January 25, 2012

URGENT FIELD SAFETY NOTICE

Navios Flow Cytometer software v1.0 & v1.1
Navios tetra Software, v1.0
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 Navios Customer,

Beckman Coulter is initiating a voluntary recall for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:

Beckman Coulter has determined that the specimen and prepared sample stability claims stated in the product labeling for specimens prepared with CYTO-STAT tetraCHROME Reagents (CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5) when analyzed using a Navios flow cytometer need to be revised. A new study was conducted on specimen and prepared sample stability resulting in revised claims as indicated in Tables 1 and 2. These claims apply to percent positive and absolute count results. Please remember to always use blood collection tubes with EDTA anticoagulant as indicated in the tetraCHROME Reagents and Navios tetra SYSTEM product labeling.

Table 1:
Navios tetra SYSTEM Guide, PN 773234
Current and Updated Specimen and Prepared Sample Stability Claims

Type of Stability Claim	tetraCHROME Reagent	Current Claim	Updated Claim
Specimen	CD45/4/8/3	72 hours	24 hours
	CD45/56/19/3	48 hours	
Prepared Sample	CD45/4/8/3	48 hours	24 hours
	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 – Navios flow cytometer analysis only
Current and Updated Specimen and Prepared Sample Stability Claims

Type of Stability Claim	tetraCHROME Reagent	Current Claim	Updated Claim for Navios flow cytometer analysis only
Specimen	CD45/4/8/3	72 hours	24 hours
	CD45/56/19/3	24 hours	
Prepared Sample	CD45/4/8/3	Analyze Promptly	24 hours
	CD45/56/19/3		

IPCA-18781

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IMPACT	• Specimens or samples processed outside the updated stability claims may produce erroneous but credible percent positive and absolute count results. • For the general population, the probability of transient health consequences is remote since any abnormality detected would trigger retesting, redraw and evaluation in the context of the clinical conditions. • For the population at greatest risk the probability of serious adverse consequences to patients is remote when reporting falsely elevated CD4+ enumeration, CD4/CD8+.since other lab and clinical parameters are taken into consideration Also, the probability of medically reversible or transient adverse health consequences for patients with HIV/AIDS with falsely low CD3+/CD4+ values or CD4/CD8 ratios is remote since any change in medication conducted would take into consideration results from other parameters (i.e. viral load, clinical conditions) and patients would be monitored periodically for treatment effectiveness and possible side effects. Similarly, the clinical status of patients with congenital/acquired immunodeficiencies, B cell proliferation is conducted using a series of laboratory tests, ranging from CBC to tissue biopsy, and clinical symptoms. Inconsistent, non-credible, and/or falsely low levels of CD19+ B cell populations would trigger further testing/repeat/ redraw.
ACTION	• The Specimen and Prepared Sample Stability Claims in Table 1 and Table 2 of this notification supersedes the claims in the Navios tetra SYSTEM Guide, PN 773234 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 a Navios flow cytometer; 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 given the fact that flow cytometric results are often used in conjunction with other diagnostic laboratory clinical parameters for making diagnostic and patient management decisions.
RESOLUTION	• The 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 Quality System documentation. If you have transferred ownership or location of the analyzer(s) to another laboratory, please provide a copy of the letter to that party.

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

If you have any questions concerning this notice, please contact your local Beckman Coulter representative. We apologize for the inconvenience that this may have caused your laboratory.

Sincerely,

Deborah Herrera

Deborah Herrera
Director Regulatory Affairs

IPCA-18781