LIPOPRINT®
A Breakthrough In
Cholesterol Management
Quantimetrix Corporation

Lipoprint Lab Sales Training Manual
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LIPOPRINT®

Incidence of Cardiovascular Disease
INCIDENCE OF CARDIOVASCULAR DISEASE

♦ 1.5 million Americans suffer from a heart attack each year with 500,000 deaths.

♦ In 2002, US spent $329 billion (includes health expenditure and lost productivity) on cardiovascular (CVD) diseases. The cost of CVD and stroke in US in 2005 is estimated at $393.5 billion.

♦ 50% of people who are diagnosed with coronary artery disease (CAD) have normal lipid levels.

♦ Only 30% of all heart attacks can be explained on the basis of total cholesterol measurement.

♦ Physicians can now take a more active role in the management of this disease by utilizing the Lipoprint Profile to identify, investigate and monitor CAD.
Traditional Lipid Profile

The National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III) guidelines for desirable lipid levels:

- Total Cholesterol < 200 mg/dL
- Triglycerides < 150 mg/dL
- LDL Cholesterol < 130 mg/dL or < 100 mg/dL ideal
- HDL Cholesterol > 40 mg/dL or > 60 mg/dL ideal

The facts are that approximately 50% of individuals diagnosed with coronary artery disease (CAD) have normal lipid levels.
Lipoproteins have been classified into five major classes based on their physical and chemical properties and functionality.

- Chylomicron
- VLDL (very low density lipoprotein)
- IDL (intermediate density lipoprotein)
- LDL (low density lipoprotein)
- HDL (high density lipoprotein)

All lipoprotein classes contain cholesterol, triglycerides, phospholipids and protein (apoproteins) in varying proportions.
Lipoprotein Subclasses

Lipoprotein classes are heterogeneous consisting of multiple subclasses varying in size and atherogenic potential.

- Chylomicron – Continuum of particle sizes
- VLDL – Continuum of particles of varying sizes including remnant particles
- IDL – Two main subclasses (large and small)
- LDL – Up to seven subclasses (large buoyant LDL-1 and 2, and small dense LDL-3 through 7)
- HDL – Two major subclasses (large, HDL-2 and HDL-3)
**Lipoprotein Subclasses and CAD Risk**

Not all lipoprotein subclasses have the same atherogenic potential.

- Large buoyant LDL-1 and 2 are associated with average CAD risk
- Presence of small dense LDL-3 through 7 are associated with 3 time greater risk for CAD independent of other risk factors
- IDL levels above the normal reference range are also associated with increased CAD risk
- Levels of small VLDL remnants above the normal reference range are also associated with increased CAD risk
- Levels of HDL cholesterol below 40 mg/dL are the equivalent of an additional risk factor while levels above 60 mg/dL are equivalent to a negative risk factor
Methods for Testing Lipoprotein Subclasses

Continuous Gradient Ultracentrifugation (Gold Standard)

♦ Separation of subclasses on the basis of density
♦ Used primarily in basic lipoprotein research

Gradient Gel Electrophoresis (GGE – Legacy Method) Berkeley Heart Laboratory

♦ Qualitative LDL subfraction distribution based on LDL peak particle size
♦ Extensive use in research

Nuclear Magnetic Resonance (NMR) LipoScience

♦ LDL distribution determined by mathematical deconvolution of NMR signal
♦ Measurement of LDL size and particle number

Vertical Analytical Profiler (VAP) Atherotech

♦ LDL distribution determined by mathematical deconvolution of the curve from elution rate
♦ Qualitative Profile

NONE OF THESE METHODS ARE FDA CLEARED
LIPOPRINT®

What Is Lipoprint?
THE LIPOPRINT SYSTEM IS THE ONLY

FDA-CLEARED

DIAGNOSTIC TOOL FOR LDL

SUBFRACTION TESTING
The Lipoprint System utilizes non-denaturing, linear (non-gradient) polyacrylamide gel electrophoresis (PAGE) to separate and measure the lipoprotein fractions and subfractions. The test uses a lipophilic dye that binds to the cholesterol in the lipoprotein particle prior to electrophoresis. The electrophoresed gels are scanned to determine the relative area of each lipoprotein subfraction which is multiplied by the total cholesterol of the sample to calculate the amount of cholesterol in each subfraction.
Sample Requirements

