PATHOLOGY & LABORATORY MEDICINE SERVICE

Results Comparability Version 2
General Procedure # GEN00003.2

Effective: April 09, 2007

Principle: In order to achieve standardization, an approach is required that provides reliable transfer of the measurement values from the highest hierarchical level to methods which are routinely used in the clinical laboratories. Such a structure is presented by the reference measurement system, based on the concepts of metrological traceability and a hierarchy of analytical measurement procedures. Key elements of the system are the reference measurement procedure and reference materials. The reference procedure is used to assign a certified value to a given reference material. Once the appropriate reference material is certified, this material and the manufacturer's testing procedure can be used by industry to assign values to commercial calibrators. Clinical laboratories use routine procedures with validated calibrators, both from commercial sources, to measure human samples. In this way, the obtained value will be traceable to the reference procedure and materials, and the standardization of measurement, that is, the process of realizing traceability, will be reached.

Procedure:

1. Each analyte that is tested using more than one waived and non-waived instrument/method, comparability of the two instruments/methods is performed at initial installation and at least twice a year for non-waived tests. The criteria used to determine acceptable performance should be established for each analyzer/method. There must be demonstrated comparability between tests done by different methodologies or on different analyzer.

2. Initial correlation studies must be performed between the new test or method and current instruments or methods providing results for the same analyte. The laboratory director will establish acceptable criteria which must at the very least follow manufacturer instructions, accreditation requirements and be consistent with the requirements outlined in 42 CFR 493.1253, as applicable.

3. Specimens must be selected to encompass the clinically appropriate ranges. Moreover, another option is to include quality control material, previously run CAP survey specimens with known values which must be used on the same instrument platform with reagents of the same manufacturer and lot number.

4. Different methodologies which do not produce similar results will have a separate reference range.

5. The results will be reviewed by the supervisor and laboratory director or designee to determine if the results are acceptable. If the determination is made that the results are not acceptable corrective action will be taken.

References:

1. CAP General Checklist, Northfield IL, 2016
2. VHA Handbook 1106.01, January 29th, 2016

DATE ADOPTED	*Author of Procedure/Policy*	Chief of Service
04/09/2007	*Paul D. Gruver, MT*	Signature: Dong H. Lee M.D.

Policy/Procedure(s) Retired:		Date retired:

Review Date	Version Number	Signature of reviewer

REVISION HISTORY

Date revised	**Revision #**	**Changes made**	**Signature**
9/29/17	2	Added overview to reach traceability and correlation requirements for waived and non-waived testing.	