

# Maverick: Revolutionizing Immunoassay Testing with Photonic Ring Resonance Technology for Faster, More Accurate Results



A. HANNA<sup>1</sup>, K. SAMIEE<sup>1</sup>, D. MCGRATH<sup>1</sup>, K. EARLY<sup>1</sup>, T. BAKER<sup>1</sup>, A. BOYER<sup>1</sup>, C. GROSS<sup>1</sup>.

## INTRODUCTION

- Immunoassays have driven clinical diagnostics for 40+ years, yet luminescence-based methods remain largely unchanged.
- Traditional immunoassays require multiple steps (label conjugation, incubation, wash) and take ≥60 minutes, with higher CVs.
- Genalyte’s Maverick uses label-free silicon photonic chips (photonic ring resonance) to detect analyte binding in real time.
- Goal: Demonstrate TSH (FDA-cleared July 2024) and hsCRP (under development) performance versus Beckman Coulter Unicl Dxl 800.

## OBJECTIVES

- Compare Maverick versus Beckman Coulter Unicl Dxl 800 for TSH and hsCRP (TSH n = 127, hsCRP N=97).
- Assess method equivalency via linear regression (slope, R, intercept, mean % difference).
- Evaluate repeatability, lot-to-lot, and instrument-to-instrument reproducibility (CV 5% repeatability; 7% total within laboratory)



Figure 1. Maverick Immunoassay Analyser (11” H x 16” W x 23” D)

## METHOD

- Samples: IRB-approved collection; n = 127 TSH and n = 97 hsCRP.
- Comparator System: “Beckman Coulter Unicl Dxl 800 (Access Immunoassay System) for both analytes.
- Analysis: “Passing Bablock regression (Analyse-It v6.15): slope, intercept, R, mean % difference.
- Precision/Repeatability: n = 80 (TSH) n = 28 (hsCRP) replicates at low/mid/high levels.
- Lot-to-Lot: n=180 (TSH), n = 72 (hsCRP) replicates over three reagent lots.
- Instrument-to-Instrument: n = 180 (TSH), n = 72 (hsCRP) replicates over three instruments.

