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Validation Protocol: First Step of a Lean-Total Quality Management Principle in a New Laboratory Set-up in a Tertiary Care Hospital in India.

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Abstract

Method validation is pursued as the first step in establishing Lean-Total Quality Management in a new clinical laboratory, in order to eliminate error in test results. Validation of all the new tests were done (with particular reference to alkaline phosphatase) by verifying reference intervals, analytical accuracy and precision, inter-assay and intra-assay variations, analytical sensitivity, limit of detection, linearity and reportable range, i.e. (i) Analytical measurement range (AMR) and (ii) Clinically reportable range (CRR). Our obtained reference range was within that of the manufacturer's and showed high degree of analytical accuracy between two laboratories (r(2) = 0.99). Precision was comparable with the manufacturer's claim with inter-assay variation CV 1.04% and intra-assay variation CV 1.54%. Lowest limit of detection was 1.0324 ± 0.007 with CV 0.34%. AMR was also verified with CV 1.26 and 0.69%, for level 1 and level 2 control sera, respectively. The assay was linear with different dilutions. Lean concept was also verified with high recovery percentage. Validation ensures that accurate and precise results are reported in a clinically relevant turn around time.

KEYWORDS: Alkaline phosphatase; Lean concept; Total quality management; Validation

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