CRP Overview

The Cobas B101 is a portable, benchtop analyser capable to testing CRP, HbA1c and Lipids. This analyser has only been validated for use with CRP discs. C-reactive protein (CRP) is an acute phase protein which is synthesised in the liver. CRP is increased in inflammation, tissue necrosis, trauma, bacterial infection and following surgical procedures. CRP on the B101 is an in vitro diagnostic test system designed to quantitatively determine the CRP in mg/L by photometric measurement. It is a very user-friendly instrument with all instructions coming up on the screen.

Instrument Overview

A. Lid - Use the **Open** button on the screen e.g. to insert a test disc for measurement. Keep this lid closed during measurement.

B. Touch screen - Shows buttons, icons, information, and test results, To use a function, tap the button on the screen lightly.

C. Front ventilation.

D. Power on/off switch.

E. Lid button - Use this button to open the lid when the instrument is switched off.

F. DC IN 12 V terminal - Connect the power cable from the power adapter to supply 12 V DC power to the instrument.

G. BUH terminal - Connection to a network through a Base Unit Hub.

H. USB 1 terminal - Connection to a personal computer.

I. Barcode scanner terminal.

J. USB 2 terminal. Connection to USB memory stick or a printer.

K. Back ventilation

L. Temperature sensor

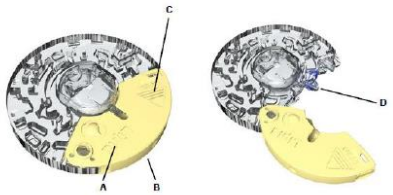
M. Upper heater

N. Barcode sensor.

O. Turntable. Holds and rotates the disc during processing.

P. Lower heater.

Overview of a Test Disc



A. Test type indication.

B. Use the underside of the hinge cover for writing information, e.g. the patient ID.

C. Open the disc on this side.

D. Suction point (at the underside of the disc)

Hold discs by hinge cover and sides only. Do not touch transparent surfaces.

Health & Safety

Operators must be aware that there is a potential risk of infection when coming into contact with human blood. To minimise this risk, ensure gloves are worn, single-use retractable lancets are used and disposed of into a yellow sharps container.

Materials

Each disc contains the reagents required to perform the test. To ensure the discs perform as expected, they must be stored, handled and filled correctly.

Materials Storage

Discs can be stored between 2 – 30 degrees until the expiry date printed on the pouch. If they are stored in the fridge, remove the disc from the fridge and allow 20 minutes at room temperature in the closed pouch before use. Once the pouch is open, use within 20 minutes.

Sample Requirements

CRP testing requires 12µL of fresh capillary blood, Lithium Heparin or EDTA venous whole blood.

Handling: Take care only to handle the edges and hinge cover. DO NOT touch the transparent surfaces.

Patient Testing

Can be via capillary fingerpick or venepuncture. Refer to ‘CRP Patient Testing’ SOP for detailed instructions.

Training

Every user of the device must be trained and prove competent in the use of the device, patient testing, QC requirements and the devices limitations before performing any patient testing. This training is performed by the Roche technical expert, the POCT Quality Manager or a Lead User. In addition, each user must complete annual competency. This may be assessed by observation or by a quiz.

When a new user has their initial training, access to the analyser will be enabled by the POCT QM. Only users that are “set up” can use the instrument. This lock out ability ensures quality results.

Outage Procedures

Power Outage

- Analyser will not be able to be used unless plugged into an essential power supply.

IT Outage

- Analyser results will not transmit to ECA/CP. Manually record results on the POCT results sheet. Once IT outage has ended, results should automatically transmit.

Analyser Failure

- There is no back-up analyser. Send samples to the laboratory in Hastings for testing until fault is repaired.