

Technical Note No. 0210 Rev. 2.1

NucleoCounter® NC-200™

NucleoCounter® NC-200™ Performance Qualification


Instrument and Materials Specifications

Purpose: To specify the instrument, test kit and cassettes being used for the performance qualification, together with the software and firmware installed at the time of performing the qualification.

Instrument Type:		NucleoCounter® NC-200™ (Cat. no. 900-0201)
Instrument Serial Number		
Firmware versions¹	NC2-Backplane	
	DSC-STEP	
Software version		
NC-200 PQ Kit (Cat. no. 912-0014) Expiry Date and Lot number		
Via1-Cassettes™ (Cat. no. 941-0012) Expiry Date and Lot number		

Zero Count Procedure N/A


Purpose: To ensure that the entire NC-200™ system counting performance is successful when no cassette is present.

Open the Select Protocol window by clicking on the  button below the F3 button and select the Zero Count Protocol (Organism: Verification of NC-200™ and Protocol: Zero Count) .	<input type="checkbox"/>	<input type="checkbox"/>
Execute the protocol by pressing the RUN button on the front of the instrument and follow the instructions.	<input type="checkbox"/>	<input type="checkbox"/>
Zero Count successful as indicated by 'OK' in the result field.	<input type="checkbox"/>	<input type="checkbox"/>

¹ Select 'About' in the *Help menu* of NucleoView™ software for detailed information about firmware and software version.

Bead Count Procedure N/A

Purpose: To verify that the NucleoCounter® NC-200™ Instrument counts correctly.

Open the Select Protocol window by clicking on the  button below the F3 button and select the Viability and Cell Count Assay Protocol (Organism: Mammalian and Protocol: Viability and Cell Count Assay) .	<input type="checkbox"/>	<input type="checkbox"/>
	OK/Yes	Fail/No

- Resuspend beads:
 - 1) **Invert vials for 30 seconds followed by vigorous shaking in hand for 5 seconds** to obtain a homogeneous single-bead suspension. Insufficient re-suspension might lead to increased variation and procedural failure. **Important: Vortex mixing CANNOT replace shaking!**
 - 2) Leave beads for 10 min to obtain room temperature.
- Gently invert the vial 5 times immediately before a Via1-cassette™ is loaded with the bead suspension. Carry out an analysis on the NucleoCounter® NC-200™ instrument and note the results in the table provided below. **Important: Close the bottle and invert it gently 5 times before each of the five required measurements in order to avoid settling of the beads.**
- Calculate the average and the CV % of the obtained results to validate precision of the NucleoCounter® NC-200™ instrument. It is permissible to exclude a single result from these calculations if a clear outlier occurs.

Beads Low N/A

	Count 1	Count 2	Count 3	Count 4	Count 5	Average	CV %
Total Count (10 ⁶ beads/ml)							
% Viability							

Is the average count within the accepted range? (Refer to lot specific Certificate of analysis)	<input type="checkbox"/>	<input type="checkbox"/>
	OK/Yes	Fail/No
Is the CV% on the count below the accepted maximum value?	<input type="checkbox"/>	<input type="checkbox"/>
	OK/Yes	Fail/No
Is the viability within the accepted range?	<input type="checkbox"/>	<input type="checkbox"/>
	OK/Yes	Fail/No
Is the CV% on the viability below the accepted maximum value?	<input type="checkbox"/>	<input type="checkbox"/>
	OK/Yes	Fail/No

Beads Medium N/A

	Count 1	Count 2	Count 3	Count 4	Count 5	Average	CV %
Total Count (10 ⁶ beads/ml)							
% Viability							

Is the average count within the accepted range? (Refer to Certificate of analysis)	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Is the CV% on the count below the accepted maximum value?	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Is the viability within the accepted range?	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Is the CV% on the viability below the accepted maximum value?	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No

Beads High N/A

	Count 1	Count 2	Count 3	Count 4	Count 5	Average	CV %
Total Count (10 ⁶ beads/ml)							
% Viability							

Is the average count within the accepted range? (Refer to Certificate of analysis)	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Is the CV% on the count below the accepted maximum value?	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Is the viability within the accepted range?	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Is the CV% on the viability below the accepted maximum value?	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No

Summary

Purpose: Are all points in the section listed below completed and 'OK/Yes'?

Instrument and Materials Specifications, including software and firmware, completed.	<input type="checkbox"/> N/A	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Zero Count Procedure successfully completed.	<input type="checkbox"/> N/A	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
Bead Count Procedure successfully completed.	<input type="checkbox"/> N/A	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
a) Beads Low within accepted ranges.	<input type="checkbox"/> N/A	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
b) Beads Medium within accepted ranges.	<input type="checkbox"/> N/A	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No
c) Beads High within accepted ranges.	<input type="checkbox"/> N/A	<input type="checkbox"/> OK/Yes	<input type="checkbox"/> Fail/No

OBS! If any of the points above are 'Fail/No', please contact ChemoMetec Support. However, make sure the below listed measures have been followed:

1. The **NC-200 PQ Kit** has NOT been opened/used previously (max 5-7 measurements).
2. The procedure above has been carefully followed.

Performed By:

Signature: _____

Date: _____

Name: _____

Dept. / Company: _____

Verified By:

Signature: _____

Date: _____

Name: _____

Dept. / Company: _____