CoaguChek® XS System

Getting Started

Follow these steps to get started using the meter:
1. Watch the CoaguChek XS System Video. It will help you get comfortable with the CoaguChek XS Meter and the loading procedure.
2. With this CoaguChek XS System Started guide by the meter, follow the steps to perform your first test.

Then, as necessary, refer to the User Manual:
The CoaguChek XS System User Manual is a comprehensive guide to the meter and test strips. It is designed to provide answers to your questions about the meter's operation and use.

INSTALLING BATTERIES & SETUP

1. Open Compartment
Open the battery compartment on the back of the meter.
2. Insert Batteries
Insert 4 AAA batteries according to the diagram inside the battery compartment.
3. Set Time
Right after you insert the batteries, you'll need to set the date and time. The date and time settings are important. Each time you run a test, the meter automatically records the date and time of the test. If the test strip is expired, the meter displays an error message and prevents you from running a test.

Whenever you put batteries in the meter, it automatically goes to Setup mode (where you set the date and time). You can also go to Setup mode at any time by pressing the SET button.

Press and hold the SET-OFF button. Make sure to change the numbers, and symbols on the display appear correctly.

Release. Press to change the year then .

Turn the meter off.

Then, as necessary, refer to the User Manual:

CoaguChek XS System User Manual is a comprehensive guide to the meter and test strips. It is designed to provide answers to your questions about the meter's operation and use.

4. Check the Display

Press and hold the SET-OFF button. Make sure all the letters, numbers, and symbols on the display appear correctly.
Release.

Press to change the minutes then . Then, as necessary, refer to the User Manual:

CoaguChek XS System User Manual is a comprehensive guide to the meter and test strips. It is designed to provide answers to your questions about the meter's operation and use.

5. Apply Sample

Find the target area on the test strip. You can view the area at the top. See the User Manual for more information.

Within 15 seconds of sticking the lancet, press the target strip within 10 seconds to accept a setting.
Tests

For quantitative prothrombin time (PT) testing in fresh capillary or venous whole blood samples, CoaguChek Systems by professional healthcare providers.

Intended Use

- For quantitative prothrombin time (PT) testing in fresh capillary or venous whole blood samples in the therapeutic range.
- For monitoring warfarin therapy.
- To ensure the anticoagulant level is maintained in the therapeutic range.
- To test INRs above 1.0.
- To test INRs below 1.0.
- To test INRs in the therapeutic range.
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For capillary specimen collection, you will need:

- Test Strip Code Chip
- CoaguChek S System Monitor

Before Testing

Reagents

For each test strip, contain thromboplastin, stabilizers, and preservatives. The CoaguChek Systems Test uses a modified version of this method.

Test Principle

The CoaguChek S System Tests are used with the CoaguChek S System Monitor, will accurately measure baseline PT values. After placing a drop of blood on the test strip, the blood is drawn into the reaction chamber and mixed with reagents that cause coagulation to begin. In this test strip, tiny iron particles are mixed with the sample. Alternating magnetic fields cause the iron particles to move within the sample. The elapsed time is recorded when the clot begins to form.

Introduction

Blood coagulation is one of the body’s protective responses. Blood clots (thrombi) form to prevent blood loss of blood. Certain disease conditions require an anticoagulant, sometimes known as blood thinners, which is sometimes known as Coumarin. As a commonly used anticoagulant, patients on warfarin must be routinely monitored to ensure the anticoagulant level is maintained in the therapeutic range. One method for monitoring the anticoagulant level is by using the one-stage prothrombin time (PT).

