

## Individualized Quality Control Plan (IQCP)

CLIA requires a minimum QC frequency of 2 levels of controls 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 to a weekly schedule if the IQCP Risk Assessment determines that risk levels are manageable.

IQCP implementation involves completing a:

- Risk Assessment
- QC Plan
- QA Assessment Plan

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 1<sup>st</sup> 2016, the EQC approach will not be permitted and IQCP will take its place.

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

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

<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochures13.pdf>

Go to [www.qualigeninc.com/assets/pdfs/IQCPguidelines.pdf](http://www.qualigeninc.com/assets/pdfs/IQCPguidelines.pdf) to see the list of states that DO NOT recognize IQCP.

### Instructions

1. Perform QC daily for 10 business days during the initial period. Record the QC results from the 10 day period in the Quality Assurance Log.\*
2. Complete the 30-day Risk Assessment Checklist (page 2-51).
3. Go to [www.qualigeninc.com/IQCP](http://www.qualigeninc.com/IQCP) to complete the IQCP Risk Assessment and QC Plan.
4. Complete a Monthly QA Assessment.

*\*Step 1 is not required if it was satisfied previously.*

QC testing frequency may be decreased from daily to weekly\* if:

- If the IQCP Risk Assessment determined that the lab's risk levels are manageable
- All QC testing performed over the initial 10 day period is satisfactory
- There are no other quality problems noted on the monthly QA Assessment

*\*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 10 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.*