The CardioChek® Plus analyzer performed exceptionally well when rigorously compared to numerous gold standard clinical reference instruments for accuracy over the linear range of all analytes, performance at key medical decision points and overall specificity and sensitivity.

- PTS Diagnostics combined evaluation summary
March to June 2015

CardioChek® Plus

Performs Exceptionally Well and Provides Clinically-Equivalent Values Compared to Reference Instruments

CardioChek® Plus test systems are one of the fastest, most cost-efficient, and most user-friendly methods to accurately determine lipid and glucose values at the point of care. Accurately testing lipid profile and glucose simultaneously with one fingerstick, the CardioChek Plus test system provides values and measurements using the same technology as clinical laboratories in as little as 90 seconds. Handheld and battery-powered, the CardioChek Plus analyzer offers wireless communication capabilities.

Study:
Aggregation of nine CardioChek Plus analyzer external evaluation studies performed in conjunction with PTS Diagnostics from March 2015 to June 2015.

Background:
PTS Diagnostics aggregated nine separate studies consisting of 280 separate samples for total cholesterol and HDL cholesterol, and 278 for triglycerides taken from corporate wellness screening companies, independent hospitals and both academic and non-academic healthcare systems.

Comparative Reference Methods:
CardioChek Plus analyzers were compared with various Beckman Coulter, Ortho Clinical, Siemens, and Roche reference instruments.

CardioChek Plus Family of Products' Accreditations:

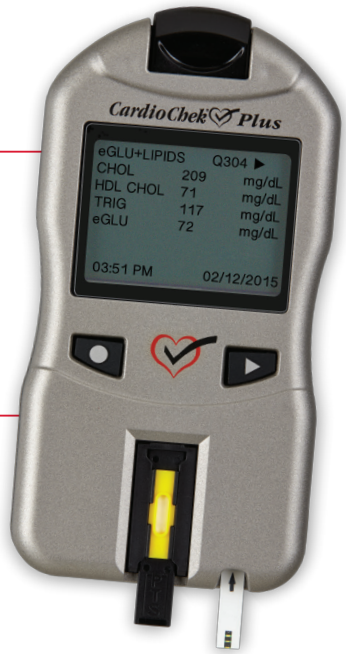
- Cholesterol Reference Method Laboratory Network (CRMLN) for cholesterol and HDL cholesterol test strips
- National Cholesterol Education Program (NCEP)
- FDA-cleared
- Internationally registered
- CE-marked
- CLIA-waived

Measures:

- Total Cholesterol
- HDL Cholesterol
- Triglycerides
- Glucose

Calculates:

