

PROCEDURE

Corewell Health East - Chemistry Method / Instrument Comparison - Taylor, Trenton, Wayne

This Procedure is Applicable to the following Corewell Health sites

Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital

Applicability Limited to:	N/A
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Functional Area:	Clinical Operations, Laboratory
Lab Department Area:	Lab - Chemistry

1. Principle

To verify patient samples yield the same results, regardless of the method or instrument used for testing, all duplicated assays are to be validated at least twice yearly for comparability. While the same lot number of quality control material is a daily indicator of equivalent results, the use of fresh human specimens is important to assess whether patient samples yield the same results. Previously assayed College of American Pathologists (CAP) survey samples may also be used.

2. Responsibility

Personnel who have completed the competency requirements will perform this testing.

3. Specimen

- A. Previously assayed patient samples.
- B. Pooled samples.
- C. Previously assayed CAP survey samples (after the due date).
- D. Quality Control materials (for low volume tests).
- E. Donor samples.

4. Reagent/Equipment Needed

- A. Patient comparisons must be performed on any duplicate testing methods or instrumentation.
 - 1. See individual procedures for reagents and operational instructions.

5. Procedure

- A. A method to method or instrument to instrument comparison will be performed at least twice yearly for all duplicate testing platforms.
- B. A minimum of five patient samples should be analyzed for all assays that have duplicate testing methods or instrumentation.
- C. If any comparison fails the level of acceptability, recalibrate assay(s), if applicable, on both instruments and repeat the comparison study.
- D. If the comparison fails again, call for service or technical assistance. Suspend any further testing for the failed test until the issue can be resolved.

Entities will reference associated Documentation contained within this document as applicable
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- E. Document all actions taken for failed comparison studies and include this information in the review process.
- F. If testing methods or instrumentation require different specimen types, such as hemoglobin on the Hematology and Blood Gas analyzers or lactic acid on the Chemistry and Blood Gas analyzers, then at least 5 pairs of donor samples may be used for the comparison studies.

6. Results/Interpretation

- A. For qualitative tests, the pathologist, or designee, will review comparisons results for acceptability.
- B. Acceptable comparisons have a correlation coefficient (r) of > 0.985 .

7. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

8. Procedure Development and Approval

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9. Keywords

Not Set