

Individualized Quality Control Plan (IQCP)

CLIA requires a minimum QC frequency of 2 levels of controls for each day of patient testing. As an alternative, your facility may customize its QC plan by implementing an Individualized Quality Control Plan (IQCP). IQCP may reduce the QC frequency from a daily to a weekly schedule if the following criteria are satisfied.

1. Perform Quality Controls (QC) daily for 12 business days with all results in range
2. Perform IQCP Risk Assessment. Risk Level must be determined to be “manageable”
 - a. Qualigen’s online IQCP Risk Assessment includes a Risk Assessment and a Quality Control Plan
 - b. Go to www.qualigeninc.com/risk to perform the Qualigen IQCP Risk Assessment
3. Complete a Monthly QA Assessment

IQCP is not required. However, if you elect not to implement IQCP, your lab must comply with the CLIA requirement of running QC each day of patient testing.

IQCP policies supersede Equivalent Quality Control policies (EQC). Previous successful implementation of EQC does not obviate or preclude IQCP. Previous successful implementation of EQC is not equivalent to implementation of IQCP. As of January 1st 2016, the EQC approach will not be permitted and IQCP will take its place.

Even if you adopt a weekly QC frequency, performing QC should still be performed at the time of opening a new shipment of FastPacks, after calibration or maintenance, if improper storage is suspected, or a patient test result appears to be questionable.

Any unacceptable QC results must be repeated. If the repeated test is acceptable, continue weekly QC frequency. If the repeated test is once again unacceptable, identify and correct the root cause. At this point, it is suggested to repeat the 12 days of Daily QC in step 1 above before resuming a weekly QC frequency.

If an analyzer is replaced, step 1 should be repeated on the replacement analyzer prior to instituting a weekly QC frequency.

To read more about IQCP, go to the following resources:

<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure12.pdf>

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf>

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html