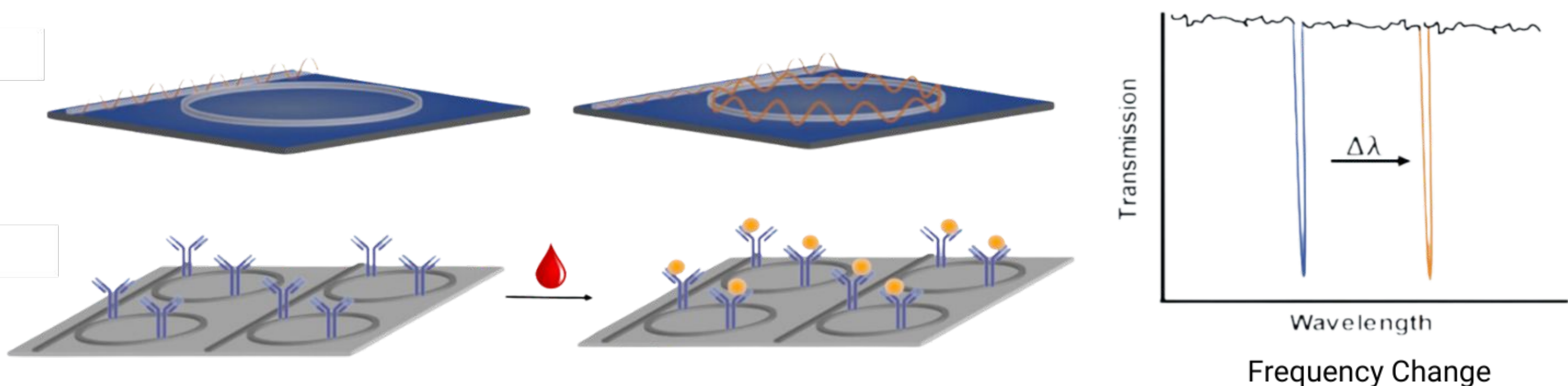


Figure 2. Maverick Photonic Ring Resonance Immunoassays Measure Frequency

## RESULTS

### TSH (Thyroid Stimulating Hormone)

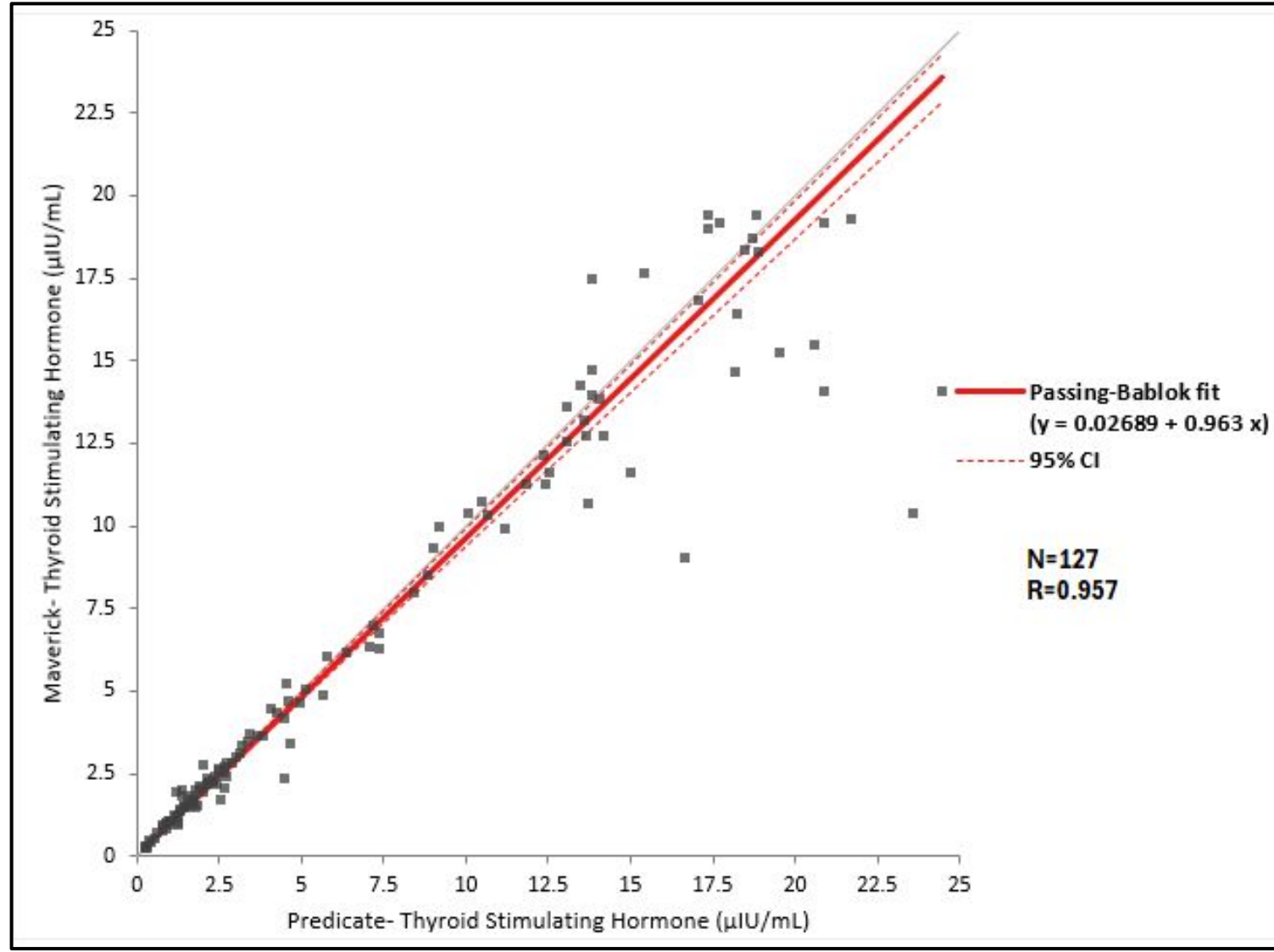


Figure 3. TSH Method Comparison

N	Slope (95% CI)	Correlation (R)	Mean % Difference
127	0.96 (0.93-0.99)	0.957	-3.90%

Table 1. TSH Method Comparison Summary

Reference Range Limits	Bias (XXY)	% Bias	95% Confidence Interval
Lower: 0.36	-0.01	-2.8%	-10.4% to 4.8%
Upper: 4.34	-0.23	-5.3%	-8.4% to -2.2%

