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# Assessment of utility of daily patient results averages as adjunct quality control in a weekday-only satellite chemistry laboratory

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**ABSTRACT**

**Background**: Our department operates a weekday-only (8AM-5PM) satellite laboratory in an infusion center with a menu of 18 chemistry tests on a Roche c501 analyzer. We examined whether daily patient results averages (PRA) in this setting might be useful as a patient-based quality control (PBQC) adjunct to standard daily liquid quality control (LQC) measurements. First, we evaluated the reproducibility (coefficient of variation, CV) of daily PRAs for each analyte, and compared these to CVs of LQC. Second, for select analytes found to have relatively low PRA CVs, we evaluated the extent to which use of daily PRA measurements could improve detection of analytical errors when combined with LQC.

**Methods**: Patient results data for approximately one month (21 weekdays) were obtained from the Sunquest laboratory information system. For calculation of patient results averages (PRA), qualifying results were restricted to those within the reference range for each analyte. PRA and standard deviation (S) of PRA across 21 days was calculated for each analyte. Coefficients of variation for PRA (CV-PRA) were compared to those observed for standard liquid quality control (LQC) measurements (CV-LQC). For those analytes for which CV-PRA was less than CV-LQC, we evaluated the potential advantage of addition of PRA to daily LQC. For each analyte, a presumed PRA shift was determined such that probability of detection (P) was 0.5 when using LQC alone (viz., using high LQC and low LQC measurements), according to criterion that at least one 1-2S deviation from mean was obtained. For this same PRA shift, P = 0.5 for LQC alone was compared to P obtained for LQC + PRA (viz., using high LQC, low LQC, and PRA measurements), according to the same criterion.

**Results**: Across 21 days, the number of results per day per assay ranged from 23 ±4 (uric acid) to 75 ±21 (electrolytes). Qualifying results (results within the reference range) ranged from 70 ± 6 % (LDH) to 99 ± 1 % (Cl). Seven analytes had CV-PRA < CV-LQC (analyte, CV%): albumin, 1.25%; Ca, 0.67%; Cl, 0.62%; CO2, 1.13%; creatinine, 3.44%; K, 1.14%; Na, 0.65%. The remainder did not meet this criterion: ALP, 3.7%; ALT, 5.2%; AST, 5.1%; BUN, 4.6%; glucose, 1.4%; LDH, 2.0%; Mg, 1.4%; P, 2.5%; protein, 0.9%; TBIL, 6.1%; uric acid, 4.3%. Among the seven analytes for which CV-PRA < CV-LQC, probability (P) of shift detection by LQC for circumstances as described in Methods (LQC P = 0.5) was increased substantially by inclusion of PRA (analyte, shift in analyte concentration, P): CO2, ±1.07 mmol/L, 0.97; creatinine, ±0.099 mg/dL, 0.93; albumin, ±0.126 g/dL, 0.85; Ca, ±0.14 mg/dL, 0.80; K, ±0.097 mmol/L, 0.76; Cl, ±1.24 mmol/L, 0.74; Na, ±1.48 mmol/L, 0.68.

**Conclusions**: For 7 analytes, daily PRA demonstrated CVs less than those for LQC. For these analytes, calculations demonstrated that daily PRA can increase probability of detection of small results shifts when used as an adjunct to LQC. Daily PRA is a simple and essentially cost-free form of PBQC that may be useful for certain analytes in part-time laboratory settings.

## INTRODUCTION

Our department operates a weekday-only (8AM-5PM) satellite laboratory in an infusion center offering a menu of 18 chemistry tests on a Roche c501 analyzer. We examined whether daily patient results averages (PRA) in this setting might be useful as a patient-based quality control (PBQC) adjunct to standard daily liquid quality control (LQC) measurements.

First, we evaluated the reproducibility (coefficient of variation, CV) of daily PRAs for each analyte, and compared these to CVs of LQC. Second, for select analytes found to have relatively low PRA CVs, we evaluated circumstances in which use of daily PRA measurements could improve detection of analytical errors when combined with LQC.

## METHODS

- Patient results data for approximately one month (21 weekdays) were obtained from the Sunquest laboratory information system.
- For calculation of patient results averages (PRAs), qualifying results were restricted to those within the reference range for each analyte.
- PRA and standard deviation (S) of PRA across 21 days were calculated for each analyte.
- Coefficients of variation for PRA (CV-PRA) were compared to those observed for standard liquid quality control (LQC) measurements (CV-LQC).
- Further analysis was restricted to those analytes for which CV-PRA was less than or equal to CV-LQC for either high or low LQC.
- For each analyte, a comparison was made between the probability of at least 1-2S detection of a shift in assay results when using LQC alone versus when using both LQC and PRA. Specifically, P(at least 1x 1-2S) was calculated as follows:
- For LQC: P(at least 1x 1-2S) = 1 - (P(no detection by LQC-1 of 1 -2S) x P(no detection by LQC-2 of 1 -2S))
- For LQC + PRA: P(at least 1x 1-2S) = 1 - (P(no detection by LQC-1 of 1 -2S) x P(no detection by LQC-2 of 1 -2S) x P(no detection by PRA of 1 -2S))
- The term "at least 1x- 1-2S" means that at least one 1-2S deviation from mean was obtained from among high LQC and low LQC measurements, or from among high LQC, low LQC and PRA measurements.

