i-STAT hs-TnI | SUGGESTIONS FOR INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

EVALUATE PLAN CHANGES IN ACCORDANCE WITH REGULATORY AGENCY GUIDELINES

The QCP should be reviewed regularly to ensure it remains an effective plan to manage risks. A review of plan should be considered when there are significant changes to testing, such as adding a new test. The laboratory director's review and approval is required for initial plan and all plan changes. An IQCP Guide and Risk Assessment Template are available in the *i-STAT System* IQCP Resources area of the www.globalpointofcare.abbott website.

RISK ASSESSMENTS (RAs)

Required for all non-waived test using an IQCP to assess potential sources of failures and errors during a testing process. When implementing a new test using an IQCP, a risk assessment covering pre-analytical, analytic and post-analytical testing phases should be performed. Contemporary troponin and high-sensitivity troponin are not considered the same assay. A risk assessment should be considered to evaluate the frequency and impact of potential sources of failures and errors. Re-evaluation of the risk assessment must be considered by the director or personnel designated by director when changes occur in any of the following components: specimen, test system, reagent, environment and testing personnel.

QUALITY CONTROL PLAN (QCP)

The QCP should be revised in accordance with potential risks identified within the risk assessment process. The plan should ensure the accuracy, reliability, and quality of the test results are appropriate for patient care. If risks are identified during the RA process, it indicates that modifications are necessary within the QC plan.

QUALITY ASSESSMENT

The QA helps to determine the effectiveness of the plan thru review and ongoing monitoring of the plan. If failures or errors are identified, then corrective action should be taken and the IQCP modified to increase the effectiveness of the IQCP. Laboratories implementing IQCP for new tests are encouraged to perform monitoring activities at more frequent intervals during implementation, allowing the lab to identify issues indicating a need to adjust the QCP.

Additional resources:
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_labpdf.pdf
https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/quality-control

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