

**Public Comment: Waived Test Criteria**  
**Docket 00N-1394**

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**Attention: Clara Sliva, MPA; MT (ASCLS)**  
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The overarching concept of the current waiver criteria emphasizes "no harm to the patient." This approach is in keeping with the very basis of Medicine, the Hippocratic Oath. However there is a risk that in applying the "no harm to the patient" concept, one can easily slip to the extreme of "no value to the patient." To some extent I believe that the current criteria has brought us a menu of waived tests that are "harmless" but also almost "valueless."

In the real world of medical care, it is possible that the most serious harm can actually be done by withholding a treatment or not doing a test that would be of value. In this submission I am proposing that the test classification process incorporate the concept of importance to patient care into its evaluation criteria. This would increase access to valuable information by those relying on waived tests, improve patient outcomes, and almost certainly have positive financial ramifications throughout the delivery system.

I speak on behalf of rural providers, those who practice medicine in locations without ready access to even moderately complex hematology and chemistry tests. Many of them are in rural Alaska, but they are also in places throughout the western and northern states, and in Hawaii. These are the MD's, PA-C's, and Nurse Practitioners, who, without benefit of a white count for a patient with abdominal pain, or without a screen for cardiac markers for a chest pain patient, must make a decision about a medivac that costs the health delivery system thousands of dollars. I speak on behalf of people whose ability to deliver medical care has suffered because of the limited test menu CLIA categories created. It is ironic that the very philosophical basis for CLIA, to "even the playing field," actually had the effect of making it uneven for rural patients and their providers.

I return to the "no harm" concept as applied to the basic tests that these providers need. Yes, it is probably arguable that there is potential for harm by an incorrect test result. However, I would submit that this tenet was violated the day the original waived test list was published. What of the potential for harm caused by an insulin overdose based on an incorrectly performed blood glucose? This scenario is probably the most immediately lethal consequence possible of any incorrectly performed test in ANY category! Or what of the potential for life-threatening complications resulting from an abortion performed on a woman who was not indeed pregnant? Or of the damage to a fetus caused by an xray done on a woman in whom pregnancy was incorrectly ruled out? And these two tests were on the original list!

More recently, the approval of prothrombin times clearly contradicted this rule, and in my opinion, proves that there is already precedent for viewing other factors with at least equal weight with 'potential harm.' When protimes were waived, consideration was obviously given to the clinical importance of the information. It was understood that a delayed result or a never-run test (logistical problems reaching the testing lab) had more potential harm to the patient than the possibility of an incorrectly performed test. I submit that this rationale needs to be

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applied more broadly.

I frequently speak to providers in rural Alaska, those front line people who make decisions about whether a patient needs to be transported to a higher level of care, or whether they can be safely treated in the remote location. These providers are in situations where a moderately complex lab is impractical, and in fact, they have no desire to run a lab. What they need is a few more SIGNIFICANT analytes available to them for their decision making. Screening (semiquantitative) tests are really quite adequate in this environment.

These providers are qualified enough to be empowered with life and death decisions about patient care, the same as their colleagues in a more urban setting (arguably more so, in view of the absence of specialty consults). They are empowered to call for patient transports that are extremely costly to the system, and pose an inherent safety risk to both the patient and the medical crew. Yet they cannot run a membrane assay for cardiac markers or get a white count out of a box! There is something wrong here.

I return to the concept of "significance" in relation to the "'no harm,' 'no value'" discussion. No one is going to die for want of a 10 minute point of care test for mono or bacterial vaginosis or H. pylori. These are the sorts of analytes that have been waived over the past several years, and, while they are fine additions to the available test menu for the physician office lab, their absolute (i.e. life and death) value is really very small. Protimes stand alone as a genuinely clinically important addition to the waived test menu over the past 4 years.

I strongly support the need for manufacturers to prove beyond question that their tests are virtually goof proof (DNP, per Dr. Gutman!) As a laboratorian, I zealously uphold the need for quality testing, and for external system validation. Yet, "DNP" acknowledges that there is in fact imperfection in ANY test system, even the most elaborate test done in a high complexity laboratory. Even a "perfect" test-- if one were to exist-- is subject to pre- and post- analytic variables as well as random systemic error in the process. So all we can truly hope for is Dr. Gutman's "near" perfection. As last year's study of medical errors demonstrates, nothing in medicine is even CLOSE to perfect, and it is unlikely that laboratory testing alone will reach that standard.

In summary, I propose that the test waiver criteria be modified to give priority to tests that providers really need for acute care, ahead of those that are merely "nice to have." Alaskan providers see white counts and cardiac marker screens at the top of this "needed" list, with electrolytes and a liver enzyme (preferably ALT) close behind them. By all means maintain the "simple-to-perform" criteria; but PLEASE make the changes necessary in the process that will get these easy assays of important analytes into the hands of providers who really need them!

*\*The author of this submission has been a medical technologist and laboratory supervisor in rural Alaska for the past 20 years, with total time in the lab field exceeding 30 years and including both hospital and out patient care, the latter in both reference lab and POL environments. My laboratory experience has been in both Canada and Alaska as both a generalist and a hematology specialist. For the past 4 years, I have also been the New Product Specialist for a laboratory supply house, Alaska Scientific.  
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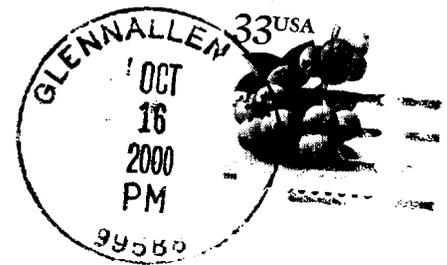
**These comments were previously submitted by fax  
and email to Clara Sliva on 10/13/00.**

**Thank you**

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