

CLIA Waived Testing for Physicians
By C. Anne Pontius, MBA, CMPE, MT(ASCP)
August 14-15, 2000 - FDA Public Meeting

RE: Docket No. 00N-1394

2941 '00 AUG 22 19:53

Dear Ladies and Gentlemen of the Food and Drug Administration,

I am Anne Pontius, President of Laboratory Compliance Consultants. I have been associated with physician office testing since 1985 first as a laboratory manager, then for COLA (formerly known as the Commission on Office Laboratory Accreditation) as an inspector and CLIA (Clinical Laboratory Improvement Amendments of 1988) crosswalk developer. Since 1992 I have been an independent consultant educating physicians on regulations and providing them with compliance tools. Over the past fifteen years, I have conversed with thousands of physicians concerning their testing issues. It is my privilege today to speak on behalf of Roche Diagnostics, Inc. [9115 Hague Road, Indianapolis, IN 46250, (800) 428-5074]. They have asked me to share my perspective on the physician needs and benefits of CLIA waived tests.

Physicians have been faced with the challenges of keeping current in their dynamic marketplace. With the onset of new medicines and technologies, formularies, clinical pathways and combined with the changes of business practices due to managed care, unmanaged care, regulations, decreased reimbursement, an aging population, and a very sophisticated demanding population, physicians have never lost sight of the value a laboratory test provides them. According to Rodney Forsman, Outcomes Administrator at the Mayo Clinic, laboratory results represents 70-80% of the *objective* data in clinical records and that data contributes 70% to the critical decisions made in patient care. Therefore, it is extremely important to have accurate results to ensure downstream patient care is appropriate.

In a reference laboratory where there is no patient, only a specimen, quality control measures are the main elements to determine the validity of patient test results. Like the reference laboratory, testing by the physician incorporates quality control measures, but unlike the reference lab, the physician also looks at a test result in the context of how it relates to the patient's presentation of signs, symptoms, and current and previous diagnoses. Physicians can evaluate whether a patient's test result is valid, or not, better than any one or two quality control measures.

As the Food and Drug Administration (FDA) looks into determining whether a test should have 85, 90, 95, or 100% specificity and sensitivity, we encourage you to include in your

00N-1394

C/11

consideration, whether that type of test result is used in combination with other clinical care factors. If the test is a stand alone diagnostic procedure, where patient signs and symptoms and/or laboratory confirmatory testing may be absent, it stands to reason that a high level of specificity for the procedure would be most prudent for the utilizer of such a result. But, for a procedure where its result is primarily a contributor to the entire clinical picture and where signs and symptoms weigh heavily in the clinical decision of patient care, then possibly, a lesser degree of specificity and sensitivity may be acceptable. One blanket level, for all tests, does not seem appropriate or reasonable for the vast number of tests currently available and for those yet to be cleared.

It is the manufacturer's responsibility to design products that are safe and effective. It is the FDA's responsibility to review those products to ensure the safety and effectiveness for a consumer's use -- a consumer being a healthcare professional and/or lay person. It is *solely* the physician's responsibility to ensure he/she provides appropriate care to a patient. That is why physicians rely on the manufacturer's expertise, along with your guidance, in the form of appropriate product labeling. Most package inserts have buried in their contents, at microscopic reading levels, information regarding specificity and sensitivity. We strongly encourage the FDA to require that type of information be bold and eye-catching. Physicians do not want to be laboratorians, but they do want to know the important aspects of the tests they utilize. In lay terms, this information could be provided to them so that it becomes a useful tool in the realm of patient care.

Congress has given you a recognized difficult task of defining the statute verbiage of "an insignificant risk of an erroneous result," and "pose no unreasonable risk of harm to the patient if performed incorrectly." Medicare has stated, as well as most managed care entities, that only tests that are "medically necessary" should be ordered by physicians. And, that is what physicians do -- they order medically necessary tests. It does not matter to the physician whether the tests are waived, moderate or high complexity; they expect a result that represents a true value within the bounds of clinical significance. All the results have some level of significance, and if the result is erroneous then adverse consequences exist, albeit, some may be minimal.

Waived testing is currently performed by all levels of analysts – from individuals with formal laboratory training to individuals that are simply self-taught. Physicians expect test results to

have the same level of accuracy -- no matter who performs them. That is what the manufacturers need to prove – that appropriate operators can obtain the same result.

The laboratory industry, and to some extent the FDA, when faced with a dilemma about a new or existing test or product, turns to the “gold standard.” When CLIA’88 was passed, the Congressional leaders accepted with their verbiage, a list of tests they felt appropriate for the waived category – thus creating the “gold standard” of what constitutes a waived test. Let’s look at one of those:

Glucose – “an insignificant risk of an erroneous result” and “pose no unreasonable risk of harm to the patient if performed incorrectly”

That has been debatable since it appeared in writing. But it was the intent of the Congressional leaders to connect that verbiage with that type of test. A test that requires reading of instructions, obtaining a specimen, proper technique to obtain a valid result, and the ability to capture a result. Look at the characteristics of the tests in the original waived list, and use those to define the gold standards of a waived procedure. It is those characteristics that will give you the definition of the verbiage.

