

procedure manuals, corrective actions and record retention. The general requirement is that the lab analyse two levels of QC materials on each day of testing, although this recommendation is subject to many 'ifs and buts' and is far from a hard and fast rule.

High complexity tests are either difficult to perform or are those that the lab has modified from the manufacturer's instructions. For statistical QC, the labs must demonstrate compliance with certain stringent requirements including evaluation of the instrument and reagent stability, and the establishment of the labs own acceptability criteria to assess QC performance.

CLIA'88 has remained at the forefront of all subsequent attempts to define acceptable standards of performance. However, the question needs to be asked: where did the CLIA'88 standards come from? As far as can be ascertained, the answer is that 'experts' decided on the standards. The standards listed in CLIA'88 are thus opinions, not facts.

Biological Variation (BV)

The concentration of many analytes can vary over an individual's lifetime, simply because of the biological factors involved in the ageing process. In addition, certain analytes have predictable biological rhythms or cycles, be they daily, monthly or seasonal. Most analytes, however, do not have such cyclical rhythms, but rather fluctuate randomly around a homeostatic setting point. These variations are collectively called Biological Variations. For example compare the wide BVs found in serum creatinine (related to exercise, diet, muscle mass etc) to the smaller variation found in serum calcium (under tight homeostatic control).

Knowledge of such BVs can be applied to the setting of quality specifications, for example, total allowable error, standards in EQAs, as well as precision and bias.

Dr. Callum Fraser, one of the leading proponents of BV as a basis for setting quality standards, said that "the quality of tests performed in laboratory medicine must allow our clinicians to practice good medicine."

BV is a valid setting point from which to begin the quest for acceptable standards of performance. It has the advantage that it is related to biology, and thus is appropriate as a means to control biological variation in pathology test results. In addition BV standards are verifiable by actual laboratory measurement and have not been 'invented' by a panel of 'experts'.

Thistle QA Acceptable Standards

The acceptable standards developed and applied by Thistle QA – and shown on Page 2 of each report - were initially based on both CLIA'88 and BV. Dr. Callum Fraser took those concepts and designed the Thistle QA acceptable standards. Subsequent changes have taken place, including a blending of CLIA'88 and BV to create a single desirable and acceptable standard, as well as modifications suggested by a local panel of experts, based on achievable technical standards, as well as clinical needs.

S A N A S



PROFICIENCY TESTING Accredited to ISO Guide 43 and ILAC G13