Advancing Point-of-Care Diagnostics – Streamlining Patient Care with the Merlin

Genalyte

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INTRODUCTION

- Traditional lab testing is often slow, manual, and disconnected from the point of care.
- Turnaround times of several days can delay diagnosis and disrupt timely treatment.
- Pre-analytical errors account for up to 70% of all lab mistakes[2], especially during sample transport and manual handling—steps that Merlin eliminates.
- Merlin is a fully automated, point-of-care system that delivers lab-quality results in under 30 minutes—without transport, pipetting, or manual blood handling.

Figure 1. The Merlin Automated Lab shown in a hospital setting.

METHOD

Study Design

- 36 analytes tested across CBC, CMP, and Lipid panels
- Samples:
  - 239 K_2EDTA whole blood (CBC)
  - 228 lithium heparinized whole blood (CMP + Lipid)
- Sites: Internal HQ + 3 external point-of-care clinics
- Testing: Single replicates run on Merlin and FDA-cleared predicate systems
- Analysis: Passing-Bablok regression (method comparison); variance component analysis (precision).

Participant Cohort

- Ages: 19–93 (mean 48)
- Gender: 155 female, 106 male
- Mix of healthy and self-reported unhealthy donors
- 8 contrived samples to expand range for some analytes

CONTACT

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REFERENCES

1. Genalyte, Inc., San Diego, CA.
2. Lippi G, Blanckaert N, Bonini P, et al. Haemolysis: an overview of the leading cause of unsuitable specimens in clinical laboratories. Clin Chem Lab Med. 2008;46(6):764-772.

RESULTS

Method Comparison

Lipid Panel

Analyte	Slope	r	<% Diff>
CHOL	1.00	1.00	-0.2%
HDL	1.00	1.00	-0.4%
TRIG	1.00	1.00	-0.1%
LDL	0.99	0.99	0.7%
VLDL	1.00	1.00	0.3%
nHDLc	0.98	0.99	0.5%
CHOL/HDL	1.00	0.99	0.2%

Table 1. Method Comparison results for the Lipid Panel on the Merlin.

CMP Panel

Analyte	Slope	r	<% Diff>
ALT	1.00	0.94	4.0%
ALP	1.00	0.97	3.1%
AST	1.00	0.93	5.2%
TBIL	1.00	0.98	1.9%
BUN	1.00	0.99	-0.02%
CRE	1.00	0.81	5.7%
NA+	0.80	0.62	-0.3%
K+	1.00	0.87	-0.1%
CA	1.00	0.87	-0.1%
CL-	1.00	0.77	0.2%
ALB	1.00	0.98	-0.02%
GLU	1.00	1.00	-0.8%
tCO2	1.00	0.82	-2.5%
TP	1.00	0.96	-0.4%

Table 2.. Method Comparison results for the Comprehensive Metabolic Panel (CMP) on the Merlin.

CBC Panel

Analyte	Slope	r	<% Diff>
HGB	1.00	1.00	0.2%
HCT	1.02	0.98	1.2%
RBC	0.99	0.99	0.1%
MCV	1.04	0.94	1.1%
RDW-CV	1.00	0.97	0.2%
RDW-SD	1.03	0.93	1.2%
WBC	1.00	1.00	-0.2%
NEUT#	1.00	0.99	0.3%
NEUT%	0.99	0.94	0.8%
MXD#	1.00	0.67	1.4%
MXD%	1.21	0.55	6.5%
LYM#	1.00	0.99	-0.1%
LYM%	0.99	0.98	0.1%
PLT	1.02	0.99	1.8%
MPV	1.00	0.95	4.6%
MCH	0.97	0.94	0.1%
MCHC	0.89	0.63	-0.9%

Table 3. Method Comparison results for the Complete Blood Count (CBC) Panel on the Merlin.

