POC102 - QC Testing for Skyla VB1

Outline

The purpose of this 2-page document is to outline how to perform quality control (QC) testing for the Skyla VB1 biochemistry analyser. The document details how to reconstitute the lyophilised QC material, prepare the analyser for testing, run the test and send the result to Vepalabs via the POC webportal.

QC testing is a critical function in any laboratory for assessing the accuracy and precision of results, using benchmarked, known target values. Vepalabs uses results collected nationally in order to monitor the performance of supported hardware, identify outlier results and individual analyser drift, and address any issues before they become clinically problematic.

Required Materials

- Skyla VB1
- Biorad Lyphochek® Assayed Chemistry Control - Level 1 (dry powder)
- 5mL Diluent (shipped with the QC material)
- 200µL micropipette (the green coloured one if you're using Vepa supplied pipettes)
- Skyla VB1 Pre-An panel or another other preferred full panel (Rotor/Disk)
- Clear 200µL pipette tips
- Laboratory PC with 'Lab Integration Client' installed
- Internet connection

Method

1. Ensure that the Skyla VB1 analyser is clean and functioning normally

2. Ensure that the Laboratory Integration Client is running on the connected PC. There will be a desktop shortcut to open the application, which may need restarting after a loss of internet connection, restart, power outage or other incident. The telltale Erlenmeyer flask icon ( ) should be visible either in the Windows taskbar, or in the icon stack in the lower right-hand corner.

3. Ensure that you are wearing gloves while in contact with all QC material.

4. Remove the integrated stopper and lid from the QC material, being careful not to disturb the powder caked on the inside of the rubber stopper.

5. Remove the plastic cap from the diluent vial, and carefully remove the rubber stopper. Slowly pour the contents into the QC vial. Pour slowly and carefully to avoid any spills.

6. Replace the integrated stopper/lid onto the QC vial and screw it closed. Slowly invert the vial for a minute or so, then leave on a bench for 20-30 minutes to ensure proper reconstitution. **Do not shake the vial.** Once all traces of the powder have disappeared and the solution no longer appears cloudy, testing can continue. This process can be sped up by inverting constantly, or if the vial is placed on a tube roller.

7. Prepare the analyser for testing. Ensure that the software version is up to date. Refer to the latest software update email from Vepa for this Check the screen from Settings > Version > Software Version. If you are auctioning these emails when they arrive your Skyla will be up to date. Current Skyla software can be found on the downloads page of our Vepa website at www.vepalabs.com.au

8. Prepare the panel (Disk/Rotor) for analysis in the usual way and pipette 200µL of the newly mixed QC sample into the rotor sample port.

9. Run the test as a "Control" test, by selecting Control from the Settings menu on the Skyla. Touch YES on the confirmation screen and load the Skyla as usual. You will not be asked for any patient information.

10. Once testing is completed, and the result has transferred across to the connected laboratory PC, open the Vepalabs web portal (poc.vepalabs.com.au) and find, then open the coloured QC result within the list of 'pending' results.

    NB: Please do not be concerned about the red information on your lab PC screen suggesting your result is out of range. This is normal – the software on your PC does not have the QC reference ranges programmed into it. We will be monitoring your QC results remotely and will advise if there's an issue.

11. Confirm that the results match the results from the analyser, then click the '**Send Test Result Now'** button at the bottom of the screen.

12. With a marker, write the current date on the QC vial, and then refrigerate. You may test this sample again (up to a week) in order to determine reproducibility.

13. You have completed the QC testing process. Congratulations!

PLEASE NOTE THESE STORAGE REQUIREMENTS:

Before reconstitution:	Refrigerate at 2-8°C. QC is stable until expiry date
After reconstitution:	Refrigerate at 2-8°C. QC is stable for 7 days; **OR** Freeze at -20°C. QC is stable for 30 days

If you choose to refrigerate or freeze your newly-mixed vial in order to run further QC tests, please note that the ice-box inside a bar/mini fridge is not an adequate freezer. A standalone freezer is required if you wish to freeze QC.

You have been provided with one vials of QC (and one vial of diluent to match). This is your quarterly supply. Our suggested regime for all clinics is below:

- Run QC on the day you receive it. Date the vial and refrigerate. (**Day 1**)
- Run QC using the same vial **7 days later**. Discard QC. (**Day 8**)

If you have any queries or concerns, please contact the Vepa team immediately on 1300 837 252

Method Revision History

Version	Date	Authorised by	Notes
1	01/07/2017	PH	Initial method
2	03/08/2017	JM	Additions, storage reqs
3	09/11/2021	SF	Change QC to 1