REPORTABLE RANGE

Unlocking its Significance

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What Is It?

It is a functional range of an assay over which the concentrations of an analyte can be measured with acceptable accuracy and precision.

It is NOT Reference Interval (RI) or Reference Range (RR)

Reportable range includes:

analytical measurement range (AMR)	clinically reportable range (CRR)

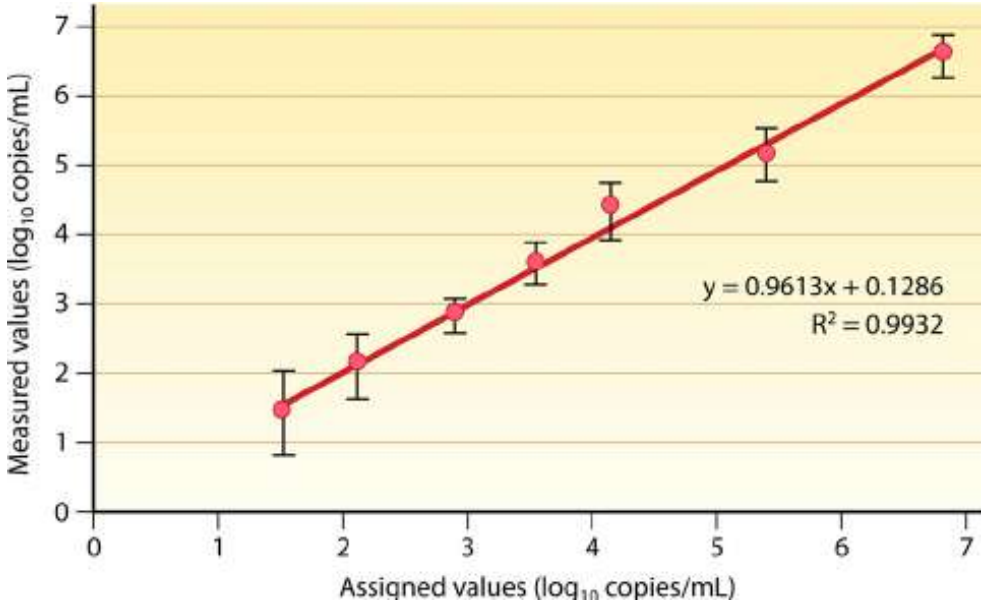
Analytical Measuring Range (AMR) vs Clinical Reference Range (CRR)

- AMR: The range of values an instrument can report directly without dilution or concentration.

- CRR is the range of values an instrument can report as a quantitative result with dilution or concentration.

To understand reportable range, you need to understand calibration and linearity….

- Calibration:
  - the process that links the analytical signal with the concentration of analyte present in serum, urine or other body fluid.

