



MEMORANDUM

STATE OF UTAH
DIVISION OF EPIDEMIOLOGY & LABORATORY SERVICES

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October 11, 2005

TO: Division of Documents Management, Food and Drug Administration

FROM: Rebecca Christiansen, MT(ASCP), Chief of Certification & Approval Section,
Utah Public Health Laboratories, Bureau of Laboratory Improvement, CLIA
Section

SUBJECT: Comments on "Draft Guidance for Industry and FDA Staff: Recommendations for
Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver
Applications" (Docket #1171)

This document is comprehensive in scope and intent. It should improve the previous process that allowed a "new" kit or method to compare results only to an existing "waived" method already on the market. Subsequent generations of approved products drifted further and further from the "gold standard" and eventually affected patient outcome (require rather than recommend on page 19 under selection of comparative method). My husband has a home use glucose meter that falls into this category. At a reading of 40 he is alert and able to care for himself. Another day a reading of 117 and his eyes roll back in his head and he falls off the chair. These results make me question the meter's accuracy for low results.

I suggest an incentive to help manufacturers follow all of the recommendations in this document and not just the required elements. Award a tiered approval. For example, a level one approval means the company met all required and all recommended elements that applied to their kit/method/instrument. Level two means the company met all required and some recommended elements. Level three means the company met only required elements.

Specific Comments

Page 8: Modify the statement between bulleted lists by deleting the first that and bolding the not: We believe a test that is simple should **not** have the following characteristics:

Page 12: Environmental factors: add altitude to the Impact of key environmental factors. In the Rocky Mountains we have experience with altitude affecting such tests as pO₂. If no one checks for altitude interference, we will not know which other methods/tests may be affected. Most manufacturing and product testing is done at sea level.

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Page 13: Modify the last sentence of the 4th paragraph to delete “recommend”. Do not identify training as a sole means of mitigating potential sources of harm. As an inspector, I see many personnel performing waived tests who were taught by another testing person, in turn taught by another testing person, back too far to understand the procedure. For most facilities, training consists of reading the Quick Reference Instructions.

Page 16: I recommend you require manufacturers to also report any clinical study sites from which they withdraw their product without completing the study. A pediatric clinic office manager reported to me her clinic was chosen to research a new rapid group A strep test. During a follow up visit, the manager told the representative she found their claims of improved sensitivity unwarranted as the false negative rate (based on back up culture) was just as high as the kit they had been using. The representative told her she was not supposed to back up the test results with culture according to the testing protocol. She stated her physicians required back up to any rapid strep test. The company immediately pulled their product and did not use her data in their submission report. This requirement is a logical part of the last paragraph under #3 on page 18 – but companies will not want to disclose trials that showed their product in a bad light.

Page 21: I agree with the note at the end of the (2) Regression Analysis section.

Page 29: Require the waived device label to be more specific about specimen type under the second bullet. For example on waived hCG kits require wording such as This kit is only waived for urine specimens. This kit is moderately complex when testing serum.

Page 30: I’m not certain your example for labeling is understandable by 7th grade level. The phrases “monitor device functions” and “external” controls are not understood by most high school graduates I inspect. You may want to have a few eighth graders read this paragraph for comprehension as you are setting it as the “gold” standard.

Please add a bullet at the bottom of the page for proficiency test failure as you ask manufacturers to encourage waived test users to participate in proficiency testing. Some accrediting agencies require proficiency testing for waived procedures. Many CMS certified labs require proficiency testing for all their waived tests.

Page 31: Add to the first bullet of C. Educational Information how to tell the most current package insert version. I have not done a waived lab survey in 5 years that anyone knew about the date at the bottom of the insert – or that the date only changed when the information changed.