



SpectroFlo® QC Beads

Instructions For Use

Catalog No.	Test/Vial	Product Name
B7-20002	25	SpectroFlo® QC Beads

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Regulatory Information

The SpectroFlo® QC Beads is CE marked in compliance with Regulation EU 2017/746 on In vitro Diagnostic Medical Devices. SpectroFlo® QC Beads is intended for use in countries where the regulation approval has been obtained from the local regulatory authorities.

  For In Vitro Diagnostic Use

Authorized Representative in the European Community



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1. Intended Purpose

SpectroFlo® QC Beads is intended for routine performance tracking and set up of Cytex® Northern Lights™-CLC (NL-CLC™) flow cytometer for in vitro diagnostic use, by providing a standardized method for quality control of the instrument optics, electronics, and fluidics.

2. Application

SpectroFlo® QC Beads contain a suspension of 3.0 µm particles with a single fluorescent intensity. Every particle contains a mixture of fluorophores that enables the particles to be excited at any wavelength from 365 to 650 nm.

SpectroFlo® QC Beads is intended for use by laboratory professionals.

2.1. Principle of Operation

SpectroFlo® QC Beads is used in Daily QC to verify system performance of an NL-CLC™ flow cytometer and to adjust settings to account for day-to-day variation. Daily QC assesses the instrument's optical alignment and the system performance drift by measuring rCVs and gains needed to place the beads at the target locations for each detector. During QC, laser delays and area scaling factors are optimized and gain settings are adjusted to account for day-to-day instrument variability. A Daily QC pass verifies that the SpectroFlo® QC Beads emission intensities and sensitivities across all channels detected by up to 3 lasers (violet (413-846 nm), blue (488-846 nm), and red (644-846nm)) are within target.

Levey-Jennings performance tracking and charting over time is available in SpectroFlo® CLC software. Refer to the Cytex® Northern Lights™-CLC User's Guide for instructions.

SpectroFlo® QC Beads is provided with a bead lot file with target settings to account for lot-to-lot differences in fluorescence intensities. The bead lot file must be imported to SpectroFlo® CLC before performing Daily QC when a new lot of SpectroFlo® QC Beads is used.

3. Reagents

3.1. Reagent Composition

SpectroFlo® QC Beads are suspended at 10^6 - 10^7 per mL in water with 0.01% NP-40 and with 0.02% Sodium Azide as a preservative.

3.2. Storage and Handling

- Store vials at 2°C–8°C and protect from light. Do not use after the expiration date shown on the label.
- After dilution, when protected from light, the beads are stable for 4 hours at 2-8°C.

4. Instruments

SpectroFlo® QC Beads are for use with the following models of Cytex® Northern Lights™-CLC cytometers running SpectroFlo® CLC software.

- N7-00071 (1L B14)
- N7-00072 (2L B14-V16)
- N7-00073 (2L B14-R8)
- N7-00074 (3L B14-R8-V16)

5. Procedure

5.1. Reagents and Materials

Reagents and materials provided:

- SpectroFlo® QC Beads, 2 mL per bottle (25 tests), 1 drop per test

Reagents and materials not provided:

- Disposable 12 × 75-mm capped polystyrene test tubes
- Sheath fluid
- Pipettes and pipette tips of 20 µL, 100 µL and 1000 µL
- Vortex mixer

5.2. Adding and Importing Bead Lot Information

Before using a new lot of SpectroFlo® QC Beads, download the appropriate bead lot file from the Cytex Biosciences website and import into the SpectroFlo® CLC Library module under the QC Beads tab.

The bead lot file and importing instructions are available at <https://cytekbio.com/pages/software-resources>.

Library QC Beads	
QC Beads	QC Beads
Fluorescent Tags	Import Export Remove
Labels	Lot ID Expiration Date
User Settings	1002 December 31, 2019
Worksheet Templates	2002 December 31, 2026
Experiment Templates	
Keywords	

5.3. Preparing a SpectroFlo® QC Beads Suspension

To prepare the SpectroFlo® QC Beads for acquisition:

- 1 Label a 12 × 75-mm capped polystyrene tube.
- 2 Thoroughly mix the SpectroFlo® QC Beads by vortexing the vial for 5 seconds.
- 3 Add 1 drop of SpectroFlo® QC Beads to the labeled 12 × 75-mm polystyrene tube.
- 4 Add 300 µL of sheath fluid.
- 5 Vortex for another 5 seconds to put beads into suspension. Acquire in the flow cytometer shortly after resuspension.

After dilution, when protected from light, the beads are stable for 4 hours at 2-8°C.

5.4. Performing Instrument QC using SpectroFlo® QC Beads

Run instrument QC according to the Cytex® Northern Lights™-CLC User's Guide.

6. Results

6.1. Reviewing the Instrument QC Report

At the completion of instrument QC, SpectroFlo® CLC software will display the Pass/Fail status of the Daily QC run and will generate a QC report. A passing result for every parameter is required for instrument QC to pass. A failure for any parameter results in failure of instrument QC.

For more details on reviewing the QC report and troubleshooting QC messages, see the Cytex® Northern Lights™-CLC User's Guide.

7. Limitations

SpectroFlo® QC Beads are for instrument QC and setup only.

8. Troubleshooting

Observation	Possible Causes	Recommended Solutions
Daily QC does not complete	Wrong QC bead sample	Ensure you are running SpectroFlo® QC beads.
	Bead sample not properly mixed	Mix the bead sample.
	Bead sample too dilute	Concentrate the bead sample or prepare a fresh bead sample.
	Air bubble in sample line	Run a SIT Flush.
Daily QC failed	Air bubble in fluidics	Run a Purge Filter.
	Dirty flow cell	Run a Clean Flow Cell. If the problem persists, run a Clean Flow Cell using cleaning solution, followed by DI water.
	Questionable sample prep	Verify the sample prep technique.
	Air in sheath filter	Run a Purge Filter.
	Sample not diluted in same fluid as sheath	Dilute the sample in the same fluid as the sheath solution.

- **Notice for EU:** Users should report any serious incident related to the use of the device to the Manufacturer and National Competent Authority.
- **Notice for outside EU:** Contact your local Cytex office for any incident related to this device.

9. Quality Control

Refer to the Cytex® Northern Lights™-CLC User's Guide for instrument maintenance.

10. Warnings

- Use appropriate personal protective equipment per the safety data sheet when using this product.
- Follow biosafety practice in compliance with federal, state, and local regulations to handle all biological samples and materials in contact with them.
- Avoid exposing the beads to direct light.
- Do not use the beads beyond their expiration date or beyond the day-of-use stability period after dilution. Beads used beyond their stability period begin to lose fluorescence, which can result in failed instrument QC.
- When running instrument QC, select the bead lot file that matches the bead lot printed on the SpectroFlo® QC Beads label. Using the incorrect bead lot file can result in failed instrument QC.
- SpectroFlo® QC Beads contain sodium azide as a preservative and NP-40 as a surfactant. Do not pipette by mouth.
- Contact Cytex Support or refer to [cytekbio.com](https://www.cytexbio.com) for details on troubleshooting.

11. History

Revision	Date	Change
B9-50004US Rev. A	12/2023	Initial Release