



GETTING STARTED ▶

Follow these steps to get started using the meter:

- 1 Read this *Getting Started* guide. You will learn how to set up and perform your first blood and optional liquid quality control tests on the CoaguChek XS Plus Meter.
- 2 With this *Getting Started* guide next to the meter, follow the steps to perform your first test.

Then, as necessary, refer to the Operator's Manual:

The *CoaguChek XS Plus* system *Operator's 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.

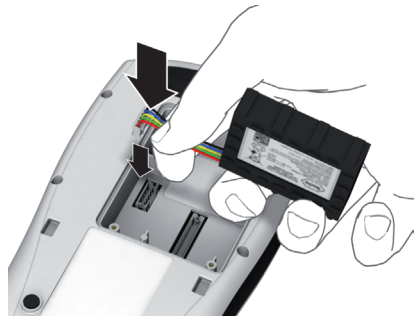
Also refer to the test strip package inserts for information about interferences and contraindications.

CoaguChek® XS Plus Getting Started

CoaguChek®

INSTALLING BATTERY PACK ▶

1. Plug in the Battery Pack



Hold the battery pack in your hand, with the wires and the plug pinched between your thumb and index finger. Plug the connector plug into the socket.

Place the battery pack inside the battery compartment

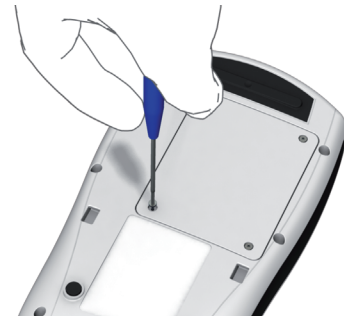
2. Close Compartment Cover



Place the cover on the battery compartment. Make sure that

- the plug connector wires do not get pinched between meter and cover
- the protrusion on the battery compartment cover fits into the corresponding groove on the battery compartment rim.

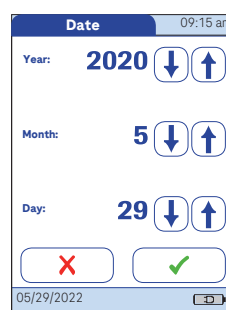
3. Tighten Screws



Tighten all four screws until snug (do not overtighten).

After you insert the battery pack, the meter powers on and shows the Date and Time settings dialog. The language is set to English by default.

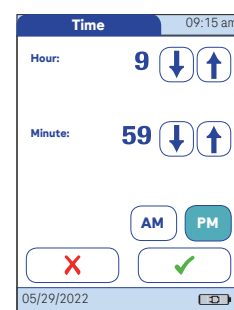
INITIAL SETUP ▶



Touch **↓** and **↑** to set the year, then the month, then the day.

Touch **✓** to complete the first date setting. The display changes to the Time screen.

The date settings are important. An incorrect date may cause an expired strip error on in-date strips preventing you from running a test.



Touch **↓** and **↑** to set the hours, then the minutes, and select **AM** or **PM**.

Touch **✓** to complete the first time setting. The display changes to the Main Menu.

You may change these or any other meter settings later by touching the **Setup** button from the Main Menu.

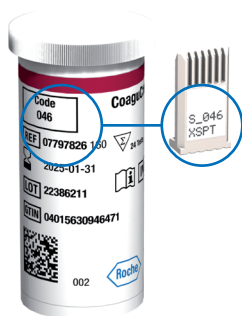
PREPARING FOR A TEST ▶

1. Gather the Following Items



- CoaguChek XS Plus meter
- Test strip container
- Test strip code chip
- Accu-Chek Safe-T-Pro Plus lancing device
- Alcohol wipe
- Cotton ball

2. Match Code



Each box of test strips contains a code chip with strip-lot-specific data. The parameter, the number on the code chip and the number on the test strip container must match.

