

**Mayo Central Laboratory
for Clinical Trials**
*A Division within
Mayo Clinical Trial Services*

November 9, 2006

3050 Superior Drive NW
Rochester, Minnesota 55901
800-826-5561

Division of Dockets Management
HFA-305
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket #2006D-0347

Dear Sirs:

Your draft guidance on IVDMIAs is welcomed by those of us Clinical Laboratorians who expect and respect scientific reliability and objectivity in medical practice. The document lacks definitiveness, however, in stating the expectations of the manufacturer of the lab applying for approval of an IVDMIA.

There are five points which I believe should be made in the guidance:

1. Explicit inclusion and exclusion criteria, based on the test and verification patient sets used for validation, will be part of the labeling. Patients who do not meet both sets of criteria will not be tested.
2. The diagnostic sensitivity and specificity data will be part of the labeling, with adequate demographic and set size information to support application to a broad patient population.
3. The distribution of the data in the test and verification sets will be published to allow a user to see how cutoffs were established, and whether or not their own patient population is comparable.
4. Since many algorithms rely on analytes that are acute phase reactants, or analytes that respond rapidly to changes in biochemical status (if they did not respond quickly, clinical evaluation alone would suffice for patient classification), biologic variability data must be part of the submission and will be included in the labeling.
5. The algorithm used in any calculation be published in full, to allow for independent replication.

I look forward to seeing this guidance implemented.

Sincerely,



Lawrence K. Oliver, Ph.D.

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2006D-0347

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