♦ Only fasting (12 hours) samples should be used
♦ Serum or EDTA plasma may be used
♦ Samples can be stored up to 7 days at 2 – 8 °C
♦ Freezing of the sample is not recommended. However, if needed, sample should be frozen cryogenically (-70 °C or below)
Lipoprint Test Procedure

The Lipoprint test procedure consists of four basic steps:

1. Electrophoresis

![Electrophoresis](image1)

2. Scanning

![Scanning](image2)
3. Analysis of patient’s results

4. Report Generation
An easy-to-interpret color graph of the patient’s lipoprotein profile is generated and printed.

**Lipoprint Profile**

- **What is Lipoprint?**

  An easy-to-interpret color graph of the patient’s lipoprotein profile is generated and printed.
Understanding the Profile

The Lipoprint System produces an easy-to-interpret patient lipoprotein profile which shows lipoprotein distribution, cholesterol level in each fraction, in comparison to cholesterol distribution for a normal lipoprotein profile.
Normal “Type A” Profile

VLDDL: Primarily triglyceride rich lipoprotein

Phenotype: Type A (desirable)

Mid Band C, B, A: Intermediate density lipoprotein (IDL)

LDL Subfractions 1 and 2: Found in almost all human serum, large, buoyant LDL

Total Cholesterol: Measured independently

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**What is Lipoprint?**

**Abnormal “Type B” Profile**

- **Cholesterol mg/dl:** Quantifies the concentration of lipoprotein fractions and their subfractions.
- **Subfractions 3 – 7:** Small dense LDL, highly atherogenic.
- **HDL:** Direct measurement of total HDL.
- **Phenotype:** Not indicative of Type A (Predominantly small, dense LDL).
- **Reference Ranges:** Flags all parameters that are above normal range – values based on ATP III.

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A graph illustrates the distribution of lipoprotein subfractions with highlighted areas indicating abnormal values. The graph includes reference ranges and specific subfractions identified as abnormal. The text provides a detailed explanation of each parameter's significance in lipid profile assessment.
Other Atherogenic Profiles

Type III dyslipidemia is a lipid disorder caused by abnormally increased levels of intermediate density lipoprotein (IDL) and remnant lipoproteins. This highly atherogenic profile can’t be identified by other lipid tests and could be misdiagnosed.
Benefits of the Lipoprint Profile

♦ Only FDA-cleared diagnostic test for the separation and measurement of lipoprotein fractions and subfractions

♦ Measures the amount of cholesterol in mg/dL in each lipoprotein fraction and subfraction From VLDL to HDL (14 parameters in total)

♦ Normal reference ranges based on the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III) guidelines.

♦ Values outside the reference range flagged in red

♦ Easy to interpret color coded profile differentiates normal, Type A lipid profile from abnormal, none Type A profile

♦ Identifies the highly atherogenic small dense LDL and IDL from the large, less atherogenic LDL and VLDL and the protective HDL

♦ Clinical utility for screening, treatment decision and monitoring of lipid disorders associated with coronary artery disease (CAD) risk

♦ Reimbursable (CPT Code 83716)
Clinical Utility of Lipoprint

Screening

♦ Conventional lipid tests do not convey the CAD risk associated with the small dense LDL or IDL subfractions

♦ These risks could be present even when other lipid risk factor (total cholesterol, LDL and HDL cholesterol and triglycerides) are normal

Treatment Decisions

♦ Different lipoprotein subfractions respond differently to diet and drug therapy, therefore, Lipoprint can assist the physician to decide on the appropriate therapy

