

# Glucose and Lipid Testing Using the PTS Diagnostics CardioChek® Plus Analyzer: A Point-Of-Care Tool to Engage Patients in Clinician-Patient Risk Discussions and Encourage Healthy Lifestyles

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## BACKGROUND

Blood lipid profiles are important in cardiovascular disease (CVD) risk assessment, diagnosis, and treatment. Additionally, patients affected by diabetes show an increased risk for CVD. The American College of Cardiology and the American Heart Association have cooperatively published guidelines in assessing CVD risk while encouraging clinician-patient risk discussion (CPRD) to engage patients in their own CVD risk reduction and management. This shared decision-making allows for more personalized interactions and empowers the patient to continue positive lifestyle changes or make a fully informed decision in beginning statin therapy.

## PURPOSE

The purpose of this study was to assess the performance of the PTS Diagnostics CardioChek Plus analyzer and PTS Panels® Smart Bundle at the point of care for measuring glucose (glu), total cholesterol (tChol), high-density lipoprotein (HDL), and triglycerides (trig) in an effort to facilitate real-time CPRD.

## METHODS

Blood from 76 subjects was collected and analyzed at four facilities across the United States. Capillary blood was tested on the PTS Diagnostics CardioChek Plus analyzer using the Smart Bundle test strips, while venous blood was tested on the Beckman Coulter AU5400, UniCel® Dx C 660i, Ortho VITROS® 4600, and Abbott Architect as the clinical laboratory analyzer comparators and Roche Cobas® Integra 400 Plus as the reference. Data analysis included correlation regression analysis to determine accuracy and percent difference to assess bias according to ISO 15197:2013 guidelines for glu and CAP guidelines for tChol, HDL, and trig. Clinical risk stratification was assessed using risk category cut points of glu, tChol, HDL, and trig to determine if differences resulted in a 0, 1, or 2 category change. Fisher's Exact test was used to assess differences amongst methods.



