

To Whom It May Concern:

I am a medical technologist with 23 years of experience, which includes time spent in the physician's office laboratory as well as in the hospital laboratory setting. I wish to comment on the questions posed by the FDA regarding the criteria used to determine waived tests. 6958 00 11 17 P2:17

One of the most significant criteria, I believe, is the possible negative outcome of an erroneous or inaccurate result. The best example that comes to my mind is that of the coagulation test where the coumadin dose is determined by the patient's test result. As everyone involved at any time in coagulation testing knows, the minute you attempt to obtain a specimen whether by venipuncture or by fingerstick, you have in some way stimulated that clotting mechanism. Excess manipulation of the needle in a venipuncture or any excessive pressure on the finger causes tissue fluid to be introduced into the sample, thus affecting the result. Having trained and supervised phlebotomist, I can attest to the fact that good techniques take time, practice and skill. My husband is a diabetic, so I have seen first hand, in my home, the lack of expertise, the excessive pressure to obtain a specimen from a fingerstick that was not sufficient in depth to obtain a proper specimen, the reluctance to repeat a possibly erroneous result due to the cost of the testing materials, and the failure to use any quality control or even to match the correct code chip with the test strip. Now, if he is off even 50mg, it is probably not life threatening. However, if he were a coag patient, the results could be deadly including anywhere from bleeding episodes including strokes to pulmonary emboli to deep vein thrombosis based on an improper dose determined by inaccurate test results.

In my experience in moderate complexity laboratories, I frequently see medical assistants given the entire responsibility for accurate test performance even when some of the testing personnel are RNs. There is no way a medical assistant can "correct" the poor techniques of a RN. In addition, often complete staffing changes occur and information is not communicated. I have found instances of intermixing lot numbers of reagents, failure to observe testing times, storage temperatures that are too hot, use of expired reagents even by physicians to name but a few things. Ask yourself, if it is my mother's test, my child's test, my own test, is this acceptable. This is what we see in the real world where staff is very limited, trying to cover many functions with too little time and too little support or supervision. This is staff whose entire training and education is oriented towards direct patient care being expected to perform testing that they have no comprehension of and no skills for.

So, in answer to the posed questions:

1. A. Should a waived test provide an accurate result with no significant clinical or statistical error: Yes.
1. B. Should the result show no error when compared with the same test performed in a CLIA-certified lab: YES. All lab results, if the test is worth doing at all, need to have the same degree of accuracy. A practitioner may make a medical decision for which he/she has liability based on the result of that test. The results may have costly

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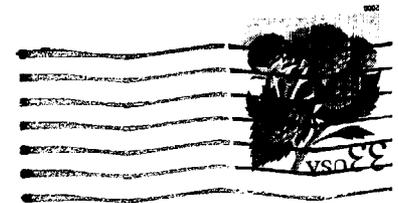
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consequences in terms of required hospitalization, potential long-term negative outcomes for the patient, possible lawsuits etc. With the continually rising cost of medicine and the number and extent of litigation, wisdom dictates caution.

2. A. What criteria should FDA use to determine if a method should be waived? Please consider adding possible negative outcome to the patient if the test result is in error. Also, I would like to address what criteria should **not** be used, specifically, that of a product approved for home use. What one uses in one's own home, where one assumes all responsibility for proper performance and suffers personally the consequences, is and should be unregulated. However, when that same procedure is performed by a medical professional in the treatment of a patient, it is not the same thing either in terms of liability or consequence. To refer to my example of my husband, if he fails to perform his blood sugar and therefor injures himself, he has no one to blame but himself since he performed the test himself. However, if a medical professional (medical assistant and on up) performs the test incorrectly and he suffers consequences, I will surely hold them legally liable. He has to live with the consequences of their mistake, not them.
2. B. Should a test be waived if it has variable accuracy, my belief is no, it should not be waived if the accuracy is variable. A practitioner may make a medical decision for which he/she has liability based on the result of that test. The results may have costly consequences in terms of required hospitalization, potential long-term negative outcomes for the patient, possible lawsuits etc. With the continually rising cost of medicine and the number and extent of litigation, wisdom dictates caution. This is not to imply that there should be any waived test. Actually, glucose testing, even with it's problems is fine, waived streps, urine dips all seem okay to me. But I fear the consequences to patients if we too liberally grant waived status based on manufacturers' pressure.
3. I think if we ask ourselves the question: If that inaccurate result is my result, the result on my child, my mother, my family member and a medication is involved, a treatment, a diagnostic decision, would that inaccurate result be acceptable so that I might have the convenience of testing at home, at the POL, in the mall, wherever.
4. My belief is that all waived tests should come with a disclaimer stating that if the manufacturer's procedure is not followed precisely, including storage instructions, then the person performing the test assumes any liability for any negative outcome. This is similar to the Surgeon General's warning placed on cigarettes. Based on inspections of laboratories, it seems that even when some one is "watching", procedures are not followed, how can we expect compliance when no one is watching.
5. To a well characterized reference method.
6. 100 samples collected and tested by professionals in a professional setting to 100 samples tested and collected by lay persons in a variety of settings. Use only actual

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Docket No. 00N-1394
Dockets Management Branch (HFA-305)
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