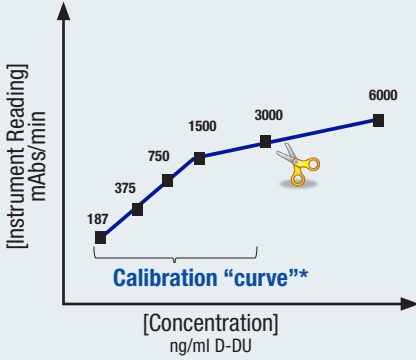


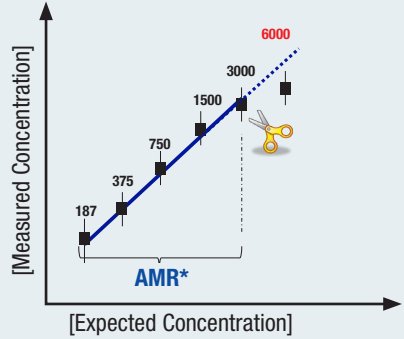
Calibration and AMR validation example

Calibration and AMR Validation of a D-dimer Quantitative Immunospectrophotometric Assay

1.A Calibration



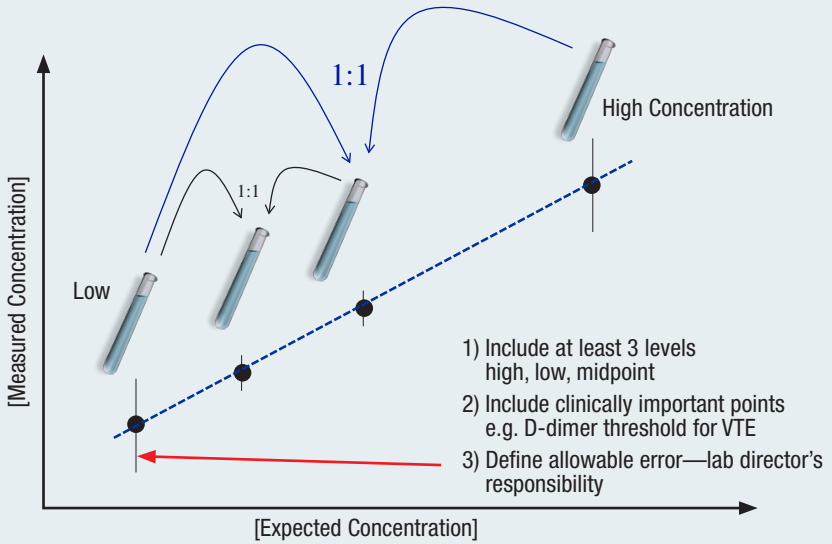
1.B Linear Recovery



* Validate at least every 6 months

Adapted from Russell Higgins, MD, UT San Antonio, vice chair, CAP Coagulation Resource Committee.

1.C Validating AMR with Patient Samples



Prepared by Russell Higgins, MD

Fig. 1.A At top left is a graph of a calibration curve for D-dimer. A single calibrator is provided by the manufacturer and the instrument performs dilutions (x axis), which produce instrument readings (y axis mAbs/min). The instrument derives and stores an equation to fit the calibration points. At least every six months, the calibration “curve” must be validated, by repeating the calibration-readout-equation process with the same or a different lot of calibrator. **Fig. 1.B** AMR validation. The maximum potential AMR range is between the highest and lowest calibrator values. Limitations on AMR occur when the measured analyte concentration or activity deviation from the expected result exceeds allowable error. The key steps in AMR validation are: **1)** obtaining suitable test material (patient samples, commercial proficiency testing or linearity survey material, or calibrators from a different lot than the one used to calibrate the assay); **2)** testing at least three concentrations close to the low end, high end, and midpoint of the expected AMR (mixing a “low” and “high” sample to obtain a midpoint sample is a common practice—see **Fig. 1.C**); **3)** comparing expected to recovered results for linearity. Guidelines for accepting or rejecting linearity are determined by the laboratory medical director. External linearity surveys provide criteria and help determine AMR limits.