spinit® BC Quick Reference Guide

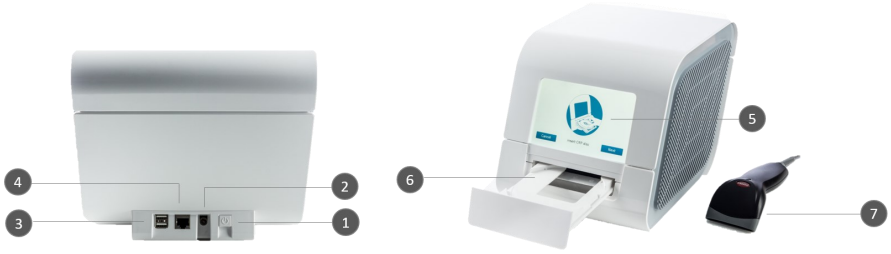
IMPORTANT!

- Read the entire spinit® BC 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/BC (label on the front.)
- See the spinit® BC Instructions for use for more information about the BC assay.
- Use spinit® BC control materials to confirm that the instrument and test kit are working properly.

1. GETTING STARTED:

spinit® instrument

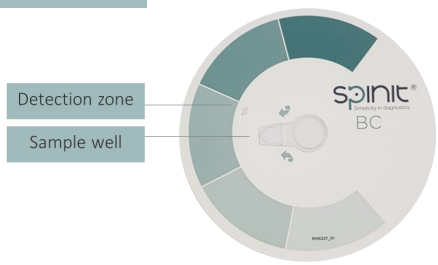
Take time to familiarize yourself with the spinit® instrument and the test kit.



1. ON button.
2. Connect the power supply unit
3. USB Ports
4. Ethernet cable
5. Touchscreen
6. Instrument tray
7. USB barcode reader

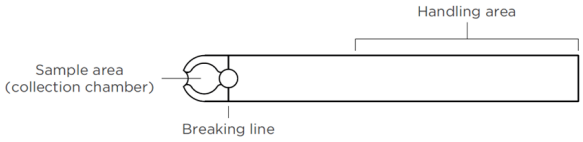
Training videos are available on the spinit® instrument. Refer to the videos at any time to become familiarized with the spinit® system.

spinit® disc



spinit® strip

Sample collection device used exclusively with spinit® tests.



Information Codes

INFO CODE	CAUSE	SOLUTION
1000	General failure of the spinit® BC discs.	Collect a new sample and repeat the test, using a new spinit® BC disc as per Instructions for Use. If the problem persists, please contact your local supplier.
1001	spinit® instrument auto-focus function was performed formed but focus quality is compromised.	
1002	Sample processing is compromised likely due to in-complete lysis of erythrocytes and/or poor staining of leucocytes.	Collect a new sample and repeat the test, using a new spinit® BC disc as per Instructions for Use. If available, test a new spinit® BC disc from an alternative lot. If the problem persists, please contact your local supplier.
1003	Low and/or compromised counts of leucocytes.	Collect a new sample and repeat the test, using a new spinit® BC disc as per Instructions for Use. Take particular attention to minimize time between sample loading and disc insertion on spinit®. If the problem persists please contact your local supplier.

2. PREPARE FOR TESTING

- Switch the instrument on and wait for it to stabilize;
- 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;

3. SAMPLE / CONTROL COLLECTION

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

Sampling from finger

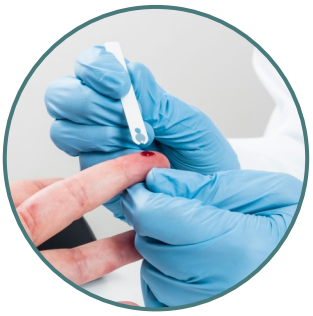
- Massage the finger and clean the sampling area using alcohol. Allow the area to air dry.
- Firmly prick the patient´s finger with a sterilized blood lancet. Properly dispose the lancet.
- Wipe the first drop of blood with tissue paper. Collect the second drop of blood using the spinit® strip.

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

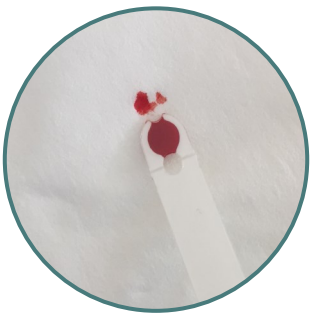
Sampling from a control vial

- 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.

⚠ Test analysis must start immediately after loading the disc.

- 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 7 min sec 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.

Refer to spinit® BC Instructions for use 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® BC Instructions for Use.

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 H_2O 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® BC Instructions for Use before use.

Important!

spinit® BC control kit (910201) is recommended for routine quality control testing.
* The final kit will only be available for sale in May-2020, but biosurfit provides quality controls at the customer's request. Please contact the biosurfit sales team.

To run Quality Controls select QC Mode in Home 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® BC 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® BC 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°F) before use;
- Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube;
- 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® BC 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 14 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.