



CardioChek Test System *Intended Use*

Thank you for selecting a CardioChek analyzer from Polymer Technology Systems, Inc. (PTS Diagnostics).

The CardioChek test system (consisting of the CardioChek analyzer and PTS Panels self-test strips) is for the measurement of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip and is intended for self-testing use. This system should only be used with single-use, auto-disabling lancing devices. This system is for *in vitro* diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The CardioChek analyzer from PTS Diagnostics is intended for *in vitro* diagnostic use to test whole blood.

The CardioChek Test System

The CardioChek test system consists of three main parts. These include the analyzer, PTS Panels self-test strips, and a MEMo Chip.

When a blood sample is applied to the test strip, a chemical reaction occurs producing a color change. The analyzer measures the color reaction and compares the information to the calibration curve stored in the MEMo Chip. The analyzer converts this color reading into a test result that is displayed on the screen.