▸ Statin drugs reduce cholesterol levels in all lipoprotein subfractions

▸ Niacin and fibrates shift the LDL particles from the small dense atherogenic to the large less atherogenic particles

▸ Combination drugs may contain a statin and niacin or other drug that reduces cholesterol and causes a shift in particle size

Monitoring

♦ Follow-up testing assists doctor and patient to determine the efficacy of the therapy over time
Six main categories of lipid lowering drugs: nicotinic acid, HMG-CoA reductase inhibitors (statins), bile acid sequestrants, fibric acid derivatives, combination drugs and cholesterol absorption inhibitors

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Dose Range (mg/d)</th>
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</thead>
<tbody>
<tr>
<td>Nicotinic acid (niacin)</td>
<td>Nicotinic acid</td>
<td>Niaspan</td>
<td>500-2,000</td>
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<tr>
<td>HMG-CoA reductase inhibitors</td>
<td>Atorvastatin</td>
<td>Lipitor</td>
<td>10-80</td>
</tr>
<tr>
<td>(statins)</td>
<td>Simvastatin</td>
<td>Zocor</td>
<td>5-80</td>
</tr>
<tr>
<td></td>
<td>Lovastatin</td>
<td>Mevacor</td>
<td>10-80</td>
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<tr>
<td></td>
<td>Pravastatin</td>
<td>Pravachol</td>
<td>10-80</td>
</tr>
<tr>
<td></td>
<td>Fluvastatin</td>
<td>Lescol</td>
<td>20-80</td>
</tr>
<tr>
<td></td>
<td>Rosuvastatin</td>
<td>Crestor</td>
<td>5-40</td>
</tr>
<tr>
<td>Bile acid sequestrants</td>
<td>Cholestyramine</td>
<td>Questran</td>
<td>4-24 grams</td>
</tr>
<tr>
<td></td>
<td>Colesevelam</td>
<td>Questran Light</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Colestipol</td>
<td>WelChol</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Colestid</td>
<td></td>
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<tr>
<td>Fibric acid derivatives</td>
<td>Gemfibrozil</td>
<td>Lopid</td>
<td>1,200 in divided dose</td>
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<td></td>
<td>Fenofibrate</td>
<td>Tricor</td>
<td>54-145</td>
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<tr>
<td>Combination</td>
<td>Niacin (extended</td>
<td>Advicor</td>
<td>500/20</td>
</tr>
<tr>
<td></td>
<td>release)-lovastatin</td>
<td>Vytorin</td>
<td>10/10-10/80</td>
</tr>
<tr>
<td></td>
<td>Ezetimibe-simvastatin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol absorption inhibitors</td>
<td>Ezetimibe</td>
<td>Zetia</td>
<td>10</td>
</tr>
</tbody>
</table>

Case Studies

The following case studies demonstrate the effect of drug therapy, diet and exercise (before and after intervention) on individuals with various Lipoprint profiles.
GB, a 65 year-old Caucasian male had his Lipoprint profile done in January 2001 (Figure 1). The profile shows small, dense LDL particles (red portion of the profile) which indicates a lipid disorder. After 3 months of niacin therapy combined with dietary changes and increased exercise the patient’s profile vastly improved. With normal lipoprotein distribution (Figure 2) and only two cholesterol values that were slightly outside the normal reference range.
JS, a 42 year-old Indian male had his Lipoprint profile done in June 2001 (Figure 3). The profile shows high levels of cholesterol in many fractions with distribution of lipoprotein particles shifted towards the smaller and denser particles (red portion of the profile) which indicates a lipid disorder. After 2 months of mainly vegetarian diet with emphasis on soy protein and increased exercise, the patient’s profile returned to essentially normal with slightly elevated LDL-2 (Figure 4).
The following Lipoprint profile was generated 1.5 months before the individual, a fifty-year old, apparently healthy (non-smoker) Hispanic male, suffered a fatal myocardial infarction.
LIPOPRINT®

