CoaguChek® S
System

This is a CLIA-waived System

Quick Reference Guide

Coagulation Testing with Fresh Whole Blood

Read your User's Manual for additional information.

◇ Roche ◇

Table of Contents

Patient Testing

1. What you need:
   - CoaguChek S monitor
   - Test Strips in foil pouch
   - Test Strip Code Chip
   - Cotton balls or tissue
   - Alcohol wipe
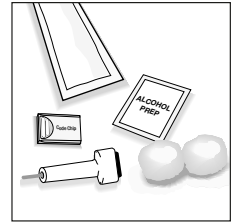
   For a capillary sample:
   - Lancet
   - Capillary tube and bulb Cat. No. 461
     (REF 11621173001) (optional)
   - Lancet device (optional)

   For a venous sample:
   - Plastic syringe (anticoagulant-free)
   - Syringe needle should be 23 gauge or larger.
     A 21 gauge or larger needle is recommended.
   - Tourniquet

2. Test strips must be out of the refrigerator for at least five minutes before use. Keep remaining pouches in refrigerator.

   Make sure Test Strip Code Chip number matches the first three numbers after the lot symbol on the test strip pouch. If numbers do not match, see User's Manual.

3. *For capillary sample:*
   Prepare lancet device. Firmly insert end of capillary tube into capillary bulb to the line.
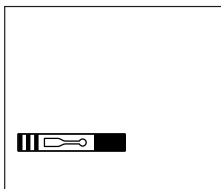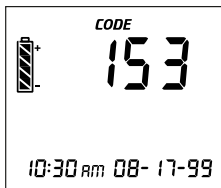
   For venous sample:
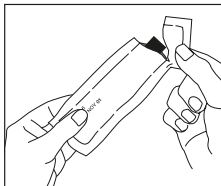   Prepare a plastic syringe that is free of anticoagulant.
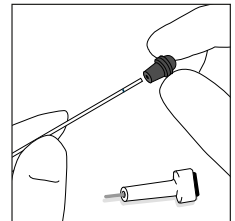
4. Place monitor on a flat surface, free of vibrations, and turn on.

   Monitor displays code number. Make sure it matches the code number of the test strips you are using. The test strip icon flashes.
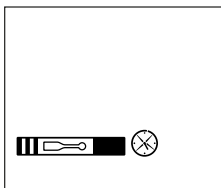

5. Open test strip pouch and remove the test strip. It must be used within FOUR minutes of opening.

6. Gently insert test strip—in the direction of the arrows—with printed side facing up. Push test strip in until it stops.

   Monitor displays the test strip icon. The clock icon flashes. Do not apply sample until the flashing blood drop icon appears.
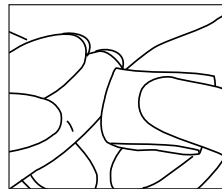
7. When the flashing blood drop icon appears, the monitor begins a 180-second countdown, beeping every 30 seconds, until sample is applied. Sample must be applied before the countdown reaches zero.
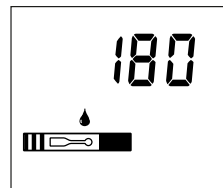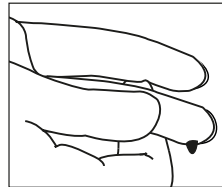
   A flashing yellow light through the test strip indicates where to apply the blood.
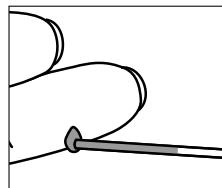
   For a capillary sample:
   Clean the finger with an alcohol wipe or use soap and warm water. Dry thoroughly. Perform fingerstick and gently squeeze finger to develop a hanging drop of blood. Use the first drop of blood.

   For a venous sample:
   Disinfect venipuncture site with an alcohol wipe. Allow to dry. Draw sample into syringe.

8. *For capillary collection only:*
   Touch the capillary tube to the drop of blood. Keep the tube level and allow it to fill by capillary action. Fill the capillary tube halfway. Do not place finger over hole in bulb.
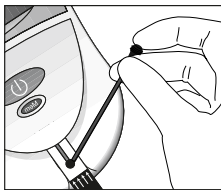

   Note: Blood may also be applied directly from the finger to the sample target area.

To apply a capillary sample:
Place finger over hole in end of capillary bulb and gently push down on top of bulb until sample has been completely expelled onto the sample target area. Avoid introducing air bubbles when applying the sample.

To apply a venous sample:
Discard the first four drops of blood from the needle, then immediately place one drop of blood from syringe needle directly onto sample target area of test strip. Avoid introducing air bubbles when applying the sample.
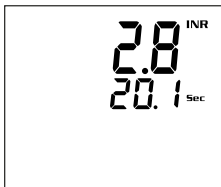
9. Monitor displays the clock icon. Do not touch the test strip or add more blood.
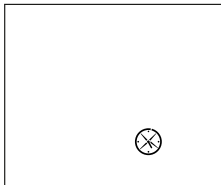
10. The result appears in about one minute. Results are stored in memory.
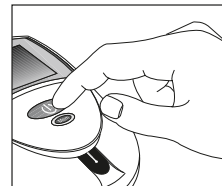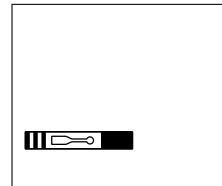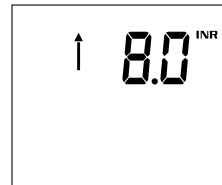

or

11. Remove test strip and discard according to proper infection control guidelines.

12. The flashing test strip icon reappears on the display. If you are finished testing, turn monitor off.
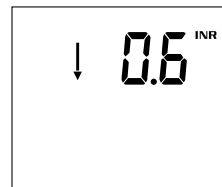

If an up or down arrow is in front of the result, the test result is higher than or lower than the measuring range of the system.

Refer to the Unexpected Results section of the test strip package insert for more information.
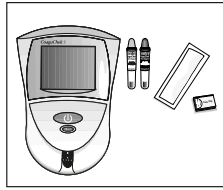

or

What you need:
- CoaguChek S monitor
- Test Strips in foil pouch
- Test Strip Code Chip
- CoaguChek S System Controls Level 1 and 2
- Timer

Place monitor on a flat surface, free of vibrations, and turn on.

Monitor displays code number. Make sure it matches the code number of the test strips you are using. The test strip icon flashes.
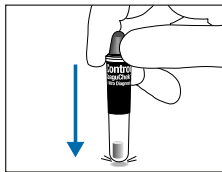
1. Remove test strips and controls from the refrigerator. Test strips must be out of the refrigerator for at least five minutes before use.

   Please Note: Test strips may be stored at room temperature for up to 60 days. Controls may be stored at room temperature for up to 30 days.
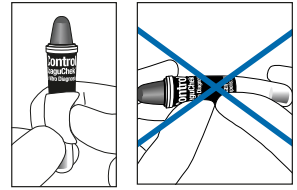
2. Remove control seal by pulling tab.

3. Tap vial to settle glass capsule to bottom of vial.

4. **To avoid the danger of injuries, it is recommended to always wrap a cloth or gauze tightly around the vial before squeezing it.**
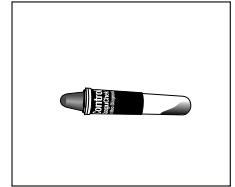
   Squeeze to break glass capsule. DO NOT BEND vial. Bending may cause glass to cut through the exterior wall of the vial.
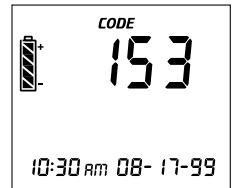
   The capsule must break.

5. Start a timer for two and a half minutes. While timer runs, immediately tap vial HARD on table top ten times to mix contents.
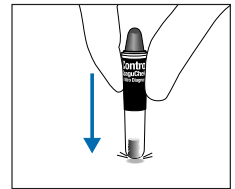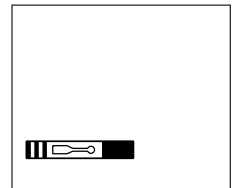
6. Lay control on table for the rest of the two and a half minutes.

