Understanding the NMR LipoProfile 2009 Report Form

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Wayne, New Jersey

The LipoScience 2009 Report Form

- The NMR LipoProfile has been tested in samples from studies with outcome data from over 30,000 subjects in three major clinical studies.
  1. Women's Health Study
  2. Epic Norfolk: European Prospective Investigation into Cancer and Nutrition-Norfolk Study
  3. VA-HIT: Veteran's Atherosclerosis HDL Intervention trial
  4. Framingham Offspring Study (supplemental support)
- FDA clearance of the NMR LipoProfile test distinguishes LipoScience as the only CV testing laboratory to receive clearances for its laboratory-developed test. The NMR technology, testing procedure, and quality and accuracy of the test results generated prior to and subsequent to obtaining FDA clearance remains unchanged

The NMR LipoProfile® test may be covered by one or more issued or pending patents, including U.S. Patent Nos. 5,343,389; 6,518,069; 6,576,471; 6,653,140; and 7,243,030.

CLIA:34D0952253

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Patient Name

Patient ID | Birth Date

Date Collected | Date Received

NMR LipoProfile® test

Perce

	nmol/L
LDL-P (LDL Particle Number)	1350

Lipids

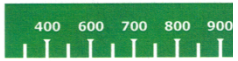
	mg/dL
LDL-C (calculated)	***
HDL-C	42

Desirable ≥ 40

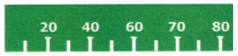
**** Test not ordered. ***LDL-C cann

Historical Reporting

LDL-P



LDL-C



1. Reference population comprises 5,362 men and women
in the Multi-Ethnic Study of Atherosclerosis (MESA). Mora e

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Page 1 of 1

LIPOSCIENCE

LipoScience, Inc.
2500 Sumner Boulevard
Raleigh, NC 27616
877-547-6837
www.liposcience.com

Patient Name | Sex | Age

Patient ID | Birth Date | Accession Number

Clinician

Client Name and Address

Client Name | Client #/Route #
Address 1
Address 2
City, State | Zip
Phone: | Fax:

Date Collected | Date Received | Report Date and Time | Requisition Number | Fasting Status

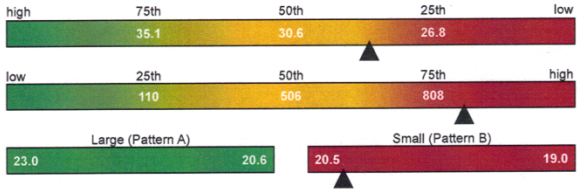
PARTICLE CONCENTRATION AND SIZE

LDL AND HDL PARTICLES

Lower CVD Risk → Higher CVD Risk

Percentile in Reference Population

HDL-P (total)	µmol/L	28.1
SMALL LDL-P	nmol/L	830
LDL SIZE*	nm	20.4



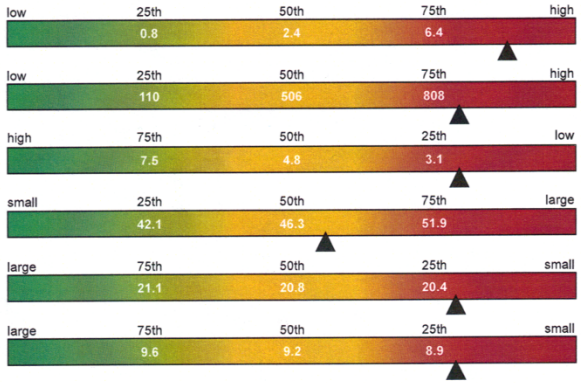
*Small LDL-P and LDL Size are associated with CVD risk, but not after LDL-P is taken into account.

LIPOPROTEIN MARKERS ASSOCIATED WITH INSULIN RESISTANCE[1,2]

Insulin Sensitive → Insulin Resistant

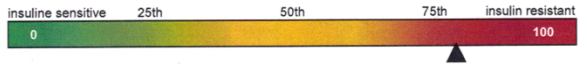
Percentile in Reference Population

LARGE VLDL-P	nmol/L	8.2
SMALL LDL-P	nmol/L	830
LARGE HDL-P	µmol/L	2.7
VLDL SIZE	nm	50.4
LDL SIZE	nm	20.2
HDL SIZE	nm	8.7



INSULIN RESISTANCE SCORE

	0-100
LP-IR SCORE**	84



**The LP-IR Score combines the information from the 6 lipoprotein markers to give improved prediction of insulin resistance.

These laboratory assays, validated by LipoScience, have not been cleared by the US Food and Drug Administration. The clinical utility of these laboratory values has not been fully established.

