941-0012 Via1-Cassette™

Certificate of Analysis

Lot number: 0623-04
Release date: Jun-2023
Exp. Date: Sep-2024
Application: The Via1-Cassette™ is part of the NucleoCounter® NC-200™ and NC-3000™ system. The cassette is used to determine total cell count and non-viable cell count in mammalian cell cultures. Only a single cassette is used for estimating both the total count and the non-viable count.

This lot has been tested according to the internal ChemoMetec® quality procedures. The Quality Test is composed of a physical qualification followed by a quantitative test of the cassettes. The results of the quantitative test are presented below.

This lot meets or exceeds all product specifications.

Reference Cassette data:

	Total Cell Count ($x10^6$ Cells/ml)	Coefficient of Variation	Viability
Ref. Cass.	1.95	1.7 %	87.1 %

Accept Ranges based on Reference Cassette data:

	Total Cell Count ($x10^6$ Cells/ml)	Coefficient of Variation	Viability
Accept Criteria	Ref. Cass. +/- 5.0 %	Fixed Max. Value[1]: 6.0 %	Ref. Cass. +/- 4.0 pp[2]
Accept Range	1.85 - 2.05	0.0-6.0 %	83.1 - 91.1 %

Sub-Lot[3] data:

Lot 0623-04	Total Cell Count ($x10^6$ Cells/ml)	Coefficient of Variation	Viability	Result of QC test
Sub-Lot M	2.01	2.2 %	86.7 %	PASSED

This lot was released by:

Thomas Andersen, QC Specialist

1 This fixed max. value is independent of the results from the testing of reference cassettes.
2 pp=percentage points
3 All cassette lots are composed of one or more sub-lots. Each production day represents a sub-lot. All sub-lots are tested together but evaluated separately. The sub-lots are denoted with a letter, and this sub-lot letter is printed on the box-label.

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