# 941-0012 Via1-Cassette™

## Certificate of Analysis

Lot number: 1122-04
Release date: Nov-2022
Exp. Date: Feb-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.** | 1.65 | 3.2 % | 88.5 % |

***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** | 1.57 - 1.73 | 0.0-6.0 % | 84.5 - 92.5 % |

***Sub-Lot[3] data:***

| Lot 1122-04 | Total Cell Count ($x10^6$ Cells/ml) | Coefficient of Variation | Viability | Result of QC test |
|---|---|---|---|---|
| **Sub-Lot M** | 1.66 | 2 % | 88.1 % | PASSED |

This lot was released by:

Naomi Lindvig, Project Manager

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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