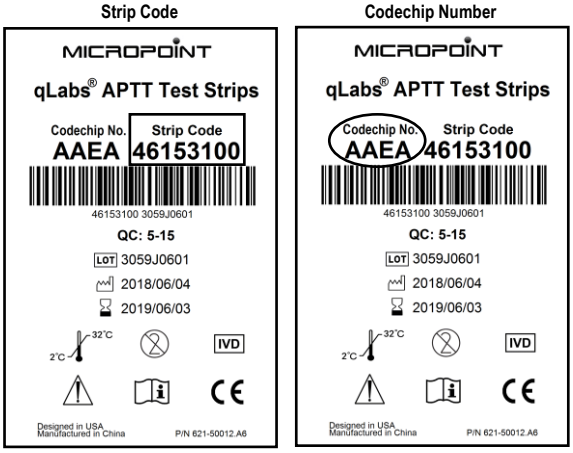
2. Enter the Strip Code / strip Codechip number.

2.1 For Q-2 Plus meter, enter the **Strip Code** printed on the label of 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, enter the strip **Codechip number** labelled on the pouch. Then insert the **Strip Codechip** into the chip slot, qLabs will automatically check if it matches the strip **Codechip number** entered. If not, meter will display an error, and user needs to re-test by entering the right strip **Codechip number** or inserting the right **Strip Codechip** to continue the test.

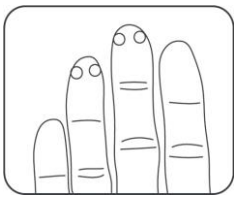
⚠ **Always match the Strip Code or Codechip number on the display with these on the strip pouch. Failure to do so may yield inaccurate results.**

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.



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 drop of blood must be abandoned.**

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

6. Perform APTT test. After adding blood sample, the system will start 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 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 31.0 - 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 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 ElectroMeter 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 or bilirubin (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 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® APTT tests were evaluated using fresh fingerstick whole blood from normal volunteer donors which is 31.0 - 42.0 seconds (n=20).

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

⚠ qLabs® 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 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

APTT		N	Mean (sec)	S.D. (sec)	CV (%)
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

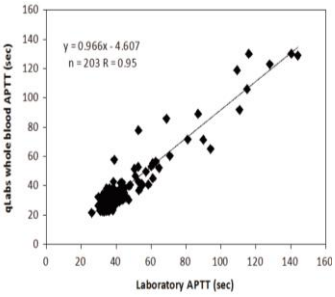
Heparinized normal donor

APTT		N	Mean (sec)	S.D. (sec)	CV (%)
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

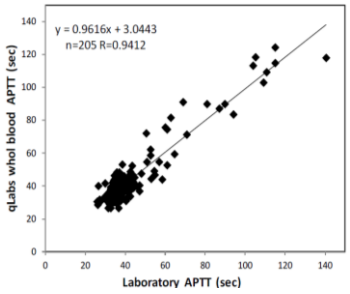
1. Fresh fingerstick whole blood

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



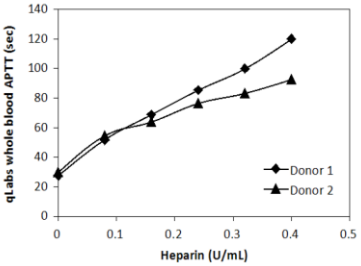
2. Fresh venous whole blood

Regression analysis of the qLabs® APTT Test Strips APTT test compared to a central laboratory analyzer (n=222)



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.



⚠ 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 or fresh venous blood. Plasma or anticoagulated whole blood should not be used.
2. The qLabs® APTT system 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 in blood samples containing up to 10 mg/dL of bilirubin, 100 mg/dL of hemoglobin (hemolysis).
5. The qLabs® APTT 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® APTT 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	20.0 - 130.0 sec
Accuracy	Reference to ACCURACY part
Precision	CV ≤ 7%
Hematocrit range	30 - 55%
Time to results	3-7 minutes
Sample volume	≥ 10 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 HISTORY

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

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