Additional Requirements

- Keep test strip in the original sealed foil pouches.
- Stick the fingertip by placing the tip of lancet device against the hole, gently push down the top of the bulb until the sample has been expelled onto the sample target of the test strip. Make sure the test strip is applied within 15 seconds of having the lancet device on the finger. After drawing the blood, do not touch the test strip during the testing. The test strip should not be disturbed until the monitor displays the PT result.
- If the blood enters the testing area of the strip, the monitor enters the testing mode. Do not retract the lancet device to touch the channel surrounding the target zone. The entire target area of the test strip must be filled completely with one drop of blood.
- If problems occur when performing tests, please check the following:
  - Have you used a wrong Test Strip Code Chip? The first three numbers may indicate a test strip that is not compatible with your monitor.
  - Have you used correctly stained test strips (see “Storage and Handling”)?
  - Have you moved the test strip between sample application and the monitor? Do not touch or move the test strip after having applied the drop of blood. Also, do not attempt to add additional drops of blood to the test strip once a first drop has been applied (double-lancing). In either case the monitor displays an error message and a flashing ERROR.
  - Are the test strip guide and the user panel correct?

Precautions and Warnings

- In vitro diagnostic use. Do not take internally.
- Do not use test sets and reagents for handling of blood specimens and laboratory reagents. Follow your facility’s infection control procedures.

Expected Results

The CoaguChek System Monitor displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in the International Normalized Ratio (INR) or Prothrombin Time (PT) seconds.

- A Quick use is made only by health care professionals in Europe, and is a ratio relative to normal (PT/Median Normal PT).
- Normal PT values vary from person to person. When the CoaguChek Systems Test was performed using the CoaguChek S Monitor on 123 normal, healthy, coumarin-free individuals, using venous samples, 85% of the所得的平均值 s ranged from 10.4 to 12.5 seconds. For the purposes of calculating a median normal range, an individual patient.

Unusual Results

- The patient’s PT value seems unusually low or high and you have performed the testing procedure correctly, test for certain conditions as indicated in the Quality Control section below.
- If the controls are not in the acceptable range, the following can cause unusually low or high results:
  - Use of reagents on expiration dates.
  - A small number of test strips is opened.
  - A small number of test strips is opened.

Qality Control

- Quality control testing ensures the user’s technique, integrity of test strips, and performance of the monitor and strips together.

French Testing Requirements-Without Testing

- Daily: 8:00-12:00, PT, INR (if available)
  - A two levels of Electronic Quality Control (EQCs) or two levels of liquid control quality must be tested to verify proper performance monitoring.
  - Additional: 1. PT samples must be tested and results must be within the designated range for the following situations:
  - A new line of test strips is used.
  - Patient PT results are unusually high or low.
  - Two levels of Electronic Quality Control (EQCs) or two levels of liquid control quality must be tested if the monitor is dropped or mishandled.

Frequency of Testing Requirements-Moderate Complexity Testing

- Daily: 8:00-12:00, PT, INR (if available)
  - A two levels of Electronic Quality Control (EQCs) or two levels of liquid control quality must be tested to verify proper performance monitoring.

Additional Requirements

- A new level of Electronic Quality Control (EQC) or a new level of liquid control quality must be used to test for certain conditions as indicated in the Quality Control section below.
- Patient PT results are unusually high or low.

Testing Conditions

- The results must be within the acceptable range.

- The PT result must be re-tested after an unexpected results are always followed up with appropriate coagulation studies and inquiries to define the cause of the unusual result.

- The Quality Control using the User’s Manual for flair.”

Additional Information

- The CoaguChek S System Monitor has a PT reportable range of 30-100 seconds.
- Sensitivity: Internal studies were performed utilizing four replicates of each Factor Level. Samples were assessed on the CoaguChek Systems and Dade Plus on the MLA 900 Analyzer. The results are shown in the following graph. The results comparison is as follows:

Accuracy: 219 venous samples were collected from outpatients at three different hospitals. The INR of each sample was measured using a venous plasma sample measured on a MLA 700/900 Analyzer, using Dade C+ reagent. The test site was a laboratory under the PT/INR and Dade Plus on the MLA 900 Analyzer. The results were displayed in the following graph. The results comparison is as follows: