

**Washington State Department of Health  
Laboratory Quality Assurance  
5-1-07**

**Minimized Instrument Validation Process – Moderate Complexity Testing**

**Validation of new instruments must be performed prior to reporting patient results. This validation must be performed at the facility where the instrument is to be used.**

1. Accuracy Check

- Analyze two levels of assayed control material 10 times each over several days
- All control values should fall within the expected QC range.
- Calculate the average (mean) for each level – these values should be close to the midpoint of the range.

2. Precision Check

- Using a scientific calculator, calculate the Standard Deviation (SD) and the coefficient of variation (CV) from your accuracy check values above for each level.
- Calculate the %CV:  $\%CV = SD/\text{average (mean)} \times 100$ .
- Determine whether the CV meets the manufacturer's specifications for the test.

3. Correlation Study with Patient Samples

- Perform testing on at least 10 patient samples for your new instrument that span your reportable range (low – mid – high) and compare these values with your old/current method or with your reference laboratory. The Director must approve the agreement of the results based on the clinical expectations and method accuracy/precision claims.

4. Reportable Range Check

- Check the high and low values that represent your reportable range. You may use calibrators (run as patients) or a linearity set to do this. You can also use patient specimens that have been tested by a reference method or proficiency testing specimens for this check.
- Analyze, in duplicate, reference material that reflect the minimum and the upper limits.
- Compare the values. The Director must approve the agreement of the results, based on clinical expectations. These must be used to set the lowest limit and upper limit for reporting patient values.

5. Reference Range Check

The manufacturers usually provide this information. The reference range should be provided with the patient test results. Have your Director review and approve the results. Assure they are appropriate for your patient population.

6. Calibration

Follow the manufacturer's instructions for the calibration of the instrument if required for your instrument.

If your instrument is to use a whole blood fingerstick specimen, please call your surveyor for additional suggestions for completing your validation.