

IMPORTANT!

- Read the entire spinit[®] CRP Quick Guide before testing patient samples or controls.
- See the spinit[®] user Manual for more information about the operation of the Instrument and Disc.
- Confirm the spinit[®] instrument you are using is a spinit[®] CRP (label on the front.)
- See the spinit[®] CRP Instructions for use for more information about the CRP assay.
- Use spinit[®] CRP control materials to confirm that the instrument and test kit are working properly.

1. GETTING STARTED:

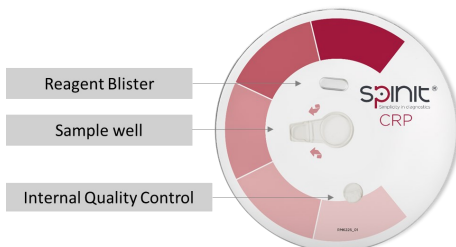
spinit[®] instrument

Take time to familiarize yourself with the spinit[®] instrument and the test kit.



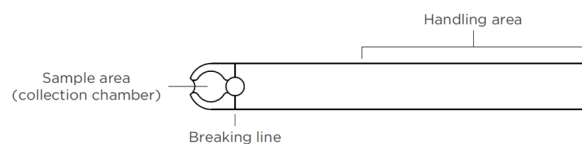
▶ Training videos are available on the spinit[®] instrument. Refer to the videos at any time to become familiarized with the spinit[®] system.

spinit[®] disc



spinit[®] strip

Sample collection device used exclusively with spinit[®] tests.



Information Codes and Messages

INFO CODE	CAUSE	SOLUTION
114	Not enough sample volume to be measured.	Collect a new sample and repeat the test using a new disc.
210	Not enough reagent volume or previously used disc.	
INFO MESSAGES		
CRP below 2 µg/ml		
CRP above 300 µg/ml		
Unable to read QR code		

2. PREPARE FOR TESTING



- Switch the instrument on and wait for it to stabilize;
- Remove test from refrigerated box and wait at least 5 minutes before opening pouch to allow disc to reach operating temperature (15-25°C) before using it;
- Press **Start** for patient samples and follow on-screen instructions;
- If control testing, press **QC mode** on main screen and follow instructions.



- Scan barcode from the pouch label;
- Remove disc from pouch and place it on a flat surface with label facing up;



- Press the reagent blister firmly using your thumb;

3. SAMPLE / CONTROL COLLECTION

Important! Remember to always use gloves when testing controls or blood samples.

Sampling from finger

- Massage the finger and clean the sampling area using alcohol. Allow the area to air dry.
- Firmly prick the patient's finger with a sterilized blood lancet. Properly dispose the lancet.
- Wipe the first drop of blood with tissue paper. Collect the second drop of blood using the spinit[®] strip.

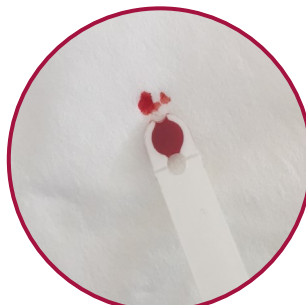


Capillary blood samples must be collected from one finger prick (do not squeeze finger for multiple collections from same finger prick)

Sampling from a control vial

- Press **QC mode** on main screen for control testing and follow on-screen instructions;
- Follow procedure described below. See page 4 for control testing recommendations.

Sample collection using a spinit[®] strip



- Remove a spinit[®] strip out of the vial and close the vial immediately after; Vial should be stored at room temperature;
- Collect the sample with the strip by bringing the tip of the strip against the surface of the patient sample or, if control testing, directly from the control vial;
- Observe the sample area is fully loaded. If not, it is only possible to refill if you have not wiped the strip.
- Clean the strip and gently wipe each side on a tissue paper paying special attention not to squeeze as this will remove the sample ;
- Make sure the sample area is fully loaded;
- If not, discard the strip and use a new one.



Fully loaded;




NOT fully loaded;

4. SAMPLE LOADING AND ANALYSIS



- Immediately insert the strip all the way into the disc and fold it back until it breaks, leaving the loaded part of the strip inside the disc's sample well;
- Discard the strip's handling area accordingly.
- Once you have the disc ready, click 'Next' on the screen and wait for the instrument tray to open;
- Place the disc on instrument tray and follow on screen instructions;
- The tray will automatically close and the assay will start;
- **Important!** Do not close the tray manually. Always use the next button to close the tray automatically.
- Wait 4 min for test result;
- The on-screen result may be printed if a printer is connected or exported to a LIS/HIS.
- Press Eject and remove the disc;
- Immediately discard the used disc as biohazard waste.

 Test analysis must start immediately after loading the disc.

Refer to spinit[®] CRP Package Insert for additional test information.

Information codes

- Important information codes are listed on page 1. Consult the spinit[®] User Manual for information codes not listed on page 1.
- Follow the actions listed in the spinit[®] User Manual to correct the error.

Verification of test results

- Consult the spinit[®] CRP Package Insert.

Verification of Control results

- The result of the control is checked against the acceptable ranges for the corresponding lot number:
 - If the result is within the limits, the information **Pass** is displayed on the spinit[®] instrument screen;
 - If the result is not within the acceptable ranges specified for the spinit[®] control kit, the information **Fail** is displayed on the spinit[®] instrument screen.

Cleaning of the spinit[®] instrument

- The use of paper and a 70% (v / v) solution in H₂O is recommended to clean the external surface of the instrument;
- The touchscreen must be cleaned with a dry cloth;
- The instrument must be turned off and unplugged before cleaning;
- Do not use any cleaning fluids or equipment other than those recommended above.

CONTROL TESTING

Read the entire spinit[®] CRP Control Package Insert before use.

Important!

spinit[®] CRP control kit (Ref. 910101) is recommended for routine quality control testing.

To run Quality Controls select QC Mode in main screen.

How often do I have to run controls?

It is recommended analysing controls:

- when installing the spinit[®] instrument for the first time;
- when testing each new lot of spinit[®] test discs;
- With each new shipment of spinit[®] CRP test discs;
- At least every 30 days;
- When training new operators in the correct use of the spinit[®] instrument;
- After installing a software update;
- Any time an unexpected value test result is obtained;
- In compliance with national or local regulations.

How should I use the spinit[®] CRP controls?

- To test controls use the spinit[®] strip. The sample can be directly loaded from the vial;
- Allow the control material to reach room temperature (15-25°C) before use;
- Mix the control thoroughly by gently tap the vial for 30 seconds;
- Inspect the vial to ensure that the control solution is homogenous;
- Analyse the control using the procedures described on page 2 (sample /control collection) and page 3 (sample Loading and Analysis);
- The result of the control is checked against the acceptable ranges for the corresponding lot number and will give you the information **QC Pass** (within acceptable control range) or **QC Fail** (below or above the acceptable control range).

What do I do if spinit[®] CRP Control results are not within the acceptable range?

- Check if the controls were tested in QC mode in the results screen;
- Do not analyze any patient samples;
- Check the control has not expired by looking on the vial label;
- Ensure that the control has not been used for more than 30 days;
- Verify that the controls and discs have been stored according to recommendations;
- Verify that there is no evidence of bacterial or fungal contamination of the control vial;
- Verify that the procedure is correct. Re-test the control material.

If the control values are still not within acceptable range, repeat the test using a new vial of control. If the control results are still not acceptable, contact your local representative for advice before analysing patient samples.