



**AMERICAN
SOCIETY FOR
MICROBIOLOGY**

Public and Scientific Affairs Board

August 14, 2003

Rhonda Whalen, Chief
Laboratory Practice Standards Branch
Division of Laboratory Systems
Public Health Practice Program Office
Centers for Disease Control and Prevention
4770 Buford Highway, NE, Mailstop F-11
Atlanta, GA 30341-3717

Re: CLIA required end user quality control for commercially prepared DTM culture media

Dear Ms. Whalen:

Thank you for contacting the American Society for Microbiology (ASM) to provide expertise to the Clinical Laboratory Improvements Advisory Committee (CLIAC) regarding a quality control issue pertaining to dermatophyte culture medium. ASM is the largest educational, professional, and scientific society dedicated to the advancement of the microbiological sciences and their application for the common good. The Society represents more than 40,000 microbiologists, including scientists and science administrators working in a variety of areas, including biomedical, environmental, and clinical microbiology.

The intent of the 1988 Clinical Laboratory Improvement Amendments (CLIA '88) was to ensure that laboratory testing is performed correctly with appropriate quality control. ASM supports CLIA's intent and furthermore believes that quality control thresholds for all microbiological media be standardized in all laboratory settings.

With respect to the concern raised by Walter Wood, M.D., in his letter to CLIAC about end user quality control (QC) for commercially prepared dermatophyte test medium (DTM), recently published data from *Results of the Survey of the Quality Assurance for Commercially Prepared Microbiology Media* (Archives of Pathology and Laboratory Medicine: Vol. 127, No. 6, pp. 661-665, 2003) demonstrates the failure rate of DTM as collected by the College of American Pathologists (CAP) in its survey of CAP accredited laboratories in 2001. According to the data, 9 lots were found to fail QC for a failure rate of 1.08%, out of 836 lots and 32,359 items tested. The value of 1.08% is more than double the cut-off failure rate of up to 0.5%, which will be required by the National Committee for Clinical Laboratory Standards (NCCLS) in its next standards revision. ASM supports the new NCCLS standard to require end user QC of DTM due to its high failure rate when tested by end users. While only those media types defined by $\geq 1,000$ lots or $\geq 100,000$ items are considered to have significant QC

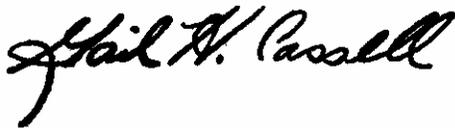
experience for calculation of an extrapolated failure rate, the article from Archives of Pathology and Laboratory Medicine clearly indicates a high failure rate for DTM.

Furthermore, an article from the Archives of Dermatology (99:203) by Taplin, Zaias, Rebell and Black (1969) indicates that saprophytic fungi may redden DTM if the specimen material is heavily contaminated, allowing saprophytic fungi to be mistaken for *Microsporum*, *Trichophyton* or *Epidermophyton*. According to the article, "...the use of quality control strains will ensure that the dermatophyte test medium is performing properly and supports the growth of dermatophytes."

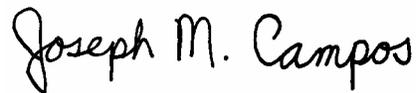
Based on the data from Archives of Pathology and Laboratory Medicine and the Archives of Dermatology referred to in this letter, ASM does *not* recommend exempting DTM from end user QC.

ASM appreciates the opportunity to comment on this matter and would be happy to respond to any additional questions or concerns that you may have.

Sincerely,



Gail H. Cassell, Ph.D., Chair
Public and Scientific Affairs Board



Joseph M. Campos, Ph.D., Chair
Committee on Laboratory Practices
Public and Scientific Affairs Board