INTENDED USE / INDICATIONS FOR USE

The Alere Cholestech LDX® Total Cholesterol Test Cassette (TC-HDL) is intended for use with the Alere Cholestech LDX® System. This cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) and non-HDL cholesterol in blood by an enzymatic method based on the method formulation of the enzymatic method of Cholestech LDX Total Cholesterol Test Cassette (TC), which is a clinical laboratory method for diagnostic use only. The cassette is to be used with the Alere Cholestech LDX® System. The assay is for use in vitro diagnostic procedures.

TEST PROCEDURE

The Alere Cholestech LDX® System contains proprietary methodology and solidphase technology to measure total cholesterol, HDL cholesterol and non-HDL cholesterol. The same reagent is used to measure total cholesterol (TC), HDL cholesterol and non-HDL cholesterol by using a calibrator containing standards in both total cholesterol and triglyceride reaction pads. Therefore, the total cholesterol, HDL cholesterol and non-HDL cholesterol results are calculated using the measured values with software version 7.17.

The sample is applied to an Alere Cholestech LDX® cassette. The reagents for total cholesterol, triglycerides and glucose can be measured simultaneously from a single drop of blood using the Alere Cholestech LDX® System. The assay is for use in vitro diagnostic procedures. The assay is for use in a clinical laboratory method for diagnostic use only.

TEST PRINCIPLE

The Alere Cholestech LDX® System contains proprietary methodology and solid-phase technology to measure total cholesterol, HDL cholesterol and non-HDL cholesterol. The same reagent is used to measure total cholesterol (TC), HDL cholesterol and non-HDL cholesterol by using a calibrator containing standards in both total cholesterol and triglyceride reaction pads. Therefore, the total cholesterol, HDL cholesterol and non-HDL cholesterol results are calculated using the measured values with software version 7.17.

The sample is applied to an Alere Cholestech LDX® cassette. The reagents for total cholesterol, triglycerides and glucose can be measured simultaneously from a single drop of blood using the Alere Cholestech LDX® System. The assay is for use in vitro diagnostic procedures. The assay is for use in a clinical laboratory method for diagnostic use only.

SUMMARY AND EXPLANATION

The Alere Cholestech LDX® Test Cassette is for the quantitative determination of total cholesterol, HDL and non-HDL cholesterol in blood by an enzymatic method based on the method formulation of the enzymatic method of Cholestech LDX Total Cholesterol Test Cassette (TC), which is a clinical laboratory method for diagnostic use only. The cassette is to be used with the Alere Cholestech LDX® System. The assay is for use in vitro diagnostic procedures.

The Alere Cholestech LDX® System contains proprietary methodology and solid-phase technology to measure total cholesterol, HDL cholesterol and non-HDL cholesterol. The same reagent is used to measure total cholesterol (TC), HDL cholesterol and non-HDL cholesterol by using a calibrator containing standards in both total cholesterol and triglyceride reaction pads. Therefore, the total cholesterol, HDL cholesterol and non-HDL cholesterol results are calculated using the measured values with software version 7.17.

The sample is applied to an Alere Cholestech LDX® cassette. The reagents for total cholesterol, triglycerides and glucose can be measured simultaneously from a single drop of blood using the Alere Cholestech LDX® System. The assay is for use in vitro diagnostic procedures. The assay is for use in a clinical laboratory method for diagnostic use only.
**RESULTS**

Test results will all be displayed in the screen when the test is complete. Calculated results are transferred after all DATA ACCESS is presented.

**QUALITY CONTROL**

External quality control materials should not be routinely used to show that your system is in control. Please refer to the following quality control procedures for the Alere Cholestech LDX® System.

- Liquid W1 and W2 should be used once a week with all the Alere Cholestech LDX® System assay groups. Both W1 and W2 contain substances listed below.

- Liquid W1 should be used on Monday and Thursday of each week.
- Liquid W2 should be used on Tuesday and Friday of each week.

- Liquid W1 and W2 should be used for results outside the measuring range.