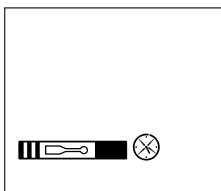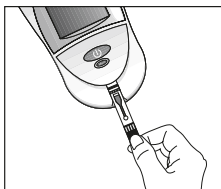7. At the end of two and a half minutes, turn the monitor ON.

8. When the test strip icon flashes, open test strip pouch and remove test strip.
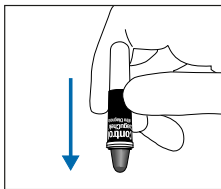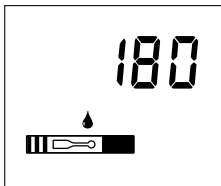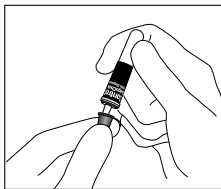
9. Insert test strip. The test strip icon appears and the clock icon flashes.

10. Once the flashing blood drop icon appears, shake contents of vial down to dropper end. Shake down hard. Approximately three minutes should have elapsed since breaking the glass ampule.
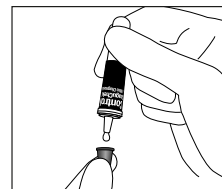

11. With dropper end down, remove cap.

12. Discard the first drop of control solution into cap. Discard cap with drop.

13. Apply the second drop of control solution to test strip. Avoid introducing air bubbles into the sample. A hanging drop must be formed on the bottle tip before applying the sample to the test strip.

14. Monitor beeps as it detects the drop.
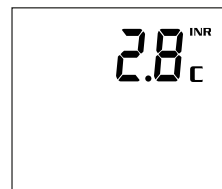
   Do not disturb test strip while testing.

   Wait for result. Control result, followed by a "c", appears in the display. Compare result to Control Value sheet.

15. Remove test strip and dispose of control vial and test strip according to proper infection control guidelines.

16. Turn monitor off if you are finished testing.

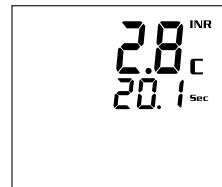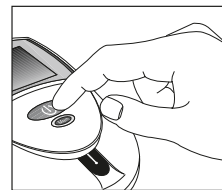## Memory

Changing Result Units

Note: This procedure changes both the test results as well as the results stored in memory to the selected unit(s). You also have the option to switch from single unit display to dual unit display. See the User's Manual for specific instructions on dual unit display.

1. Place the monitor on a level surface and turn it on.
2. When the test strip icon flashes on the display, press the SET button located at the back of the monitor. The monitor enters the Set mode.
3. Press the SET button until the primary unit line flashes.
4. Press the Mem button to select the primary units.
5. Press the SET button. The secondary unit line flashes.
6. Press the Mem button to select the secondary units.
7. Press the SET button.
8. Turn the monitor off.

Reviewing Memory

Place monitor on a flat surface and turn it on.
Wait for the flashing test strip icon to appear.
Press the Mem button. The monitor stores the last 60 results in memory, along with the time and date. The most recent result is displayed first.
Use the Mem button to scroll through the monitor's memory.
The control test results are followed by a "c".
Turn the monitor off.

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The CoaguChek S system (monitor and test strips) and its use are covered by one or more of the following U.S. Patents: 4,849,340; 5,110,727; 5,164,598; 5,300,779; 5,522,255; 5,710,622; 5,789,664; 5,792,944; and 5,886,252.

The CoaguChek S monitor and its use are covered by one or more of the following U.S. Patents: 5,053,199; 5,526,111; 5,792,944; 5,841,023; and 5,886,252.

The CoaguChek test strips are covered by U.S. Patent No. 5,488,816; and 5,975,153.
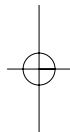
Our medical professionals are ready to answer your questions, 24 hours a day, 7 days a week, 365 days a year. Call Roche Diagnostics Technical Service Center at 1-800-428-4674.