Selling the Lipoprint Profile
# Healthcare Professionals Interested in Lipoprint

- **Cardiologists**  
  Monitor treatment and effectiveness of intervention

- **Endocrinologists**  
  Prescribe preventive therapy and monitor progress of Type II diabetics

- **Internists**  
  Identify lipid profile abnormalities, target treatment and monitor progress

- **Family/General Practitioners**  
  Prevention of CAD

- **Optimal Health/Wellness Groups**  
  Assist with Health Assessment

- **Research Professionals**  
  As a Clinical and Pharmaceutical Research tool
**Who Should Have A Lipoprint Test?**

**ANYONE WITH TWO OR MORE OF THE FOLLOWING RISK FACTORS**

*Risk Factors That Cannot Be Changed*

- Increasing Age - 84 % of people who die of CHD are 65 or older
- Gender - Men (45 years or older) have a greater risk of heart attack than women (55 years or older)
- Heredity (including Race) - Family history of early heart disease (father or brother affected before age 55; mother or sister affected before age 65)
- African Americans, Mexican Americans, American Indians, native Hawaiians and some Asian Americans all have higher risk of heart disease

*Risk Factors That Can Be Modified By Lifestyle Change or Medications*

- Tobacco Smoke - Smokers and non-smokers exposed to cigarette smoke are at increased risk of heart disease
- High Blood Cholesterol and Triglycerides
- Total blood cholesterol (> 200 mg/ dL)
- High LDL ("bad") cholesterol (>100 mg/dL)
- Low HDL ("good") cholesterol (<40 mg/dL)
- Triglycerides (> 150 mg/dL)
- Diet - less meat, more fish, vegetables and fruit
Who Should Have A Lipoprint Test? (cont.)

- High Blood Pressure - Blood Pressure of 140/90 mmHg or higher
- Physical Inactivity - Inactive lifestyle is a risk factor for CHD
- Obesity and Overweight
  - Overweight = Body Mass Index (BMI) of > 25-29.9
  - Obesity = BMI of 30 or greater
- Diabetes Mellitus

Other Risk Factors

- Stress
- Drinking too much alcohol
Complementary Tests

- Total Cholesterol
- Triglyceride
- Lipoprotein (a)
- Apolipoprotein A – I
- Apolipoprotein B
- High Sensitive C-Reactive Protein (hsCRP)
- Homocysteine
Benefits of the Lipoprint Profile

♦ Only FDA-cleared diagnostic test for the separation and measurement of lipoprotein fractions and subfractions

♦ Measures the amount of cholesterol in mg/dL in each lipoprotein fraction and subfraction From VLDL to HDL (14 parameters in total)

♦ Normal reference ranges based on the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III) guidelines.

♦ Values outside the reference range flagged in red

♦ Easy to interpret color coded profile differentiates normal, Type A lipid profile from abnormal, none Type A profile

♦ Identifies the highly atherogenic small dense LDL and IDL from the large, less atherogenic LDL and VLDL and the protective HDL

♦ Clinical utility for screening, treatment decision and monitoring of lipid disorders associated with coronary artery disease (CAD) risk

♦ Reimbursable (CPT Code 83716)
Lipoprint® System can be utilized to generate testing revenue in today’s CPT code-governed testing reimbursement system.

Clinical laboratories have already billed and continue to bill HMO’s, private insurance companies and Medicare for the Lipoprint tests.

The following information was obtained from the CMS website:

**ICD-9-CM diagnosis codes Covered by Medicare:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>V81.0-V81.2</td>
<td>Special screening for cardiovascular, respiratory, and genitourinary Diseases</td>
</tr>
<tr>
<td>80061, 82465, 83718 and 84478 only</td>
<td></td>
</tr>
</tbody>
</table>

