



## Performance Characteristics of the PTS PANELS™ Lipid Panel Test Strips

### INTRODUCTION

A reliable and accurate lipid point-of-care test method enables healthcare professionals to easily test and immediately counsel their patients on lipid-lowering therapies, to understand their risk for developing coronary heart disease, their medication regimen, and the benefits of long-term persistence of therapy.

A new lipid panel test, PTS PANELS Lipid Panel Test Strips, provides lipid results (total cholesterol, HDL cholesterol, triglycerides, and calculated LDL cholesterol) from a single drop of blood, when run on the PTS CardioChek™ P•A test system. CardioChek P•A is a portable whole blood test system that uses reflectance photometry to determine three lipid concentrations on a single test strip. The system calculates LDL cholesterol levels using the Friedewald equation through the use of total cholesterol, HDL cholesterol and triglycerides levels.<sup>1</sup> Lipid Panel Test Strips have a cholesterol measuring range from 50 to 400 mg/dL, HDL cholesterol range from 15 to 100 mg/dL, and triglycerides range from 25 to 500 mg/dL.

PTS PANELS Lipid Panel Test Strips are CLIA Waived. This classification establishes that the PTS Lipid Panel Test Strip provides accurate, reliable and timely patient test results.

These studies describe the performance characteristics of the PTS Lipid Panel Test Strips.

### MATERIALS AND METHODS

#### Specimens

Whole blood was used for all PTS Test Strips studies. The blood was drawn in K<sub>2</sub>EDTA tubes for all studies, except for the correlation studies. In the correlation studies, whole blood, obtained from a fingerstick was used. Serum and whole blood samples were used for all reference methods.

### Accuracy / Method Correlation

#### Reference Methods:

- Cholesterol: Abell-Kendall traceable method and PTS PANELS Cholesterol Test Strips
- HDL Cholesterol: Abell-Kendall traceable method and PTS PANELS HDL Cholesterol Test Strips
- Triglycerides: CRMLN reference method and PTS PANELS Triglycerides Test Strips

Samples for Cholesterol and HDL cholesterol were run by the Abell-Kendall method by a certified Cholesterol Reference Method Laboratory Network (CRMLN) lab. Triglycerides were also run at the same CRMLN lab using an enzymatic assay. Method standardization studies were also performed for PTS test methods in comparison to CDC reference methods at a CRMLN laboratory. These studies are done to validate appropriate calibration of a manufacturers' lipid testing method.<sup>2</sup>

Additionally, Lipid Panel Test Strips were run by laboratory professionals and the results were compared to results from PTS PANELS Test Strips run on a PTS BioScanner™ 2000 instrument. Results from both methods were then compared using least squares linear regression.

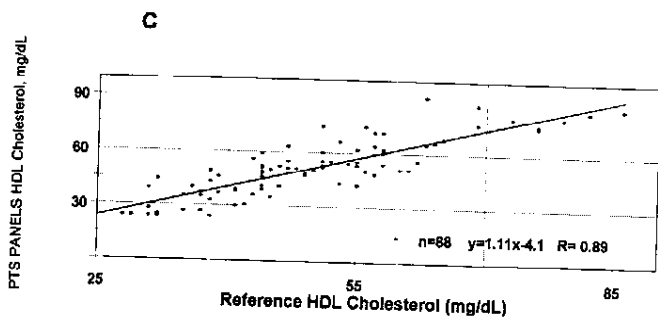
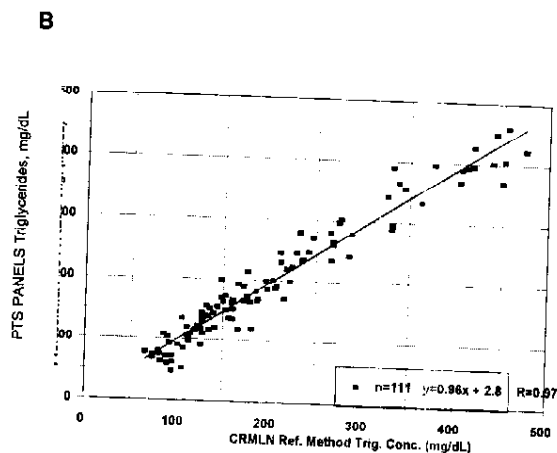
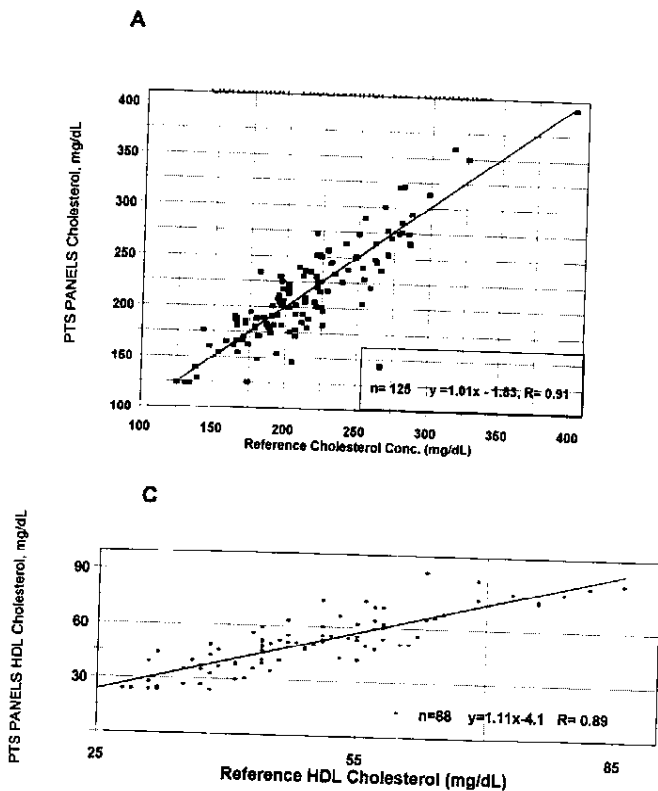
#### Precision