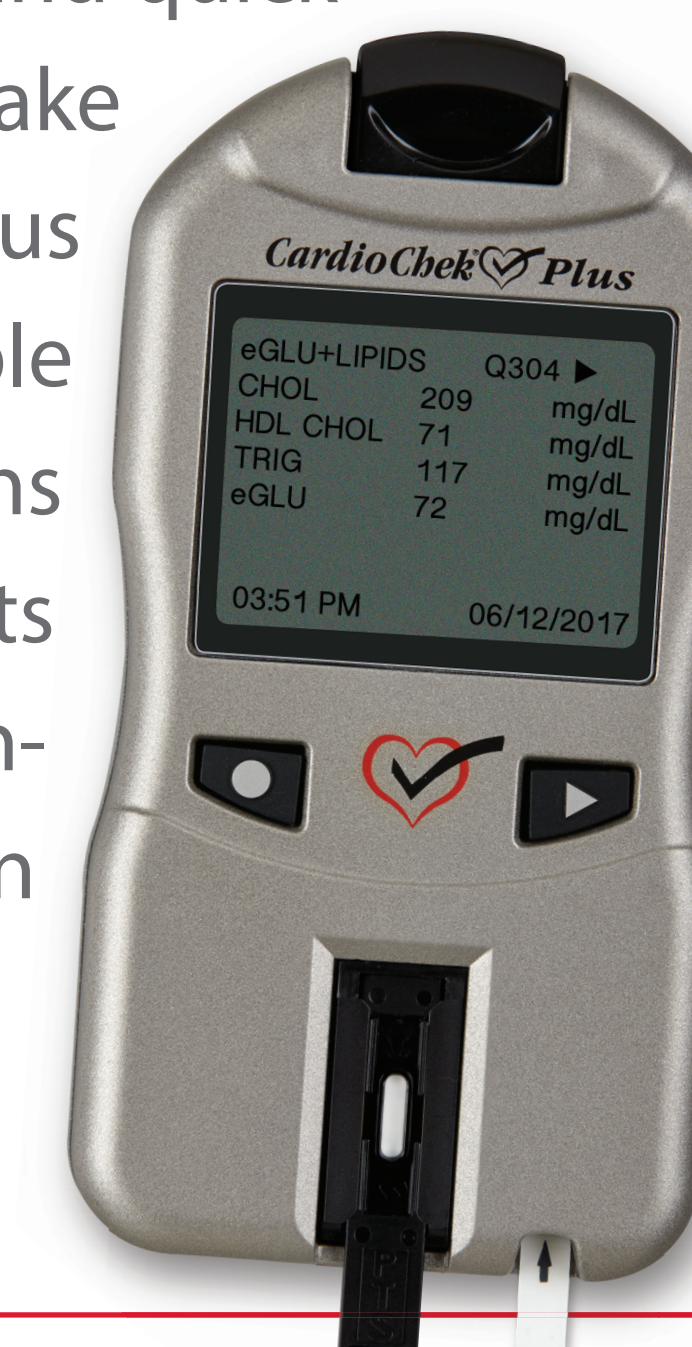
## RESULT SUMMARY TABLE

	ACCURACY															
	Glucose		Total Cholesterol				HDL Cholesterol				Triglycerides					
	2013 ISO Guideline < 100 mg/dL ± 15 mg/dL ≥ 100 mg/dL ± 15%		CAP Guideline ± 10%				CAP Guideline ± 30%				CAP Guideline ± 25%					
	CardioChek Plus Analyzer	Clinical Lab Analyzers	CardioChek Plus Analyzer	Clinical Lab Analyzers	CardioChek Plus Analyzer	Clinical Lab Analyzers	CardioChek Plus Analyzer	Clinical Lab Analyzers	CardioChek Plus Analyzer	Clinical Lab Analyzers	CardioChek Plus Analyzer	Clinical Lab Analyzers				
AVERAGE BIAS	-0.33%	-1.02%	-2.18%	-1.74%	-4.67%	-5.68%	5.65%	0.62%								
	LINEAR REGRESSION															
	Glucose		Total Cholesterol				HDL Cholesterol				Triglycerides					
	SLOPE	0.881	0.987	1.009	1.048	0.923	0.860	1.049	1.087							
INTERCEPT	11.196	0.377	-5.643	-12.045	1.685	4.121	-0.326	-7.657								
R	0.983	0.990	0.953	0.964	0.936	0.955	0.979	0.990								
	CLINICAL RISK STRATIFICATION															
	Glucose < 100, 100-125, ≥ 126 mg/dL		Total Cholesterol < 200, 200-239, ≥ 240 mg/dL				HDL Cholesterol < 40, 40-59, ≥ 60 mg/dL				Triglycerides < 150, 150-199, ≥ 200 mg/dL					
	AGREE	62	82%	66	87%	66	87%	69	91%	62	82%	69	91%	72	95%	73
1 CATEGORY	14	18%	10	13%	10	13%	7	9%	14	18%	7	9%	4	5%	3	4%
2 CATEGORY	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
p value	0.5052				0.6079				0.1573				> 0.9999			

## CONCLUSION

PTS Diagnostics CardioChek Plus analyzer and PTS Panels Smart Bundle lipid and glucose results were shown to be as accurate as clinical laboratory analyzers and within CAP and ISO guidelines for bias. Lipid analytes showed linear correlations equivalent with the clinical laboratory analyzers. Risk stratification revealed no statistical differences between capillary samples analyzed on the CardioChek Plus analyzer and venous blood tested on clinical laboratory analyzers. The CardioChek Plus analyzer offers accurate lipid and

glucose results immediately at the point-of-care, thereby allowing clinicians real-time education and encouragement to patients managing diabetes and cardiovascular disease. The accuracy, small sample size, and quick turnaround time make the CardioChek Plus analyzer a valuable tool for clinicians to engage patients in shared decision-making of their own healthcare.



The Consensus Error Grid is used as a means of interpreting laboratory glucose values as they relate to therapeutic decisions. Zone A is defined as no effect on clinical action and Zone B is defined as altered clinical action with little to no effect on clinical outcome, while Zones C - E define altered clinical outcome

