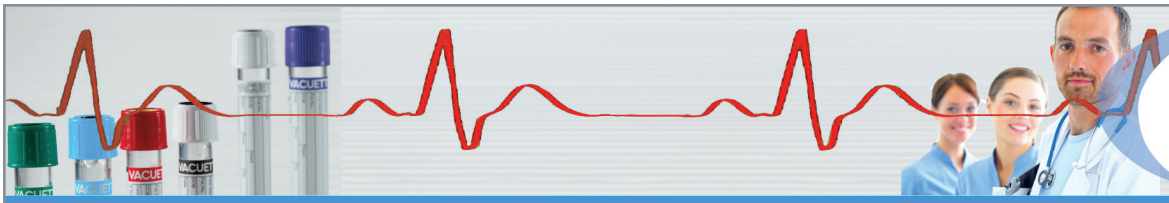

Tube Validation and Verification

CLSI recently published a guideline document, GP34-A, on validation and verification specific to venous and capillary blood collection tubes. This guidance document will help customers navigate the process of ensuring that their blood collection devices are acceptable for use. The terms validation and verification can be confused and are often used interchangeably.

Validation is the process of conducting studies to prove that a device or system meets the requirements of its intended use. Customers must validate the performance characteristics of a blood collection tube if they deviate from the handling recommendations stated in the manufacturer's instructions for use.

Verification is a process similar to validation but typically involves less rigorous studies that the customer uses to show manufacturer performance claims for a particular tube hold true in their testing environment.

The design of validation and verification method comparison studies should take into account the components of the tube and any preanalytic variables that may impact testing before, during and after sample collection. Additionally, it must be decided how many samples will be tested and which representative assays will be used to assess differences between the currently used or control tube and the tube to be evaluated. Though customers would like more definitive guidance, decisions on sample size and the analytes tested are left to the site so the study protocol is appropriate for their analytical range and testing circumstances and will accomplish the statistical power they feel is necessary.

The design of customer verification studies should include the factors summarized below.

Steps to Consider When Designing a Tube Verification Study

1. When designing the study, all possible regulatory and organizational requirements should be considered including measures for protection of human subjects and acceptability criteria in accordance with Institutional Review Board policies and procedures.
2. Allow a period of time for those participating in the study to become familiar with the protocol.
3. Collect and handle samples using standard precautions and in accordance with all applicable requirements.
4. An appropriate number of samples distributed across the analytical range for the assays included should be tested in order to achieve the desired statistical power for the study. Decisions on the number of samples and the representative tests are often in accordance with what the Laboratory Director deems to be medically necessary for the facility.
5. Within tube precision should be assessed by performing duplicate analyses on control and evaluation tubes for a minimum of 20 subjects.
6. Randomize collection and testing order to avoid bias.
7. Analyze all specimens within the same run according to the laboratory standard operating procedure. This will help reduce potential error.

Steps to Consider When Designing a Tube Verification Study *continued*

8. Sample storage should only be necessary if evaluating sample stability. Otherwise, samples should be tested within manufacturer recommended time frame for the each assay.
9. Assess data for outliers (refer to CLSI document EP09 for additional information).
10. Record all data and review for acceptability. If the data meets study parameters, perform data analysis and review results for statistical and clinical significance.

To facilitate the capture of preanalytic information for customer validation or verification studies involving blood collection, Greiner Bio-One created a Validation Checklist. The checklist was released with associated explanation in a previously published version of the Preanalytic Pulse (November 2010).

References

CLSI. Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline. CLSI document GP34-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition (Interim Revision). CSLI document EP09-A2-IR. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

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