



Summary of Regulatory Requirements for CVL

The CAP Calibration Verification/Linearity Surveys provide specimens and statistical evaluations of the reported results for verification of your current calibration settings as well as for assessing the analytical measurement range (AMR) of your laboratory method. The CVL Surveys satisfy the requirements for scheduled calibration verification and AMR verification as specified in the CAP Laboratory Accreditation Program (LAP) and Current CLIA Regulations Section 493.1255 for most analytes.^{1,2} As defined in the CAP LAP Chemistry and Toxicology Checklist, the AMR is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment that is not part of the usual assay process.

The CAP CVL Surveys materials are intended to cover broad ranges of concentrations or activities to challenge assays from near the low end to the top of the AMR for most analytes and methods. To fulfill CAP LAP requirements for AMR verification, you must know your analytical measurement range for each analyte, and CVL Survey concentrations must fall near the low, middle, and high values of your AMR. If specimens do not meet these requirements, you may find additional information on regulatory requirements in the CVL Users Guide.

You may use either your calibration verification or linearity evaluation, or a combination of both, to fulfill requirements for calibration verification or AMR verification. You must confirm that the performance limits specified in the evaluation are acceptable to your laboratory. For AMR verification, you must confirm that the evaluation includes specimens near the low, midpoint, and high values of the AMR. If your CVL Surveys evaluation does not satisfy your own criteria, you have the option of performing a self-evaluation with alternate target values and/or with modified limits of allowable error.

NOTE: See the calibration verification and linearity troubleshooting guides for suggested actions if you have problematic results. Appendix 1 provides a worksheet for calibration verification self-evaluation. Appendix 2 provides a detailed investigation checklist.

Coagulation

According to the CAP LAP Hematology and Coagulation Checklist, coagulation tests based on direct measurement of an analyte require AMR verification at least every six months.⁸ Specifically, calibrated tests that directly measure activity or concentration of an analyte by enzyme immunoassay, immunoturbidity, or chromogenic methods require AMR verification. Clot-based tests do not require AMR verification.

Hematology and Flow Cytometry

According to the CAP LAP Hematology and Coagulation Checklist, linearity studies are not required to satisfy calibration verification for complete blood count (CBC) instruments. Similarly, the Flow Cytometry Checklist does not contain explicit requirements for confirmation of linearity for enumeration of blood lymphocytes. In an effort to standardize reports and documentation, we use the CAP LAP Chemistry and Toxicology Checklist terminology for most CVL program documents. Participants should be aware that specific accreditation and regulatory requirements could vary.