

Technical Note No. 0210 Rev. 3.0

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)		Field
Instrument Serial Number			1
Firmware versions ¹	NC2-Backplane:		2
	DSC-STEP:		3
Software version			4
NC-200 PQ Kit (Cat. no. 912-0014)	Expiry Date		5
	Lot number		6
Via1-Cassettes™ (Cat. no. 941-0011)	Expiry Date		7
	Lot number		8

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


Zero Count Procedure

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

	OK/Yes	Fail/No	N/A	Field
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) .				9
Execute the protocol by pressing the RUN button on the front of the instrument and follow the instructions.				10
Zero Count successful as indicated by 'OK' in the result field.				11

Bead Count Procedure

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

	OK/Yes	Fail/No	N/A	Field
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) .				12
Resuspend beads as described below and follow instructions for Beads Low, Beads Medium and Beads High				13

- 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

Table 1	Count 1	Count 2	Count 3	Count 4	Count 5	Average	CV (%)	Field
Total Count (x 10⁶ beads/ml)								14
Viability (%)								15

Acceptance Criteria For Beads Low P/N: 071-0032	From	To	Variation Limits CV %	Field
Total Count (x 10⁶ beads/ml) Range				16
Viability % Range				17

Beads Low	OK/Yes	Fail/No	N/A	Field
Use Beads Low (P/N: 071-0032) to fill in Table 1				18
Use lot specific Certificate of analysis for Kit Part no.: 912-0014 to fill in Acceptance Criteria for Beads Low (P/N: 071-0032)				19
Is the average count within the accepted range? (Refer to lot specific Certificate of analysis)				20
Is the CV % on the count below the accepted maximum value?				21
Is the viability within the accepted range? (Refer to lot specific Certificate of Analysis)				22
Is the CV % on the viability below the accepted maximum value?				23

Beads Medium

Table 2	Count 1	Count 2	Count 3	Count 4	Count 5	Average	CV (%)	Field
Total Count (x 10⁶ beads/ml)								24
Viability (%)								25

Acceptance Criteria For Beads Medium (P/N: 071-0033)	From	To	Variation Limits CV %	Field
Total Count (x 10⁶ beads/ml) Range				26
Viability % Range				27

Beads Medium	OK/Yes	Fail/No	N/A	Field
Use Beads Medium (P/N: 071-0033) to fill in Table 2				28
Use lot specific Certificate of analysis for Kit Part no.: 912-0014 to fill in Acceptance Criteria for Beads Medium (P/N: 071-0033)				29
Is the average count within the accepted range? (Refer to lot specific Certificate of Analysis)				30
Is the CV % on the count below the accepted maximum value?				31
Is the viability within the accepted range? (Refer to lot specific Certificate of Analysis)				32
Is the CV % on the viability below the accepted maximum value?				33

Beads High

Table 3	Count 1	Count 2	Count 3	Count 4	Count 5	Average	CV (%)	Field
Total Count (x 10⁶ beads/ml)								34
Viability (%)								35

Acceptance Criteria For Beads High (P/N: 071-0034)	From	To	Variation Limits CV %	Field
Total Count (x 10⁶ beads/ml) Range				36
Viability % Range				37

Beads High	OK/Yes	Fail/No	N/A	Field
Use Beads High (P/N: 071-0034) to fill in Table 3				38
Use lot specific Certificate of analysis for Kit Part no.: 912-0014 to fill in Acceptance Criteria for Beads High (P/N: 071-0034)				39
Is the average count within the accepted range? (Refer to lot specific Certificate of Analysis)				40
Is the CV % on the count below the accepted maximum value?				41
Is the viability within the accepted range? (Refer to lot specific Certificate of Analysis)				42
Is the CV % on the viability below the accepted maximum value?				43

Summary

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

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

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:	
Name:	
Dept./Company:	
Date:	

Verified By	
Signature:	
Name:	
Dept./Company:	
Date:	