



PTS Diagnostics Announces New FDA 510(k) Clearance for Extended HDL Range Lipid Panel Test Strips

Expanded range of HDL cholesterol measurement allows CardioChek® analyzers to serve a larger population

Indianapolis, IN – April 4, 2017 - PTS Diagnostics, the US-based manufacturer of point-of-care biometric testing devices, announced today that the US Food and Drug Administration (FDA) has cleared¹ an expanded top range for measurement of HDL cholesterol (HDL) to 120 mg/dL (3.1 mmol/L) for the company's PTS Panels® lipid panel test strips. The PTS Panels lipid panel test strip now has a measurement range of 20 to 120 mg/dL (0.52 to 3.1 mmol/L) for HDL. Additionally, the lipid panel shelf life has increased due to the use of new test strip vials.

This change means the CardioChek® lipid analyzers can now serve about 98 percent of the adult population², expanding the device's ability to provide results for those individuals who tend to have higher HDL (good) cholesterol.

"While very much desired in the United States, there is significant global customer demand for our CardioChek system to measure higher HDL cholesterol levels," said Robert Huffstodt, President and CEO of PTS Diagnostics.

"Especially in countries like China, guidelines require an LDL measurement for all patients who get a lipid panel test, which can sometimes be difficult if HDL ranges are too high. For individuals with very healthy HDL cholesterol above 100 mg/dL, our customers have relied on retesting with venous blood to obtain LDL results. This expansion to our upper range for HDL will result in more LDL results being available and should eliminate a lot of retesting and the associated cost and inconvenience. This will create even greater efficiencies."

The change provides a further competitive edge over other point-of-care lipid analyzers on the market today.

"Our nearest competition's technologies cannot read HDL as high as the CardioChek system," said Huffstodt. "While CardioChek analyzers can now provide measurements for an estimated 98 percent of the population, other competitive lipid analyzers can only provide results to an estimated 93 to 95 percent^{2,3}. This means as many as one in 20 individuals may not be able to get a result from other lipid analyzers."

CardioChek analyzers and PTS Panels® test strips have a proven success record of providing lab-quality results in as little as 90 seconds, all from a fingerstick.

“We have not changed the chemistry of our test strips. Additional data has been presented to the FDA to support the expansion of the measuring range. The HDL range extension also allows a broader range of calculated LDL results than our lipid analyzer could previously report,” said Huffstodt.

Recognizing the strong connection between heart attack, stroke, and diabetes, CardioChek analyzers provide rapid on-site blood chemistry values and measurements to help identify at-risk individuals. As one of the fastest, most cost-efficient, and user-friendly analyzers on the market today, the CardioChek Plus system accurately tests lipid profile and glucose simultaneously with one fingerstick. In as little as 90 seconds, it provides on-site results using the same technology as clinical laboratories.

PTS Panels lipid panel test strips measure total cholesterol, HDL cholesterol, and triglycerides, and allow calculation of LDL cholesterol and TC/HDL ratio. No refrigeration of reagents is needed, which now have a shelf life of 20 months from the date of manufacture. The CardioChek Plus system and PTS Panels test strips are stored at room temperature. This handheld, battery-operated analyzer is compact and lightweight, making it easy to transport and store. CardioChek systems are CLIA-waived and meet NCEP guidelines for accuracy and precision. The CardioChek Plus analyzer, which offers simultaneous testing of lipid profile and glucose, has wireless communication capabilities which simplify data transfer. In addition, the CardioChek Plus analyzer is CRMLN-certified for cholesterol and HDL cholesterol testing.

About PTS Diagnostics

PTS Diagnostics is an innovative, global, point-of-care diagnostics solutions provider that partners with patients and healthcare professionals to provide the right information at the right time to make the right decisions. The company's name represents the three pillars upon which it has built its long-term success: People, Technology and Service. Headquartered in Indianapolis, Indiana, PTS Diagnostics designs, manufactures, distributes and markets products for distribution in more than 135 countries around the world. PTS Diagnostics, along with Trividia Health, have become members of Sinocare, a biosensor technology company that enables both medical professionals and individuals across the globe to identify, monitor and diagnose chronic diseases at the point of care. For more information, visit www.ptsdiagnostics.com or contact Kelley McClain at 317-870-5610 or kmclain@ptsdiagnostics.com.

1. The FDA clearance letter can be found at www.fda.gov and searching K151545.
2. THE CANHEART Study, Vol. 68, No. 19, 2016, The Journal of The American College of Cardiology
3. Alere™ Cholestech LDX Lipids CLSI Packet

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