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Dockets Management Branch (HFA-305)
Food and Drug Administration
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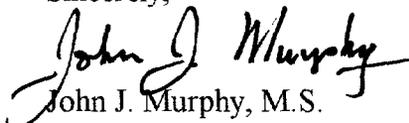
Re: Docket No. 99D-2726

Dear Sir / Madame,

Thank you for accepting comments regarding : **Guidance on Labeling for Laboratory Tests**, FR Sept. 8, 1999, Vol. 64, No. 173, Pages 48843 - 48844. Although it is a non-binding Level 1 guidance, it will reduce the misuse of emerging technologies in laboratories, by reinforcing standards such as "Operational Truth" and "Laboratory Equivalence". The year 2000 is only weeks away, and yet there are laboratories that are misusing darkfield microscopy for the performance of **Live Blood Cell Analysis (LBA)**. Many LBA laboratories routinely report unsubstantiated positive findings of *Candida albicans* from blood specimens. The Clinical Laboratory Improvement Amendments of 1988 can address this problem by requiring validation of methods. However, CLIA has failed to entirely stop this misapplication of laboratory methods because laboratory tests are not properly labeled and some surveyors failed to recognize the test's deficiencies. I hope that this guidance will help the laboratory and medical community establish "operational truth" before questionable tests are put into use. Please consider the following recommendations.

- The definition of "Laboratory Equivalence" is not written clearly. The guidance defines laboratory equivalence as: "Performance of the new test is characterized in terms of a comparison to a predicate." The word "predicate" could be interpreted to mean a proposition or assertion. Assertions by medical personnel have been used to mislead CLIA laboratory inspectors into certifying laboratories for Live Blood Cell Analysis. When a "true" diagnostic state is not identifiable, because a well-defined diagnostic algorithm is not available, then the label should include statements similar to those used for Analyte Specific Reagents, and the kit should be used for "Investigational" or "Research Use Only". There should be some correlation studies with positive clinical findings before a test is used for the diagnosis or treatment of patients.
- The sentence: "Relative performance may be described in terms of agreement, co-positivity and co-negativity, or using other similar terms." is a loophole for those who wish to misuse laboratory tests. The guidance should include examples to elucidate the appropriate use of "co-positivity".

Sincerely,


John J. Murphy, M.S.
Medical Laboratory Consultant

99D-2726

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