Figure 2. Method Comparison results for RBC Analyte.
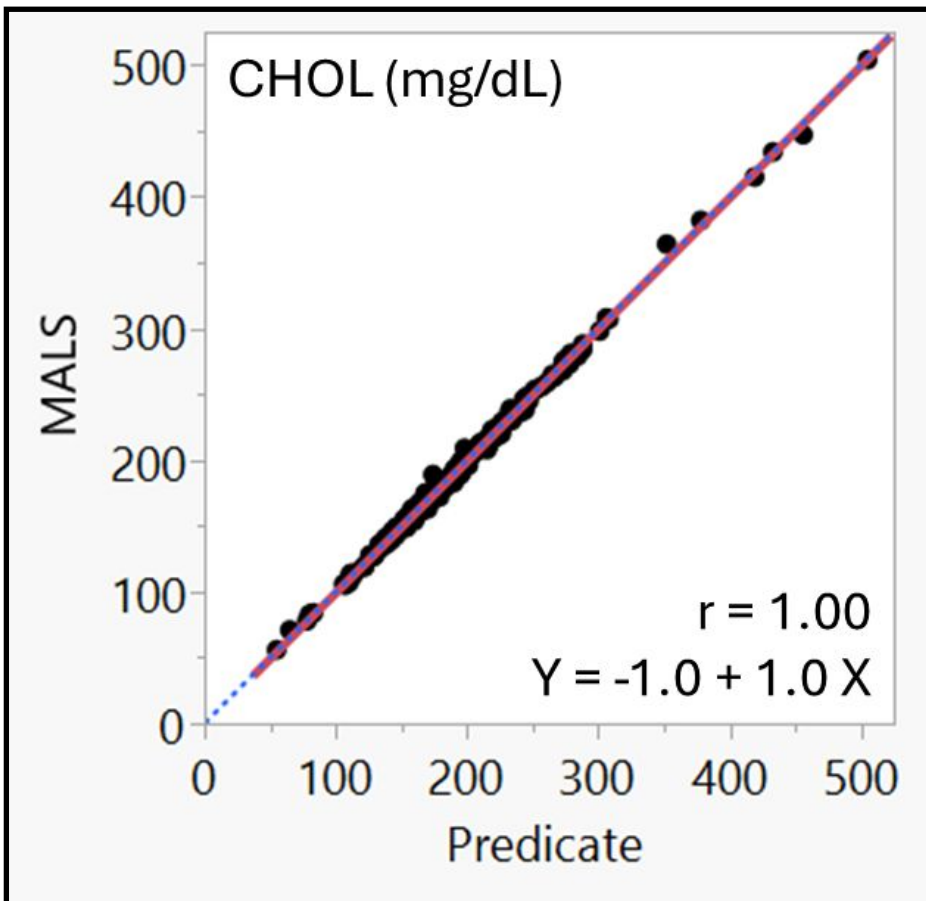
Figure 3. Method Comparison results for CHOL Analyte.