1. Garvey WT, et al. *Diabetes.* 2003;532:453-462.
2. Goff DC, et al. *Metabolism.* 2005;54:264-270.

91-002-00R1.0

Demographic Report

The NMR LipoProfile® test may be covered by one or more issued or pending patents, including U.S. Patent Nos. 5,343,389; 6,518,069, 6,576, 471; 6,653,140; and 7,243,030

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Clinician

Patient Name	Sex	Age

Patient ID	Birth Date	Accession Number

Client Name and Address

Client Name
Address 1
Address 2
City, State
Phone

Zip
Fax

Client #/Route #

Date Collected	Date Received	Report Date and Time	Requisition Number	Fasting Status

The NMR LipoProfile Test Form

- Provides a direct measure of the total number of low density lipoprotein particles (LDL-P). Results can be used with other lipid measurements and clinical evaluation to aid in the management of lipoprotein disorders associated with CVD
  - This section of the report also includes information in a traditional lipid panel
  - There is also a new historical reporting section that shows up to three prior results for each patient.

NMR LipoProfile® test

Reference Range [1]

		Percentile[1]	20th	50th	80th	95th
	nmol/L	Low	Moderate	Borderline-High	High	Very High
LDL-P (LDL Particle Number)	**1350**	**<1000**	**1000-1299**	**1300-1599**	**1600-2000**	**>2000**

Lipids

		Optimal	Near or above optimal	Borderline-High	High	Very High
	mg/dL	<100	100-129	130-159	160-200	>200
LDL-C (calculated)	***					

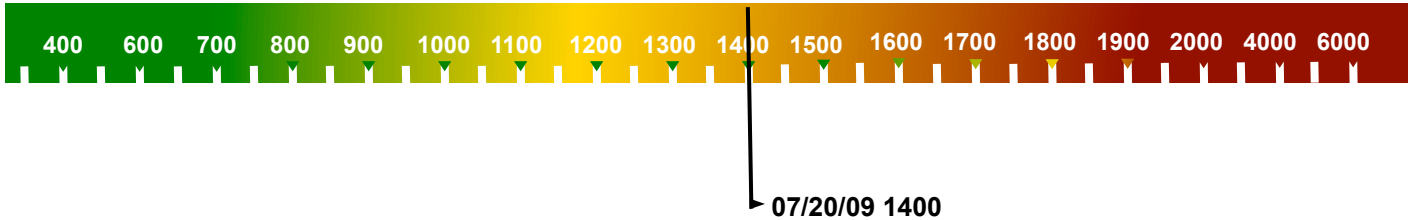
HDL-C	**Triglycerides**	**Total Cholesterol**
mg/dL	mg/dL	mg/dL
42	410	185
Desirable ≥ 40	Desirable < 150	Desirable < 150

**** Test not ordered

*** LDL-C cannot be calculated if triglycerides are > 400. LDL-C will be inaccurate if patient is nonfasting

Historical Reporting

LDL-P



LDL-C

1. Reference population compromises 5,362 men and women not on lipid medication enrolled in the Multi-Ethnic Study of Atherosclerosis (MESA). More et al. Atherosaclerosis 2007

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LDL-P and Lipid Panel Report

NMR LipoProfile® test

		Reference Range [1]				
	Percentile[1]	20th	50th	80th	95th	
LDL-P (LDL Particle Number)	nmol/L	Low	Moderate	Borderline-High	High	Very High
	1350	<1000	1000-1299	1300-1599	1600-2000	>2000

Lipids

LDL-C (calculated)	mg/dL	Optimal	Near or above optimal	Borderline-High	High	Very High
	***	<100	100-129	130-159	160-200	>200

HDL-C	**Triglycerides**	**Total Cholesterol**
mg/dL	mg/dL	mg/dL
42	410	185
Desirable ≥ 40	Desirable < 150	Desirable < 150

**** Test not ordered

*** LDL-C cannot be calculated if triglycerides are > 400. LDL-C will be inaccurate if patient is nonfasting

LDL-P refers to the **total number** of LDL particles per liter (nmol/L)

TG and HDL-C are standard assays and not NMR derived

The LDL-C is calculated using the Friedewald formula:

