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Recommended Citation
Joneja, MD, Upasana; McCloskey, MD, Laura J.; and Stickle, MD, Douglas F., "Analysis of patient results distributions to reevaluate a reference range change for calcium, after a change in assay reagents on the Roche Cobas c500 analyzer" (2015). Department of Pathology, Anatomy, and Cell Biology Resident's Posters. Paper 17.
https://jdc.jefferson.edu/pacbresidentposters/17

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Analysis of patient results distributions to reevaluate a reference range change for calcium, after a change in assay reagents on the Roche Cobas c500 analyzer

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INTRODUCTION
A change in reagents for calcium (Ca) on the Roche Cobas c500 used in our laboratory analyzer took place in 2013. The previous reference range (8.5-10.5 mg/dL) was replaced with that from the manufacturer’s study (8.6-10.0 mg/dL), based on correlation of results between the new and old assays. As a matter of quality assurance, we undertook a post-assay-change reevaluation of the reference range change, using a method based on that of Bhattacharya [1]. In short, the method relies on the assumption that the reference range is a normal distribution, which assumption enables this distribution to be isolated mathematically from within all-comers patient distribution data that are not normally distributed.

METHODS AND RESULTS
Primary data were all patient Ca results retrieved for a one-month interval (Figure 1).

Isolation of the data subset compatible with a normal distribution was a two-stage process. The point of maximum slope of the cumulative patient results distribution was determined to define the mean/median of the embedded normal distribution (9.4 mg/dL; Figure 2).

For each of these intervals, an iterative search was made to determine the central fraction of a normal distribution encompassed by each interval, as evidenced by the linearity of a normality plot when the correct fraction was specified (Figure 4).

Varying widths of intervals of results having symmetry around this midpoint (a necessary condition for a normal distribution) were assigned for analysis (Figure 3).

The reference range from Figure 5 data was essentially identical (±0.1 mg/dL) to "textbook" reference ranges (e.g., [2]). A comparison of the patient results distribution to the reference range distribution is shown in Figure 6.

RESULTS
Results of these procedures converged on a reference range for Ca of 8.6-10.2 mg/dL. (Figure 5).

CONCLUSIONS
The results were used to update our Ca reference range. Normal distribution analysis of patient data subsets by this method can be a powerful tool to evaluate reference ranges, simply because it can include a large number of patients using retrospective data. In comparison, identification and testing of "normal" patients in similar numbers would be difficult or impractical. In particular, clinical verification of a normal population for Ca would be expensive for any large number of patients, involving combined evaluation of Ca, renal function, vitamin D status, and PTH. These results demonstrate that one can have reasonable confidence in an esoteric method for extraction of a reference range from an all-comers patient results population. The related method of Hoffman [3] is more well-known but less stringent, being applied with varying degrees of success in recent literature [4-7].