Association for Molecular Pathology
Promoting Clinical Practice, Translational Research, and Education in Molecular Pathology
9650 Rockville Pike, Bethesda, Maryland 20814
Tel: 301-634-7939 ▪ Fax: 301-634-7990 ▪ Email: amp@amp.org ▪ www.amp.org

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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Docket ID: FDA-2013-D-0258

Comments submitted electronically at www.regulations.gov

To Whom It May Concern:

Thank you for the opportunity to submit these comments on the draft guidance titled, "Molecular Diagnostic Instruments with Combined Functions." The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,000 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.

AMP commends the U.S. Food and Drug Administration (FDA) for publishing this draft guidance, and for recognizing the importance of allowing FDA approved/cleared instruments to include "open channels." Purchasing approved/cleared molecular diagnostic instruments imposes significant costs on laboratories. Therefore, the ability to use these tools for a wide range of assays, both FDA approved/cleared and laboratory developed, helps support cost effectiveness and the ability of laboratories to choose to purchase FDA approved/cleared test systems. Finally, it helps broaden the benefits our members can provide to their patients.

On Recommendation #6, "Third Party Assay Developers," AMP encourages the FDA to be more specific about the requirements to submit amendments to previously approved or cleared applications for third party assays. Specifically, if the instrument manufacturer modifies the instrument or software, the draft guidance document is unclear as to whether or not providing updated instructions to the developers is sufficient. AMP asks that the FDA further clarify and explain what instrument or software changes, or other related circumstances would cause FDA to require a third party developer to resubmit or amend an application for a previously approved/cleared assay.

Additionally, further information about the reporting requirements in the section on "MDR Reporting" would be very helpful. Though these events may be rare, manufacturers need clear instructions on the notification actions required when an adverse event related to non-FDA approved/cleared molecular diagnostics performed on these "open channels" occur. In some instances, reporting to the manufacturer of the platform meets all regulatory standards, but at other times, laboratories are required to report the event directly to the FDA. The draft guidance refers to 21 CFR 803 with respect to reporting

requirements, but appears to limit reporting requirements to "malfunctions, injuries, and deaths," which is potentially less broad than 21 CFR 803.10. AMP requests that the FDA outline in which instances the FDA must be notified of an adverse event when using the instrument for a non-FDA cleared or approved diagnostic. Further, AMP urges that for instrument uses for which approval/clearance is not required, FDA explicitly clarify that only deaths or injuries to patients that occur as a direct result of test malfunction are reportable events. This clarification will focus attention squarely on direct patient harms due to a malfunctioning test, and potentially help conserve valuable resources through the elimination of ambiguity. Finally, with multi-purpose instruments, there are numerous parties involved in the test process, and AMP requests delineation of the particular entity on which the reporting obligation is placed under specific circumstances of use.

To reap the most benefit from this policy, educating the user community on these practices is essential. With its focus on molecular diagnostics, AMP is well positioned to educate its members and others from the laboratory community. AMP hopes to partner with the FDA on a meeting to educate stakeholders about this significant and much needed policy regarding molecular diagnostic instruments with combined functions.

Thank you again for the opportunity to submit these comments on the draft guidance and AMP looks forward to working with the FDA to finalize this guidance document. If you have any questions or if AMP can be of further assistance, please contact Mary Williams at mwilliams@amp.org or 301-634-7921.

Sincerely,

Jennifer L. Hunt, MD, MEd
President