Read this package insert carefully before use. For more detailed information, please refer to the corresponding manual.

SAFIA Check

Intended Use

The SAFIA Check System is a quality control tool for flow cytometers. It comprises of SAFIA Check beads and the SAFIA Check Software, which together ensure the proper functionality of the instrument, including the fluidics system and the performance of the optical system.

Intended to be used by professionals or trained personnel only.

Testing Principle

The SAFIA Check particles are a mixture of 10 Red and Green fluorescent beads, which should yield

- A uniform peak in the light scatter detector channels (forward scatter, FSC, and side scatter, SSC)
- Different Peaks in the green (FITC) Fluorescence channel
- Different Peaks in the Far-Red (Cy5) Fluorescence channel

Kit Components

Package contains the following components

REF	SCP2L005 and SCP1L010	• 1 x 200 µL of SAFIA Check Particle stock solution
REF	SCS2L006 and SCS1L011	• 1 x 200 µL of SAFIA Check Particle stock solution • USB flash drive with SAFIA Check Software

Additional Required Materials and Equipment

Devices/Material

- 15 mL tubes for dilution of SAFIA Check particles
- A single channel pipette, suitable for pipetting a volume of 10 µL.
- Sample tubes for Sysmex Cube 6 flow cytometer (For manual measurement, Sysmex order number: 04-2000).

Additional reagents required

Reagents for operating the flow cytometer (Sheath Fluid, Cleaning Fluid, Decontamination Solution).

Storage and Stability

Unopened product

In case of product SCS2L006 and SCS1L011 (SAFIA Check Starter Kit) remove flash drive before storage. Store the reagent at 2-8 °C in the dark. Do not freeze or expose the reagent to elevate temperature or direct sunlight. Under these conditions the reagent will be stable until the expiration date printed on the label. Do not use beyond its shelf life.

Opened product

The shelf life after first opening is the same as the shelf life for unopened reagent, if stored under conditions stated above. Always close the vials tight after use and use a new pipette tip each time the reagent is sampled to avoid contamination.

Diluted particles

The diluted particles remain stable for 5 days after dilution. Any remaining reagent after this time must be discarded.

Hazard and Precaution Statements

The kits may contain substances (Ethanol) that are hazardous. Please refer to the safety data sheets (SDS) for safety instructions and precautionary measures for the components contained in the kit.

Instructions

Installation of SAFIA Score

Insert the USB flash drive into your computer and launch the SAFIA Check Software (EXE-File). Please note that the USB flash drive must remain connected to operate SAFIA Check. If desired, a shortcut can be created on the desktop.

Preparing Particle Working Solution

Allow all reagents to reach room temperature before beginning. Vigorously shake the particle stock solution for at least 20 seconds to ensure the particles are evenly distributed. The resulting solution should appear as a uniform, turbid suspension.

Dilute 10 µL of particle stock solution in 10 mL of Sheath Fluid. Shake Particle dilution for 20 seconds vigorously. The diluted particle solution can be used for a further 5 days.

Read-out and Data Analysis

Check levels of waste and sheath fluid before starting the measurement. Ensure, that the instrument is primed according to the manual.

Open the configuration file Mycotoxins-SCR_A_Robby.cv85, go to QC Cube and ensure the following settings: Sample Source Sample Port, Measure mode Cells in Region, 0.5 µL/s flow rate.

Start the measurement by pressing the Play button. After the run, your data will be exported from FCS Express as a .csv file and can be analyzed with SAFIA Check. The evaluation is performed automatically, and an optional .pdf report can be generated. To assess the long-term performance of your device, compare the obtained values using Levey–Jennings plots.

