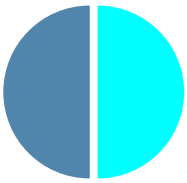
AXINON® lipoFIT®*

Advanced Lipoprotein Testing for Cardiovascular Risk Assessment

AXINON® lipoFIT® – NMR Lipoprotein Analysis for CVD Risk Management

- Determination of lipoprotein particle numbers & sizes for advanced cardiovascular risk assessment in a single measurement
- Standardized on-site NMR system
- Easy usability and automated platform with QC standards for reliable, high-throughput results

Cardiovascular disease (CVD) is the number one cause of death worldwide [1]. Clinical CV risk factors include hypertension, diabetes mellitus, chronic kidney disease, obesity, cigarette smoking and family history. The most important biomarkers for CV risk determination are lipids including total cholesterol, triglycerides, LDL and HDL cholesterol. However, about 50% of patients hospitalized for coronary artery disease (CAD) have LDL cholesterol (LDL-C) levels within the normal range [2].



50% of patients hospitalized for coronary artery disease (CAD) do not have elevated LDL-C.[2]

Particle Number and Size Matter

Considerable discordance between LDL-C and the number of LDL particles (LDL-p) has been observed, especially in those individuals with other comorbid conditions such as diabetes mellitus [3-5]. Despite having the same level of LDL-C, patients can have different concentrations of LDL-p (Fig. 1). Small, dense LDL particles are described to be more atherogenic than large ones [6-9].

Multiple studies have shown that CV risk is more closely associated with LDL particle concentration rather than cholesterol content [4, 5, 10-12]. Recent studies demonstrated the cost-effectiveness of LDL-p guided therapy [13-16].

Furthermore, lower concentrations of high-density lipoprotein particles (HDL-p) are associated with increased risk of CVD [17], while large HDL particles (LHDL-p) seem to have a protective effect [18, 19]. Thus, the determination of lipoprotein parameters beyond the conventional lipid panel can offer a more accurate risk assessment.

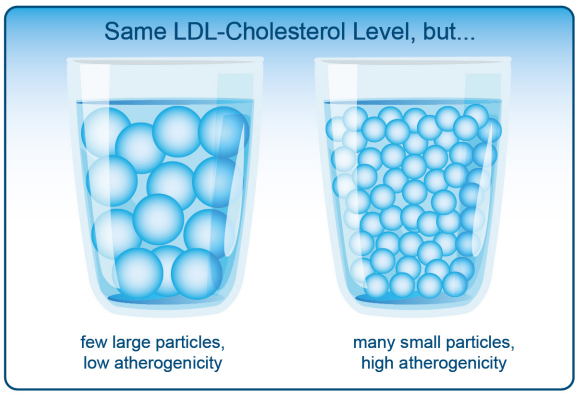


Fig. 1: Different LDL-p can sum up to the same LDL-C.

AXINON® lipoFIT® provides a detailed analysis of lipoprotein subclasses allowing further CV risk stratification. In addition to the standard lipid panel, the test measures concentration and size of lipoprotein particles.

Standard lipid panel +	Particle concentrations +	Particle sizes
Total cholesterol	LDL-p	VLDL-s
LDL cholesterol	HDL-p	LDL-s
HDL cholesterol	LVLDL-p	HDL-s
Triglycerides	SLDL-p	
	LHDL-p	

In particular, *AXINON® lipoFIT®* parameters include

■ **LDL-p: Concentration of LDL particles.**
Strong cardiovascular risk marker beyond LDL cholesterol [4,5].

■ **Small LDL-p: Concentration of small LDL particles.**
Elevated concentrations are associated with increased risk for coronary heart disease [11].

■ **HDL-p: Concentration of HDL particles.**
Reduced levels are strongly and independently linked to atherosclerotic risk [17].

** Available as a CE-labeled in vitro diagnostic product in the European Union and as Research-Use-Only product in the United States. numares´ products have not yet been approved or cleared by the U.S. Food and Drug Administration.*

Expert Panels Recommend LDL-P

AXINON® *lipoFIT*® can help to identify those at increased risk despite normal LDL-C levels. Several expert panels recommend use of LDL-p to optimize treatment of intermediate and high risk patients [20-25].

Year	Expert Panel
2020	**AACE/ACE Diabetes Management Algorithm** [20] American Association of Clinical Endocrinologists/ American College of Endocrinology' Comprehensive Diabetes Management Algorithm
2017	**AACE/ACE Guidelines** [21] American Association of Clinical Endocrinologists' and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease
2015	**NLA Recommendations** [22] National Lipid Association recommendations for patient-centered management of dyslipidemia
2013	**AACC Assessment** [23] Association of apolipoprotein B and nuclear magnetic resonance spectroscopy-derived LDL particle number with outcomes in 25 clinical studies: assessment by the AACC Lipoprotein and Vascular Diseases Division Working Group on Best Practices
2011	**National Lipid Association (NLA)** [24] Clinical utility of inflammatory markers and advanced lipoprotein testing: advice from an expert panel of lipid specialists

How to Use the Test

The combination of *Magnetic Group Signaling* (*MGS*®) and the *AXINON*® System allows for spectral analysis with highly-reproducible results. The system is fast and efficient with automation capabilities allowing short hands-on-time, minimal operator interaction and high walk-away capability.

Test Features

Capacity: Five racks hold positions for up to 93 analytical samples each. Samples are processed in batches. The test system can be continuously loaded over just a few minutes.

Throughput: ~ 450 samples/24 h.

Walk-away operation: *AXINON*® supports the fully-automated measurement of up to 465 samples.

Hands-on Time: ~ 1 min. per sample (shorter when an automatic pipetting system is used)

Specimen collection, storage and transport

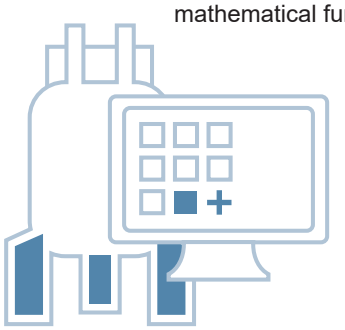
AXINON® *lipoFIT*® is performed on human serum samples collected according to standard techniques for laboratory testing. Appropriate tubes without anti-coagulation additives must be used. Standard serum tubes without gel separation have been tested to be suitable for use. Specimens can be stored at 2-10°C for up to one week.

Test Principle

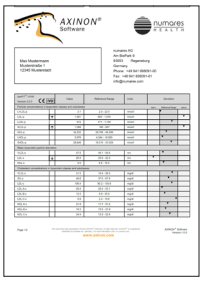
Samples are prepared with the *AXINON*® serum kit and measured using a qualified *AXINON*® 600 MHz NMR system. The high magnetic field strength of 600 MHz enhances signal resolution and sensitivity. The test parameters are calculated by fitting the broad methyl group signals of lipoproteins using mathematical functions.

AXINON® *lipoFIT*® Workflow

1) One-step sample preparation



2) Automated processing - 24/7



3) Output into LIS

Literature

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