912-0006 NucleoCounter® Test Kit

Certificate & Package Insert for lot 0424-201. Expires by Apr-2025

		Accept Criteria	
	ChemoMetec A/S Master Instrument	Average of 5 analysis	CV %
BEAD 0 (Zero)	0.00 x 10E6 beads/mL	0-0.01 x 10E6 beads/mL	-
BEAD 1 (Low level)	0.42 x 10E6 beads/mL	0.22-0.62 x 10E6 beads/mL	Max. 8 %
BEAD 2 (Medium level)	0.80 x 10E6 beads/mL	0.6-1 x 10E6 beads/mL	Max. 7 %
BEAD 3 (High level)	1.51 x 10E6 beads/mL	1.31-1.71 x 10E6 beads/mL	Max. 6 %

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

Certificate released by Jennifer Fermina Madsen, QC Specialist, in April 2024.

Content

Three bottles each containing 1.5 mL fluorescent bead suspension and one bottle containing 1.5 mL of a bead free suspension (ZERO). The beads are suspended in an aqueous solution containing 0.02 % detergent. The bottles contain sufficient volume for at least five analyses. Never perform more than 10 analyses on each bottle.

Application

The NucleoCounter® Test Kit is intended to be used for routine check of the NucleoCounter® instrument. It is recommended to perform a test of the NucleoCounter® twice per year. The beads of the kit are fluorescent and will appear like somatic cells in the image presented by the NucleoView™ software.

Procedure

- **Shake the bottles very vigourously for 10 seconds before use.** In order to obtain a single-bead suspension it is extremely important to shake the bottle sufficiently prior to use. Even though the bottles are mixed according to the instructions, it is not possible to avoid certain degree of bead clumping. Therefore, the suspensions cannot be considered as counting standards. Vortex mixing CANNOT replace shaking!
- After shaking, let the bottle stand for 3 minutes to allow the foam to settle.
- Invert the bottle gently, remove the lid, load a NucleoCassette™ with the bead-suspension and then carry out an analysis on the NucleoCounter®.
- Test each concentration using at least five (5) NucleoCassettes™. Close the bottle and invert it gently before each measurement in order to avoid settling of the beads.
- Calculate the average count in millions/mL for each suspension. Discard up to one outlier for each calculation of average counts. Calculate the CV % (100 % x standard deviation/average) for each suspension. Discard up to one outlier for each calculation of CV %.
- If the average counts and the CV % are within the specified range (refer to the top of this document) the NucleoCounter® is working satisfactory. If this is not the case it may indicate problems with the instrument, the NucleoCassettes™, the Test Kit or the handling of the system. Pay special attention to shaking of the bottles prior to use.

Stability

The storage stability is at least 12 months if stored at 2-8 °C. See expiry dates on the kit labels.

Storage

Store the kit at 2-8 °C until opening. DO NOT FREEZE! After opening the kit shall be used immediately. After use discard the bottles.

Shipment

The kit can be shipped at ambient temperature (0-50 °C for max. 10 days).

Safety Information

This material is not considered hazardous. However, exercise due care and wash hands after usage as a precaution. Do not eat or drink the product.

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