DATA SHEET

QC ASSAY

CONTENTS

1. Microfluidic cartridge with buffer
2. Dried reagents in tube

STORAGE

Dry cool place protected from light

DESCRIPTION

The Accellix QC reagent contains fluorescent particles (beads), with different fluorescence intensities, referred to as bead groups 1-7.

Bead groups 1-6: Contains beads of multiple fluorescent intensity levels that inform of the Accellix Instrument's optical linearity and sensitivity.

Bead group 7: Contains beads utilized for calibration of detector voltages verifying that the Accellix Instrument remains calibrated.

The Accellix Platform automates your entire GMP cell phenotyping process from sample preparation to data acquisition and analysis, to generate rapid results directly in the manufacturing suite. Central to our enabling technology are standard and custom assays. These assays enable sample preparation in a single-use microfluidic cartridge using unitized and dried reagents that are stable at ambient temperatures. The dried reagent also has control beads, enabling cell counting and in-run QC for every assay. Each assay incorporates an Accellix cartridge with a unique QR code, simplifying the workflow and reducing the chances for human error.

INTENDED USE

In flow cytometry, a comprehensive quality control program is essential for achieving accurate and consistent results between experimental runs. Routine instrument QC is required to provide feedback that a flow cytometer is functioning properly, and regular QC measurements ensure that the instrument falls within predetermined standardized ranges for all required parameters. The Accellix QC assay is used for routine verification of Accellix instrument performance. The assay contains a series of fluorescent particles that have a defined fluorescence intensity across all channels utilized to assess parameters such as optical alignment, sensitivity, linearity, and calibration of the Accellix instrument. QC assay results are displayed automatically on the screen in less than 20 minutes, clearly indicating the instrument integrity. A detailed protocol on how to run the Accellix QC assay can be found in the Accellix QC Assay kit Instructions of Use.

KEY BENEFITS

+ **Verifies that the Accellix instrument is functioning properly before analyzing precious samples**
+ **Simplifies the QC workflow by enabling traceability of instrument performance**
+ **Ensures consistent and reproducible results by tracking the instrument stability over time**

DATA SHEET

Example of On-Screen Summarized Results of the QC Assay

ACCELLIX QC ASSAY RESULTS SUMMARY

PARAMETER	PASS/FAIL
Bead Count	PASS
Linearity (R^2)	PASS
Sensitivity (Stain Index)	PASS
Sensitivity (% CV)	PASS
Calibration (% Difference)	PASS
DEVICE PASSED QC	

Results Output: Summarized results indicating pass/fail are displayed on the screen at the completion of each assay run.

Detailed results and all relevant run information are provided in a pdf report:

- Summarized QC assay results table
- Detailed QC assay results table showing measured values and pass/fail for each parameter
- Associated graphs, including cumulative QC results over time to monitor potential trends
- Audit trail information, including date, time, operator, instrument ID, cartridge ID, lot number

Measured values for each parameter and the defined tolerance limits are provided in a csv file for simplified data retention and analysis. In the event of a QC failure, the operator is instructed to restart the instrument and re-run the QC assay. If the instrument fails QC three times in a row, contact support@accellix.com.

CATALOG NUMBER	ASSAY NAME	DESCRIPTION	CONTENTS
Q1001-1L	Accellix QC RTF Assay	QC assay with fluorescent particles of a defined fluorescence intensity for routine verification of Accellix instrument performance	Fluorescent calibration beads Microfluidic cartridge with buffer