QUALIGEN

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May 29, 2001

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20850

Re: Docket No. 01D-0044; Comments on "Medical Devices Draft Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver: Draft Guidance for Industry and FDA."

Dear Sir/Madam:

These comments are being submitted on the above-referenced document on behalf of Qualigen, Inc., a manufacturer of in-vitro diagnostic products. We commend the FDA for initiating this proceeding and we urge the FDA, in evaluating the comments it receives and undertaking the subsequent rulemaking, to focus squarely on the intention of Congress in passing CLIA which is that the CLIA review and waiver process provide increased patient access to timely and reliable diagnostic testing. With that standard in mind, we offer the following comments.

A substantial source of innovation in IVD testing is coming from small, entrepreneurial companies such as Qualigen that do not have the resources of the large multinational corporations. The development of a CLIA waived test is a risky and uncertain undertaking. It can require years of research and development work that can cost million of dollars, with no guarantee of success. The ultimate commercial success of an in-vitro diagnostic product and the return on and of investment for the developer can be highly dependent on its ability to obtain CLIA waived status for the test. In order to stimulate such innovation and risk taking, it is essential for FDA to provide developers with clear, logical and consistent guidelines for the classification of CLIA waived tests. Absent such clear, consistent and logical guidelines, research and development efforts can be misdirected and product development expenditures needlessly wasted, resulting in fewer innovative diagnostic test products being brought to market and higher costs for those that are.

One example of the ambiguity and conflict that should be clarified by the FDA is the criteria that a simple test use "direct, unprocessed specimens." This requirement has prevented tests that use a centrifuged blood sample to obtain plasma or serum from being classified as CLIA waived. The same criteria has been applied to prevent CLIA waived status for urine and other fluid-based tests

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that require a spun sample. We urge the FDA to revise this standard in a manner that will not categorically deny CLIA waived status to tests that use a centrifuged sample. In this respect, the FDA should consider the following:

1. The "direct, unprocessed specimens" standard is in conflict with the standard that a simple test "requires only basic, non-technique-dependent specimen manipulation." The use of a centrifuge satisfies the latter criteria. Small, modern centrifuges are non-technique dependent, require no specialized or technical training, and can be operated by a person with a seventh grade education. Logically, the use of a centrifuge to prepare a plasma or serum sample is, in fact, non-technique dependent sample manipulation and should not prevent a test from being granted CLIA waived status.

2. No CLIA certification is required to operate the centrifuge. Thus, it is illogical to deny CLIA waiver status to a test that satisfies all of the other CLIA waiver criteria solely on the grounds that a centrifuge is used to spin the sample before performing the test. Most physician offices have a centrifuge and use it to prepare samples being sent to a laboratory and no CLIA certification is required to do this. If an untrained, uncertified operator can centrifuge a sample before it is sent to a lab for testing, the same standard should be applied to CLIA waived tests.

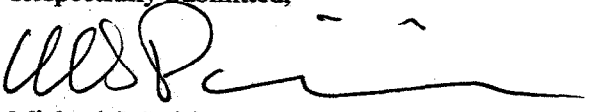
3. The requirement that waived tests use only whole blood specimens, as opposed to plasma or serum, significantly complicates the product development process, adds significantly to the cost and complexity of the systems used to perform these tests, and thereby discourages companies from developing new, innovative IVD tests. In each case, the issue should not be whether a test requires the use of a centrifuge to spin the sample, but rather whether the developer can demonstrate that a test employing a centrifuge for sample preparation is sufficiently simple that untrained lay users and trained laboratory technicians can obtain acceptably comparable test results when following identical manufacturers instructions for use. In the end, if there is a clinical advantage to the use of whole blood in performing a test, as opposed to plasma or serum, market forces will lead to its development and use in preference to the serum or plasma-based test.

Not only does such arbitrary criteria cause confusion and stifle development, it also has led to inconsistent and irreconcilable decisions on waiver classifications. A spun hematocrit test that uses a centrifuge is waived and the centrifuge used to perform this test is no more simple to operate than any other modern centrifuge. There also are CLIA-Waived tests for which the level of sample preparation is more technique dependent than the simple process of spinning a sample in a centrifuge. Examples of this are the QuickVue Chlamydia and QuickVue Influenza tests manufactured by Quidel Corporation. A review of the directional inserts for these tests discloses a multi-step manipulation process that requires close adherence to the directions and is more complicated to perform than spinning a sample in a centrifuge.

Another standard contemplated by the Guidance document that is unnecessarily burdensome and will be particularly stifling to the small, entrepreneurial companies that foster innovation in IVD testing is the huge, non-statistically based clinical studies proposed to be required. Studies of the size contemplated by the guidelines will be extraordinarily expensive for many types of test products and will decrease developers' willingness to invest in the development of CLIA waived tests. Smaller studies can be statistically supported and will not jeopardize the public interest.

We encourage FDA to use its leadership in this area to articulate clear and consistent standards for CLIA waiver of IVD products. In doing so, we urge FDA to continue to consider the intention of Congress in seeking to expand the availability of IVD test for patients and to recognize the interests of small, entrepreneurial companies that are the stimulus for many innovative products in IVD testing.

Respectfully Submitted,



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