

ORIGINAL ARTICLE



## Quality planning and control strategy for AQT90 flex Radiometer<sup>®</sup> in point of care testing

Claudio Ilardo, Cecile Reynaud, Regine Bonneton and Joel Barthes

LABOSUD laboratory (Inovie member), Montpellier, France

### ABSTRACT

In the context of point of care testing (PoCT) and ISO 22870, internal quality control (IQC) is a crucial part of PoCT accreditation processes. Quality Control materials shall be periodically examined with a frequency that is based on the robustness of the analytical procedure and the risk of harm to the patient from an erroneous result. We propose to apply the statistical quality control (SQC) procedure to develop an individualized QC plan for AQT90 flex instrument used in PoCT. The robustness is determined by the sigma-metric and analytical goal represented by an allowable total error (TEa) is evaluated using a Varela graphic tool. A Sigma-metric SQC run size nomogram for estimating the number of patient samples between IQC events. According to the calculated robustness we can distinguish 3 groups of parameters: HCG and CRP with large sample size per event, D-Dimer and Procalcitonin with an average sample size per event and Myoglobin, NT-proBNP, and Troponin T with a limited sample size per event. In PoCT, the SQC strategy can promote more effective, and not necessarily more frequent, IQC.

### ARTICLE HISTORY

Received 20 November 2019  
Revised 23 March 2020  
Accepted 10 May 2020

### KEYWORDS

Quality control; Analytical run; SQC Strategy; Six Sigma; Point of care testing