

## CLSI Publishes EP14—Evaluation of Commutability of Processed Samples, 4th Edition

*EP14 was developed for manufacturers and providers of proficiency testing or external quality assessment programs.* 

MALVERN, PENNSYLVANIA, UNITED STATES, July 28, 2022 /EINPresswire.com/ -- The Clinical and Laboratory Standards Institute has published the 4th Edition of EP14—Evaluation of Commutability of Processed Samples.

|   | 4th Edition  |  |  |
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| EP14  |              |  |  |
| Evaluation of Commutability<br>Samples  | of Processed |  |  |
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| This document provides guidance for evaluating the  |              |  |  |
| commutability of processed samples by determining if they<br>behave differently than unprocessed patient samples when t<br>dwantitative measurement mocedures are compared. | two          |  |  |
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EP14 was developed for manufacturers and providers of proficiency testing or external quality assessment programs, although it is useful to clinical laboratories as well. The document helps users 1) determine whether noncommutability is the source of unexpected results that are

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EP14 helps identify noncommutability by comparing a limited number of processed samples with unprocessed samples in a regression across two measurement procedures." Jeffrey R. Budd, PhD, Member of the EP14 Document Development Committee sometimes observed with processed samples when two quantitative measurement procedures are compared, 2) display the magnitude of the effects, and 3) ensure that laboratory performance is evaluated fairly if noncommutability is present. The suggested protocol was developed using unprocessed patient samples as the standard of comparison.

EP14 focuses on:

- •Documenting results of the commutability evaluation.
- •Materials and sample assembly.
- •Assessment methods.
- •Data analysis.

Karl De Vore, BA, SSBB Chairholder of EP14 said, "The EP14 document is a valuable tool for proficiency testing samples providers to establish and demonstrate commutability of their products with high confidence. It is also very useful as a basic research tool for matrix effects

and reagent shift issues. The updated version now also includes a preset criteria option rather than a prediction interval in the final commutability assessment."

Jeffrey R. Budd, PhD, member of the EP14 Document Development Committee further noted, "Processed samples, such as those made for external quality assessment, proficiency testing, measuring interval verification, or quality control may not behave like unprocessed patient samples in selected measurement procedures. EP14 helps identify such non-commutability by comparing a limited number of processed samples with unprocessed samples in a regression across two measurement procedures."

CLSI sets the standard for quality in medical laboratory testing. A not-for-profit membership organization, CLSI brings together the global laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine.

For over 50 years, our members, volunteers, and customers have made CLSI a respected, transformative leader in the development and implementation of medical laboratory testing standards. Through our unified efforts, we will continue to set and uphold the standards that drive quality test results, enhance patient care delivery, and improve health care around the world.

By using CLSI standards, laboratorians can improve process quality, speed the development of standard operating procedures, and implement safer practices with greater ease and efficiency.

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