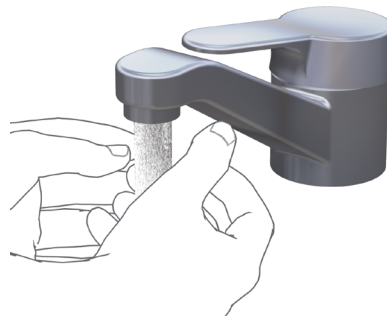
A capital **S** in front of the number indicates that this code chip is for test strips.

3. Insert Code Chip



Slide the new code chip with the number facing upwards into the code chip slot (as shown) until you feel it snap into place.

4. Wash Hands



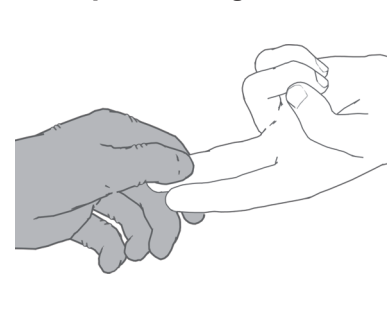
Have the patient wash his or her hands in warm, soapy water. Or, clean the fingertip with an alcohol wipe.

Make sure the fingertip and your gloved hands are thoroughly dry.

Consider the following tips for getting a good blood drop.

Increasing the blood flow in the finger will help you get a good drop of blood, so keep in mind these tips:

5. Prepare Lancing Site



- Warm the hand. Have the patient hold it under his or her arm, use a hand warmer, and/or wash with warm water.
- Have the patient let that arm hang by his or her side.
- Gently massage the finger from its base. Disinfect the blood collection site on the finger. Dry thoroughly.

TESTING ▶

1. Remove a Test Strip



Take a test strip out of the container. **Close the container tightly to avoid degrading of the test strips.**

You have 10 minutes to use a test strip once you remove it from the container.

Caution: In rare cases leakage currents could be passed from a power supply to patients when an inserted test strip is touched. To avoid potential contact with leaking currents, we recommend the following:

- Always remove the meter from the Handheld Base Unit before inserting a test strip.
- Always disconnect the meter from the power supply before inserting a test strip.

2. Insert Test Strip

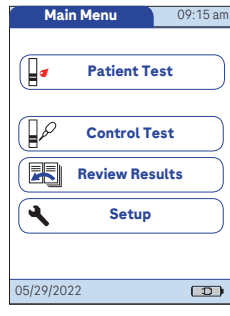


Slide the test strip into the test strip guide in the direction of the arrows until it stops.

The meter powers on, and the Main Menu appears.

If the strip lot and the code chip do not match, the meter will display the number of the test strip code chip required. Remove the old code chip and insert the new one.

3. Select Patient Test



Touch **Patient Test** on the Main Menu screen.

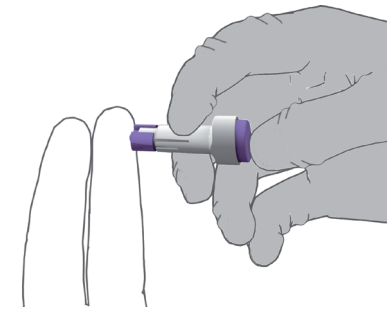
Enter the Patient ID, if required. *

An hourglass symbol appears.

A test strip symbol appears with a flashing blood drop. You have 3 minutes to apply the sample.

* To enter a Patient ID using the barcode scanner see *Using the Barcode Scanner* on the reverse side. A Patient ID is required, if Patient ID handling has been enabled.

4. Collect Sample



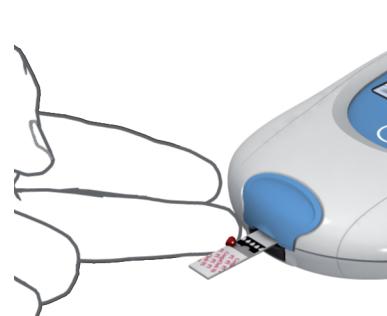
Twist the protective cap off the lancet.

Massage the finger until you see increased color in the fingertip.

