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July 14, 2004

***BY E-MAIL AND OVERNIGHT DELIVERY***

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health  
Food and Drug Administration  
HFZ-440  
2098 Gaither Road  
Rockville, MD 20850

**Re: Correlogic Systems Inc. Reference Laboratory – OvaCheck Testing Service**

Dear Dr. Gutman:

We received your letter of July 12, 2004, providing the results of the Food and Drug Administration (“FDA”) review of the OvaCheck testing service based upon our presentation of March 17, 2004 and follow-up letter of May 8, 2004. As you know, the OvaCheck testing service is intended as an aid in the detection and early identification of protein expression patterns associated with ovarian cancer. We are pleased with FDA’s decision that it does “not intend to regulate the activities of Correlogic’s Reference Laboratory (CSIRL) or its laboratory collaborators, LabCorp and Quest, in the ongoing provision of the OvaCheck testing service.” As FDA recognized, there is sufficient regulatory oversight of this testing service under the Clinical Laboratory Improvement Amendment of 1988 (“CLIA”) (42 C.F.R. Part 493).

We respectfully do not agree, however, with FDA’s position that the software used to provide the OvaCheck testing service is a medical device in commercial distribution and subject to FDA premarket review. Your letter explained that the software falls under the definition of a medical device in 21 U.S.C. § 321(h)(2), but does not explain why FDA believes that the requirement of commercial distribution of a medical device in interstate commerce is met. As best we can discern, FDA is likely basing its regulatory jurisdiction on Correlogic’s installation of software at the facilities of its laboratory partners.



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As we explained in our letter of May 8, we believe that the installation of this auxiliary software is an insufficient foundation for FDA jurisdiction. Nonetheless, we are revising the configuration of the service to remove the software from LabCorp and Quest. Our collaborators will now collect spectral data using their own general laboratory equipment and related software; we will not provide them with any special software or equipment whatsoever. They will send us a computer disk with all of the spectral data thus generated through the U.S. mail or one of the overnight parcel services. We will analyze the data using in-house developed software and provide a written report. The attached flow chart illustrates the new configuration of the service.

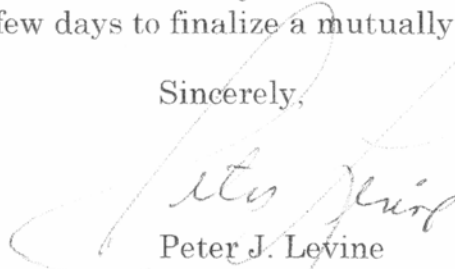
We trust that, with this new configuration, FDA will agree that it does not have jurisdiction over the in-house developed, Maryland-based software Correlogic uses to provide the CLIA-regulated OvaCheck testing service at its own site.

Of course, if at a later time Correlogic determines that it wishes to install specialized software on-site at other laboratories, we will consult FDA about the regulatory implications of the plan.

We think it is critical to meet at the earliest possible opportunity to more fully discuss these complicated regulatory issues. We believe that a meeting would be conducive to a full interchange of views and help prevent any misunderstandings as to the factual, legal, and regulatory issues under consideration.

I would be available to meet any time next week except for Friday, July 23. I will call you in a few days to finalize a mutually convenient date.

Sincerely,



Peter J. Levine  
President and CEO

cc: Jonathan S. Kahan, Esq.  
Jeffrey K. Shapiro, Esq.