Precision studies were determined by performing replicate measurements of the same whole blood samples and calculating the coefficient of variation (CV).

#### Interference

Interference testing was performed using critical concentrations of the appropriate substances spiked into whole blood. To evaluate the effect of blood hematocrit, plasma was added back to blood collected from a normal, healthy donor. Hematocrits were adjusted to provide the range of 30 to 55%. Results of testing the spiked samples were compared to results of a Control (unspiked) sample.

**RESULTS**



**Fig. 1 Linear regression plots for PTS Methods and Reference Methods.**

(A) Total Cholesterol, Equation for line: PTS Cholesterol =  $-1.83 + 1.01(\text{Abell-Kendall cholesterol})$ ;  $r = 0.91$ ,  $N = 125$ .  
 (B) Triglycerides, Equation for line: PTS Triglycerides =  $2.8 + 0.97(\text{CRMLN Laboratory Trig. Method})$ ;  $r = 0.97$ ,  $N = 111$   
 (C) HDL Cholesterol, Equation for line: PTS HDL Cholesterol =  $-4.1 + 1.1(\text{Abell-Kendall HDL Chol.})$ ;  $r = 0.89$ ,  $N = 87$ .

Table 1. Lipid Panel Method Comparison			
	Lipid Panel - Cholesterol	Lipid Panel - HDL Cholesterol	Lipid Panel - Triglycerides
No. of Samples	95	95	95
Correlation Coefficient (r)	0.90	0.90	0.96
Bias	at 200 mg/dL, +0.05%	at 40 mg/dL, -3.25%	at 150 mg/dL, +1.32%
Bias	at 240 mg/dL, -3.13%	At 60 mg/dL, +4.17%	at 200 mg/dL, +3.24%

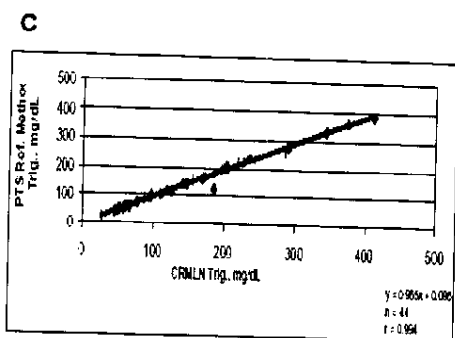
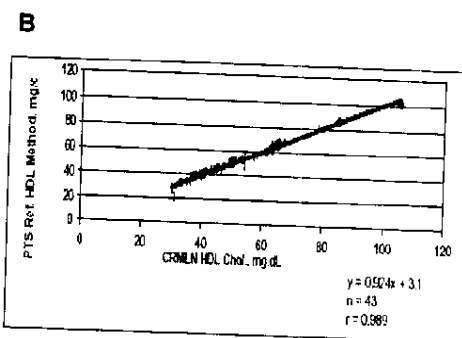
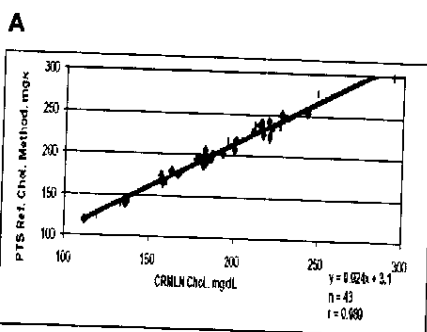
PTS PANELS Cholesterol ( $r=0.91$ , Fig. 1A), Triglycerides ( $r=0.97$ , Fig. 1B), and HDL Cholesterol ( $r=0.89$ , Fig. 1C), correlated well to the Abell-Kendall traceable methods for total cholesterol and HDL cholesterol, as well as to the CRMLN triglycerides laboratory method. In comparison of the Lipid Panel Test Strips against the single test method, Cholesterol ( $r=0.91$ , Table 1), Triglycerides ( $r=0.96$ , Table 1), and HDL Cholesterol ( $r=0.90$ , Table 1) all correlated well. Overall, a small bias was observed, between 3 to 4% (Table 1) at clinical decision points for cholesterol, HDL cholesterol, and triglycerides testing.

