

BD™ QUALITY ASSESSMENT SCHEME

Announcement

Dear BD Customer,

You receive this letter since you have participated in the past in our BD CEQUAL program which was run for more than a decade without changes in the general setup. For reasons explained in more detail below, we will replace the BD CEQUAL program with a new Quality Assessment Scheme named BD QAS. The first round of BD QAS is scheduled to run in 2008.

Why a new Quality Assessment Scheme?

Today we find many different models of BD flow cytometers working in our customer's laboratories, ranging from the BD FACScan™ flow cytometer with three fluorescence detectors (colors) to the BD FACSCalibur™ flow cytometer with four colors, the BD FACSCanto™ / BD FACSCanto™ II flow cytometers with six or eight colors, the BD FACSAria™ flow cytometer and the BD™ LSR II flow cytometer with up to 18 colors.

The BD CEQUAL program provided only two color BD Simultest™ reagents, whereas an increasing number of laboratories are using multi-color reagents with more than two fluorochromes.

The new BD Quality Assessment Scheme (BD QAS) will reflect the increased heterogeneity of BD™ flow cytometers in the participating countries.

How will BD QAS work?

Under the BD QAS program, BD will provide you with our well known BD Multi-Check™ control blood. Participating labs will be asked to do the sample analysis in the same way using the same reagents and protocols as used in daily laboratory routine. Results will be sent to BD, analyzed and statistically evaluated and a certificate of participation will be issued.

Setup and conditions of BD QAS

- The service will be free of charge for BD customers.
- Participation is voluntary and there are no commercial obligations associated with your participation.
- The service will be offered once a year.
- The entire process of registration and result submission will be in English language.
- Participants will have to confirm the receipt of the sample.



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BD Quality Assessment Scheme

Procedures

- As a participant you will receive a Confirmation of Participation on an individual basis (laboratory level) stating the markers you have analyzed.
- The sample material is 2.5 ml stabilized human blood in a BD Vacutainer® tube (BD Multi-Check™). No other materials or reagents will be provided.
- Your BD local office or distributor will be your contact for the sample delivery.
- You will use your own reagents in your preferred color combination to reflect your laboratory routine.
- Only the following CD markers will be evaluated: CD3, CD4, CD8, CD16/56, CD19, and CD45 in case you will provide the respective results.
- The indication of your BD Flow Cytometer type and serial number is mandatory.

In order to participate in the new BD QAS program, you need to register by sending back the attached registration form by fax until November 30th, 2007. Registrations received after that date can not be considered for the 2008 program.

It is expected that participants will receive the BD QAS sample in April 2008.

A period of two weeks is foreseen for the submission of the results of your analysis directly to an internet-based database. No data submission will be possible after the closing date.

Confirmation of results will be sent to the individual laboratories latest after three months.

Kind regards,

Dr. Christoph Rothfuchs
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Eastern Europe, Middle East, Africa



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live healthy lives