**HCPCS Codes (Alphanumeric, CPT® AMA):**

<table>
<thead>
<tr>
<th>Code</th>
<th>Descriptor</th>
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</thead>
<tbody>
<tr>
<td>80061</td>
<td>Lipid panel</td>
</tr>
<tr>
<td>82465</td>
<td>Cholesterol, serum or whole blood, total</td>
</tr>
<tr>
<td>83715</td>
<td>Lipoprotein, blood; electrophoretic separation and quantitation</td>
</tr>
<tr>
<td>83716</td>
<td>Lipoprotein, blood: high resolution fractionation and quantitation of lipoprotein cholesterol (for example, electrophoretic, nuclear magnetic resonance, ultracentrifugation)</td>
</tr>
<tr>
<td>83718</td>
<td>Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)</td>
</tr>
<tr>
<td>83721</td>
<td>Lipoprotein, direct measurement, LDL cholesterol</td>
</tr>
<tr>
<td>84478</td>
<td>Triglycerides</td>
</tr>
</tbody>
</table>


**Indications**
The medical community recognizes lipid testing as appropriate for evaluating atherosclerotic cardiovascular disease. Conditions in which lipid testing may be indicated include:

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of atherosclerotic disease, or any disease leading to the formation of atherosclerotic disease
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure
- Signs or symptoms of dyslipidemias, such as skin lesions, as follow-up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (>240 mg/dL), or borderline-high (200-240 mg/dL) plus two or more coronary heart disease risk factors, or an HDL cholesterol <35 mg/dl.


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**Selling the Lipoprint Profile** 35
When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it may be reasonable to perform the lipid panel annually. A lipid panel (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD-9-CM code 272.1, Pure hyperglyceridemia).

Any one component of the panel or a measured LDL may be reasonable and necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved. Electrophoretic or other quantitation of lipoproteins (CPT codes 83715 and 83716) may be indicated if the patient has a primary disorder of lipid metabolism (ICD-9-CM codes 272.0 to 272.9).

Effective January 1, 2005, the Medicare law expanded coverage to cardiovascular screening services. Several of the CPT codes included in the lipid NCD may be covered for screening purposes subject to specified frequencies. See section 210.4 of the NCD Manual for a full description of this benefit.
Limitations

When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it is reasonable to perform the lipid panel annually. A lipid panel (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD-9-CM code 272.1, Pure hyperglyceridemia).

Any one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.
Obstacles in Selling Subfraction Testing

♦ NCEP ATP III describes the benefit of testing for subfractions but there is currently no mandate for testing

♦ Lack of knowledge about the benefits of subfraction testing by the medical community

♦ Lack of knowledge about the benefits of subfraction testing by the general public

♦ Not always covered by insurance (patients may have to pay out of pocket)

♦ Low Medicare reimbursement

♦ Competition
Frequently Asked Questions

1. Why is LDL subfraction testing so important?

The fact that 50% of people who suffer from coronary artery disease (CAD) have normal cholesterol levels indicates the need for a more specific diagnostic tool. The relationship between small dense LDL particles and an increased risk for CAD has been well established. Research indicates that individuals exhibiting a non-A pattern are at 3 times increased risk for CAD.

Thus, by identifying non-A patterns using the Lipoprint system and treating them at an early stage, CAD may be greatly reduced.

2. How does the Lipoprint System differ from other currently available test methods?

The Lipoprint System is the only FDA-cleared LDL subfraction testing system. This is the first system with on-site testing capabilities with short turn around times for reports that give clear quantitative measurements of LDL or HDL subfractions. In comparison to other technologies for measuring lipoprotein subfractions, the Lipoprint® System is more accurate, cost-effective, convenient and best suited for routine use in any medical laboratory.

3. How can physicians utilize the results from the Lipoprint test?

There is strong evidence which indicates a positive shift in the LDL subfraction profile in response to lipid lowering medications as well as non-drug therapies. Based on the patient’s Lipoprint profile and assessment of certain complementary tests, a physician can prescribe a personal treatment plan.
Frequently Asked Questions (cont.)

4. Is the Lipoprint test expensive?

No. Since testing is done on-site, costs per tests can be established based on in-house testing expenditures, which makes this test the least expensive.

