

CLINICAL RELEVANCY SPECIMENS REVIEW

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WHAT IS THE PURPOSE OF CLINICAL RELEVANCY QUALITY CONTROL SAMPLES?

In 1995 CMPT introduced quality control samples to test not only a laboratory's analytic ability to identify organisms and perform susceptibility testing, but also to evaluate the total processing of the sample — the pre- and post-analytical phases by the laboratory.

In **CMPT Connections** premier issue - March 1997, Michael Noble chair, CMPT stated that CMPT is endeavoring to provide samples that are more representative of clinical specimens.¹ Thus, polymicrobial samples and samples containing only normal flora have been sent out as challenges.

Clinical relevancy was introduced during the 1970s and since then many publications including *Cumitech*, the *Clinical Microbiology Procedures Handbook*, and the NCCLS manuals have provided Microbiology laboratories with practical guidelines for processing samples from pre-analytical assessment to final reporting.

HOW DOES CMPT EVALUATE THESE SAMPLES?

Two questions of paramount importance to consider are:

1. Does this report provide the physician with relevant information?
2. How does this result affect patient care?

For example, M61-1, May 1996 presented as a simulated urine sample from an elderly female containing mixed flora including *Escherichia coli*, *Serratia* species, *Pseudomonas aeruginosa* and coagulase negative staphylococci. With cultures of this type, laboratories are expected to evaluate the culture to determine if further workup is appropriate. Basing the decision on the commonly accepted opinion that a mixed growth of 100×10^6 cfu/L from a voided sample is considered probable contamination², speciating and reporting antimicrobial susceptibility results could give misleading information to the physician.

Similar interpretation was expected for samples M62-1, August 1996 and M71-1, May 1997. These were simulated nose and throat swabs. Both contained multiple organisms representative of normal respiratory flora. Again, laboratories were not expected to report these organisms individually, but were expected to indicate that the isolates were consistent with nonpathogenic flora. The report to the physician would influence decisions regarding antimicrobial therapy.

Another aspect of clinical relevancy is the number and appropriateness of the antibiotics reported. NCCLS publishes guidelines for suggested groupings of antibiotics that should be tested against specific isolates.³ **CMPT expects participants to report antibiotics that are appropriate for both the organism and the site from which the organism was isolated.** Commercial methods

for susceptibility testing often include large panels of antimicrobials to accommodate a wide and varied range of organisms. The laboratory must determine the appropriate antibiotics to choose for their facility. **Reporting excessive numbers of antibiotics is not only confusing to physicians, but can also be misleading and should be avoided.**

PAPER CHALLENGES

Since specimen collection, transport, and accession scenarios cannot be easily challenged by conventional CMPT samples CMPT will be providing paper challenges to determine laboratories specimen rejection criteria.⁴ Again, CMPT will evaluate these samples by asking such questions as:

1. What is an acceptable time for specimens to be in transit prior to processing?
2. What samples are deemed unacceptable for the tests requested?

IS CLINICAL RELEVANCY DIFFERENT FROM "REPORT AS PER LABORATORY PROTOCOL"?

Yes, the intent of clinical relevancy specimens is to encourage laboratories to question their processing and reporting procedures. In order to get the most benefit out of clinical relevancy challenges laboratories should use the same wording as they would use in a clinical sample with the same results.

CMPT hopes to provide samples which, in addition to testing a laboratory's technical abilities also stimulate interest and discussion.

REFERENCES

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3. M100-S8. 1998. Performance standards for antimicrobial susceptibility testing. 8th informational supplement, NCCLS 18:1.
4. Noble MA. 1998. Proficiency testing around the laboratory cycle. *CMPT Connections* 1:4. p. 1.