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Division of Dockets Management
Food and Drug Administration

Submitted via Regulations.gov

Re: Docket No. FDA-2013-D-1358 - **Draft Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Transfusion and Transplantation**

The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine and the *in vitro* diagnostics industry.

We are aware of the comments submitted by the American Society for Histocompatibility and Immunogenetics (ASHI), dated February 3, 2014, and share its concerns. Section G of the proposed guideline - Additional Consideration: changes to the device (page 9 and 10) - does raise concerns about the ability of manufacturers to provide critical reagent and software updates. HLA allele definitions change frequently as rare alleles are described; nomenclature changes; HLA typing ambiguities are found.

Manufacturers must regularly update HLA typing kits and a requirement to submit a new 510(k) would make it impossible for them to do so in a timely enough fashion to enable HLA laboratories to provide their transplant physicians with the most current and accurate molecular typing results. Negative outcomes for transplant patients could be severe if critical HLA mismatches between donors and recipients are not recognized.

AMP respectfully recommends that FDA allow manufacturers of HLA typing kits continue following the FDA guideline "Replacement Reagent and Instrument Family Policy," without having to submit a 510(k), and to consult with ASHI and transplant physician organizations on the potential consequences of new requirements before finalizing the guidance.

Thank you for your consideration of our comments.