## RESULTS

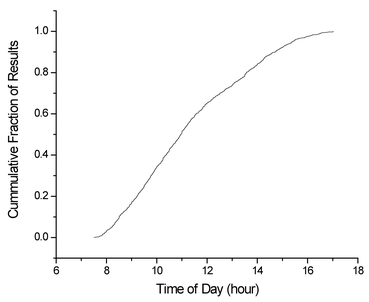


**Figure 1**. Sample accrual during the 9-hour daily interval of operation of the laboratory - example. In this instance, there were essentially two phases of accrual rates: First (4h, 65% of results), and second (5h, 35% of results). The difference in samples/time was approximately -43% (second compared to first).

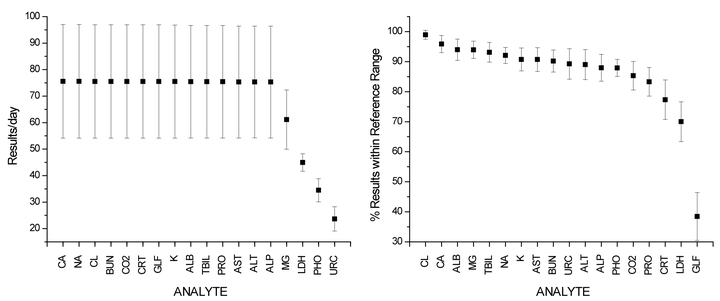


**Figure 2**. Results per day and percentage of qualifying results. Across 21 days, the number of results per day per assay ranged from 23 ±4 (uric acid) to 75 ±21 (electrolytes) (**A**). Qualifying results (results within the reference range) ranged from 70 ± 6 % (LDH) to 99 ± 1 % (Cl) (**B**).

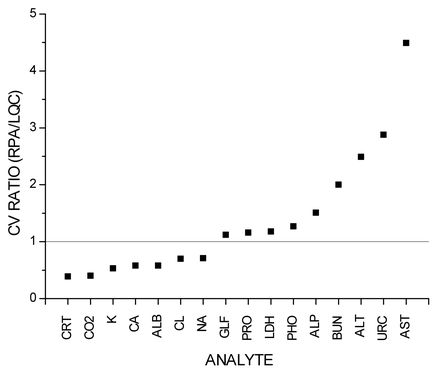


**Figure 3**. Ratios of coefficients of variaton (CVs) for daily PRAs vs. LQC. Seven qualifying analytes had PRA-CV less than LQC-CV. These were (analyte, CV%): albumin,1.25%; Ca, 0.67%; Cl, 0.62%; CO2, 1.13%; creatinine, 3.44%; K, 1.14%; Na, 0.65%. The remainder did not meet this criterion: ALP, 3.7%; ALT, 5.2%; AST, 5.1%; BUN, 4.6%; glucose, 1.4%; LDH, 2.0%; Mg, 1.4%; P, 2.5%; protein, 0.9%; TBIL, 6.1%; uric acid, 4.3%.

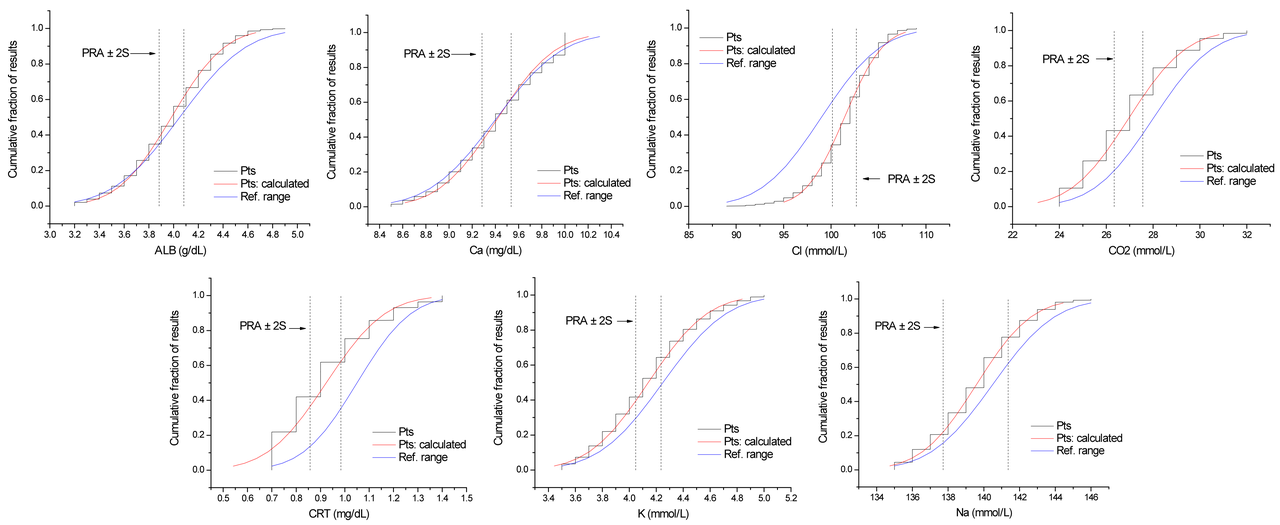


**Figure 4**. Distributions of qualifying results along with PRA (average ± 2S, vertical lines) for seven analytes. Step line (black): cumulative results distribution. Solid line (red): normal distribution based on average and S of cumulative results distribution. Solids line (blue): normal distribution associated with reference range (central 95%). Data shown are inclusive of all 21 days of patient results data.