Table 2. TSH Medical Decision Limit Summary Table

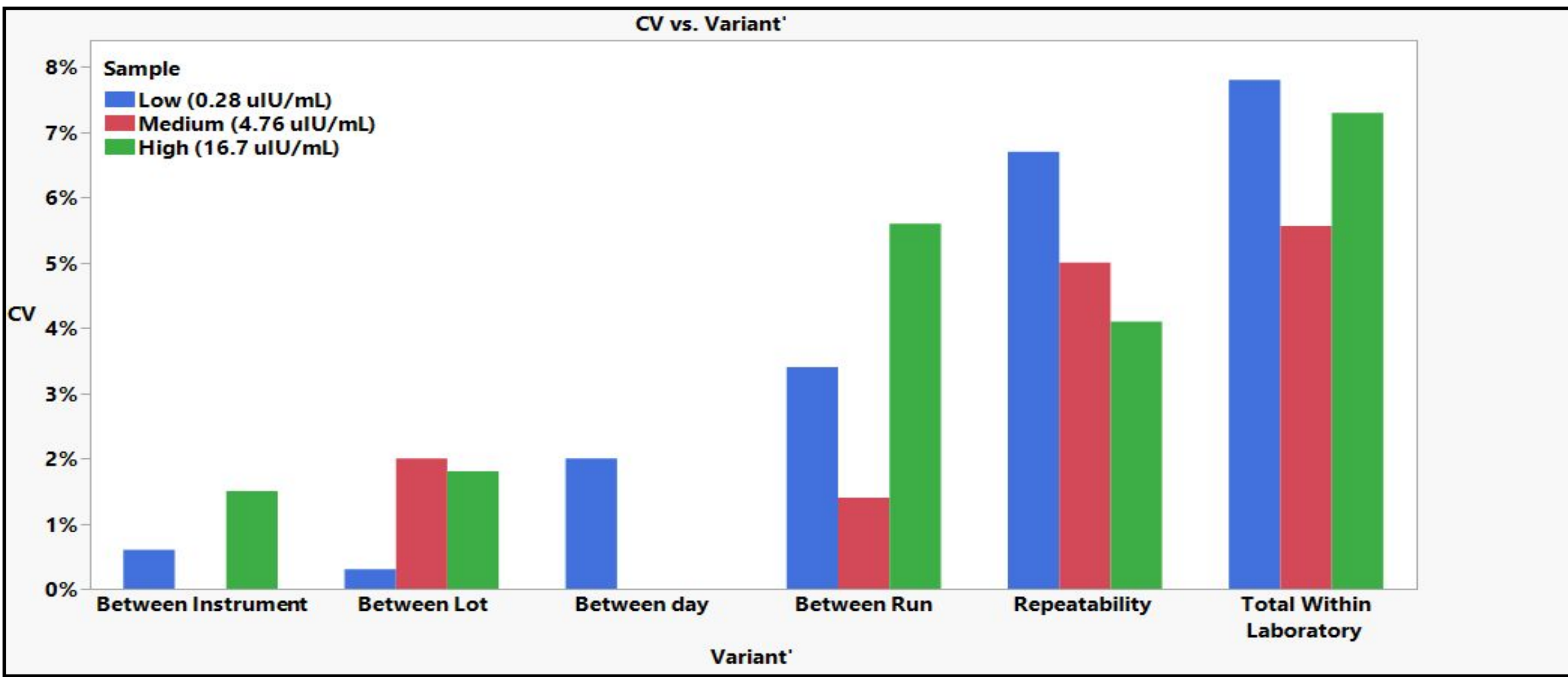


Figure 4. Reproducibility CVs for TSH at low, mid, and high concentrations

Sample	Mean	Between Instrument	Between Lot	Between Run	Between Day	Repeatability	Total within Laboratory
Low	0.28	0.6%	0.3%	3.4%	2.0%	6.7%	7.8%
Medium	4.76	0.0%	2.0%	1.4%	0.0%	5.0%	5.6%
High	16.7	1.5%	1.8%	5.6%	0.0%	4.1%	7.3%

