

ThermoFisher
SCIENTIFIC

DADE^(®) Quality Controls

December 5th 2007

Re. Reduced open vial claim for NT-proBNP in DADE[®] Cardiac TL

Product: DADE[®] Cardiac TL Assayed Cardiac Marker Control
Part Numbers: B5960-1, B5960-2, B5960-S (Sample pack 1 x 3 x 3ml)
Lot Numbers: CTL10041, CTL10041D, CTL10042, CTL10042D, CTL1004SD

Dear Dade Behring Customer,

We have identified that NT-proBNP in level 1 and level 2 of above control product is not meeting the open vial stability claim of 30 days stated in the package insert. We are revising the open vial stability claim to 10 days.

Beyond 10 days of use, if using these controls for NT-proBNP, please discard the vial and open a fresh vial of product.

Please note that level three of this product lot (CTL10043 and CTL10043D) has an open vial claim of 3 days for NT-proBNP, which was communicated by inclusion of a notification in kits at the time of release.

We sincerely apologize for any inconvenience and thanks for your continued support of our DADE[®] Control products.

Please attach this letter to your product insert for your records.

Yours sincerely



International Product Manager MAS
Microgenics Products, Diagnostics Division
Thermo Fisher Scientific

Thermo Fisher Scientific

46360 Fremont Boulevard, Fremont, CA 94538 USA • Tel: (510) 979 5000 • Fax: (510) 979 5002