

Read and follow instructions carefully.

Note: Changes to previous version highlighted

1 Identification of the IVD reagent

<i>Name</i>	CyFlow™ DailyQC (IVD)
<i>Ref. No.</i>	BC767693
<i>UDI-DI</i>	04250878906294
<i>Content</i>	2 x 15 mL

2 Intended purpose

IVD For In Vitro Diagnostic Use.

CyFlow™ DailyQC (IVD) is a ready-to-use suspension of fluorescent labelled polystyrene microparticles, to be used for a qualitative daily verification of a flow cytometer's optical alignment and fluidics system. It is recommended for use with the Sysmex flow cytometer, equipped with red, blue or violet excitation light sources. CyFlow™ DailyQC (IVD) can be manually or automatically loaded on the Sysmex flow cytometer depending on the product configuration. CyFlow™ DailyQC (IVD) is a flow cytometer reagent and does not provide any diagnostic information. The use of CyFlow™ DailyQC (IVD) is restricted to healthcare professionals and properly trained personnel. For appropriate use of the product, refer to instructions for use of the Sysmex flow cytometer.

3 Principle of the procedure

CyFlow™ DailyQC (IVD) are particles for daily verification of a Sysmex flow cytometer's optical alignment and fluidics system.

For further information refer to the instructions for use (IFU) of the flow cytometer.

4 Storage and shelf life

4.1 Unopened product

Store CyFlow™ DailyQC (IVD) at 2-8 °C in the dark. Do not freeze or expose to light. Do not use after the expiration date stated on the label.

4.2 Product after first opening

Avoid reagent exposure to direct light or freezing conditions after opening. Store at 2-8 °C in the dark. CyFlow™ DailyQC (IVD) retains its performance characteristics after having been placed into use for a minimum of 12 months. Do not use after the expiration date stated on the label.

5 Components

CyFlow™ DailyQC (IVD) is provided as 2 x 15 mL of a ready-to-use fluorescent labelled polystyrene microparticles in water-based solution containing 0.01% (w/w) NP-40 substitute and 0.02% (w/w) sodium azide.

6 Evidence of deterioration

Avoid contamination of reagents. In case of component deterioration or contamination seen as discoloration of the reagent or if data obtained show any performance alteration, please contact the Technical Support of your local Sysmex representative.

Any problem that has occurred in relation to the product shall be reported by the user to the manufacturer. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user is located.

7 Precautions and warnings

Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet (available at <http://www.sysmex-partec.com/services>).

Always follow the national and international guidelines and regulatory standards for personal protective equipment.

8 Additional required equipment

Instrument: Sysmex flow cytometer, equipped with red, blue or violet excitation light sources (e.g., XF-1600)

Laboratory equipment: Sample tube(s) compliant with the flow cytometer
Adequate personal protective equipment
Vortex mixer

Other materials may be required. Refer to the appropriate Sysmex flow cytometer IFU for more information.

9 Disposal

Disposal procedure should meet requirements of applicable local regulations.

10 Analytical Performance Characteristics

Precision	rCV(%)
Repeatability Within-run precision	≤ 15.00%
Repeatability Within-laboratory precision	≤ 30.00%
Reproducibility Instrument-to-Instrument precision	≤ 30.00%

11 Instructions

- 1) Vortex the ready-to-use beads for a minimum of 30 seconds (3000 rpm).
- 2) Dispense 10-12 drops of CyFlow™ DailyQC (IVD) into a test tube. Protect from exposure to direct light.
- 3) Vortex the tube immediately before use (3000 rpm).
- 4) Refer to the Sysmex flow cytometer IFU for further information.

12 Limitations

The product is intended for healthcare professionals and properly trained personnel in clinical laboratories performing flow cytometry analysis.

Performance Validation and Verification has been performed on the Sysmex Flow Cytometer XF-1600.

13 Contact

Manufacturer



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14 Symbols

REF	Reference number	Manufacturer	LOT	Batch code
Keep away from sunlight		Temperature limit	IVD	In vitro diagnostic medical device
Use-by date		Consult instructions for use	CE	CE mark
Unique device identifier		UK Responsible Person	UKCA	UKCA mark
Content of kit		Statement for various Latin-American countries		

15 Date of issue or revision

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