**Guideline for Cross Instrument Correlation Studies**

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**Purpose**:

This document provides guidelines for correlation of all instruments testing the same analyte. If more than one instrument in a laboratory is used to produce results for a study, either as a backup or in normal usage, it is important that all instruments produce similar results. To verify that all instruments are producing similar results the laboratory must have a plan of correlation between instruments.

One of the instruments should be designated and remain as the primary instrument. Only the primary instrument should be covered by EQA materials. All other instruments whether backup instruments or duplicate instruments are considered secondary instruments. These secondary instruments should be correlated back to the primary instrument using patient samples.

There are three main reasons for using correlation studies as opposed to covering all instruments with EQA:1) buying a proficiency panel for every instrument in every laboratory is cost prohibitive, 2) EQA materials have inherent limitations such as: often composed of stabilized or synthetic materials, limited availability, and effects of shipping and 3) using patient correlation is immediately available to the laboratory and provides a means to prove how all results generated by all instruments for a particular analyte relate to one another.

**The regulatory requirements:**

1. Secondary instruments must be correlated to the primary instrument at minimum each six months.
2. Samples should cover as much of the full analyte instrument range as possible.
3. Criteria must be established by the Laboratory Director to grade the results of the correlation.
4. Instrument results that fail to fall within Director approved criteria should be investigated, corrected and then repeated.
5. All documentation is approved by the Laboratory Director or designee and then maintained in a central location for inspections and audits.

**Acceptance Criteria:**

The criteria used to evaluate the correlation study are left up to the laboratory to establish. Things that influence this are the methodologies of the two instruments and the tolerance the laboratory has for instrument-to-instrument data bias. Often laboratories begin with criteria that are relatively easy to meet and then over time tighten them to a point that will quickly show any problems developing.

To begin correlation studies laboratories can use Clinical Laboratory Improvement Amendments (CLIA) criteria, which are normally expressed as a percent difference from the target, a number of standard deviations from the mean or in the low ranges sometimes an absolute value from the target. The primary instrument would be considered the target value. The following website lists these criteria <http://wwwn.cdc.gov/clia/regs/subpart_i.aspx> for the various areas of the laboratory.

If an analyte is not listed by CLIA, then often acceptable criteria can be found listed in the College of American Pathology (CAP) Participant Summary Result booklet for the survey that contains the analyte.

After the correlation studies have been performed for a period of time the laboratory should review the correlations and work toward narrowing the correlation criteria. This will produce a sensitive indicator of instruments not performing correctly.

**Suggested Correlation Plan:**

Although the laboratory is only required to run correlation once each six months it is often easier when the instruments are in the same laboratory to run correlation studies more frequently. By running correlations weekly, bi-weekly or monthly with a few samples each time the laboratory will find it easier to meet the instrument range requirement for all analytes. They will also improve their chances of finding correlation errors earlier. One such scheme is listed below.

1. Correlate weekly between all instruments running the same analyte.
2. Each week select three samples from the patient run. Try to select samples that vary in some analytes from the low to high analyte range. Samples should be selected with sufficient volume to run on all instruments.
3. Run all the samples once on the primary instrument. Record the values produced for these analytes as the target values.
4. Run the samples on the secondary instrument(s). Record the values produced.
5. Evaluate each sample independently of the other samples. This may give some indication of problems that can be traced to high, low or proportional bias.
6. Review the data by the established correlation criteria in relation to the target values and approve or disapprove the correlation.
7. Instrument results that fail to fall within Director approved criteria should be investigated, corrected and then repeated.
8. All documentation is approved, signed and dated by the Laboratory Director and/or designee and then maintained in a central location for inspections and audits.
9. More information can be gained if the patient correlations are also run at the same time the EQA samples are run. Then if biases are noted in the EQA results of the primary you can review your correlation for similar bias, etc.

**Additional Options:**

1. In some cases the EQA material can be run successfully on a second instrument after the primary instrument’s results have been resulted to the provider. Submitting the primary results before retesting the materials on a second instrument is required on most EQA schemes, unless the survey allows submission of a second instrument or patients are normally tested in such a method. Results from secondary instruments can be documented and then compared with the provider peer results and your primary results. Use the established correlation criteria when evaluating results. (Note: EQA materials that are instrument specific, such as certain hematology analytes may not test successfully on a second instrument of a different type.) These records should also be reviewed, signed off and included in the correlation records, not with the EQA records.
2. Excellent correlation and peer information can be obtained by participation in peer programs from quality control materials vendors. This requires regular submission by the laboratory of their QC data electronically and results in reports that show how you compare with your external peer group. This information can be tremendously helpful in determining your laboratory’s relation to peers at other locations and alert you to potential problems. Bio-Rad is one vendor that has programs such as *OnCall* and *Unity*. Most vendors have these programs and you can often negotiate them to no or little extra cost by using their product. Keep these records reviewed and signed off either with the correlation records or as a separate QA program documentation.

**References:**

 Clinical and Laboratory Standards Institute. *Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline.* CLSI document C54-A . (ISBN 1-56238-671-9). Wayne, PA; 2008.

NCCLS. *Method Comparison and Bias Estimation Using Patient Samples: Approved Guideline –Second Edition.* NCCLS document EP9-A2 [ISBN 1-56238]. Wayne, PA; 2002

Clinical and Laboratory Standards Institute. *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition.* CLSI document C24-A3 . (ISBN 1-56238-613-1). Wayne, PA; 2006.