# 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: Bioreach Laboratories validates test performance of all CLIA non-waived test systems.

1. Manufacturer validation reports are used for method validation. These include Verification of Accuracy, Precision and Reportable Range.
2. 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.
3. 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. Chemistry/Immunoassay values should agree within 0.3 mg/dl, ng/dL, IU/ml, mIU/ml or other applicable reporting unit
   2. Chage of test methodology: Analyzer to analyzer comparison of at least 20 sample 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 manufacturer upon implementation.

# All Performance Validations summary documents are to be signed by Laboratory Director.