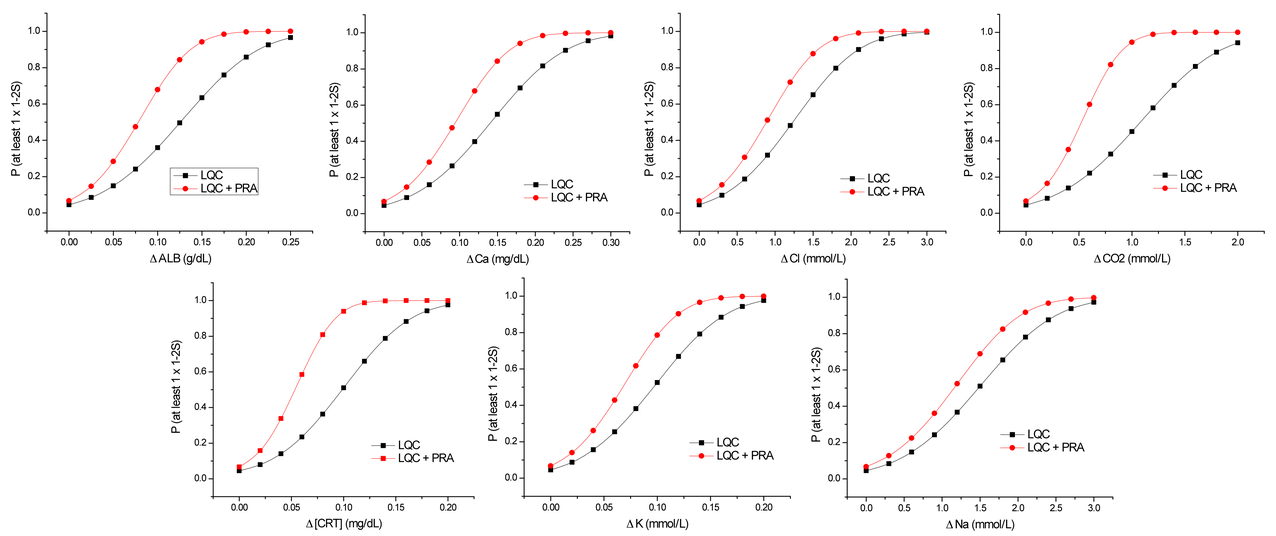


**Figure 5**. P(detection of at least 1x 1-2s), LQC, LQC + PRA vs. results shift. Among the seven select analytes, probability of 1-2S detection of a results shift was increased substantially at low shifts.

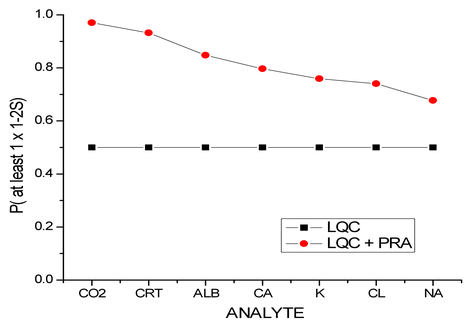


**Figure 6**. Example of P(1-2S) detection. For circumstances as described in Methods, for fixed 0.5 probability (P) of 1-2S shift detection by LQC, P(1-2s) was increased substantially by inclusion of PRA (analyte, P): CO2, 0.97; creatinine, 0.93; albumin, 0.85; Ca, 0.80; K, 0.76; Cl, 0.74; Na, 0.68.

## CONCLUSIONS

Daily PRA results across 21 days for 7 select analytes demonstrated CVs less than those for LQC:

albumin, Ca, Cl, CO2, creatinine, K, Na.

For these analytes, calculations for presumed results shifts demonstrated that daily PRA can under some circumstances increase probability of detection of error when used as an adjunct to LQC. Daily PRA is an essentially cost-free form of PBQC that may be useful for certain analytes in part-time laboratory settings.

A shortcoming of the analysis is that we assumed a shift affecting all results within a day as a boundary case for calculations. This is an improbable although not unobserved scenario. At the very least, then, the analysis identified those analytes that in this setting would be most suitable as candidates for standard running-averages patient-based quality control [1].

### Reference

[1] Ye JJ, Ingels SC, Parvin CA. Performance evaluation and planning for patient-based quality control procedures. Am J Clin Pathol. 2000 Feb; 113(2):240-8. PMID: 10664626.