

CardioChek[®] P.A

Pediatric Lipid Profile

Universal Lipid Screening for Children Strongly Endorsed by New Industry Guidelines

While cardiovascular disease is rare in children, risk factors present in childhood can greatly increase the likelihood a child will develop heart disease as an adult. The American Academy of Pediatrics (AAP) encourages parents to follow the Dietary Guidelines for Americans and recommends that children increase their activity to reduce the risk factors associated with high cholesterol and obesity. One of the main risk factors for children who develop high cholesterol is a diet high in fat. Heredity, obesity and lack of exercise also play a role. **Testing and prevention now will greatly benefit our children in later years.**^{1,2,3}



Pediatric Cholesterol Levels

(for children and adolescents aged 2 to 19 years)

	Total Cholesterol	LDL Cholesterol
Normal	<4.40 mmol/L	<2.85 mmol/L
Borderline	4.40-5.15 mmol/L	2.85-3.34 mmol/L
High	>5.15 mmol/L	>3.34 mmol/L

In addition, HDL cholesterol should measure 0.91 mmol/L or higher and triglycerides less than 1.70 mmol/L.⁴

	Total Cholesterol	LDL Cholesterol
Normal	<170 mg/dL	<110 mg/dL
Borderline	170-199 mg/dL	110-129 mg/dL
High	≥200 mg/dL	≥130 mg/dL

In addition, HDL cholesterol should measure 35 mg/dL or higher and triglycerides less than 150 mg/dL.⁴

Pediatric Guidelines for Screening

The AAP follows the cholesterol screening recommendations created by the National Cholesterol Education Program (NCEP), established in 1992. It recommends that children and adolescents with a family history of elevated cholesterol or premature heart disease be screened. Children should also be screened if family history is not known or they have risk factors for heart disease, such as high blood pressure, diabetes, obesity, or cigarette smoking. Lipid screening should occur after age 2, but no later than age 10. The AAP recommends that children with normal cholesterol levels should have a lipid test done once every three to five years.⁴



Pediatric Lipid Screening: Why CardioChek?



CardioChek® PA Test System Features & Benefits

- Fast:** Results in about 2 minutes
- Portable:** Handheld and battery-operated
- Certified:** CLIA-waived, FDA-cleared, CE-marked, and CRMLN-certified (*Cholesterol and HDL cholesterol test strips only*)
- Stable:** Room temperature test strip storage; no refrigeration required
- Reliable:** Meets NCEP Guidelines

PTS Panels® Lipid Panel Test Strips

- Measures:** Total Cholesterol, HDL Cholesterol & Triglycerides
- Calculates:** LDL Cholesterol, Total Cholesterol/HDL Ratio

Cholesterol Reference Method Laboratory Network (CRMLN) Certified

Total Cholesterol

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK
Certificate of Traceability
This certifies that

Polymer Technology Systems
Indianapolis, Indiana

has documented traceability to the National Reference System for Cholesterol by performing a direct comparison with the cholesterol reference method for recertification using fresh human specimens which cover the National Cholesterol Education Program medical decision points. This analytical system is representative of the manufacturer's product and has demonstrated the ability to meet the NCEP's performance criteria for accuracy and precision. The comparison shows that the performance of this analytical system is as follows:

Among-run %CV	Average %Bias	%Total Error
0.5%	-1.5%	2.4%

HDL Cholesterol

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK
Certificate of Traceability
This certifies that

Polymer Technology Systems
Indianapolis, Indiana

has documented traceability to the National Cholesterol Education Program's recommended base for HDL Cholesterol by performing a direct comparison with a CRMLN laboratory using fresh specimens which cover the NCEP medical decision points. This analytical system is representative of the manufacturer's product and has demonstrated the ability to meet the NCEP's performance criteria for accuracy and precision. The comparison shows that the performance of this analytical system is as follows:

Among run % CV	Average % Bias	% Total Error
0.9%	1.9%	3.7%

Certifications

CRMLN-Certified
PTS Panels Total Cholesterol and HDL Cholesterol tests are CRMLN-certified and meet the National Cholesterol Education Program (NCEP) performance criteria for accuracy and precision.

CE-Marked
This means that the products fulfill the requirements of Directive 98/79 EC on in vitro diagnostic medical devices.

CLIA-Waived
CLIA stands for Clinical Laboratory Improvement Amendment.

FDA-Cleared
The CardioChek test system is FDA-cleared, which is in accordance to the pre-market notification part 510 (k) regulation set forth by the FDA.

Ordering Information

CardioChek® PA Devices & Accessories	Units	Catalog No.
CardioChek® PA Device	1	1708
Lipid Panel Test Strips (Cholesterol, HDL, Triglycerides; calculates LDL Cholesterol and TC/HDL ratio)	15	1710
40 µL Capillary Tube (glass, heparinized, red line) for PTS Panels 3-test strips. Requires 1749.	25 per tube	1745
Capillary Plunger for 40 µL Capillary Tubes	25 per tube	1749
40 µL Capillary Blood Collectors (plastic, red line)	16 per bag	739
Unistik® 3, Single Use Safety Lancets (21 gauge, 2.0mm depth)	100 per box	1701

1 <http://www.health.gov/dietaryguidelines/>
 2 <http://www.livestrong.com/article/417016-children-high-cholesterol/>
 3 <http://www.healthychildren.org/English/news/Pages/Physicians-Recommend-All-Children-Ages-9-11-Be-Screened-For-Cholesterol.aspx?nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nftstatusdescription=ERROR%3a+No+local+token>
 4 <http://www.livestrong.com/article/223134-pediatric-cholesterol-guidelines/>

Please contact your distributor for more information.

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