# AXINON<sup>®</sup> lipoFIT<sup>®</sup>



# NMR Lipoprotein Profiling Test System



AXINON<sup>®</sup> is a flexible test system for in vitro diagnostic and research use. numares now provides AXINON<sup>®</sup> *lipoFIT*<sup>®</sup> – the first CE-marked\* test which supports comprehensive NMR lipoprotein profiling and metabolite analyses in serum.

## AXINON<sup>®</sup> lipoFIT<sup>®</sup> features

- Easy lipoprotein and metabolic profiling in high throughput
- Highly standardized and automated for comparable results
- Seamless integration into standard lab workflows
- Ready-to-use reagents, on-board quality control
- Reliable and reproducible, cost-effective

\* 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. 2022\_AXINON\_lipoFIT\_Product\_Information, Version 3.0

# Get to know AXINON® lipoFIT® ...

*AXINON® lipoFIT®* is the first CE-marked test providing a comprehensive lipoprotein profile ranging from large VLDL to small HDL particles and respective quantities of the key compounds triglycerides, cholesterol and phospholipids.

# Principle of Analysis

The *AXINON*<sup>®</sup> *lipoFIT*<sup>®</sup> test is based on the evaluation of standardized NMR spectra. These are generated by preparing human serum samples with the *AXINON*<sup>®</sup> *serum kit.* The prepared serum samples are measured using the *AXINON*<sup>®</sup> *Software* and a qualified 600 MHz NMR spectrometer.

## Time to result & Throughput

### Time to result:\*

| Number of analytical samples in a run | All results are available after |
|---------------------------------------|---------------------------------|
| 10                                    | 1 h 20 min                      |
| 20                                    | 1 h 50 min                      |
| 93                                    | 5 h                             |

\*including sample preparation

**Capacity:** Five racks hold positions for up to 93 analytical samples each. Samples are processed in batches.

Throughput: > 450 samples/24 h.

**Walk-away operation:** *AXINON*<sup>®</sup> supports the fully-automated measurement of up to 465 analytical samples.

## Hands-on Time

*AXINON® lipoFIT®* test systems are very easy to operate and require minimal operator interaction. The hands-on time, including manual sample preparation, is about 50 minutes for a batch of 93 analytical samples. This is roughly half a minute per sample. **The test system can be continuously loaded over just a few minutes.** 



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# Parameters of NMR Lipoprotein Profiling

| Parameter  | Unit   | Description                                   |
|--|--------|---|
| Particle concentrations in lipoprotein classes and subclasses *) |        |   |
| 1. LVLDL-p   | nmol/l | Concentration of large VLDL particles         |
| 2. LDL-p   | nmol/l | Concentration of LDL particles                |
| 3. LLDL-p  | nmol/l | Concentration of large LDL particles          |
| 4. SLDL-p  | nmol/l | Concentration of small LDL particles          |
| 5. HDL-p   | nmol/l | Concentration of HDL particles                |
| 6. LHDL-p  | nmol/l | Concentration of large HDL particles          |
| 7. SHDL-p  | nmol/l | Concentration of small HDL particles          |
| Particle sizes *)  |        |   |
| 8. VLDL-s  | nm     | Mean diameter of VLDL particles               |
| 9. LDL-s   | nm     | Mean diameter of LDL particles                |
| 10. HDL-s  | nm     | Mean diameter of HDL particles                |
| Standard lipid param   | eters  |   |
| 11. Total-Chol.  | mg/dl  | Concentration of total cholesterol in serum   |
| 12. LDL-Chol.  | mg/dl  | Concentration of LDL cholesterol in serum     |
| 13. HDL-Chol.  | mg/dl  | Concentration of HDL cholesterol in serum     |
| 14. Triglycerides  | mg/dl  | Concentration of total triglycerides in serum |

<sup>1</sup>These parameters were validated against another NMR method, already used in clinical routine.



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# Sample Requirements

### **Specimen collection**

Fasting specimens are preferred, but not required. For better comparability of results, it is recommended for specimens to be taken in the morning <sup>[1]</sup>. Blood specimens should be collected aseptically by qualified staff using approved venipuncture techniques <sup>[2]</sup>. Appropriate tubes must be used without anticoagulation additives. Standard serum tubes without gel separation have been tested to be suitable for use. The following tubes have been tested and approved for use with *AXINON*<sup>®</sup>: S-Monovette<sup>®</sup> Serum (Sarstedt). Any other tubes are subject to qualifying <sup>[3]</sup>. Serum should be prepared by standard techniques for laboratory testing <sup>[2]</sup>. Ensure complete clot formation prior to centrifugation. Do not use hemolyzed, heat-treated or contaminated specimens.

#### **Specimen volume**

At least 700 µL of serum is required for the analysis.

### Specimen storage and stability

Serum can be stored at 2°C to 10°C for up to 7days.

### Sample transport

Samples are shipped refrigerated.

1. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002; 106(25):3143-421.

2. H.-P. Seelig, T. Schmidt-Wieland et al., Präanalytik – Abnahme & Transport von Probenmaterial. 2011.

3. Laura L. Needham, et al., Phlebotomy tube interference with nuclear magnetic resonance (NMR) lipoprotein subclass analysis. Clinica Acta 488 2019; 235–241

# Find out more at www.numares.com

For inquiries and further information, please contact

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