

Alere Affinion Analyser Instructions for PACE

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A. SETTING UP AND SWITCHING ON THE ANALYSER

1. Place the Analyser away from direct sunlight, and not directly above a radiator. There should be 10cm of space all around the Analyser.
2. Plug in the Analyser and turn on the plug.
3. Turn the Analyser on. (To turn the machine on/off, you MUST use the button on the Analyser not the plug).
4. The Analyser will run a self-test.
5. Do not move the Analyser once it is switched on.
6. You can leave the Analyser turned on indefinitely. It will enter sleep mode when not in use.
7. If Analyser is in sleep mode, touch the screen to wake it up. It will then run a self-test (before a patient sample can be run).
8. Observe lights on the top of the Analyser. **Red Light** = Analyser running self-test. **Green Light** = Analyser ready to go.
9. If a red padlock is displayed on the screen then a control must be run before the patient test can be done.
10. Check the temperature shown on the screen. The Analyser can operate at temperatures of 15- 30°C.

B. TAKING A CAPILLARY BLOOD SAMPLE FOR THE CRP TEST

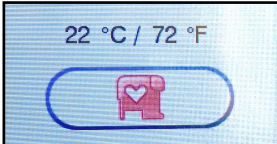
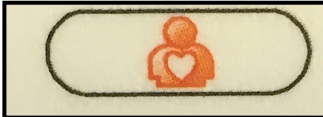
Make sure the machine is ready as analysis must start within 1 minute of taking the blood sample into the cartridge.

1. Remove a CRP Cartridge from the fridge if necessary and leave this unopened to equilibrate to room temperature for 15 minutes. (Cartridges can be stored at room temperature for 4 weeks to avoid this step)
2. Record Cartridge Batch number and expiry date on the **PACE Afinion CRP Cartridge Log**
3. Have to hand an alcohol wipe, a pad of gauze and a lancet. Put on gloves.
4. It is easier to obtain a sample if the patient's hand is warm and the patient is not dehydrated.
5. Open the CRP cartridge avoiding touching the bar code on the side. Once opened, the finger prick sample must be taken within 10 minutes.
6. Carefully release the top section of the Cartridge with the attached capillary tube and lay to one side.
7. Use the side of ring or middle finger of the patient's non-dominant hand.
8. Clean the skin with the disinfectant wipe and dry well to avoid blood running rather than beading.
9. Use the lancet.
10. To make blood flow use your index finger like a tourniquet above the patients knuckle. Apply pressure until blood drop appears.
11. Use gauze to wipe away the first blood drop and dry the area.
12. Squeeze out a second drop of blood to use as the sample.
13. Take the blood into the capillary by holding the capillary just above horizontal position and touching the surface of the blood drop. Do not immerse the capillary in the blood drop. The blood is drawn up quickly.
14. Give the patient the gauze to hold over puncture.
15. Carefully, replace the capillary section back into Cartridge.



C. RUNNING A PATIENT SAMPLE ON THE ANALYSER

Analysis of the test must start within 1 minute of taking the blood sample into the CRP Cartridge.

1. Make sure the Green light is on.
2. NEVER try to open the door manually.
3. Select the red patient icon (like red elephant with heart) on the screen for opening the Analyser door and running a patient sample. 
4. Insert the Cartridge containing the blood sample with the bar code on the left. (Avoid touching the bar code on the Cartridge)
5. Close the lid manually.
6. The test will now run.
7. Select the red icon (red figure with heart) to enter the patient ID. Select the 'back-arrow' icon to move back to main screen. 
8. Once the CRP result is shown on the screen record this on the PACE baseline CRF. The readable range is 5-200mg/L. (The machine will also store the CRP result with the patient ID)
9. Select the tick icon on the screen to open the door. The Analyser will open automatically only when the patient ID has been entered.
- 10.** Remove the Cartridge and discard in clinical waste. *(If not enough blood collected in capillary then code 201 appears. Reject Cartridge and start again).*

D. RUNNING A CONTROL SAMPLE ON THE ANALYSER

1. Run a **low and a high** control each time a QC is performed. Perform your first QC as soon as you receive your machine and before you run a patient sample
2. The controls should be analyzed in the following circumstances:
 - With each shipment of AfinionT AS100 Analyzer test kits.
 - With each new lot of AfinionT AS100 Analyzer test kits.
 - When training new operators in the correct use of the AfinionT AS100 Analyzer.
 - Following software upgrades.
 - In compliance with national or local regulations - for the PACE study = **once a month**
3. Use an ordinary CRP test Cartridge. Leave the unopened Cartridge out of the fridge for 15 minutes to equilibrate to room temperature. Once the Cartridge is open it must be used within 10 minutes.
4. The control samples can be used straight from the fridge.
5. There are 4 controls (Low and high): 2 are level 1 controls (CI) and 2 are level 2 controls (CII).
6. When first opening the control box make a note of the control concentration and acceptable range (given on leaflet) inside the lid of the control box e.g. CI: 19 (14-24)mg/L, CII: 57 (48-68)mg/L (in case the leaflet is lost).
7. Once opened, controls are stable for 4 weeks in the fridge. Write the date when each control is first opened on the label of the control being used – discard after 4 weeks.
8. Mix the control by inverting the bottle 8-10 times.
9. To collect the sample, tilt the bottle and keep the capillary just above a horizontal position. Touch the liquid surface.
10. The control samples are a clear fluid so it is difficult to see when control is taken into the capillary tube.
11. Select the Blue control icon to open the lid. Insert cartridge.
12. Close the lid manually when prompted. The test will start to run.
13. The lid will not re-open unless the sample ID is added. You can add the ID (e.g. C1 or C11) while running the test or afterwards.
14. To enter sample ID select the Blue Bottle Icon. Once entered press the back arrow to return to main screen.
15. Press the tick to open the door. (If the tick symbol is not present then a sample ID has not been entered).
16. Check the control result is within the acceptable range (e.g. CI: 19 [14-24] mg/L). Note the control result in your **PACE quality control log sheet** (FAX to site monthly: 02920 687612)

