Transition to laboratory information system (LIS) based quality control (QC) uncovers vendor requirement to increase significant digits for QC data compared to patient data

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In our transition from manual input of QC data into a microcomputer based QC system, we interfaced the UNITY PLUS PRO (Bio-Rad Laboratories, Irvine CA) to the MYSIS LIS (Mysis, Tucson, AZ). The MYSIS QC module does not accommodate customization of the QC result's least significant digit (LSD) and the QC result is rounded to the same LSD as the patient result. According to Cembrowski and Carey (Laboratory Quality Management, 1989), control results need to span at least six concentration intervals to prevent degradation of the performance of quality control rules such as the 1-3SD rule. We computed the number of concentration intervals occupied by 99 percent of the control results for each of the 65 tests transferred to the MYSIS system. For 18 out of the 65 tests, at least one control level had fewer than six different concentration intervals. The 18 tests follow as well as the number of control levels with fewer than 6 concentration intervals.

Analyte	Number of controls ≤ 6 intervals
ALT	1
Albumin	1
AST	1
β hCG	1
Carbamazepine	1
CO_2	1
Chloride	1
CKMB	1
Digoxin	2
Direct Bilirubin	2
Ethanol	1
Ferritin	1
Iron	2
Lactate	1
Potassium	2
T3 Uptake	1
TSH	1
Total Protein	2

Overall, we have improved laboratory efficiency by eliminating manual QC data entry but the intervention required to change significant figures in MYSIS is tedious and decreases sample throughput. To achieve a complete automated QC data handling system, MYSIS must work towards QC data customization.