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Establishing Quality Control Values for Hematology Parameters: An Insight

Sir,

Quality Control (QC) in the medical laboratory is a statistical process used to monitor and evaluate the analytical process that produces patient results. A quality control product is a patient-like material ideally made from human body fluids and contains one or more analyte in known concentration. In order to assess the validity of results on patient specimens, use of QC material is a requirement put forth by regulatory agencies. It is essential for laboratories to fulfill or surpass the regulatory standards set by regulatory agencies.

For most hematology analyzers, the target QC value and its limits for each analyte are provided by the vendor. These values are calculated by repeated testing of QC material and are provided in an assay-sheet with each new lot of controls. However, owing to variation in different laboratories, instrument calibration, maintenance, reagents and operator technique, these values may not be the exact target value in a given laboratory.

Both The College of American Pathologists¹ (CAP) and Joint Commission on Accreditation of Healthcare Organizations² (JCAHO) recommend calculation of own target values by each laboratory. This approach may not be a cost-effective option for the laboratories catering to a small number of patient samples. Utilization of manufacturer provided QC values, however, is permitted as a guide for establishing own QC values, and for very low volume tests where the range is narrow enough to detect clinically significant errors.

Calculation of own target values is a rather easy task. The new control should be analyzed a minimum of 20 times across 3 - 5 days. The average of these 20 values

should be within the range stated on manufacturer provided assay sheet. A two standard deviation range should be calculated from this new target value for setting up the upper and lower limits. These new values should then be incorporated into the system and utilized throughout the dating of the product.

Mean Corpuscular Volume (MCV) is a hematologic parameter that requires special consideration. It has the tendency to rise by two units over the life of the control material. To accommodate this, it is acceptable to raise the new calculated target value by half this change (by one unit). This will result in values starting below the mean, rise through the mean and finish above the mean.

One drawback of establishing the own QC values is an increased utilization of expensive commercial controls. However, in view of recommendations of Regulatory Bodies, each laboratory should establish its own quality control values to ensure reliability of test results thus avoiding medically significant errors.

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