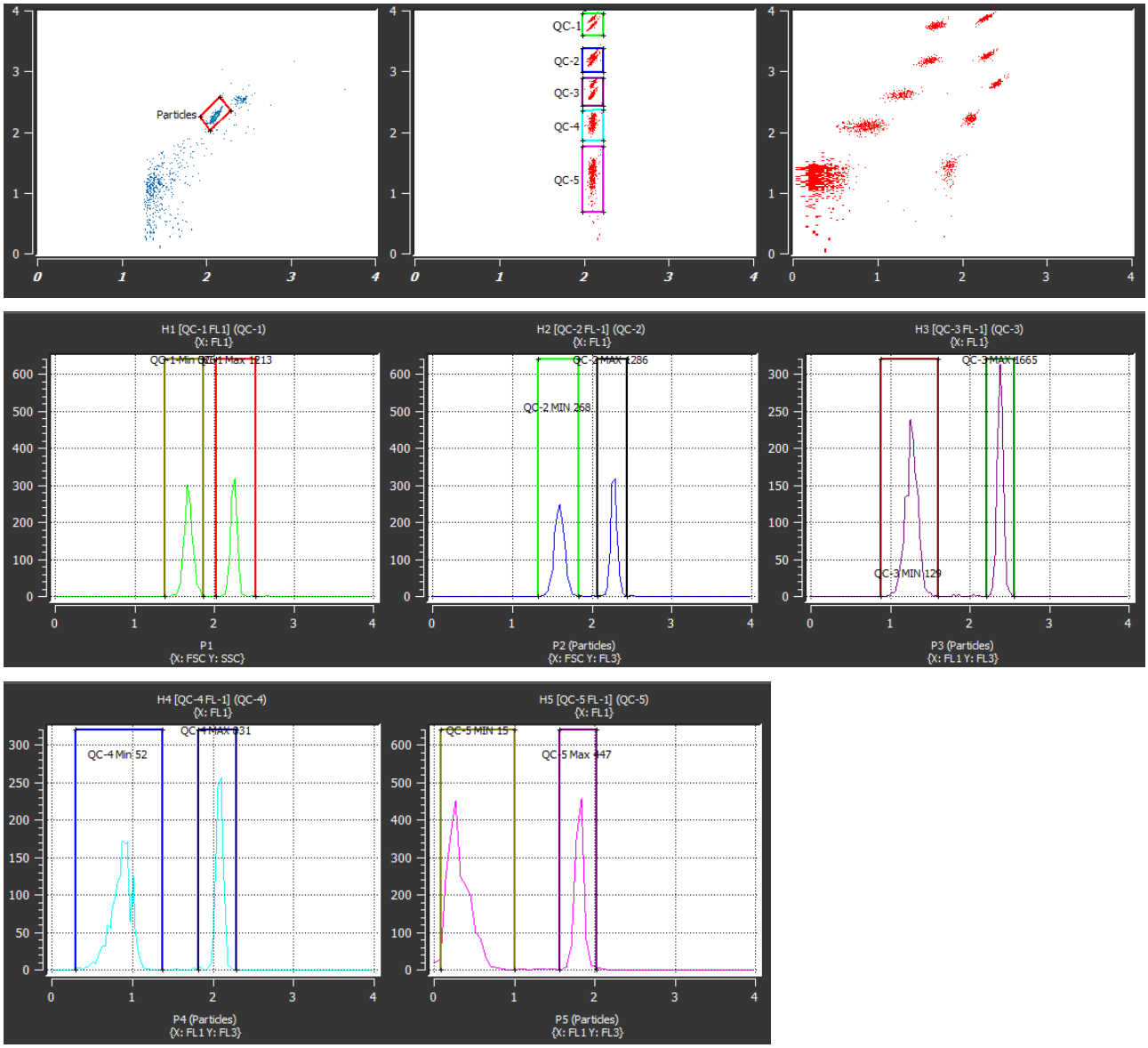

Figure 1 Visualization of SAFIA Check measurement data. The first row displays 2-D dot plots: SSC vs. FSC with gated particles, FL-3 vs. FSC (middle plot) showing distinct populations (QC-1 to QC-5) in the FL-3 channel, and FL-1 vs. FL-3 displaying all 10 bead populations. The second row shows FL-1 channel histograms for QC-1 to QC-3 (left to right). The third row presents FL-1 histograms for QC-4 and QC-5 (left to right). Each FL-3 QC population forms two peaks in the FL-1 Histograms within the specified regions. Please note that the position of the peaks may vary depending on the batch of SAFIA Check particles used.

Disposals Procedure

All reagents and materials must be disposed of properly and responsibly after use. Please observe the applicable national regulations for disposal and refer to the safety data sheets if necessary.

Manufacturer

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Symbols

REF Reference number

Consult instruction for use

LOT Batch Code

Manufacturer

Use-by-date

Temperature limit

SAFIA Manual: safia.tech/manual/

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