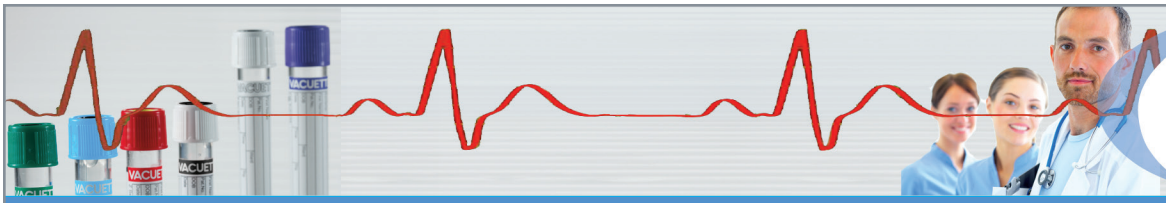

PREANALYTIC PULSE

The 5 Most Frequently Asked Conversion Questions…

	QUESTION:	ANSWER:
1	When converting from another manufacturer's tubes, what steps are necessary to validate/verify the performance of Greiner Bio-One **VACUETTE®** Blood Collection Tubes to satisfy regulatory requirements?	CLSI has recently published a guidance document (GP34-A; Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection) specific to tube verification to assist customers with this process. Verification testing should include method comparison with representative analytes between your current tube and the **VACUETTE®** Tube. If your facility chooses, within-tube precision can be done by performing duplicate analyses during the method comparison. The number of samples tested should be sufficient to be statistically valid. A minimum of 20 samples is typically required, though most laboratories prefer 30-40 samples.
2	How much will it cost to perform an evaluation (testing appropriate for verification/validation purposes) in my laboratory?	Cost of evaluation testing is derived from the cost of the tube, the cost per test (or cost of reagent per test), the average hourly pay rate of the technologists in your laboratory and the estimated time to run each test. Greiner Bio-One has a tool available to calculate the cost of evaluation testing in realistic terms specific to your facility.
3	What is required if **VACUETTE®** Tubes are centrifuged at a different time or g-force than what the Instructions for Use (IFU) recommend?	Many labs are limited by centrifuges unable to achieve the recommended g-force or have turn-around-time constraints that do not allow for the recommended time. Centrifugation of tubes outside of manufacturer IFU is, therefore, not unusual. However, this is considered off-label use and requires testing to validate that changes to the manufacturer recommended settings do not affect analytical outcomes. This testing need not be exhaustive but should include a method comparison with representative analytes of recommended settings relative to those used in your laboratory with a minimum of 20 samples. Typically, there are studies available to support these changes in centrifugation.

The 5 Most Frequently Asked Conversion Questions…

	QUESTION:	ANSWER:
4	Are **VACUETTE®** Tubes validated on the instrument platforms in my laboratory?	Greiner Bio-One works very closely with instrument vendors to ensure that **VACUETTE®** Blood Collection Tubes are compatible with the instrument platforms utilized in the clinical laboratory. In some circumstances, Greiner Bio-One is able to provide documentation from the instrument manufacturer indicating that specific tubes are approved for use. However, some manufacturers simply publish specifications of tubes appropriate for their instrumentation in the associated instrument manual or literature.
5	What resources can Greiner Bio-One offer to assist me in the conversion/ implementation process?	Greiner Bio-One Account Managers act as consultants to determine your needs and assist you in making the change to **VACUETTE®** products. Additional onsite resources are available during the conversion process to ensure that staff is adequately educated, trained and competent in use of the **VACUETTE®** products. At the completion of your evaluation, our Technical Support Specialists will assess your data using EP Evaluator® software to provide a method evaluation report for your regulatory needs. We also offer educational materials and literature that can be customized for your purposes that is beneficial during the implementation process as well as training on an ongoing basis.

VACUETTE® one step ahead ▶