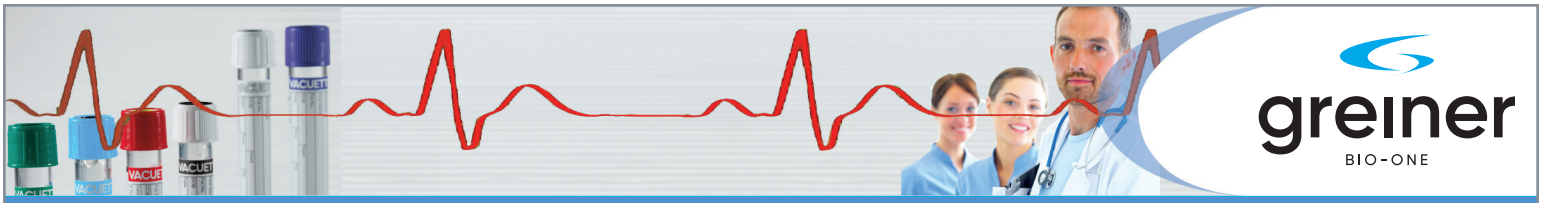

Validation Checklist

We are often asked what Greiner Bio-One recommends for validation of VACUETTE® Blood Collection Tubes. In an effort to assist customers with this process, we have developed a Validation Checklist that is based on CLSI guidelines for validation studies. The checklist guides the customer through factors that should be considered and/or documented as part of a validation protocol. The number of samples included, the specific analytes tested and the acceptability criteria are site specific determinations based on what the medical director deems necessary.

The checklist includes the following sections:

1. Account Information: Captures the laboratory section and tube type being evaluated. Each laboratory department or workstation should fill out a separate Validation Checklist.

2. Tube Information: Contains specific information on the customer's current or control tube as well as the information on the VACUETTE® tube. Information on specimen collection is documented as well because the equipment used and sample handling can impact the analysis.

3. Centrifuge Conditions: Details on the centrifuge type and setting should be included especially if there are changes from manufacturer's recommendations. It may be prudent to suggest that an extra tube be collected in order to evaluate the settings in the manufacturer's instructions for use relative to the actual settings the site will utilize to show that test results are not affected by the change.

4. Visual Assessment: Issues such as hemolysis, fibrin or poor gel barrier can have an impact on test results and should be documented, identifying the specific tube(s) affected.

5. Analytes Tested: This section is preceded by information on the instrument used for analysis and includes a table meant for documentation of what analytes will be tested and the associated acceptance limit for each (as determined by the laboratory).

6. Storage Conditions: Various time points may be tested in determining sample and/or analyte stability. Therefore, the storage conditions should be captured.

7. Statistical Analysis: The statistical method used for data analysis is determined by the facility. It is mentioned that Greiner Bio-One offers this service utilizing EP Evaluator® as an assessment tool.

8. Points for Consideration: There are several things the laboratory should consider when developing the specific protocol including preanalytic factors and procedural options for the testing itself.

This checklist is meant to provide customer's with a tool to guide them through the validation or verification process. It may be used as a companion piece to the Custom Conversion Program or as a stand alone for sites beginning an evaluation or making changes from our documented recommendations. (Overview of checklist [L1043004RN] on reverse)

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Greiner Bio-One Validation Checklist*

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Storage Conditions

Control Tube	Evaluation Tube
Temperature:	Temperature:
Time:	Time:
Stability Time Points Tested:	Stability Time Points Tested:

Statistical Analysis

Perform statistical analysis according to facility policy.
Note: *Greiner Bio-One offers data analysis services using EP Evaluator® as part of customer conversion.*

When performing verification or validation testing, the following points should be considered:

- The laboratory should comply with federal and local regulations with respect to informed consent and participant solicitation.
- Tourniquet should never be left in place for longer than one minute. If venipuncture cannot be carried out within 1 minute of tourniquet application, the tourniquet should be removed for two minutes and then reapplied.
- Adequate sample volume should be collected to ensure completion of all testing.
- Order of collection and testing should be randomized.
- Samples should be appropriately mixed with gentle inversion according to manufacturer specifications.
- Serum samples should be allowed to sit in an upright position for 30 minutes for complete clot formation prior to centrifugation.
- Samples should be centrifuged within 2 hours of collection.
- Samples should be representative of the test reference range including both normal and pathological values.
- Consideration should be made for measuring repeatability and reproducibility when developing the validation/verification protocol.
- Both control and evaluation tubes should be analyzed within the same testing batch with appropriate calibration and QC performed and sufficient reagent loaded.
- Refrigerated or frozen samples should be brought to the appropriate temperature prior to testing according to manufacturer instructions.

XXXXXXXX

*NOTE: *This document is only meant to provide a guideline for validation/verification purposes. The specific protocol for validation should be based on what the facility's Medical Director deems is medically necessary and is ultimately the responsibility of the testing laboratory in accordance with institutional policy and regulatory standards and guidelines.*

Account Information

Laboratory Department: _____ Date: _____

Tube Type: _____

Testing Completed By: _____

Tube Information

Control Tube	Evaluation Tube
Manufacturer Part #: _____	Manufacturer Part #: _____
Lot #: _____	Lot #: _____
Expiration Date: _____	Expiration Date: _____
Draw volume: _____	Draw volume: _____

Number of Samples for Evaluation: _____

Phlebotomy Equipment: _____

Needle Type: ☐ winged-collection set ☐ multi-sample needle

Manufacturer: _____

Evacuated Tube System ☐ or Syringe Transfer ☐? Transfer Device Used? ☐ Yes ☐ No

Number of Tubes per patient: _____

Control: _____ Evaluation: _____

Number of Inversions (note if different from manufacturer's recommendation): _____

Control: _____ Evaluation: _____

Greiner Bio-One Validation Checklist*

Centrifugation Conditions

Centrifuge Manufacturer: _____ Model: _____

Control Tube	Evaluation Tube
Time: _____	Time: _____
RCF: _____	RCF: _____
RPM setting: _____	RPM setting: _____
Temperature: _____	Temperature: _____

Note: *Recommended manufacturer relative centrifugal force (RCF) can be converted to RPM using a nomograph or the following formula:*
$RCF\ (g) = 1.118 \times 10^{-5} \times r \times RPM^2$ where r = radius of rotor in cm

Visual Assessment

Control Tube *(identify affected tubes)*	Evaluation Tube *(identify affected tubes)*
Poor Barrier Formation	Poor Barrier Formation
Fibrin	Fibrin
Hemolysis	Hemolysis

Note: *Red cells trapped in the gel layer are not clinically significant.*

Platelet count *(if verification of adequate centrifugation is required)*: _____

Instrument Manufacturer: _____ Model: _____

Cap Piercing? ☐ Yes ☐ No Uncapped tube? ☐ Yes ☐ No

Primary tube or aliquot tested? _____

Analytes Tested

Analyte	Acceptance Limit (with units of measure)	Analyte	Acceptance Limit (with units of measure)

Single or duplicate sampling per tube? _____

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