Accurate Health Risk Classification for Heart Disease using Point of Care Testing in a Health Screening and Wellness Environment and Lipid Quantitation

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Introduction: POCT Testing in Health Screening

The screening for cholesterol levels is normal and apparently healthy populations is an important part of a "Wellness Program." Such programs have gained increasing popularity in the United States and abroad. The use of Point of Care testing (POCT) is a desired element in many settings and an absolute necessity in remote locations. Wellness programs have gained increasing popularity in the United States and abroad. The screening for cholesterol level in normal and apparently healthy populations is an integral part of a "Wellness Program." Such programs have gained increasing popularity in the United States and abroad.

Methods

The CardioChek uses venous blood or capillary blood to quantitate cholesterol and triglycerides. One of the most popular screening panels is the lipid panel which consists of three analyte test strips which simultaneously measure total cholesterol, HDL cholesterol, and triglycerides and then using these measurements calculates the LDL cholesterol. The end point detection is based on reflectance. Blood added to the strip is vertically transported via gravity to cause a sequential red blood cell separation, cholesterol enzymatically degraded to produce by products which yield a colorimetric reaction in the presence of specific chromophore agents. The intensity of the color is recorded as reflectance.

Evaluation Protocol

In a 4-site health screening setting we evaluated the comparative effectiveness of the CardioChek POCT lipid panel and a chemistry reference instrument (Olympus, Quest Labs) in heart disease risk classification based upon TC, HDL, and Trig to assess whether the POCT device was a diagnostic equivalent. A total of 169 comparisons were conducted at geographically diverse centers using professional health screen organizations.

Results

Establishing the Correlation of the CardioChek Lipid Panel Assays and the Reference Laboratory

The correlation of the CardioChek to the reference analyzer is shown for the combined site data. The regression statistics for the individual analyte cholesterol, HDL, and Triglyceride for each lipid panel are used to describe the system bias. Bias is estimated using the difference of the reference value and the calculated CardioChek value at the respective clinical limits for each analyte.

Assessing Site Differences of Accuracy and Precision

Site Differences of Accuracy & Precision

Overall (Average) Accuracy & Precision

Results Discussion and Conclusion

The critical part of any POCT testing in a health screening application is that the test properly categorizes patients with respect to health risk. Two different measurement methodologies (Total, HDL, Triglycerides) are never 100% aligned. POCT results are generally used for screening applications and the results of any wellness testing are to identify those patients that require further medical follow-up. Correlation studies help to initially establish the relationship of the POCT test to the laboratory reference but ultimately it is the categorization of patients to a health risk group that provides the true measure of a POCT test. The multi-site study concluded here demonstrates that the CardioChek is an accurate means to properly categorize patients as to their heart disease risk category based on the level of cholesterol, HDL cholesterol, and triglycerides.