May 22, 2012

UPDATE TO PCA-15268
URGENT FIELD SAFETY NOTICE
tetraCXP Software
CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5, Part Number 6607013
CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5, Part Number 6607073

Attention Beckman Coulter Customer,

This letter updates an Urgent Product Correction PCA-15268, dated September 27, 2010, for the products listed above. This letter contains important information that needs your immediate attention.

The information contained in this notification supersedes the notifications and product labeling listed below.

- Product Corrective Action letter PCA-15268 dated September 27, 2010
- Important Product Information notice PN B00405-AA that accompanied your new instrument.
- tetraCXP System Guide PN 625172 and CYTO-STAT tetraCHROME Reagents product labeling PN 4238068.

ISSUE: Beckman Coulter has determined that the specimen and prepared sample stability claims stated in the product labeling for tetraCXP Software and CYTO-STAT tetraCHROME Reagents (CD45-FITC/CD4-RD1/CD8 ECD/CD3-PC5 and CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5) need to be updated for alignment with current standards and clinical decision-making associated with lymphocyte immunophenotyping results.[1, 2, 3, 4] The updated claims are indicated in Tables 1 and 2 below. These claims apply to percent positive and absolute count results.

Table 1:
tetraCXP SYSTEM Guide, PN 625172
Current and Updated Specimen and Prepared Sample Stability Claims

Type of Stability Claim	tetraCHROME Reagent	Current Claim	Updated Claim
Specimen	CD45/4/8/3	48 hours room temperature	24 hours room temperature
	CD45/56/19/3	24 hours room temperature	
Prepared Sample	CD45/4/8/3	5 days refrigerated 2 hours room temperature	24 hours refrigerated 2 hours room temperature
	CD45/56/19/3		

Table 2:
CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 &
CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5
IFU, PN 4238068 – XL/XL-MCL and FC 500 flow cytometers
Current and Updated Specimen and Prepared Sample Stability Claims

Type of Stability Claim	tetraCHROME Reagent	Current Claim	Updated Claim for XL/XL-MCL and FC 500 flow cytometers
Specimen	CD45/4/8/3	72 hours room temperature	24 hours room temperature
	CD45/56/19/3	24 hours room temperature	
Prepared Sample	CD45/4/8/3	analyze promptly	24 hours refrigerated 2 hours room temperature
	CD45/56/19/3		

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IMPACT: Specimens or samples processed outside the updated stability claims may produce percent positive and absolute count results that are inaccurate.

ACTIONS:

- The Specimen and Prepared Sample Stability Claims in Table 1 and Table 2 of this notification supersedes the claims in the tetraCXP SYSTEM Guide, PN 625172 and the CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 IFU, PN 4238068 for analysis on XL/XL-MCL and FC 500 flow cytometers. Please update your Quality System documentation accordingly.
- A look-back at previous results for any specimens or samples processed outside the updated claims should be performed at the discretion of the Laboratory Director. Flow cytometric results are often used in conjunction with other diagnostic laboratory clinical parameters for making diagnostic and patient management decisions, in which case risk from potential errors would be unlikely. However, if the Director believes the results may have adversely affected diagnosis, a review would be appropriate.
- *NOTE: Please remember to always use blood collection tubes with EDTA anticoagulant as indicated in the tetraCXP SYSTEM and tetraCHROME Reagents product labeling.*

RESOLUTION:

- The tetraCXP SYSTEM Guide and CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 & CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 product labeling will be revised to reflect the updated claims.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded the affected product listed above to another laboratory, provide a copy of this letter to them.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact your local Beckman Coulter representative.

Sincerely,

Nancy Nadler
Group Manager, Regulatory Affairs

1. CLSI 2007 H42-A2. Enumeration of Immunologically Defined Cell Populations by Flow Cytometry. Vol. 27, N 16.
2. MMWR 1997 Revised Guidelines for performing CD4+ T cell Determinations in Persons Infected with HIV. Vol. 46 / RR-2.
3. MMWR 2003 Guidelines for Performing Single-Platform Absolute CD4+ T-Cell Determinations with CD45 Gating for Persons Infected with Human Immunodeficiency Virus. Vol. 52 / RR-2.
4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Agents in HIV-1-Infected Adults and Adolescents, Department of Health and Human Services. January 10, 2011; 1-66.