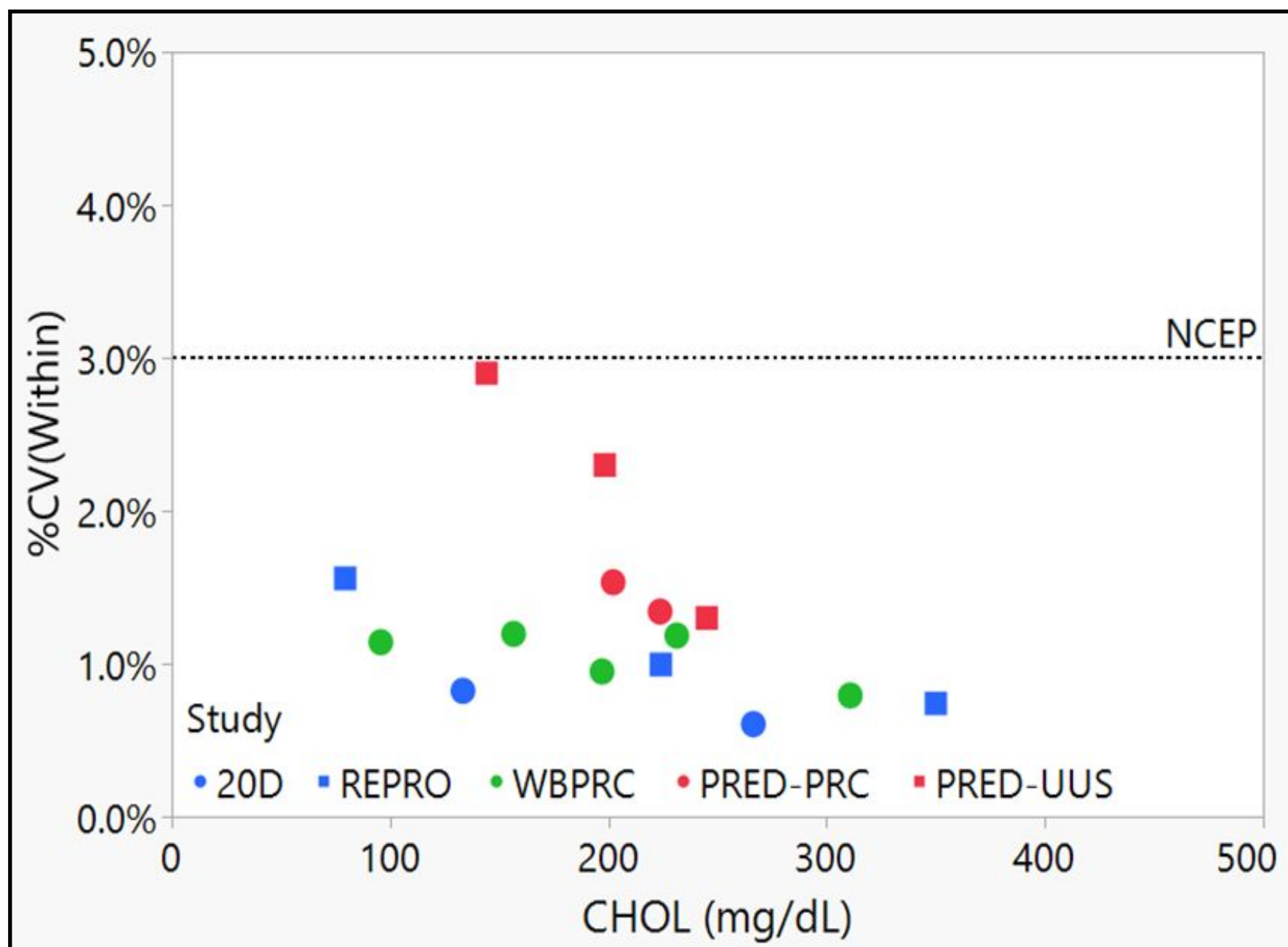### Example Precision Profiles

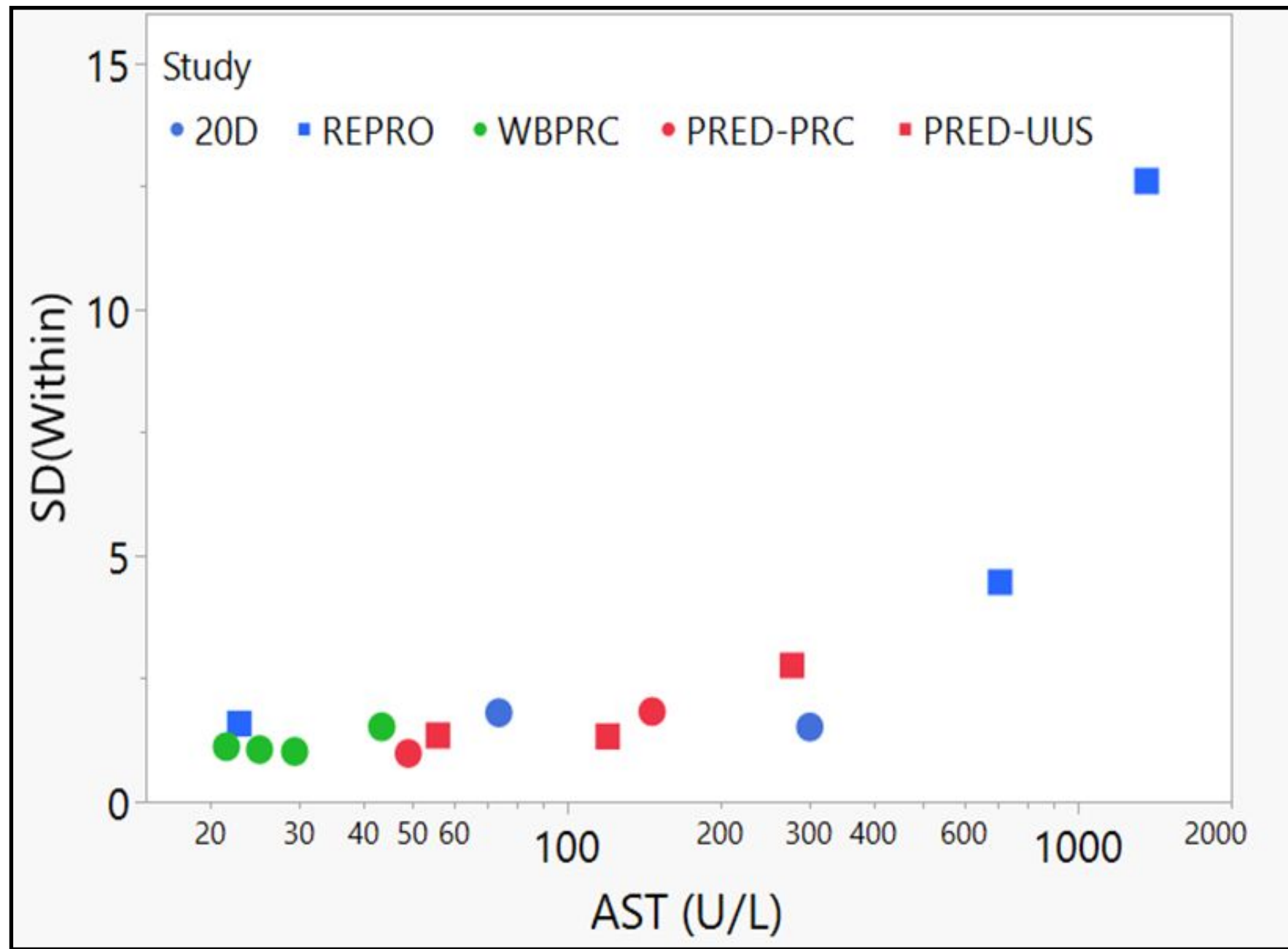