Table 3. Reproducibility CVs for TSH at low, mid, and high concentrations

### hsCRP (High Sensitivity C-Reactive Protein)

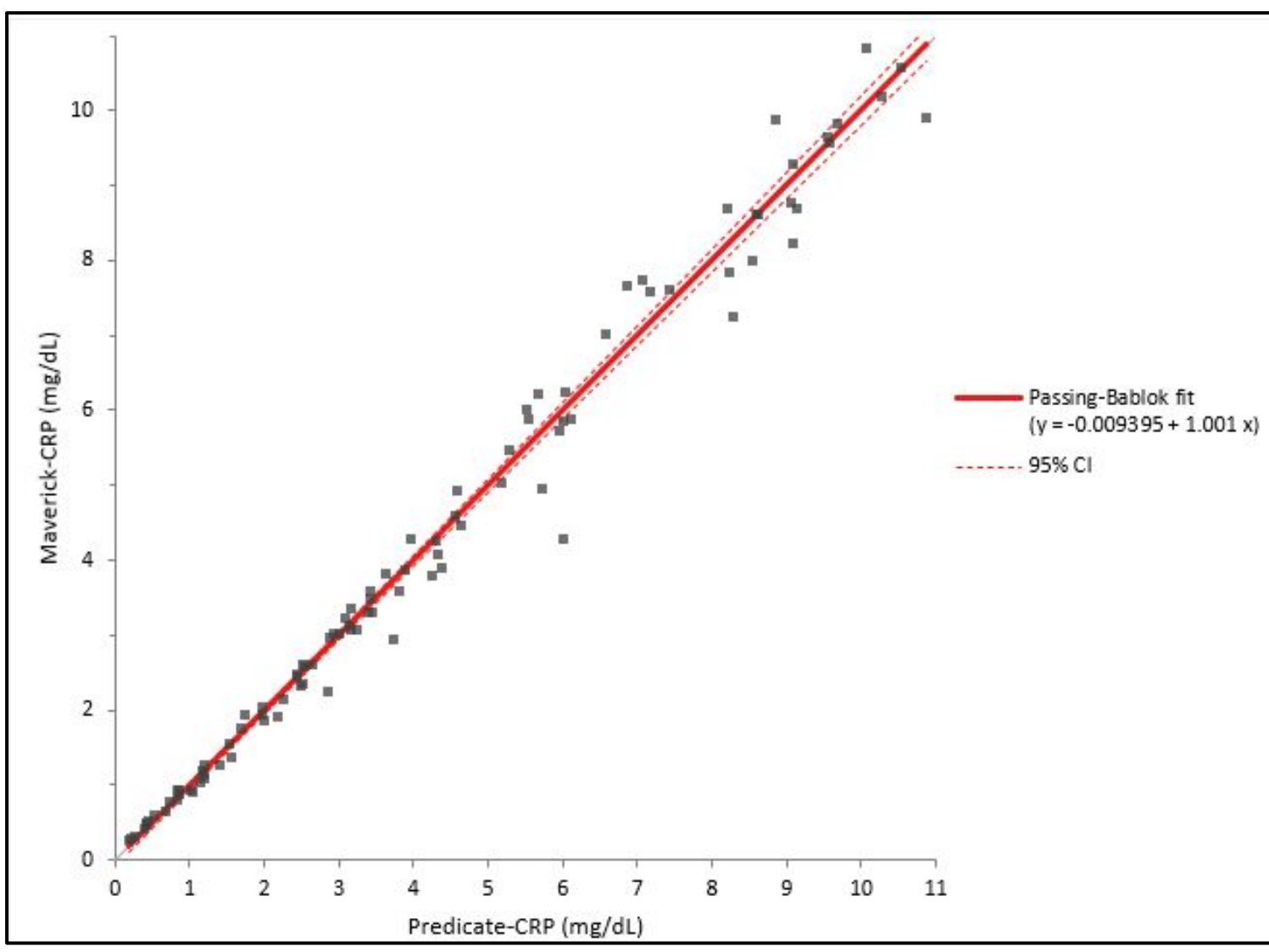


Figure 5. hsCRP Method Comparison

N	Slope (95% CI)	Correlation (R)	Mean % Difference
97	1.00 (0.98-1.03)	0.992	-1.0%

Table 4. hsCRP Method Comparison Summary

Reference Range Limits	Bias (mg/dL)	% Bias	95% Confidence Interval
Lower: 1.0	-0.009	-0.9%	-7.2% to 2.7%
Upper: 3.0	-0.007	-0.2%	-2.3% to -1.3%

