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July 16, 2001

Dockets Management Branch
Docket # 01D-0044 for CLIA Waiver Guidance Document
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20850

Desk Copy by FAX: Ms. Nina Chace, Scientific Reviewer
Immunology/Hematology Branch, Division of Clinical Laboratory Devices

RE: Docket No. 01D-0044-Guidance for CLIA Criteria for Waiver; Draft Guidance for Industry and FDA

Dear Dr. Hackett,

Enclosed please find two additional comments to the above-referenced guidance document. I realize the comment period closed at the end of May, but I have received instruction from DCLD to add these comments at this time. A brief synopsis of the situation follows.

On June 19, 2001, I submitted an add-to-file on behalf of Metrika, Inc. (Metrika, Sunnyvale, CA) requesting a labeling changes to the *Controls* section of the **A1cNow™** test for professional use (K000887). On July 12, 2001, I was informed by Ms. Nina Chace that FDA is, understandably, reluctant to review quality control (QC) labeling changes to CLIA-waived products while the guidance document is in a state of flux. Instead, it was suggested that the key elements from that add-to-file be generalized as comments to the Draft Guidance Document, and this has been done. Metrika appreciates the opportunity to convey its position in this manner.

Comment #1: Testing of external QC samples for each change in operator within a test kit

I am proposing that the recommendation for external QC testing for each change in operator within a test kit be removed. This verbiage is a vestige from the time when CDC had oversight of CLIA-waiver activities, and a sound scientific basis for this labeling instruction was never established. Since the director of the waived laboratory is legally responsible for adequate training of staff personnel, it

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is unclear what value is added by training an operator with multiple kits, or "QC-ing" a kit with multiple operators. Once an operator is trained with one kit, no new factors are introduced when testing is performed with another kit. Further, since the instruction is not tied to testing volume nor the time duration between tests, it is entirely ludicrous.

Comment #2: Testing of external QC samples with each shipment of product

Current CLIA-waived labeling instructs users to perform external QC testing with each new shipment of product. While I certainly concur that potential adverse effects from shipping must be recognized and evaluated, external QC testing is not the only way to do this. If is has been shown that various environmental conditions do not negatively impact the product, or if internal controls are in place to alert the user of a negative condition, then the testing of external controls is redundant. In this particular case, Metrika had performed shipping studies were the product was exposed to:

- excessive heat
- excessive cold (freeze/thaw cycles),
- high altitudes and excessive vibrations,
- high impact (drop testing)

The data from these studies confirmed that A1cNow™ still functioned according to product specifications after the various exposures. Summaries of those studies will be re-submitted to FDA once the CLIA Waiver Guidance Document is finalized. The results from the shipping studies provide an excellent example of how hazard analysis can be incorporated into the CLIA review process.

Thanks again for including my comments after the deadline. I look forward to the release of the final guidance this Fall, for this project and for other CLIA-related projects.

Sincerely,

Erika B. Ammirati, R.A.C., MT(ASCP)
Clinical/Regulatory Consultant to Industry

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