Method standardization studies demonstrated that the Lipid Panel Test Strips are standardized to methods traceable to CRMLN laboratory methods. Figure 2 demonstrates the very high

level of agreement of the PTS reference method to the CRMLN values for cholesterol ( $r=0.989$ ), HDL cholesterol ( $r=0.989$ ), and triglycerides ( $r=0.994$ ).

Precision results (Table 2) for the Lipid Panel Test Strips demonstrated accurate and reliable results for cholesterol, HDL cholesterol, and triglyceride measurements with CV's ranging from 4 to 6%.

Interference testing (Table 3) with a wide variety of routinely occurring substances present in the blood demonstrated minimal interference with Lipid Panel Test Strip cholesterol, HDL cholesterol, and triglyceride results.



**Fig. 2 Method standardization comparison.**  
 (A) Total Cholesterol, Equation for line: PTS Reference Cholesterol =  $3.1 + 0.924(\text{CRMLN Cholesterol})$ ;  $r = 0.989$ ,  $N = 43$ .  
 (B) HDL Cholesterol, Equation for line: PTS Reference HDL Cholesterol =  $3.1 + 0.924(\text{CRMLN HDL Cholesterol})$ ;  $r = 0.989$ ,  $N = 43$ .  
 (C) Triglycerides, Equation for line: PTS Reference Triglycerides =  $0.098 + 0.955(\text{CRMLN Triglyceride})$ ;  $r = 0.994$ ,  $N = 44$ .

Cholesterol		
No. of Observations	20	20
Mean Concentration (mg/dL)	197.2	251.3
Standard Deviation (mg/dL)	8.4	10.0
Coefficient of Variation (%)	4.3	4.0
HDL Cholesterol		
No. of Observations	20	20
Mean Concentration (mg/dL)	39.2	61.5
Standard Deviation (mg/dL)	2.5	2.8
Coefficient of Variation (%)	6.4	4.6
Triglycerides		
No. of Observations	20	20
Mean Concentration (mg/dL)	157.0	284.0
Standard Deviation (mg/dL)	6.1	16.8
Coefficient of Variation (%)	3.9	5.9

Table 3. Lipid Panel Test Strip Interference Testing Results

Substance	Level at no significant interference with PTS Cholesterol	Level at no significant interference with PTS HDL Cholesterol	Level at no significant interference with PTS Triglycerides
Bilirubin	20 mg/dL	20 mg/dL	20 mg/dL
Uric Acid	11 mg/dL	11.8 mg/dL	-
Hemoglobin	200 mg/dL	775 mg/dL	-
Acetaminophen	20 mg/dL	20 mg/dL	20 mg/dL
Ibuprofen	40 mg/dL	40 mg/dL	40 mg/dL
Salicylate	50 mg/dL	50 mg/dL	50 mg/dL
Methyldopa	2.5 mg/dL	2.5 mg/dL	See Notes
Dopamine	3.25 mg/dL	See Notes	See Notes
Potassium EDTA	-	702 mg/dL	702 mg/dL
Sodium Heparin	-	57.6 U/mL	57.6 U/mL

Substance	PTS Cholesterol	PTS HDL Cholesterol	PTS Triglycerides
Hematocrits	30 – 45% No significant interference.  >50% Decreased cholesterol levels observed.	31 – 45% No significant interference.  <30% Increased HDL levels observed.  >50% Decreased HDL levels observed.	30 – 50% No significant interference.  >50% Decreased triglyceride levels observed.
Notes:			
<ul style="list-style-type: none"> <li>Ascorbate interferes with PTS cholesterol, HDL cholesterol, and triglycerides starting with 0.75 mg/dL ascorbate, producing decreased levels.</li> <li>Dopamine interferes with PTS HDL cholesterol and triglycerides starting with 3.25 mg/dL dopamine, producing decreased levels.</li> <li>Methyldopa interferes with PTS triglycerides starting with 0.625 mg/dL methyldopa, producing decreased levels.</li> <li>Lipemia, up to 5% of a 20% Abbott Liposyn solution, produced no significant interference with PTS cholesterol or HDL cholesterol</li> </ul>			

### CONCLUSION

The PTS PANELS Lipid Panel Test Strips, as run on the CardioChek P•A system, provide accurate and reliable results for total cholesterol, HDL cholesterol, and triglycerides from a simple fingerstick, whole blood sample. This new, portable, point-of-care lipid test system provides an alternative to bench-top systems enabling healthcare professionals greater flexibility and efficiency in performing routine lipid testing as well as managing their patients.

### References

- Friedewald et al. 1972. Clin. Chem., 18:499-502.
- Warnick, et al. 2002. Clin Chem., 48(1):11-17.