QUALITY CONTROL
The integrity of the reaction should be monitored by use of a two level control with known HDL Cholesterol values.

The National Cholesterol Education Program (NCEP) in the USA has recommended that two levels of controls, one in the normal range (35 - 65 mg/dL) and one near the concentration for decision making (<35 mg/dL), be run in the same manner as patient samples. An acceptable range of HDL Cholesterol values should be established with this method by repeat analysis. Control results falling outside the upper or lower limits of the established ranges indicate the assay may be out of control.

EXPECTED VALUES
The expected value for serum HDL Cholesterol is as follows: 40 - 60 mg/dL.

Each laboratory must establish its own range of expected values. According to the NCEP, HDL values greater than or equal to 40 mg/dL are considered to offer some protection against coronary heart disease. Values below 40 mg/dL are considered to be a significant independent risk factor for coronary heart disease.

PERFORMANCE

Method Linearity: When run as recommended the assay is linear from 1 to 180 mg/dL.

Method Comparison: Accuracy of the LIASYS HDL Immunoinhibition reagent method was verified by comparison to the instrument manufacturer's reagent.

Number of samples pairs: 50
Range of samples (mg/dL): 13 – 117
Correlation Coefficient: 0.9876
Slope: 0.9072
 Intercept (mg/dL): 1.35

REFERENCE