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DERMATOLOGY

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Re: COMMENT to the CLIAC regarding CLIA required end user quality control for commercially prepared DTM culture media

Dear Members of the Clinical Laboratory Improvement Advisory Committee (CLIAC):

I am sending this formal comment to you for consideration of revision of the current CLIA regulation requirement that **end users** perform their own quality control for DTM media.

In the past a document from the National Committee for Clinical Laboratory Standards (NCCLS) was referenced as a reason for requiring end user quality control for dermatophyte test media (DTM), much to the consternation of dermatologists who used to use this media in their offices. The requirement made it impractical for dermatologists to use DTM and forced them to change to other media that do not have this end user QC requirement. By submitting my expert opinion, I hope to help convince your committee that this "end user" media QC requirement should be abandoned for DTM as well as remain optional for Mycosel and Sabouraud's agar for purposes of dermatophyte culture. The most recent May 9, 2003 draft of the revised NCCLS document M22-P2 pertaining to quality control for commercially manufactured media notes that there is insufficient data about DTM failure rates, but exempts Sabouraud's agar and Sabouraud's agar with antibiotics from end user QC because there is sufficient data.

In my expert opinion, variants of Sabouraud's agar with antibiotics including DTM and Mycosel agar (Mycosel is not separately listed on table 1B of the draft M22-P2) should be considered variants of Sabouraud's agar with antibiotics, which should all be in the same end user QC exempt category based on the very sufficient data for Sabouraud's agar with antibiotics.

I disagree with the rigid policy of footnote "b" of Table 1B that states, "...Media with insufficient data for categorization is considered non-exempt and QC is required." On the contrary, I think that if there is insufficient data, consideration should be given to the individual circumstances of use and the broad consensus among the majority of end users as to whether "end user" QC makes any logical sense, and whether the similarity to other exempt media means end user QC should NOT be required.

I am particularly concerned as a practicing dermatologist because the current CLIA end user QC requirement for DTM media has prohibited its practical use by essentially all office based dermatologists and NCCLS guidelines have apparently been used as the excuse. DTM has been used very successfully over many years by dermatologists as an office test, and apparently NCCLS was consulted but the American Academy of Dermatology was not consulted. DTM apparently is not used as much by larger reference labs and therefore there is not much data. However, I would like to point out that DTM would be useful to dermatologists even if its failure rate were shown to be much higher than currently estimated.

It does not make sense to me that either NCCLS or the CLIAC would require the same QC thresholds for all microbiological media in all laboratory settings. For example, I would expect a large reference lab to have much more stringent standards than those recommended for the lab of an office physician. This issue aside, at the present time the revised M22-P2 draft does not present credible evidence that the failure rate of growth support for DTM varies at all from the failure rate of the similar exempt medium SAB w/CG. Table 1B gives some very limited data from the College of American Pathologists and notes that the data are insufficient. This Table 1B also does not separately list Mycosel agar, another variant of Sabouraud's agar w/ antibiotics, which traditionally has been widely used by office dermatologists without any need for "end user" QC. Unless there is significant data otherwise, I think both DTM and Mycosel agar should simply be footnoted on the table 1B or added to the table as included under Sabourauad's agar with antibiotics, and therefore exempted from "end user" QC based on the Sabouraud's agar data. Again, in the absence of sufficient data that DTM is substantially different, and in view of the similarity to Sabouraud's agar, the benefit of the doubt should go to the absence of need for "end user" QC, not for instead requiring "end user" quality control. Again, the draft presents no credible reason to believe that the failure rate of growth for DTM is any different from the failure rate of SAB w/ CG, but simply notes that the data from the American College of Pathologists are not sufficient. No effort seems to have been made to obtain additional quality control data from manufacturers who are most likely to have the appropriate data. Instead, the committee simply imposed an end user QC requirement because of insufficient data. I believe that media manufacturers data should be considered so that QC data from the American College of Pathologists is not the only source of QC data relied upon by either the NCCLS or the CLIAC. This is particularly true for the CLIAC, where the conclusions create mandatory CLIA requirements as opposed to the NCCLS where the conclusions are advisory in nature.

The NCCLS draft also does not clarify the end point being used to define failure of QC for DTM in Table 4. This endpoint definition is important because an end point of failure to distinguish dermatophyte from not dermatophyte for QC purposes would not be a fair comparison to an endpoint of growth or no growth on SAB w/antibiotics. DTM could be getting an unfair comparison leading to a misleading failure rate if the endpoints are not in fact the same. Again, I do not believe that there is any data or logical reason to believe that SAB w/CG is any different than DTM with regard to growth or no growth, and DTM should simply be footnoted as "exempt" because it is essentially a variant of SAB w/ antibiotics.

With regard to the NCCLS arbitrary choice of 0.5% as a threshold failure rate above which requires end user QC, I would like the committee to question the assumption that any arbitrary failure rate should trigger mandatory end user QC in all cases. Why is the trigger 0.5% instead of 5% or 10%? Why is a standard of a large "reference" lab being imposed upon a small physician office lab? Is it reasonable or desirable for the standards of all labs to be exactly the same? I think is not reasonable. Large clinical labs that identify genus and species of fungi frequently use other media listed on table 1B and have ready access to ATTC control organisms and the ability to incubate at both 25 degrees and 35 degrees centigrade for end user quality control. However, the office-based dermatologist who does a relatively small volume of cultures does not find "end user" quality control practical -- this has essentially forced the office-based dermatologist to abandon useful DTM media and use instead use Sabouraud's only. This has probably harmed accuracy of testing rather than helped. Please note that many tests and examinations that physicians do come nowhere even close to such a low false positive or false negative rate as 0.5% and they are still very useful tests. Physicians do have the good sense to realize that a fungal culture is not 100% accurate and that there are false positives and negatives, and that these tests need to be repeated and results often correlated with other tests as well as physical examination. The consequences of an inaccurate dermatophyte fungal culture are not the same as the consequences of inaccuracy of certain other cultures or tests which might be more serious. The CLIAC should use good judgment and flexibility and not misuse NCCLS guidelines that are advisory in nature to create CLIA mandatory requirements. I think the NCCLS M22-P2 draft needs a **bold** paragraph stating clearly that NCCLS recommendations are in fact recommendations, and that these are NOT intended to be interpreted as appropriate in all situations and are not intended to be incorporated into regulatory requirements such as CLIA regulations.

In summary, it is my expert opinion that manufacturer quality control is practical for office dermatologists -- however, "end user" QC is not practical. The requirement for end user QC should be eliminated as soon

a possible so that dermatologists can better serve their patients. I believe your committee should of course seek other expert opinion than mine, in particular those of other dermatologists and qualified academic dermatophyte mycologists who can render additional opinions about the suitability of DTM as an office test. Thank-you for your attention and consideration.

Sincerely,

Walter Wood

Walter H. Wood, M.D.

cc: The American Academy of Dermatology
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