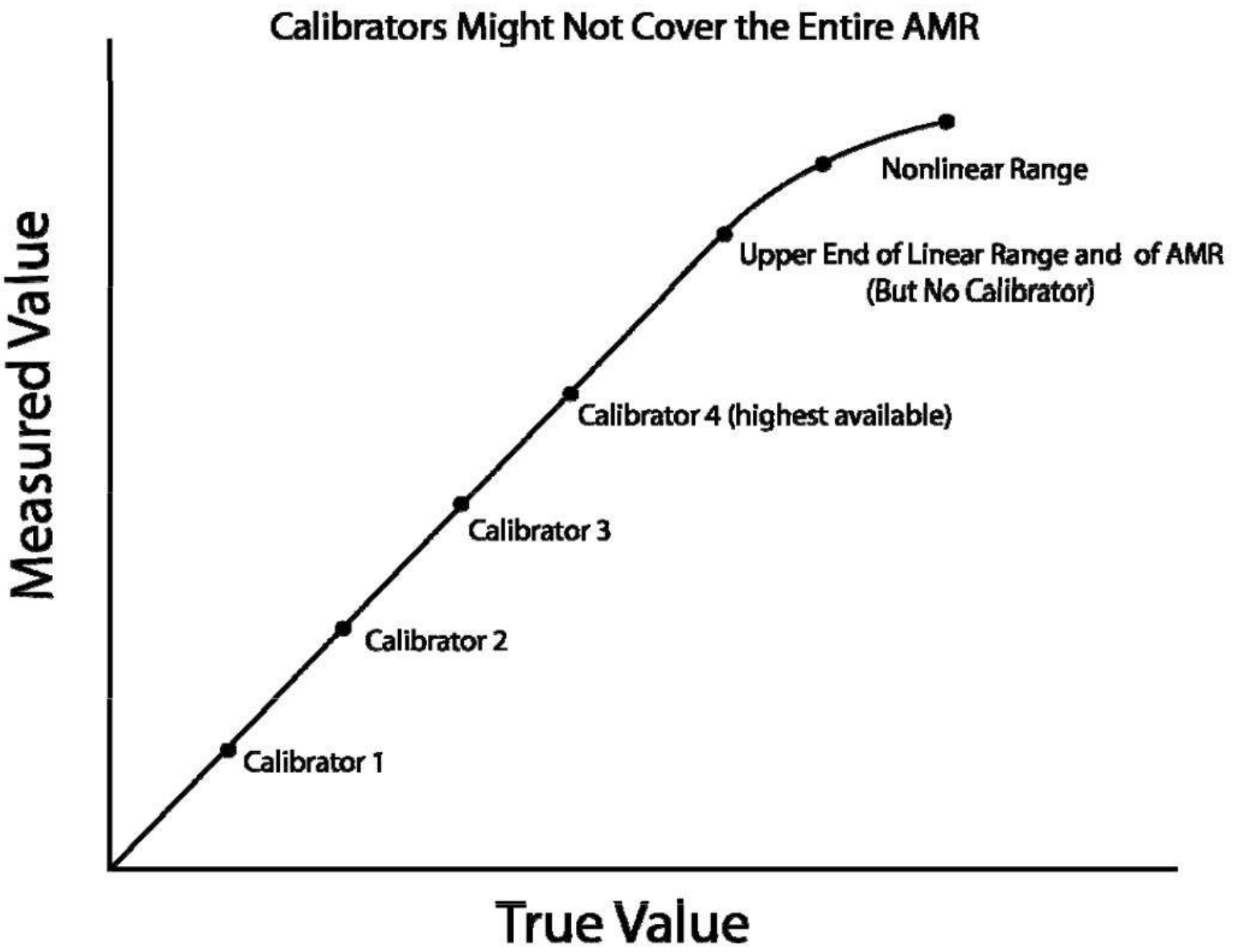


- Linearity:
  - the ability to provide laboratory test results that are directly proportional to the concentration of the measurand (quantity to be measured) in a test sample.

Verifying the Reportable Range…

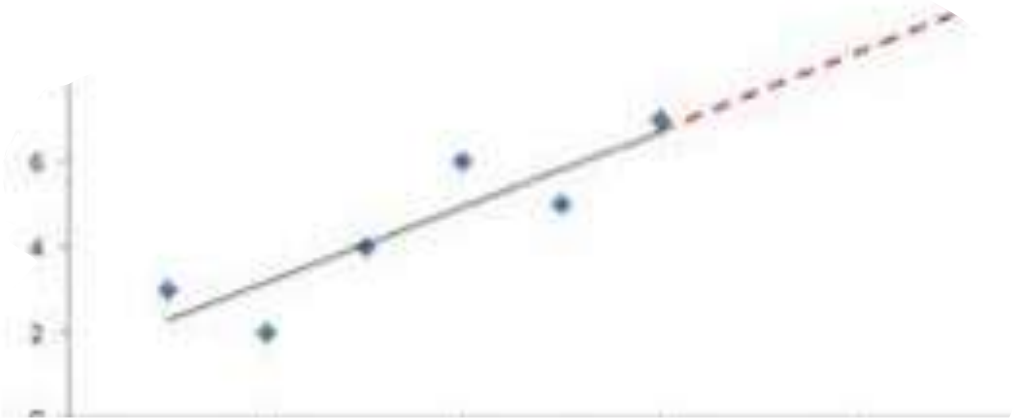
- Method Verification
  - Whenever a new test is introduced/ new instrument put in place.
  - MV is done before the new test/ instrument is used on patients.
  - It includes verifying the reportable range by doing a linearity study.
- Linearity study:
  - Checks that the reportable range gives you an accurate result by running known concentration samples and checking if a straight line is obtained when the measured results are plotted on the y-axis vs the expected or known values on the x-axis.

Calibration & Linearity



What happens when lab gets a result that is out of the reportable range?

- Two options:
  1. Report the result as >/ < AMR
  2. Dilute the sample:
     - dilute at a ratio recommended by the manufacturer (up to a recommended maximum dilution)
     - rerun the sample
     - get the new result
     - convert it to the actual reading based on the dilution ratio
     - final result generated



Other Matters Where We Need Your Help...

Wrong blood tube cap with the test tube type.

Example of incident: TSH cord blood (tube plain) being capped with EDTA tube cap. During cord blood sampling, the plain tube cap was removed & during recapping of tube, the requester mistakenly switch the cap of plain tube with EDTA.

Repetitive HbA1C request

(HbA1C test ordered in less than 8 weeks apart)

Special Chemistry Test Appointment. Call ext. 10807.

Reason: the lab staff need to inform requester on the correct test tube & other samples collection precautions /requirements.

[e.g. Synacthen Test, Acylcarnitine tests, Calprotectin, Beta-2-glycoprotein, Phospholipase-A2 Receptor Ab, IEM screening, Blood Amino Acid, Urine Organic Acid, Urine Orotic Acid, Zinc & other trace metal tests, Myoglobin, Mercury (serum & urine)]

Rejection Rate (HASA)

2023							
Month	**January**	**February**	**March**	**April**	**May**	**June**	
Rejection Rate	1.1	0.8	0.7	1.0	0.9	1.0	
Requester	Emergency Department (33%)	Emergency Department (27%)	Emergency Department (18%)	Emergency Department (23%)	Emergency Department (27%)	Emergency Department (21%)	
Specimen Type	Serum (49%)	Serum (39%)	Serum (48%)	Blood Gas (34%)	Serum (34%)	Blood Gas (38%)	
Rejection Criteria	Haemolysed sample (25%)	Clotted sample (21%)	Hemolysed sample (22%)	Clotted sample (32%)	Clotted sample (25%)	Clotted sample (28%)	

THANK YOU

QUESTIONS?