Keeping the hand down, press the tip of the lancet firmly against the side of the fingertip. Press the purple trigger button.

CAUTION! Massage the lanced finger gently until a drop of blood is formed. Do not press or squeeze the finger. Apply the first drop of blood from the finger.

5. Apply Sample



Within 15 seconds of lancing the fingertip, apply the blood directly from the finger to the semicircular, transparent sample application area on top of the test strip. You can apply the blood from the side or top.

Hold the blood drop to the test strip until you hear a beep. The flashing blood drop symbol will disappear and an hourglass symbol appears and the test begins.

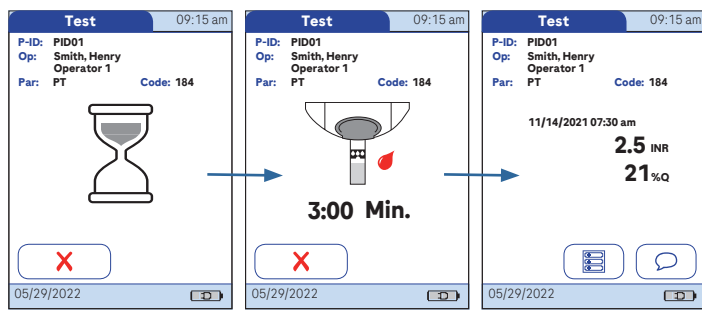
Do not add more blood to the test strip. Do not touch the test strip during measurement after you have applied blood.

The meter performs an automatic quality control check on the strip before it displays the test result.

QC ✓ appears in the display briefly following a successful QC check.

The result appears in less than a minute.

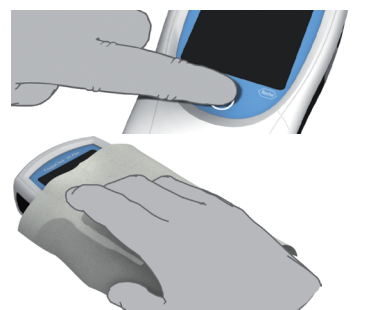
6. Record Result



The meter displays the measurement result. Tap the **☑** button to add comments, if required. If this function is enabled, you may also be asked to accept or reject the test result.

Note: If during testing the meter displays an error message, refer to the Error Messages section of the Operator's Manual for an explanation and steps on how to proceed.

7. Finish Procedure



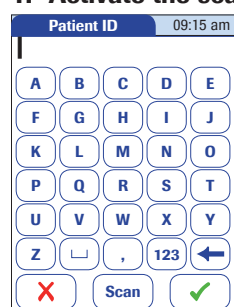
Place the used strip and lancet in an approved biohazard container.

Power the meter off. The meter, test strip guide and test strip guide cover must be cleaned and disinfected between each patient use.

See *Cleaning and Disinfection* on the reverse side.

USING THE BARCODE SCANNER

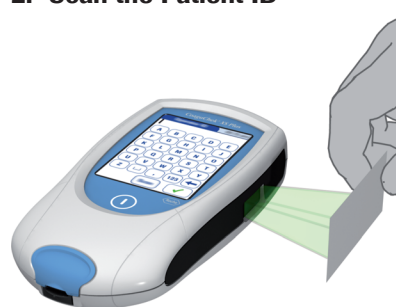
1. Activate the scanner



When you are prompted to enter the Patient ID:

On the *Patient ID* screen, touch **Scan** to activate the scanner.

2. Scan the Patient ID



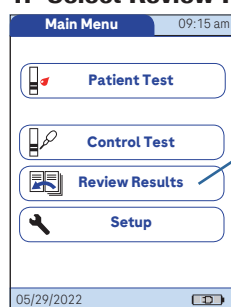
Scan the patient barcode from a distance of approx. 4-8 inches (10-20 cm), according to the barcode size.

The meter beeps once the barcode has been read successfully.

The barcode information appears in the patient ID field. The scanner turns off after 10 seconds, if a barcode is not recognized.

