



Date: September 27, 2010

URGENT: FIELD SAFETY NOTICE
CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5
CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5
Part Numbers: 6607013 and 6607073

Dear Beckman Coulter Customer,

Beckman Coulter has confirmed two issues related to the stability claims associated with the CYTO-STAT® tetraCHROME™ Reagents.

ISSUE 1:	Current specimen age stability labeling claims for tetraCHROME reagents (when used with tetraCXP), list 48 hours for the CD45/4/8/3 tube for both % positives and absolute counts, and 48 hours for the CD45/56/19/3 tube for % positives and 24 hours for absolute count.
ISSUE 2:	Current prepared sample stability claims for manual gating with the tetraCHROME reagents, as indicated in the Limitations section of the reagent Instructions for Use, list a 5 day refrigerated prepared sample stability claim.
IMPACT:	There is no impact to the product safety or functionality. A labeling error resulted in the specimen age stability and the prepared sample stability being stated incorrectly in the instructions for use.
ACTION/RESOLUTION:	For Issue 1: The specimen stability claims should be as follows: - 48 hours for both % positives and absolute counts for the CD45/4/8/3 tube - 24 hours for both % positives and absolute counts for the CD45/56/19/3 tube For Issue 2: Results produced are not impacted when samples are prepared and run within the post collection timeframes provided in the product instructions for use: - Preparation within 72 hours of collection for the CD45/4/8/3 tube - Preparation within 24 hours of collection for CD45/56/19/3 tube

Complete and return the enclosed response form within 10 days so we may maintain our records. Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation.

If you have any questions regarding this Product Corrective Action, please contact your local Beckman Coulter Representative.

We sincerely apologize for any inconvenience that this may have caused your laboratory. Thank you for your continued support of Beckman Coulter products.

Sincerely,

Group Manager, Corporate Quality and Regulatory Affairs

PCA-15268

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