**INTRODUCTION**

Blood clots are crucial for maintaining life. In order to prevent excessive bleeding, the body forms a clot at the site of damage, which helps to stop the flow of blood. However, if a clot is not broken down properly, it can cause serious health issues. Blood clots may form in blood vessels, in order to prevent excessive flow in response to the damage of blood clot. Blood normally clots to slow down its flow. When bleeding events such as a stroke or heart attack happen, it is necessary to have a rapid and accurate measurement of the blood’s clotting ability. This measurement is done through the PT-INR tests.

**TEST PRINCIPLE**

The PT-INR test has been used by qLabs® ElectroMeter and test strips to determine the patient’s clotting ability. The reagents in the strip are applied to the strip, the capillary channels are punctured, and the blood is collected. The blood is then sent through a sequence of enzyme reactions and a spectrophotometric analysis. This process occurs in the ElectroMeter, which provides the results. The qLabs® ElectroMeter and test strips provide both PT and INR values.

**QUALITY CONTROL**

The qLabs® ElectroMeter also monitors the quality control of the test strips. Any time the test results are outside of the expected range, the ElectroMeter will prompt the user to remove the test strip. The safety of the test strips is ensured by the manufacturer. Test strips are stored and used under precise conditions to ensure the accuracy of the test results. The test strips are not recommended for use after the expiration date.

**TEST PROCEDURE**

1. Insert a test strip into the test strip guide so that the electrode end goes in first. On the light blue end of the test strip pouch, simply press the “PT-INR” appearing from left to right.
2. Wait for the meter to warm up. 
3. After the meter beeps, insert the test strip into the test strip guide. The ElectroMeter will beep and prompt the user to apply a blood sample.
4. Use the lancet of your choice to obtain a capillary blood sample. The system will detect the amount of blood sample. If the procedure is done correctly, the ElectroMeter will display a PT-INR result.
5. Press the “OK” button. If the code doesn’t match, the ElectroMeter will turn itself off after 5 minutes.
6. Finish the test.

**STORAGE & HANDLING**

Each test strip contains:
- Plasma reagent
- Thromboplastin reagent
- Buffer solution
- Control reaction zone
- Both of vegetable, frequent modernizing

**PRECAUTIONS & WARNINGS**

Do not use strong repetitive pressure to move the meter during a test.
Do not use isopropyl alcohol, or an alcohol pad.

**TEST RESULTS**

**PT/INR Test Strips**

Contains 24 test strips for Self-Testing Use Only

**Normal Range:**

- PT: 10-14 seconds
- INR: 0.7-1.4

**Therapeutic Ranges:**

- INR: 2 to 4.5

**What causes unexpected results:**

- Hematocrit: The qLabs® ElectroMeter system is validated for hematocrit values well below or well above that may be encountered in normal blood.

**Results for normal blood were determined by testing 120 subjects who were not taking any anticoagulant medication. The ranges found are to be within an INR range of 2 to 4.5, where 2 is considered the optimal therapeutic range.**

**What causes unexpected results:**

- Warming the hand before a blood sample.
- Holding the hand below the heart level.
- Warming the hand with a heating pad.
- Keeping the hand still for 1-2 minutes.
- Use of the same lancet points.
- Be careful not to move the meter during a test.
- Do not use strong repetitive pressure to move the meter during a test.
- Do not use isopropyl alcohol, or an alcohol pad.
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**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.

**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)