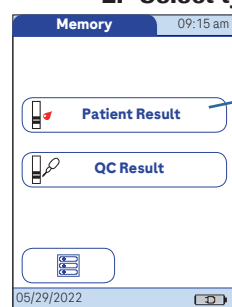
REVIEWING PATIENT TEST RESULTS

1. Select Review Results



Touch **Review Results**.

2. Select type of results

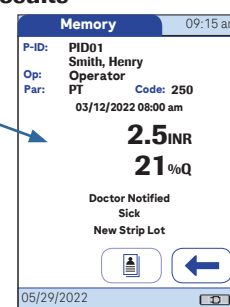


Touch **Patient Result**.

Touch or to scroll to the entry of choice on the screen.

Touch the entry you want to open.

3. Display results



The entry is displayed.

Touch . The results for the selected patient are displayed.

PREPARING TO RUN AN OPTIONAL LIQUID QUALITY CONTROL TEST

1. Gather the Following Items



- CoaguChek XS Plus meter
- Test strip container
- Test strip code chip
- CoaguChek XS Pro PT Controls
- Diluent dropper
- Quality control code chip

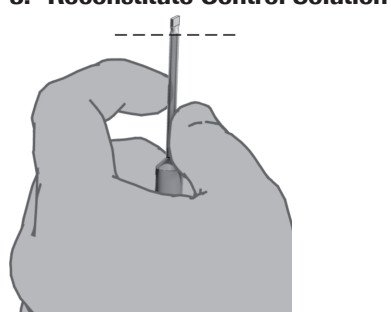
2. Match Code



The code number on the control solution and the Quality Control Code Chip must match.

Each box of controls comes with a matching code chip with strip-lot-specific data. Control code chips are identified with a "C" in the number.

3. Reconstitute Control Solution



Open a bottle of lyophilized control.

Cut off the flared tip of the dropper at the end of the stem.

Hold the diluent dropper vertically by the stem, not the bulb, to avoid loss of diluent.

Do not hold the dropper close to your face.



Transfer the entire contents of the dropper to the bottle. Do not touch the dropper to the dried material or to the sides of the bottle.

Do not discard the dropper. You will need it to apply a drop of control to the test strip later in the test.



Close the bottle.

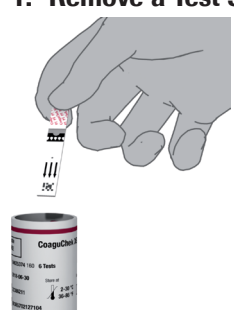
Gently swirl the bottle using a circular motion to dissolve the dried material.

Do not shake or turn the bottle on its side or upside down. Avoid creating bubbles.

Let the bottle sit undisturbed for at least a minute to ensure that the dry material dissolves completely.

RUNNING AN OPTIONAL LIQUID QUALITY CONTROL TEST

1. Remove a Test Strip



Take a test strip out of the container.

Close the container tightly to avoid degrading of the test strips.

You have 10 minutes to use a test strip once you remove it from the container.

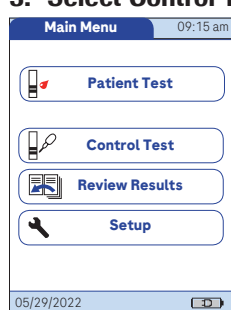
2. Insert Test Strip



Slide the test strip into the test strip guide in the direction of the arrows until it stops.

The meter powers on, and the Main Menu appears.

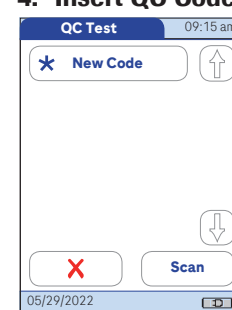
3. Select Control Test



Touch **Control Test** on the *Main Menu* screen.

In the *QC Test* menu, touch **Control Test** again.

