

# Between-Laboratory Bias and Impact on Potential Test Results Used in Pay-for-Performance

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## INTRODUCTION

Pay-for-Performance incentives that use laboratory tests as measures of quality must assume that routine testing methods in different labs provide test results that are comparable.

**Objective:** To evaluate between-lab comparability of analytes commonly used to measure clinical performance.

## METHODOLOGY

- 50 fresh-pooled patient specimens were collected and distributed for analysis to 8 major ESRD clinical laboratories.
- These 8 ESRD clinical laboratories provide service to over 80% of ESRD patients in the US.
- We calculated bias as the difference between the observed laboratory result and the mean result for all labs.
- We estimated the effect of bias on the percentage of patients above a single performance threshold using representative patient results submitted by participating laboratories.

## RESULTS

Table 1. Between-laboratory bias for six analytes among 8 ESRD laboratories. Results are also shown for differences between laboratories with the highest (High) and lowest (Low) values for each analyte.

Analyte	Mean	Avg Bias	Max Bias	High-Low	%High-Low
Albumin (g/dL)	3.8	0.05	0.10	0.17	4.6
Hb (g/dL)	11.7	0.17	0.40	0.73	6.3
TSAT (%)	26.3	1.66	3.7	5.74	21.8
Ferritin (ng/mL)	699.9	38.4	81.0	145.8	20.8
Calcium (mg/dL)	8.9	0.09	0.36	0.51	5.7
Phosphate (mg/dL)	5.6	0.09	0.20	0.39	7.0

## CONCLUSIONS

- Significant between-laboratory bias exists for analytes in use or considered for use in assessing clinical performance.
- The magnitude of between-laboratory bias is sufficient to markedly affect apparent clinical performance at commonly-cited concentration thresholds.
- Methods differences between ESRD laboratories could be predicted to contribute to a greater-than 20% performance (population) shift for selected analytes.

## KEY LEARNINGS

- ✓ Any measures proposed for use in Pay-for-Performance incentives should be carefully evaluated to assess the effects of between-laboratory bias.
- ✓ These findings confirm the importance of establishing traceability and demonstrating comparability of any measures to be used in Pay-for-Performance incentives.

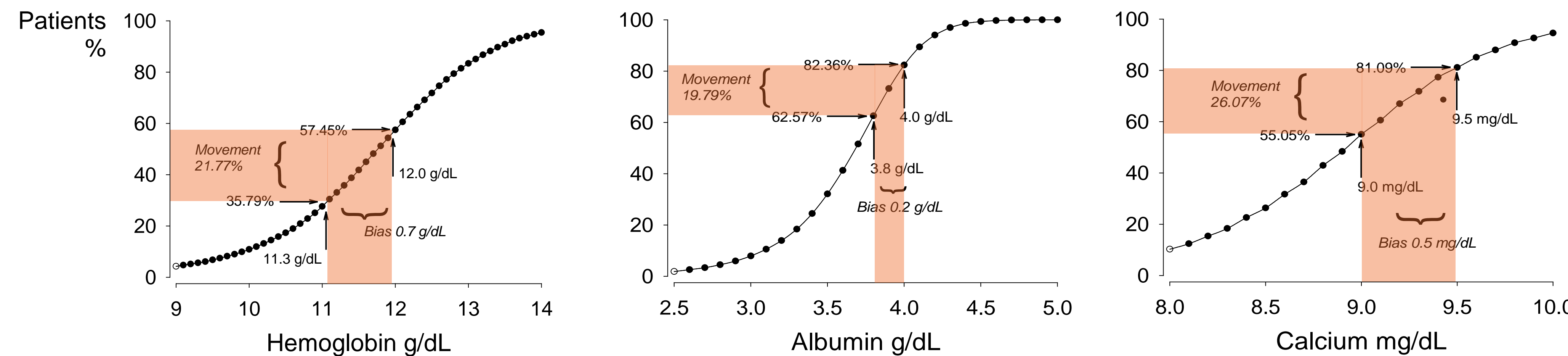


Figure 1. Effect of between-laboratory bias on potential population movement to above respective performance thresholds for Hemoglobin, Albumin and Calcium. Each distribution curve reflects patient results from that participating laboratory with the lowest value for each analyte. Bias reflects the magnitude of High-Low (see Table 1).

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