# CHM.13600

1. **How can I span my AMR with calibrators that do not cover the entire range? (Reviewed 01/2023)**

   The laboratory would need to use additional materials that cover the entire AMR for verification. Additional materials may be linearity materials, QC materials, previously tested patients or other laboratory approved materials.

2. **If the lab is using multipoint calibrators that span the AMR, what is the frequency to perform AMR verification? (Reviewed 01/2023)**

   This would need to be performed initially, when a new method is introduced, and then at least every 6 months thereafter. If the laboratory is calibrating more frequently and they span the entire AMR with at least 3 points (high, mid and low) then the AMR verification has been met.

3. **How close to the upper and lower limit of the AMR must we achieve to consider the AMR verified? (Reviewed 01/2023)**

   The laboratory director must define the closeness and acceptability of the AMR verifications.

4. **If the laboratory has multiple instruments of the same model with the same tests performed on them, do we need to verify the AMR on each instrument, or can we rotate the verification between/amongst the instruments? (Reviewed 01/2023)**

   Analytical Measurement Range must be validated initially on each instrument and then verified every six months for every analyte tested and for each instrument, regardless of whether they are the same model.

5. **How will we do AMR Verification for certain parameters where CAP is not providing the materials and it's very difficult to get patient samples for the purpose? (Added 11/2023)**

   The provides various examples of materials that can be used for AMR verification in the checklist, including the following:
   - Linearity material of appropriate matrix, eg, CAP CVL Survey-based or other suitable linearity verification material
   - Previously tested patient/client specimens, that may be altered by admixture with other specimens, dilution, spiking in known amounts of an analyte, or other technique

- Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method
- Patient samples that have reference method assigned target values
- Control materials, if they adequately span the AMR and have method-specific target values

If you are having difficulties finding appropriate materials, laboratories should contact the manufacturer for assistance. Aside from the CAP's linearity materials and manufacturer provided materials, commercial materials are often available for purchase from third party vendors.

6. **If an instrument performs a 6-point calibration by making serial dilutions using just one calibrator material, does the test still need AMR verification? (Added 11/2023)**

   As stated in CHM.13600, it is not necessary to independently verify the AMR if the calibration of an assay includes calibrators that span the full range of the AMR, with low, midpoint and high values represented (ie, three points) and if the system is calibrated at least every six months. If the calibration process for your instrument satisfies these criteria, it would meet the intent of the requirement, as long additional AMR verification processes are not required by the manufacturer's instructions.

7. **For AMR Verification, is AMR the same as "Reportable Range"? (Added 11/2023)**

   The terms analytical measurement range and reportable range are often used interchangeably; however, the term reportable range can be more broadly interpreted to also include the clinical reportable range. For AMR verification, the checklist is referring to 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.

8. **Is AMR verification required for qualitative tests where the analyte concentration of specimen is not measured or known? (Added 11/2023)**

   No, AMR verification does not apply to qualitative test systems that do not provide a quantitative result.

9. **Is AMR verification considered a verification for linearity? If not, do we need to do linearity verification separately? (Added 11/2023)**

   The checklists require laboratories to perform AMR verification. 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. While linearity materials are commonly used to verify AMR, the checklists allow other approaches to be used. The CAP checklists do not contain requirements to perform linearity verification. There are some methods that are known not to produce a linear response.