4. Insert QC Code Chip



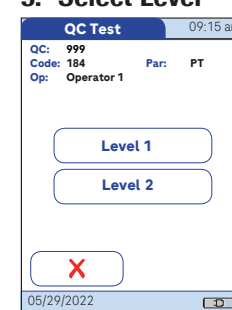
Touch **New Code** on the *QC Test* menu.

A code chip symbol with a flashing arrow appears on the screen.

Remove the Test Strip Code Chip and insert the Quality Control Code Chip with the number facing up until it snaps into place.

The meter stores the code chip information in memory for future use.

5. Select Level



Touch **Level 1** for running a level one control.

An hourglass symbol appears.

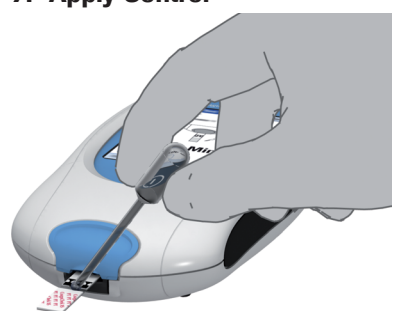
A test strip symbol appears with a flashing dropper symbol. You have 3 minutes to apply the quality control solution.

6. Collect Control



Using the dropper, gently squeeze and hold the bulb. Insert the tip of the dropper into the control solution. Slowly release the bulb to draw the control up to the bulb. Avoid creating bubbles in the control.

7. Apply Control

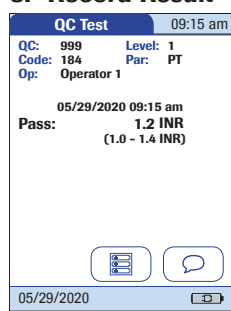


Apply a drop of control solution to the semicircular, transparent sample application area on top of the test strip.

Hold the control drop to the test strip until you hear a beep. The flashing dropper symbol will disappear. An hourglass will appear, indicating the test is in progress.

Return any unused control to the bottle for additional tests. Reconstituted controls are good for 30 minutes.

8. Record Result



The result appears in less than one minute.

Record your result as instructed by your facility.

Note: If during testing the meter displays an error message, refer to the Error Messages section of the user manual for an explanation and steps on how to proceed.

Run a level 2 control test with a new test strip following the same steps.

9. Remove Control Code Chip



Remove the Quality Control Code Chip and store it with the remaining controls.

Re-insert the Test Strip Code Chip.

Roche Diagnostics recommends that you keep a code chip in the slot to keep the electrical contacts free of dirt.

10. Finish Procedure



Place the used strip and control bottles in an approved biohazard container.

Power the meter off.

Clean as per *Cleaning and Disinfection* section below.

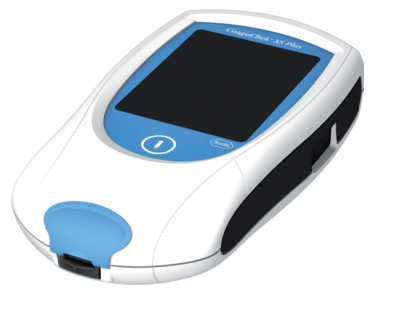
CLEANING AND DISINFECTION

1. Preparing

Always use Super Sani-Cloth Germicidal Disposable Wipes (EPA* reg. no. 9480-4) to clean and disinfect the meter, test strip guide and test strip guide cover. Do not use any other cleaning or disinfecting solution. Using other solutions could result in damage to the system components.

- Follow the infection control procedures of your institution when handling testing equipment
- Wear gloves
- The gloves worn during cleaning and disinfecting should be removed and hands washed thoroughly with soap and water before performing the next patient test.

