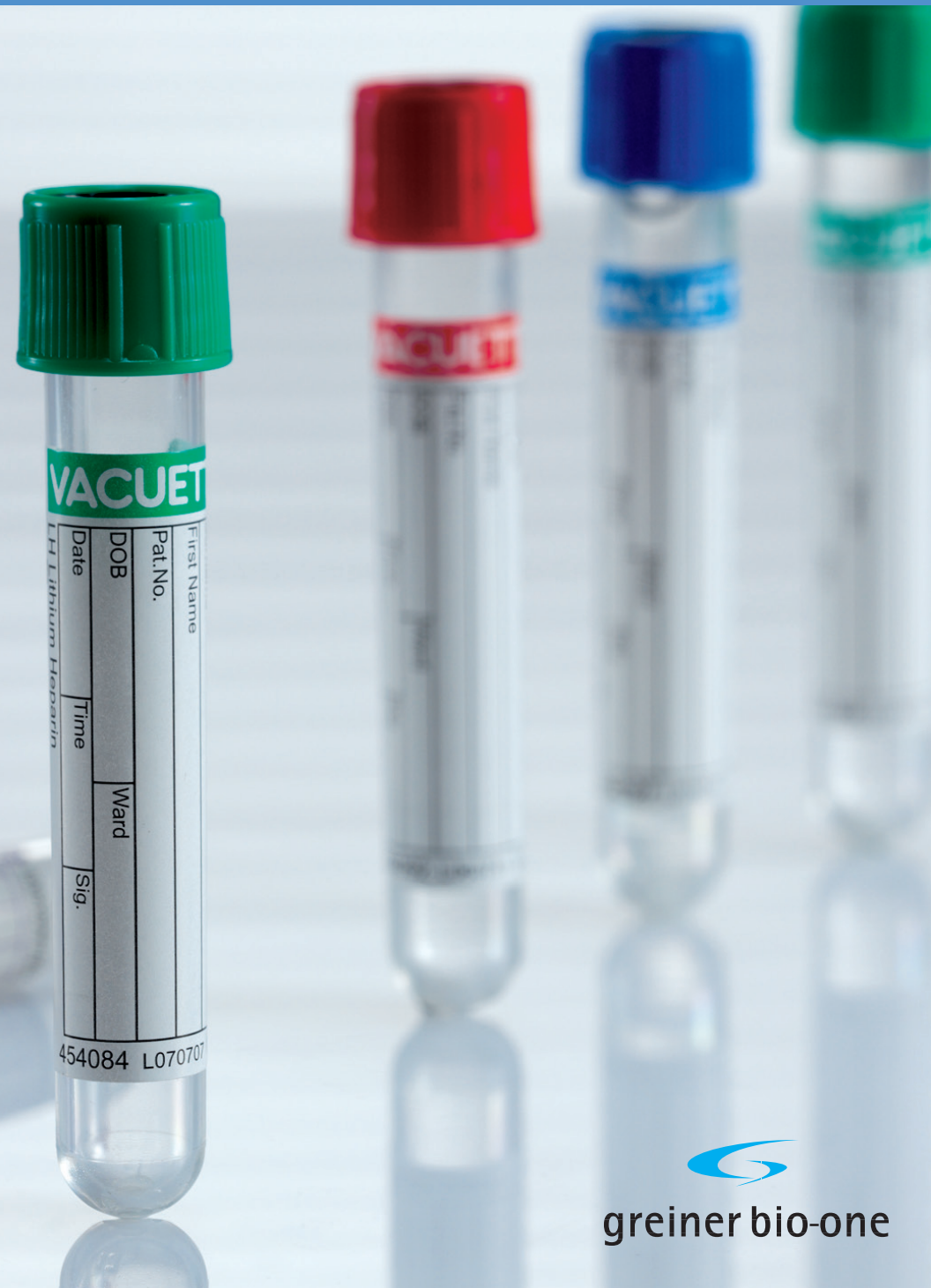
VERIFICATION GUIDELINES

for Converting Blood Collection Tubes



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Elements of a Study Protocol

Most regulatory and standard-setting agencies recommend that method comparison studies be carried out to verify that any new blood collection tube will meet the performance claims of the manufacturer and yield test results comparable to the tube currently in use.

Each facility must decide what the verification studies will include based on what they believe to be medically necessary for their environment. There are, however, some basic criteria that all laboratories should consider when developing a tube conversion study protocol.

1. Studies should be designed to meet all regulatory requirements; local, state and federal.

2. An adequate number of samples should be run to achieve the desired statistical significance. A minimum of 20 samples is typically necessary for this purpose.

3. Collect samples from a variety of patient settings such as the Emergency Department, Intensive Care Units (cardiac, critical care, surgical, etc.) and Dialysis for example. This will improve the likelihood of covering the reportable range of results and obtaining values at medical decision points.

4. The facility must decide what assays/tests to run. Representative assays may be selected based on test frequency, sensitivity of the method to variability, the critical nature of the result, etc., but justification for the tests selected should be documented.

5. The method comparison will assess test accuracy but precision can be simultaneously evaluated by performing duplicate analyses on both the current or control tube and the evaluation tube.

6. The order of tube collection and analysis (control vs evaluation) should be randomized to avoid bias.

7. It is important that samples be collected, handled and analyzed according to documented procedures to minimize variability.

8. The control and evaluation tube should be analyzed on the same instrument in the same test run.

9. Samples should not be stored prior to analysis unless sample stability is being assessed as part of the study protocol.

10. After testing is complete, a preliminary review of the data should be carried out and any issues addressed. A statistical analysis of the data is then conducted to determine if performance of the evaluation tube is acceptable according to the criteria set by the facility. *Greiner Bio-One North America will conduct the statistical analysis using EP Evaluator® upon request.*

The laboratory evaluates its specimen containers to ensure that they do not contribute to analytic interference in the assays to be performed.

NOTE: *This may be done through some combination of direct testing by the laboratory, review of the clinical literature, and evaluation of information from manufacturers. It does not mandate exhaustive testing by each laboratory.*

CAP. Laboratory General Checklist, CAP Accreditation Program. GEN.40942. Northfield, IL: College of American Pathologists; 2011.

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). CLSI document EP09-A2-IR. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

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