Status Active PolicyStat ID 11878518

Beaumont

Origination	7/17/2020
Last Approved	6/14/2022
Effective	6/14/2022
Last Revised	6/14/2022
Next Review	6/13/2024

Document Contact	Michelle Alexander: Medical Technologist Lead
Area	Laboratory-Chemistry
Applicability	Dearborn

Dearborn Laboratory Auto Technical Calibration Verification/ Analytical Measurement Range (AMR) Validation For Chemistry

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The verification of calibration can be defined as the assaying of calibration materials (or other samples which can be related to the material used to standardize the assay) in duplicate, in the same manner as patient samples, to confirm that the calibration of the assay has remained stable throughout the reportable range for patient test results. The upper and lower limit of the linear relationship should define the Analytical Measurement Range (AMR) of the assay. Below list the steps for this procedure.

II. PROCEDURE:

A. In order to substantiate continuous assay accuracy, calibration verification must be performed at least every 6 months. Calibration verification should also be performed:
    1. At changes of reagent lots if there is a >1 SD shift in the QC.
    2. After major maintenance or service.
    3. When recommended by the manufacturer.

B. Calibration verification consists of two parts: verification of correct method calibration and validation of the instrument reportable range (AMR).
    1. Calibration Verification.

a. Methods that are recalibrated more frequently than every 6 months do not require the calibration verification process.
b. Follow manufacturer recommendations for all assays.
c. Never extend calibration frequency.

2. AMR Validation
    a. Must be done at least every 6 months
    b. Must include analyte values which are, at a minimum, near the low, midpoint and high values of the AMR.

C. Materials used are to be of appropriate matrix for the assay/instrument being tested. These include, but are not limited to:
    1. College of American Pathologists (CAP) linearity surveys
    2. Commercial linearity material (i.e. Maine Standards, Audit, Cliniqua, Radiometer Qualicheck).
    3. Abnormal serum specimen, which may be diluted to provide points low, middle and high on the linearity range.

D. Acceptable criteria for AMR validation:
    1. CAP Linearity Surveys
        a. Values are linear and calibration is verified. Verified 1 or 2; Linear 1 or 2
        b. AMR **low** values must be within 25% of current AMR value.
        c. AMR **high** value must be within 25% of current AMR value.
        d. If either the low or high value is not acceptable, recalibration of, and troubleshooting of the assay should be performed. If this does not correct the values, then the AMR must be changed to reflect the actual attainable values.
        e. If the calibration verification fails, recalibration of, and/or troubleshooting of the assay should be performed. If this does not correct values, contact tech support for trouble shooting assistance.

E. Commercial Linearity Material:
    1. For those analytes which have an established variance limit (42 Code of Federal Regulations (CFR) 493 Laboratory Requirements), that limit is used as a criteria for acceptable results.
    2. For other analytes, values are compared to peer group values.
    3. The results are assessed for linearity across the AMR.
    4. AMR **low** value must be within 25% of current AMR low value.
    5. AMR **high** value must be within 25% of the current AMR high value.
    6. If either the low or high value is not acceptable, recalibration of, and troubleshooting of the assay should be performed. If this does not correct the values, then the AMR must be changed to reflect the actual attainable values.

7. If the calibration verification fails, recalibration of, and/or troubleshooting of the assay should be performed. If this does not correct values, contact tech support for trouble shooting assistance.

F. Abnormal serum diluted:

1. Run at least a minimum of low, middle and high dilutions.
2. AMR **low** value must be within 25% of current AMR low value.
3. AMR **high** value must be within 25% of the current AMR high value.
4. If either the low or high value is not acceptable, recalibration of, and troubleshooting of the assay should be performed. If this does not correct the values, then the AMR must be changed to reflect the actual attainable values.
5. If the calibration verification fails, recalibration of, and/or troubleshooting of the assay should be performed. If this does not correct values, contact tech support for trouble shooting assistance.

G. All data for calibration verifications and AMR validations is analyzed using either EP Evaluator or the manufacturer's program (i.e. Maine Standard Data Reduction or VK Linearity template). Assays which use 3 or more (low, middle, high) calibrators for calibration on instruments must pass the instrument-programmed criteria for acceptability. A separate AMR study is not required under these conditions as long as the AMR is not extended beyond the level of the highest calibrator.

Approval Signatures

Step Description	Approver	Date
Medical Director	Jeremy Powers: Chief, Pathology	6/14/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy [IH]	6/14/2022
Policy and Forms Steering Committee Approval (if needed)	Michelle Alexander: Medical Technologist Lead	6/13/2022
	Kimberly Geck: Dir, Lab Operations B	6/13/2022
	Michelle Alexander: Medical Technologist Lead	6/9/2022

Applicability

Dearborn