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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061,
Rockville, MD 20852

RE: Comments on Draft Guidance, Multiplex Tests for Heritable DNA Markers, Mutations and Expression Patterns
Docket # 03D-0120

June 11, 2003

Dear Sirs;

We read with interest the proposed guidance and would like to offer the following comments:

In Section II, the currant draft document recommends that submissions include evidence of accurate and reliable analytical performance, as well as appropriate controls. It is the purpose of traditional external controls to assure the acceptable performance of the assay system; however, it is worthy of note that traditional controls may not be necessary for certain genetic tests. The operating principles of some new platforms incorporate internal mechanisms to adequately qualify results. Due to the low risk of undetected error and high unit costs, the use of run-based external controls may not be practical or appropriate for all types of systems. Conversely, reliance upon a negative output (no response) to yield an informative result carries the inherent risk of false negatives. Technologies which rely on this approach may place a greater burden on the end user to assure quality. Such risk should be mitigated through the use Alternative QC procedures considered within the framework of genetic tests. Thus, since the technology presents the full range of control issues, it may be appropriate for this guidance to further address minimum requirements for controls.

In Section IV.B.2, it would be useful to clarify the meaning of "clinical truth."

Thank you for the opportunity to provide input to this document.

Sincerely,

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