5. Are Lipoprint testing costs reimbursable?

Yes, clinical laboratories can bill HMOs, private insurance and Medicare for the Lipoprint tests under CPT code 83716.

6. Is there a lab currently using Lipoprint that I could contact?

Yes, call 800.624.8380 or e-mail: info@lipoprint.com.

7. How can I get more information?

Quantimetrix Account Executives will be happy to answer any of your questions by e-mail: info@lipoprint.com, telephone: 800-624-8380 or fax: 800-845-1834. Quantimetrix Corporation would be delighted to set up a demonstration of this very exciting product just for you.
“We used continuous disc electrophoresis [Lipoprint System], which is rapid and easier to perform in assessing large numbers of samples […]. LDL-PPD [peak particle diameter] measured using continuous electrophoresis was identical to peak particle diameter of LDL which was isolated by ultracentrifugation and was measured directly using an electron microscopy [sic].”

“A quantitative method for the assessment of LDL particle size phenotype was developed using the Quantimetrix Lipoprint LDL System. The method can be performed in less than 3 hours in batch mode and is suitable for routine use in clinical laboratories.”

“LDL score [as determined with the Lipoprint System] was the best individual discriminant factor for CAD. LDL scores tend to increase with the number of diseased coronary arteries.”

“[…] the presence of bands LDL-3 – 6 was exclusively related to the presence of CAD since none of the CAD-patients showed these bands.”

2 T. Kazumi et al., Atherosclerosis 142 (1999) 113-119
## COMPETITIVE ANALYSIS

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>Liproint&lt;sup&gt;®&lt;/sup&gt;</th>
<th>Berkeley</th>
<th>VAP</th>
<th>NMR</th>
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<tr>
<td>TEST METHOD</td>
<td>Polyacrylamide Gel Electrophoresis</td>
<td>Gradient Gel Electrophoresis</td>
<td>Density Gradient Ultracentrifugation</td>
<td>Nuclear Magnetic Resonance</td>
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<td>RESOLUTION</td>
<td>Physical and measurable separation of lipoprotein subfraction</td>
<td>Physical, non-measurable separation of LDL proteins only</td>
<td>Mathematical deconvolution of aggregate bands</td>
<td>Mathematical deconvolution of aggregate NMR signal</td>
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<td>FDA CLEARED</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
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<tr>
<td>NORMAL REFERENCE RANGE FOR SUBCLASSES</td>
<td>Yes (quantitative based on ATP III guidelines)</td>
<td>NO</td>
<td>Qualitative Classification only (based on population distribution)</td>
<td>Qualitative Classification only (based on population distribution)</td>
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<td>NUMBER OF LDL FRACTIONS</td>
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<td>7</td>
<td>Pattern A, AB or B</td>
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<td>Does not report IDL</td>
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<td>Cholesterol mg/dL</td>
<td>LDL-peak particle size</td>
<td>No</td>
<td>Particle Number</td>
</tr>
</tbody>
</table>

**SIGNIFICANCE:**

**Test Method:** PAGE is a fast, easy, accurate method for protein separation. This allows the physician to receive the test results in a timely manner and translates into savings, as the test is not as costly as other methods.

**Resolution:** PAGE is the only method that physically separates all the proteins resulting in an accurate measurement of the bands, not estimated from a calculation.

**FDA cleared:** Liproint<sup>®</sup> is the only FDA cleared test for LDL subfraction testing.

**Normal Reference Ranges:** Excellent for patient education and monitoring of therapy. Patient involvement results in better compliance with therapy.

**Number of LDL Fractions:** Researchers have identified 7 LDL subfractions. It has been shown that subfractions 3-7 are correlated with 3 times greater risk for CAD.

**Number of IDL Fractions:** Research has shown a significant correlation between IDL and CAD.

**Quantitative Analysis:** Shows measurable concentrations of each subfraction. Other profiles indicate only where the cholesterol concentration is the highest. This allows the physician to see measurable changes in each subfraction to determine if treatment is successful.