

## Application Note No. 994-4502

# Xcyto® 5

### Operation Qualification Protocol for the Xcyto® 5 system

#### Product description

The Xcyto® 5 image cytometer combines the statistical power and fluorescence sensitivity of standard flow cytometry with the spatial resolution and quantitative morphology of digital microscopy. This unique combination allows for new applications that would be unfeasible using the two methods separately. The Xcyto® 5 system integrates image acquisition, image analysis, feature extraction and data presentation in one step, providing seamless quantitative data of individual cells. This instrument produces high-resolution images, including UV microscopy, dark field, and more than 20 fluorescent channels, with sensitivity exceeding conventional flow cytometry.

#### Application

This protocol for the Xcyto® 5 system is used for operation qualification (OQ).

#### Introduction

The Xcyto® 5 image cytometer comprises several actuators, sensors, cameras and electronic boards. This OQ protocol performs a series of functional and quantitative measurements to verify correct operation of all these units. The test results are displayed at the end of the test, in a message box, and grouped in two categories: 'OK' or 'Failed'.

#### Principle

The OQ test is divided into two parts:

The first part is performed with an empty sample tray. The following is verified:

- Instrument settings
- Sample tray positioning
- Focusing
- X, Y motor precision

The second part is performed with Xcyto® 2-Chamber Type 100-A slides loaded with the **Xcyto® 5 OQ Beads** – Fluorescent Beads. The following is verified:

- Signal to background ratio
- Light sources
- Slide positioning and alignment
- Optical filters
- Magnification
- Motors
- Camera

**OQ test:**Materials needed

- **Xcyto® 5 OQ Beads** - Fluorescent Beads (Cat. No. 071-0027)
- Xcyto® 2-Chamber Type 100-A slides (Cat. No. 942-0010)

Protocol (duration of the OQ test is around 40 minutes)

1. Engage the Xcyto® 5 by starting the XcytoView™ software. The Xcyto® 5 is ready to use when the RUN-indicator turns green (this may take a minute).
2. Open the *Protocol Browser* available from the main window.
3. Select the **Xcyto5 OQ** protocol and press **RUN**.
4. Follow the instructions on-screen to perform the OQ test.

**Note:** When prompted to load the Xcyto 2-Chamber Type 100-A slides with **Xcyto® 5 OQ Beads** – Fluorescent Beads, remember to invert the vial 5-10 times or vortex briefly in order to bring the fluorescent beads into solution right before loading the slide.

5. After completion, a message box will confirm whether the OQ test has passed 'OK' or 'Failed'.

OQ documentation files:

- Two csv files holding all the results named with the Xcyto® 5 serial number, date and time (OQSummary\_sn\_yyyymmdd\_hhmmss.csv and OQ Test Status\_sn\_yyyymmdd\_hhmmss.csv) are placed in the verification directory as documentation for the performed OQ test.

### Handling and storage

For handling and storage of ChemoMetec® instruments, reagents and Xcyto® slides refer to the corresponding product documentation. For other reagents refer to the material data sheet from the manufacturer of the reagents and chemicals.

### Warnings and precautions

For safe handling and disposal of the ChemoMetec® reagents and Xcyto® slides refer to the corresponding product documentation and the Xcyto® Software User Guide. For other reagents refer to the safety data sheet from the manufacturer of the reagents and chemicals required for this protocol. Wear suitable eye protection and protective clothes and gloves when handling biologically active materials.

### Limitations

The Xcyto® 5 system is FOR RESEARCH USE ONLY. NOT FOR DIAGNOSTIC OR THERAPEUTIC USE. The results presented by the Xcyto® 5 system depend on correct use of the reagents, Xcyto® slides and the Xcyto® 5 instrument and might depend on the type of cells being analyzed. Refer to the Xcyto® 5 Software User Guide for instructions and limitations.

### Liability disclaimer

This application note is for RESEARCH PURPOSES ONLY. It is not intended for food, drug, household, or cosmetic use. Its use must be supervised by a technically qualified individual experienced in handling potentially hazardous chemicals. The above information is correct to the best of our knowledge. Users should make independent decisions regarding completeness of the information based on all sources available. ChemoMetec A/S shall not be held liable for any damage resulting from handling or contact with the above product.

### Product disclaimer

ChemoMetec A/S reserves the right to introduce changes in the product to incorporate new technology. This application note is subject to change without notice.

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