



AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

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June 6, 2000

Joseph L. Hackett, PhD
Dockets Management Branch (HFA-305)
Docket Number 00D-0109
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Dr. Hackett:

Thank you for providing the opportunity to comment on the draft guidance document entitled "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices."

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists (PhD), and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the world's leading organization for the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually.

ASCP understands the purpose of the guidance document is to ensure well-standardized, reliable, and reproducible tests for determining the *in vitro* susceptibility of infectious bacteria. However, ASCP is concerned about moving ahead in this exciting field too quickly, especially because failure of *in vitro* tests to detect *in vivo* bacterial resistance has been shown to be clinically significant. As is stated in the draft guidance document (pages 2-3), the National Committee for Clinical Laboratory Standards (NCCLS) standard reference methods are based on 16-24 hours of incubation for aerobic bacteria and 48 hours for anaerobes. ASCP recognizes that earlier results may provide clinical advantages, but there is no NCCLS reference standard utilizing a less than 16-hour incubation period. Should this not be done prior to FDA reclassifying these devices?

Regarding challenge organisms selected for comparative study of the device, the guidance document requires that the challenge isolates be sent to only one site for performance testing (page 10). In that scenario, site-to-site comparisons are lost. ASCP recommends using more than one site for challenging the device's reliability in detecting intermediate and resistant strains. Also, ASCP requests clarification from the FDA as to why testing challenge strains using the reference method has been deemed unnecessary.

00D-0109

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Dr. Joseph L. Hackett
May 30, 2000
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ASCP appreciates the statement in the clinical testing section of the guidance document, "performance from the clinical studies should be representative of the finished product, as intended for use in the clinical laboratory." However the subsection on broth and agar dilution test methods (page 13) states that "regardless of the final marketed format of the Minimal Inhibitory Concentration device, the comparative test panel should match the reference panel full dilution format," which seems to contradict the former statement.

The draft guidance states that repeat testing is an *option* for the determination of a systematic error. ASCP recommends mandatory repeat testing in order to determine whether an error was a single occurrence or if it signifies an inability to correctly classify a microorganism.

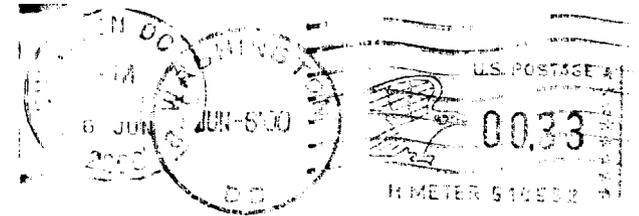
If you have questions or need additional information, please give me a call or contact Jennifer Burpee, MPH, ASCP Regulatory Associate, at (202) 347-4450.

Sincerely,

Stebbins Chandor, MD, FASCP
President



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