Certificate of Analysis for lot no. 1222-205

NC-200 PQ Kit 4

Kit Part no.: 912-0013
Lot no.: 1222-205
Release Date: Dec-2022
Expire Date: Mar-2024
Application: NC-200 PQ Kit 4 is part of the NucleoCounter® system, and is used for performance qualification (PQ) using the Via1-Cassette™ and the NucleoCounter NC-200™. For further information please refer to package insert (992-0031) and technical notes (994-0222 and 994-0223).

Lot no. 1222-205		Test Results Master Instrument	Acceptance Criteria Customer Instrument	
			Acceptance Range	Variation Limits
Beads LOW (Low Count / High Viability) No. 071-0024	Total Count (Beads/ml)	7.39×10^4	$5.17 - 9.6 \times 10^4$	CV% < 28%**
	Viability (%)	98	93 - 100	CV% < 3%
Beads MEDIUM (Medium Count / Medium Viability) No. 071-0025	Total Count (Beads/ml)	4.83×10^5	$3.63 - 6.04 \times 10^5$	CV% < 11%**
	Viability (%)	48	41 - 55	CV% < 5%
Beads HIGH (High Count / Low Viability) No. 071-0026	Total Count (Beads/ml)	4.21×10^6	$3.46 - 4.97 \times 10^6$	CV% < 6%
	Viability (%)	0	0 - 6	SD < 2*

* = When viability is close to 0, even insignificant changes in dead counts can result in extremely high CV%. Instead, Standard Deviation (SD) is used to evaluate the result.

** = The high Coefficient of Variation is primarely due to Poisson distribution .

This lot has been tested according to the internal ChemoMetec quality procedures. The lot meets or exceeds all product specifications.

This lot was released by:

Camilla Poulsen, QC Assistant

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