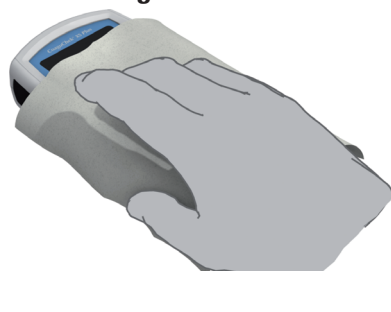
2. What to Clean/Disinfect



The following parts of the meter and system components may be cleaned and disinfected:

- The area around the test strip guide
- The meter display (touchscreen)
- The meter housing (entire meter surface)
- The test strip guide and cover

3. Cleaning the meter



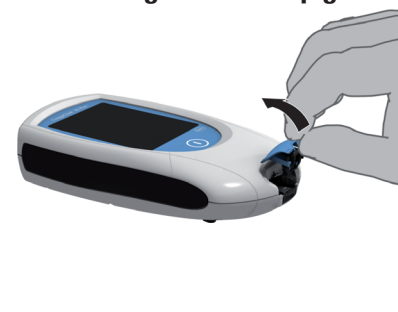
Place the meter on a level surface.

Power off the meter.

Gently wipe the outside of the meter with a Super Sani-Cloth Germicidal Disposable Wipe. Carefully wipe around the test strip guide area, making sure that no liquid enters the test strip guide and then wipe dry with a tissue.

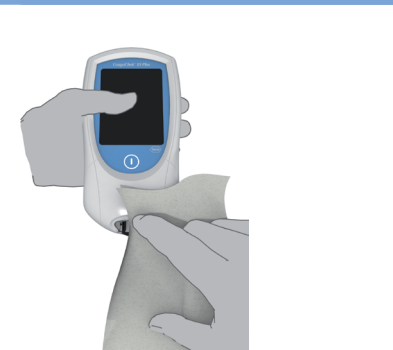
Dry the meter thoroughly with a dry cloth or gauze.

4. Cleaning the test strip guide



Remove the test strip guide cover to clean it. (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Wipe the cover clean.

Hold the meter upright with the test strip guide facing down. Clean the easily accessible white areas with a moistened wipe.



Use a fresh Super Sani-Cloth Germicidal Disposable Wipe and clean the test strip guide by gently wiping the easily accessible white areas, making sure that no liquid pools into the test strip guide.

Let the test strip guide dry for at least 10 minutes before re-attaching the test strip guide cover.

Re-attach the test strip guide cover to the housing.

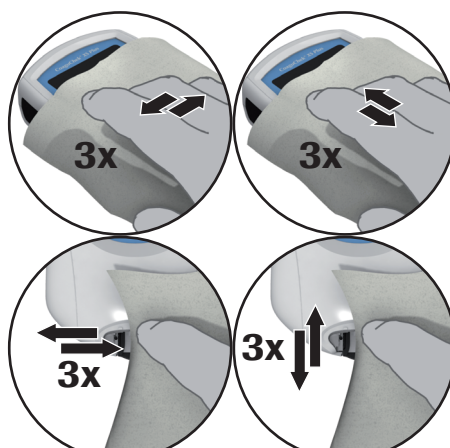
5. Disinfecting

For disinfecting the meter use the same procedure as described above for cleaning.

Additional instructions for disinfection:

Wipe to disinfect by gently wiping the outside of the meter, the test strip guide cover and the test strip guide **three times horizontally and three times vertically**.

All surfaces must stay moist with the disinfection solution for at least 2 minutes.



6. Scanner window

The scanner window should be cleaned periodically. Use a clean, dry cloth to wipe the scanner window.

7. Maintenance cleaning

In addition to the cleaning and disinfection cycles with disinfection wipes, maintenance cleaning of the test strip guide is required to prevent disinfection solution buildup. Disinfection solution buildup on the test strip guide may lead to aborted measurements.

⚠ The test strip guide must receive a maintenance cleaning after 50 cleaning and disinfection cycles, or at least once per week, depending on which occurs first.

For further information on cleaning, maintenance cleaning and disinfection, refer to the chapter "Maintenance and Care" in the Operator's Manual.

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Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

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Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

Rx Only

www.roche.com
www.coaguheck-usa.com
navyportal.roche.com