Figure 4. Precision Profile (%CV) for CHOL
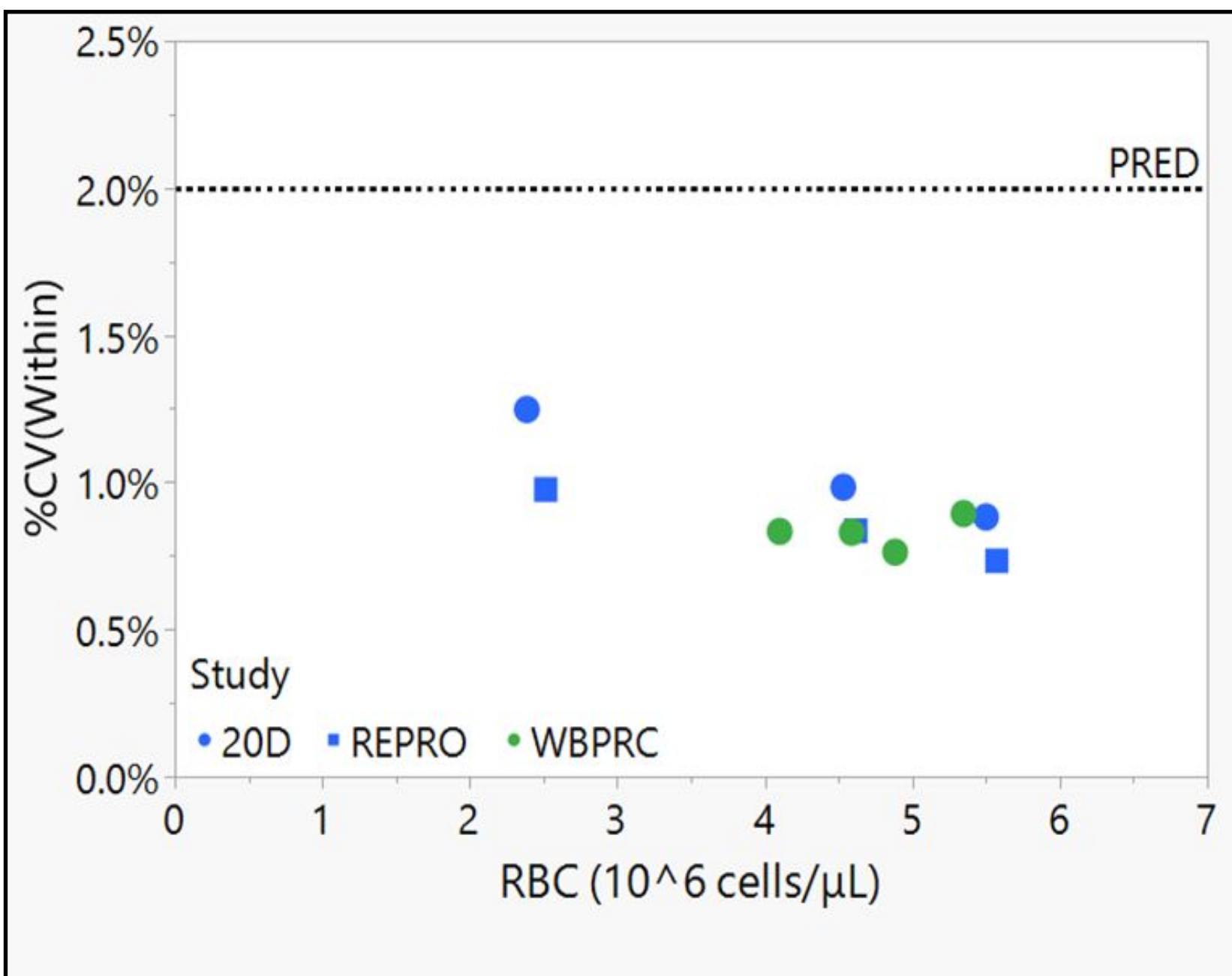

