



From: Immunology Quality Assessment

To: Immunology Quality Assessment International CD4 PT Program Participants

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As companies follow through with instrument phase out plans, some platform specific reagents may become scarce. In the case of the BD FACSCount Control Kit, there are alternative QC measures that may be utilized in the event of shortage. Stabilized positive procedural controls for lymphocytes, available at both CD4 normal and CD4 low levels may be stained in the same manner as patient specimens prior to patient runs to confirm that the FACSCount instrument is performing within tolerance limits.

Immunology Quality Assessment has noted success running the following procedural positive controls on the FACSCount platform:

1. CDChex Plus (Normal and CD4 Low) from Streck
 - 2 x 3.0 mL CD-Chex Plus Low, Normal *Catalog Number 213391*
 - 4 x 3.0 mL CD-Chex Plus Low, Normal *Catalog Number 213369*
 - 10 x 3.0 mL CD-Chex Plus Low, Normal *Catalog Number 213370*

2. BD Multi-Check Control (Normal and CD4 Low) from BD Biosciences
 - BD™ Multi-Check Control *Catalog Number 349700*
 - BD™ Multi-Check CD4 Low Control *Catalog Number 349703*

Other stabilized positive procedural controls for lymphocytes may also be considered, provided that they are available with both CD4 Normal and CD4 Low values. Before utilizing a new control product, the laboratory should establish and document the tolerance limits for acceptance according to DAIDS GCLP guidelines.

The staff at Immunology Quality Assessment is available for technical consultation concerning flow cytometry and laboratory techniques. Please direct any questions to Raul Louzao at 919-684-5861 (raul.louzao@duke.edu) or Sylvester Hood at 919-681-1629 (sfh7@duke.edu).

Regards,

Immunology Quality Assessment