LDL-C = TC – [HDL-C + VLDL-C] where VLDL-C = TG/5

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LDL and HDL Particles

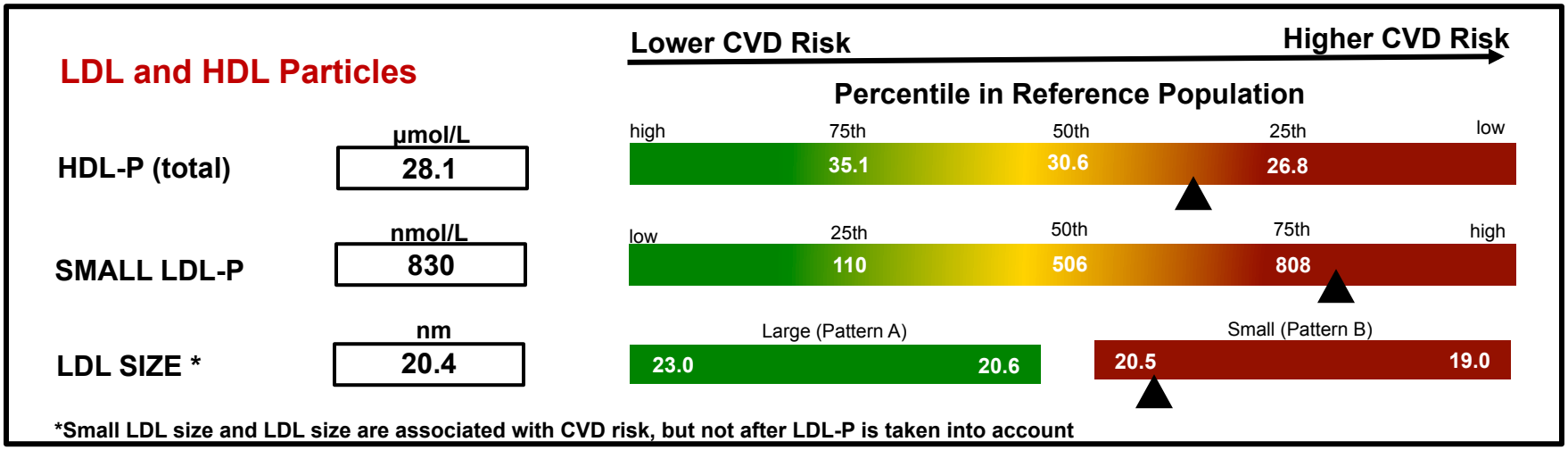
►This section of the report includes the total number of HDL particles (HDL-P), the number of small LDL particles, and LDL size. A relative estimate of CVD risk is indicated by an arrow on the scale to the right of each result.

►HDL-P is the total number of HDL particles. HDL-P has been shown to be more strongly related to atherosclerosis and future CVD than HDL-C.

►Many physicians use small LDL-P and LDL size to guide therapy. Small LDL-P and LDL size are not independent predictors of CVD risk.

Particle Concentration and Size

Particle Concentration and Size



The particle concentration and size is now provided on a separate report. In addition to small LDL-P (nmol/L) and LDL size (nm), total HDL-P is reported (μmol/L).

Lipoprotein Markers Associated with Insulin Resistance

- This section includes the six lipoprotein markers associated with insulin resistance and type 2 diabetes risk, and are included in the calculation for the **LP-IR score.**
  - Large VLDL-P
  - Small LDL-P
  - Large HDL-P
  - VLDL size
  - LDL size
  - HDL size