Table 5. hsCRP Medical Decision Limit Summary Table

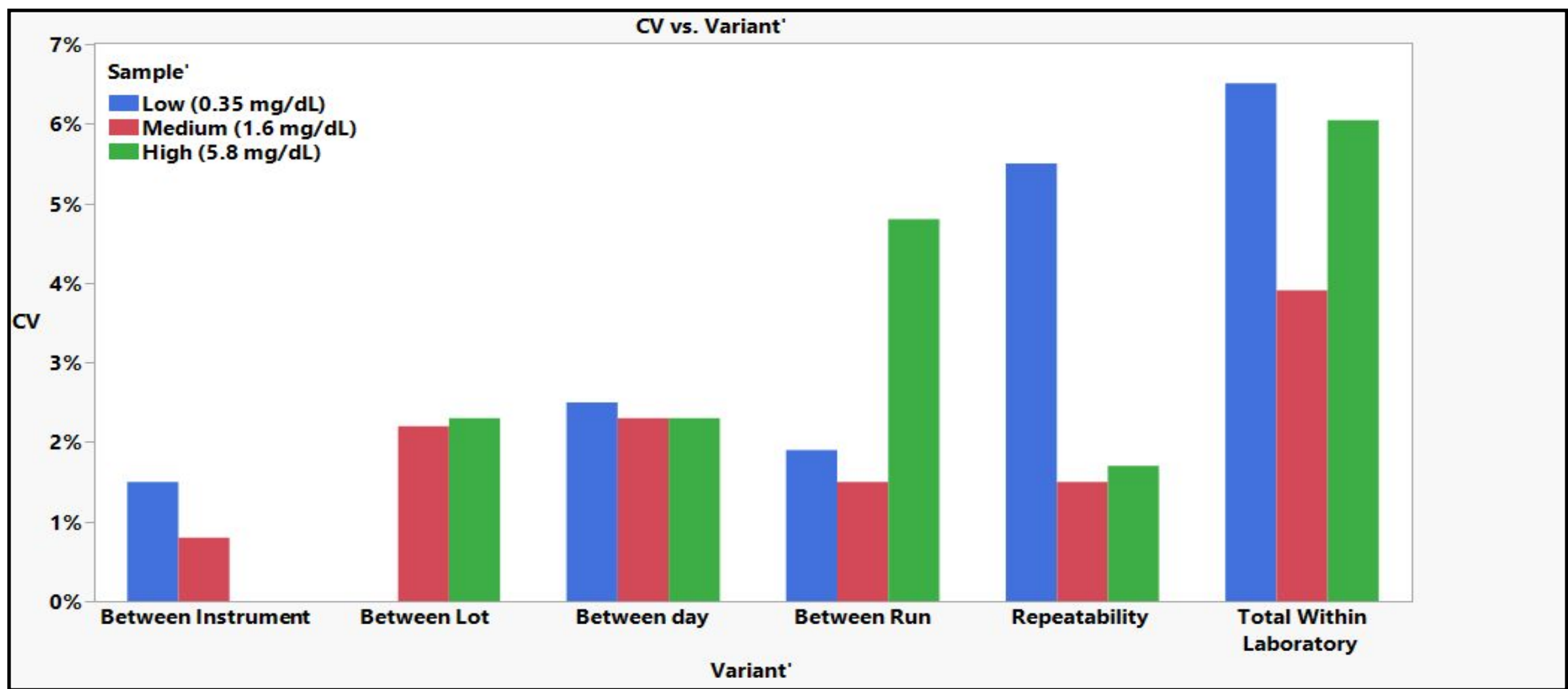


Figure 6. Reproducibility CVs for hsCRP at low, mid, and high concentrations

Sample	Mean	Between Instrument	Between Lot	Between Run	Between Day	Repeatability	Total within Laboratory
Low	0.35	1.5%	0.0%	1.9%	2.5%	5.5%	6.5%
Medium	1.6	0.8%	2.2%	1.5%	2.3%	1.5%	3.9%
High	5.8	0.0%	2.3%	4.8%	2.3%	1.7%	6.0%

Table 6. Reproducibility CVs for hsCRP at low, mid, and high concentrations

## CONCLUSIONS

- Maverick demonstrates excellent agreement with Beckman Coulter Unicl Dxl 800: TSH (R = 0.96), hsCRP (R = 0.99).
- Mean % differences are within clinically acceptable limits (−3.9% and −1.0%).
- Repeatability CVs 5% at all concentration levels; total within laboratory CVs 7% across three instruments and three kit lots
- Label-free photonic ring resonance enables sub-30 minute turnaround—no labels required.
- FDA clearance for TSH (July 2024) validated; hsCRP clearance pending. Platform supports future custom assays.

### CONTACT

Alexah Boyer  
Alexah.Boyer@Genalyte.com

### REFERENCES

- Genalyte, Inc., San Diego, CA.
- CLSI EP09-C: Method Comparison and Bias Estimation Using Patient Samples.
- FDA clearance: Genalyte Maverick TSH (July 2024).
- Analyse-It Software v6.15 (Deming regression).