

## **INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) GUIDELINES**

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing performed on humans through the Clinical Laboratory Improvement Amendments (CLIA) and requires laboratories to have quality control (QC) procedures in place in order to monitor the accuracy and precision of the complete testing process. QC encompasses all activities used to detect errors that occur due to test system failure. CLIA compliance requires that for each test system, a minimum of two levels of external QC materials be tested each day of patient testing for non-waived tests. Equivalent Quality Control (EQC) regulations allowed for the reduction in frequency of testing QC materials because of advancements in laboratory technologies made available within current instrumentations. This allowed users of the FastPack® IP System to perform once per week control testing after completing a satisfactory 10 consecutive business day regiment of control testing.

As of January 1, 2016, EQC will be retired to make room for the new Individualized Quality Control Plan (IQCP). CMS has implemented this new QC option that is based on individual risk factors involved in the performance of each test in your laboratory. January 1, 2014 launched the beginning of an education and transition period for laboratories to learn and implement IQCP within their QC systems should they choose to do so. This education and transition period ends on January 1, 2016 when IQCP will be in full force. IQCP is voluntary and provides laboratories with flexibility in customizing QC policies and procedures based on the unique aspects and test systems found in your laboratory. Laboratories will still have the option to continue to achieve compliance by following all CLIA regulations as written.

The information above is provided as a courtesy. Qualigen, Inc. cannot guarantee its accuracy at any given time as the information is subject to change without notice. Please see the Centers for Medicare & Medicaid Services (CMS) website for the most complete and up to date information regarding IQCP.