Figure 5. Precision Profile (SD) for AST

Figure 6. Precision Profile (%CV) for RBC

AUTOMATION & USEABILITY

Merlin Workflow Advantages

- Fully automated from tube scan to result
- No pipetting, mixing, or manual reagent handling
- Integrated with EMR test orders
- Built-in safety checks for:
  - Tube type verification
  - Expired materials
  - Sample stability windows
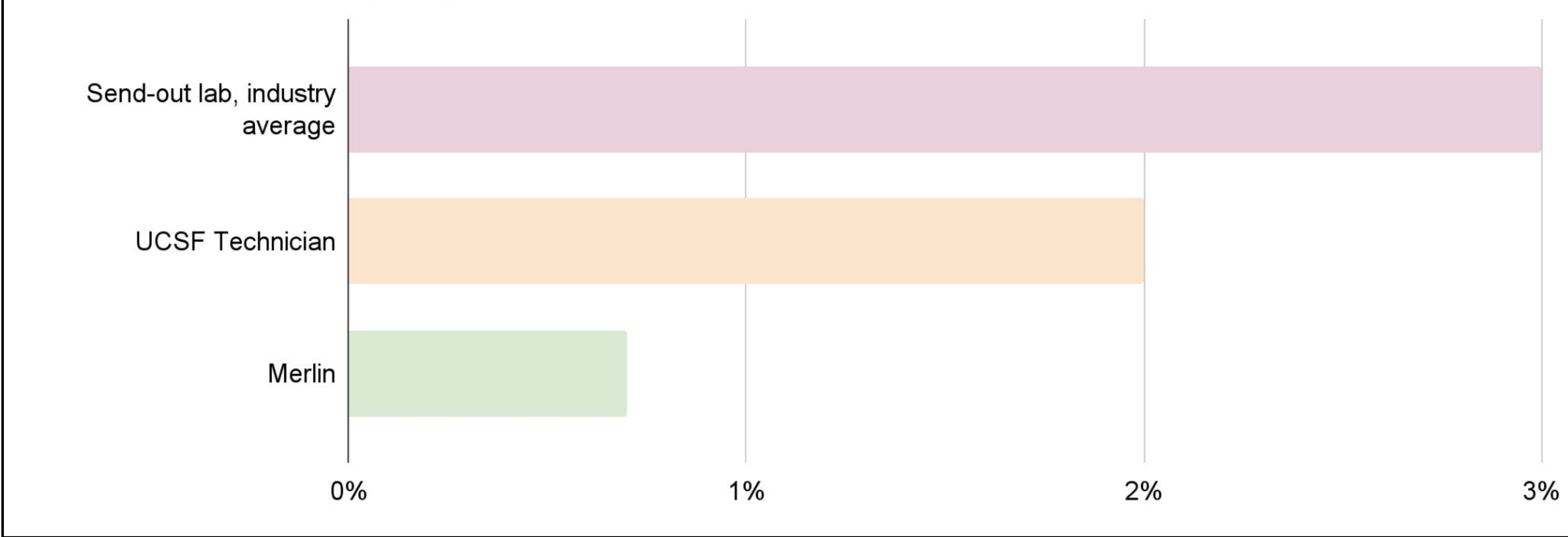- Operator-free, one-button workflow

Figure 7. Test Not Performed (TNP) Rate Comparison

CONCLUSIONS

- Merlin demonstrated lab-equivalent performance across all three panels (CBC, CMP, Lipid)
- Method comparison showed strong correlation with predicate devices for most analytes (r ≥ 0.98)
- Precision was consistent across multiple sites and sample types
- Merlin's automation reduces TNP rates, eliminates key error points, and enables same-visit treatment decisions without requiring trained lab personnel
- A scalable point-of-care solution to improve access, speed, and safety in outpatient diagnostics