- LDL Cholesterol
- TC/HDL Ratio
- LDL/HDL Ratio
- Non-HDL Cholesterol

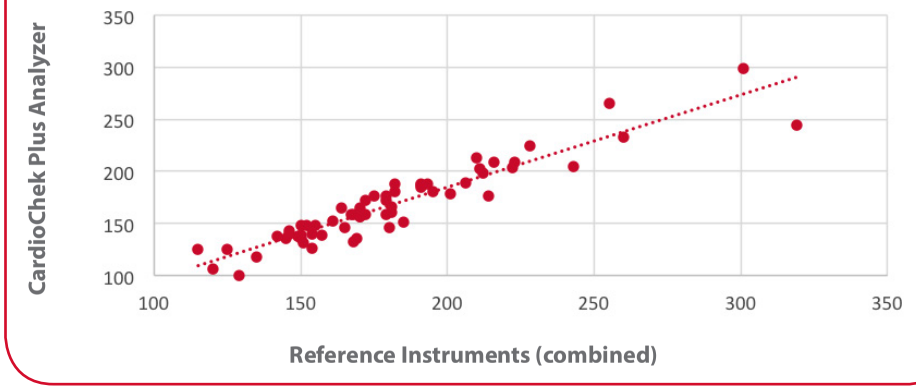


Demonstrates Excellent Performance

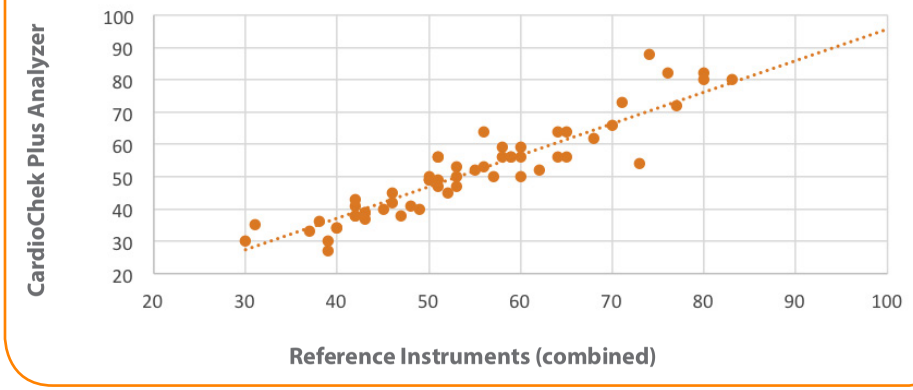
CardioChek Plus analyzers perform exceptionally well across each analytes linear range, and provide clinically equivalent values compared to reference instruments.*

* Data on file

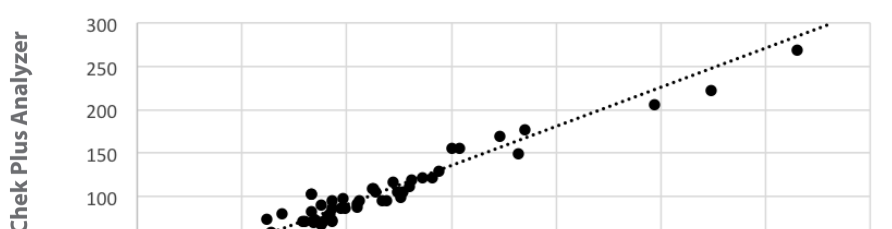
Total Cholesterol (mg/dL)



HDL Cholesterol (mg/dL)



Triglycerides (mg/dL)



Exceptional Performance at Key Medical Decision Points

The performance of a point-of-care analyzer is important not only across a linear range, but also at key values for each analyte where decision for risk, care and diagnosis may be made. These key values are commonly referred to as medical decision points. The performance of an analyzer around these decision points can be determined by applying the statistical values gained from the linear regression analysis to predict performance.*

* Data on file

Total Cholesterol (mg/dL)

Reference Instruments (combined)	CardioChek Plus Analyzer
160	159
200	196
240	232
280	269

HDL Cholesterol (mg/dL)

Reference Instruments (combined)	CardioChek Plus Analyzer
40	38
60	59
80	80
100	102

Triglycerides (mg/dL)

Reference Instruments (combined)	CardioChek Plus Analyzer
100	97
150	147
200	196
250	245

Performs Especially Well for Specificity and Sensitivity

Performance at medical decision points also plays a large role in determining the specificity and sensitivity of a point-of-care analyzer. Specificity and sensitivity reveal the likelihood of false negatives and false positives. Specificity is the ability of an analyzer to correctly exclude individuals who do not have a given risk for a disease or disorder. The more specific a point-of-care analyzer is, the fewer "false-positive" results it produces. The sensitivity of an analyzer addresses its ability to correctly identify people who have a given risk for a disease or disorder. Similar to specificity, the more sensitive a point-of-care analyzer is, the fewer "false-negative" results it produces.

The National Cholesterol Education Program (NCEP) has developed risk placement guidelines that served as the cut-points to determine the sensitivity and specificity for each analyte. The cut-points utilized for a given screening or diagnostics test have considerable impact on the sensitivity and specificity of risk placement. This is also influenced if other laboratory values are used in conjunction to determine overall risk. Given these factors, large population health studies have concluded that when applying the NCEP recommended risk placement guidelines sensitivity above 71%, and specificity above 80% provides acceptable performance levels for population health management.*

CardioChek Plus Analyzer	Total Cholesterol	HDL Cholesterol	Triglycerides
Sensitivity	76%	87%	98%
Specificity	93%	93%	99%

Discussion: Benefits of POC Testing in the Clinical Setting

PTS Diagnostics and its family of point-of-care analyzers and wellness solutions have been at the forefront of point-of-care testing, providing robust and portable analyzers that are both highly reliable and accurate when compared to traditional laboratory testing methods.* The use of clinical laboratory tests in decision making is an integral part of clinical care, with over 60 percent of diagnosis and treatment decisions made by health care professionals being based on laboratory values alone.* This has resulted in laboratory medicine and point-of-care testing playing an increasingly important role in the screening and management of chronic disease. Given these demands, point-of-care analyzers must produce values that are consistent with larger reference instruments for accuracy over the linear range of an analyte, perform well at key medical decision points and provide acceptable levels of overall specificity and sensitivity.

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* Data on file