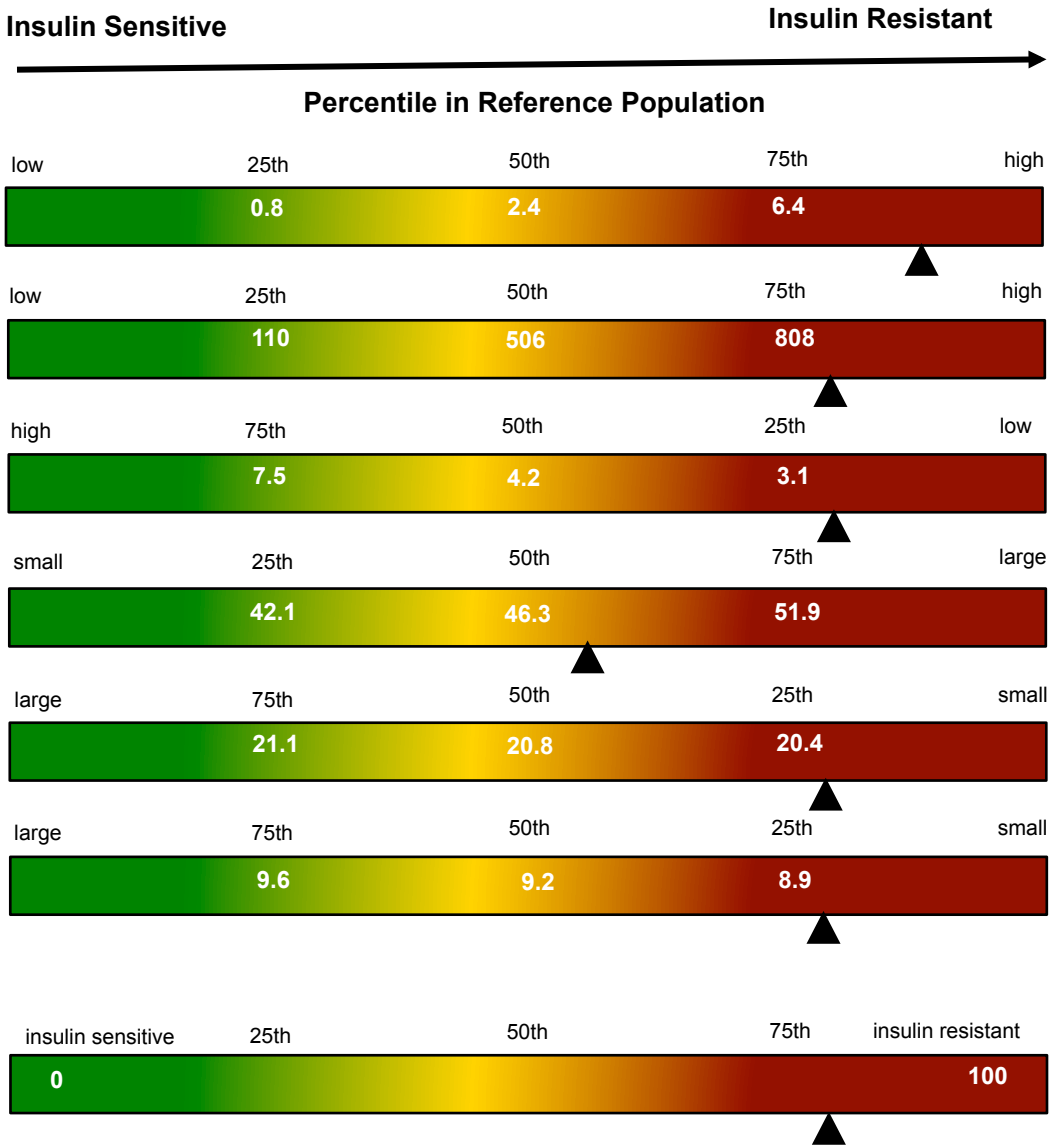
The Lipoprotein Insulin Resistance Score **(LP-IR)** assesses the patient's insulin resistance level and T2DM risk.

This score (0-100) is derived using the results from the six lipoprotein markers listed. Therapeutic lifestyle changes may reduce the score.

This test is not FDA cleared and needs to be ordered separately

Genuth & Kahn. Diabetes Care 2008;31:1093-1096

LIPOPROTEIN MARKERS ASSOCIATED WITH INSULIN RESISTANCE[1,2]



INSULIN RESISTANCE SCORE

**** The LP-IR SCORE combines the information from the 6 lipoprotein markers to give improved prediction of insulin resistance****

These laboratory assays validated by LipoScience have not been cleared by the US Food and Drug Administration. The clinical utility of these laboratory values has not been fully established.

1.Garvey WT et al. Diabetes 2003;532:453-462
2. Goff DC. et al. Metabolism. 2005;54:264-270

Particle Concentration and Size

LDL and HDL Particles

Lower CVD Risk → Higher CVD Risk

Percentile in Reference Population

		high	75th	50th	25th	low
HDL-P (total)	µmol/L 28.1		35.1	30.6	26.8	

		low	25th	50th	75th	high
SMALL LDL-P	nmol/L 830		110	506	808	

		Large (Pattern A)		Small (Pattern B)	
LDL SIZE *	nm 20.4	23.0	20.6	20.5	19.0

*Small LDL size and LDL size are associated with CVD risk, but not after LDL-P is taken into account

LIPOPROTEIN MARKERS ASSOCIATED WITH INSULIN RESISTANCE[1,2]

Insulin Sensitive → Insulin Resistant

Percentile in Reference Population

		low	25th	50th	75th	high
LARGE VLDL-P	nmol/L 8.2		0.8	2.4	6.4	

		low	25th	50th	75th	high
SMALL LDL-P	nmol/L 830		110	506	808	

		high	75th	50th	25th	low
LARGE LDL-P	µmol/L 2.7		7.5	4.2	3.1	

		small	25th	50th	75th	large
VLDL SIZE	nm 50.4		42.1	46.3	51.9	

		large	75th	50th	25th	small
LDL SIZE	nm 20.2		21.1	20.8	20.4	

		large	75th	50th	25th	small
HDL SIZE	nm 8.7		9.6	9.2	8.9	

INSULIN RESISTANCE SCORE

		insulin sensitive	25th	50th	75th	insulin resistant
LP-IR SCORE**	0-100 84	0				100

** The LP-IR SCORE combines the information from the 6 lipoprotein markers to give improved prediction of insulin resistance**