The President / CEO of the Medical Group Management Association (MGMA), William F. Jessee, MD states “MGMA and our members are increasingly concerned about expanded administrative requirements that add new costs to medical practices, without demonstrated benefits to patients. We believe that the current CLIA waived testing policy has worked well to protect patient safety, without adding undue costs to medical practices. We urge that commonly performed tests in office practice continue to be waived unless clear evidence is presented that patients may be harmed as a consequence.”

The September 13, 1995 proposed rule states the CDC’s, now the FDA’s, intent is to follow CLIAC’s recommendation that PHS reevaluate tests that were previously categorized as waived against any new regulatory criteria. We propose that, in the absence of any statistics to document that the current waived tests have caused harm to patients or consumers, that those procedures be permanently grandfathered into the waived category. This would provide a significant cost saving to physicians, manufacturers, and the FDA.

Just as the FDA deal with issues for quick turn around time for device clearances, so do physicians. They want products that are available to them quickly once developed and products

that provide quick results once in hand. In areas needy of clinical care, physicians often have but one opportunity to exam, treat, prescribe, and educate a patient. Without the objective data from a test, readily at hand, the physician is crippled from providing the best possible care. I quote Dr. John Benjamin, Professor of Pediatrics at the Medical College of Georgia, “Waived testing has been good for the health of children. Without access to these tests, children would have suffered. As a professor of pediatrics in a medical school for the last 6 years, I have created a course to teach pediatric residents how to perform waived testing. All residents going into practice have taken this elective; they know that this will be an important part of their providing good care to their patients.”

In conclusion, we ask that the FDA encourage manufacturers to develop technologies that are simple, accurate, and precise. Then, reward these innovative manufacturers by removing obstacles that delay or impede their ability to market their achievements to physicians. If you feel there are simply too many tests showing up in the waived category for comfort, take it as a hint. They are showing up for a reason -- physicians are demanding them. As of April 2000, there were roughly 71,000 physician offices that held CLIA Waived and Provider Performed Microscopy Procedures (PPMP) certificates. In addition over one thousand hospitals have a Waived certificate. Waived tests are in demand because they promote the efficiencies necessary to provide high quality patient care. So, this is not a subtle hint, but an obvious one. Physicians want affordable, user-friendly testing methods and devices with clear and obvious defined levels of accuracy and precision.

We are pleased that the FDA is now responsible for CLIA categorization and look forward to your success of dealing with this issue. Thank you for this opportunity and consideration of these remarks.

Respectfully submitted,

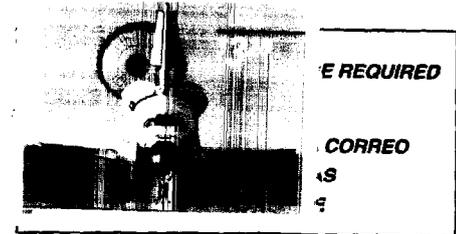
C. Anne Pontius, President
Laboratory Compliance Consultants, Inc.
4900 Waters Edge Drive
Suite 170
Raleigh, NC 27606
(919) 859-3793
(919) 859-3792 fax
caplcc@aol.com



**PRIORITY
MAIL**

UNITED STATES POSTAL SERVICE

www.usps.com



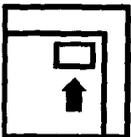
**HOW TO USE:
COMO USAR:**



- 1. COMPLETE ADDRESS LABEL AREA**
Type or print required return address and addressee information.

ESCRIBA LA DIRECCION EN EL AREA INDICADA
Escriba en letras de imprenta la dirección del remitente y la del destinatario.

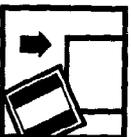
Laboratory Compliance Consultants, Inc.
4900 Waters Edge Drive
Suite 170
Raleigh, NC 27606



- 2. PAYMENT METHOD**
Affix postage, meter strip or PC postage label to area indicated in upper right hand corner.

FORMA DE PAGO
En el área superior del lado derecho, coloque sello postal, franja de máquina franquadora o etiqueta de franqueo Impreso por computadora.

Dockets Management Branch (HFA-305)
Food AND Drug Administration
5630 Fishers Lane
Rockville, MD 20857



- 3. ATTACH LABEL (If provided)**
Remove label backing and adhere where indicated.

ADHIERA ETIQUETA (Si le fue provista)
Remueva la parte posterior y adhiera sobre la zona de dirección indicada.

RE: Docket No. 00N-1394

PLACE LABEL HERE
ADHIERA ETIQUETA AQUI

The efficient **FLAT RATE ENVELOPE**. You don't have to weigh the envelope... just pack all your correspondence and documents inside and pay only the 2 lb. Priority Mail postage rate. **We Deliver.**

El eficiente **SOBRE DE TARIFA ÚNICA**. No tiene que pesar este sobre... simplemente coloque toda su correspondencia y documentos adentro y pague sólo la tarifa de franqueo por correo Priority Mail de 2 libras. **Le Servimos.**