Changes in Grey

# Purpose: This is required prior to reporting patient test results whenever an unmodified, FDA-cleared or approved non-waived test system is introduced into the laboratory. This includes the following:

## A test system that is introduced into the laboratory for the first time to measure an analyte that the laboratory has not previously measured.

## A test system introduced for the first time into the laboratory for a test that the laboratory currently performs on an alternative test system.

## An analyte added to a test system that can measure multiple analytes, which the laboratory has been using for patient testing, but has not previously reported patient results for this particular analyte.

## When multiple instruments (including the same make and model are used to perform the same test, the laboratory must verify performance specifications for each instrument.

# Policy for Method Verification: Bioreach Laboratories verifies manufacturers test performance validation of all CLIA non-waived test systems.

* 1. Bioreach Laboratories must be actively involved with Method Validation activities. This included documented training and documented implementation involvement such as
     1. Cooperation with analyzer placement and initial setup.
     2. Cooperation with initial precision and reportable range verification.
     3. Direct involvement with initial accuracy determinations.
  2. Manufacturer validation reports are used for method validation. These include Verification of Accuracy, Precision and Reportable Range.
  3. Precision: Precision is determined by repeat analysis of QC or Linearity Material. Precision should agree within
     1. 5% for chemistry analytes
     2. 8% for Enzyme assays
     3. Hematology/Urinalysis acceptability limits set by manufacturer’s limits.
  4. Accuracy determinations:
     1. New test implementation: Linearity Standards and QC results are analyzed to ensure accuracy
        1. Values must agree within 10% or
        2. Slope of plotted values must be within 0.90 and 1.10 or
        3. Low Range Chemistry/Immunoassay values should agree within 0.3 mg/dl, ng/dL, IU/ml, mIU/ml or other applicable reporting unit
     2. Change of test methodology: Analyzer to analyzer comparison of at least 20 samples is obtained.
        1. Values must agree within 10% or
        2. Slope of plotted values must be within 0.90 and 1.10 or
        3. Chemistry/Immunoassay values should agree within 0.3 mg/dl, ng/dL, IU/ml, mIU/ml or other applicable reporting unit
     3. Urinalysis: Accuracy determinations must agree within 1 unit/scale of measurement. IE: 1+ to 2+
     4. Reportable range determinations are set by the manufacturer upon implementation.
  5. All Performance Verifications summary documents are to be signed by Laboratory Director.

1. **Policy for Specimen Stability study verifications**
   1. Any modifications to manufacturer’s specimen stability guidelines place the assay in the Modified FDA realm and change the complexity of the assay to highly complex.
   2. All specimen stability studies must agree within the established Total Allowable Error (TEa) for that assay.
2. **Policy for Calibration Verification:** Calibration Verification must be performed at the minimum of every six months and after any major service work in which critical hardware is replaced, such as photometers and cooling/incubation systems.
   1. Values must agree within 10% or
   2. Slope of plotted values must be within 0.90 and 1.10 or
   3. Chemistry/Immunoassay values should agree within 0.3 mg/dl, ng/dL, IU/ml, mIU/ml or other applicable reporting unit
   4. Select assays may require the use of Total Allowable error limits for comparison.
3. **Policy for Analyzer to Analyzer comparison:** Analyzer to Analyzer comparisons are performed every six months and ensure paired analyzers are within allowable error limits.
   1. Values must agree within 10% or
   2. Slope of plotted values must be within 0.90 and 1.10 or
   3. Chemistry/Immunoassay values should agree within 0.3 mg/dl, ng/dL, IU/ml, mIU/ml or other applicable reporting unit
   4. Select assays may require the use of Total Allowable error limits for comparison.