Implementation of internal quality control program for monitoring of HBsAg ELISA performance at a tertiary care hospital

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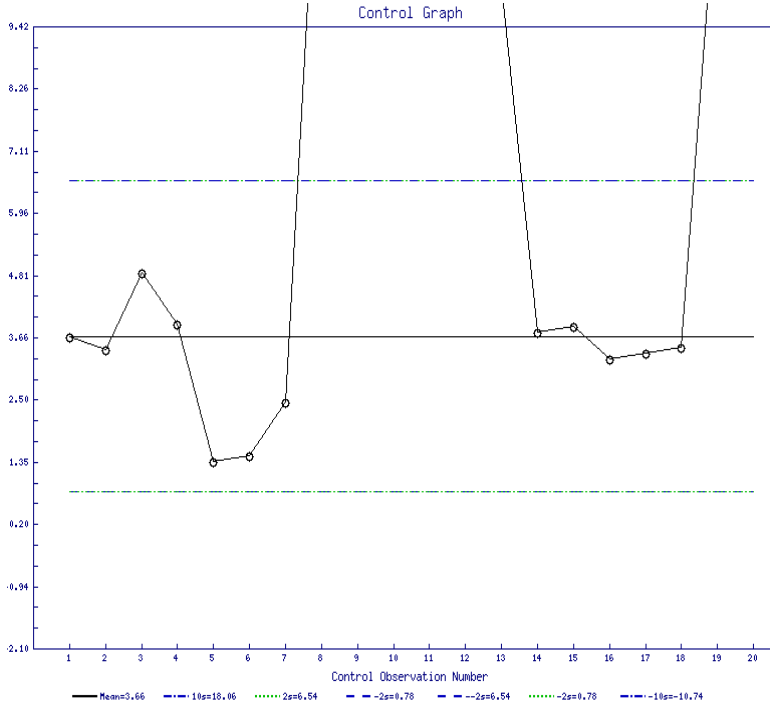
Background and Objectives:

Internal quality control samples may be incorporated in ELISA routinely for the detection of errors occurring due to change in environmental conditions, Test system or operator performance. Aim of the study was to prepare HBsAg internal quality control samples, monitoring of results using Levey-Jennings (LJ) charts, their interpretation, identification of errors and corrections applied.

Materials and methods:

This was a prospective cross sectional study conducted at Department of Immuno Hematology and Blood Transfusion, Tirunelveli Medical College, Tirunelveli, Tamilnadu, India. Internal quality control samples for HBsAg ELISA were prepared 'in-house' by using positive pooled samples after 56ºC incubation for one hour. Sample with 1:256 dilution gave E ratio of 1.9 and was taken as internal quality control. After 20 runs, mean and SD was calculated. Inter aliquot variation was performed using Coefficient of variation and interpreted to detect errors. LJ chart demonstrating the performance of Internal quality control samples on 26 runs [07 July to 23 September] for HBsAg ELISA was drawn and analyzed.



Results: The Mean of first 20 runs was 3.66 1.44 (Mean 1) and LJ chart was drawn. The first 7 runs, when plotted were within normal limits. But the next run showed a shift with value outside 3 SD. The next 6 runs were near the new results (Mean 2). This was followed by another 5 runs near Mean 1. The next 7 runs were near Mean 2. When these results were investigated and analysed, it was found that a new ELISA screening kit was supplied where the runs resulted in Mean 2. A new e ratio and thus a new mean need to be calculated for continuous check if quality.