Declaration of Conformity

Afinion™ Lipid Panel

Manufacturer name: **Abbott Diagnostics Technologies AS**

Manufacturer address: Kjelsåsveien 161,
P.O.Box 6863 Rodeløkka
NO-0504 Oslo, Norway

SRN No.: NO-MF-000001423

Product information:

Product name	Product Code	UDI Code	Basic UDI Code
Afinion Lipid Panel	1116801	07070060014050	7070060LIP0001DA
Afinion Lipid Panel	1116802	07070060014074	7070060LIP0001DA
Afinion Lipid Panel Control	1116800	07070060014036	7070060LIP0002DC

GMDN:

Afinion Lipid Panel	53357
Afinion Lipid Panel Control	30214

EMDN:

Afinion Lipid Panel	W0101060401
Afinion Lipid Panel Control	W0101050202

Intended Use:

AFINION™ LIPID PANEL

The Afinion™ Lipid Panel is an *in vitro* diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in whole blood, serum and plasma. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion Analyzer. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

For use with the Alere Afinion™ AS100 Analyzer/ Afinion™ 2 Analyzer.
For professional near-patient testing and laboratory use.

AFINION™ LIPID PANEL CONTROL

The Afinion™ Lipid Panel Control kit is intended for use as assayed control material for total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig). The control material is human serum based liquid preparations containing constituents of human origin. Preservatives and stabilizers have been added to maintain product integrity. The controls should be used to confirm that your Afinion Analyzer System is working properly and provides reliable results. Only when controls are used routinely and the values obtained are within acceptable ranges can accurate results for patient samples be assured.

For use with Afinion™ Lipid Panel Test and Alere Afinion™ AS100 Analyzer/Afinion™ 2 Analyzer. For professional near-patient testing and laboratory use.

Classification and rule: Class B, Rule 6

Common Specifications: N/A

Notified Body: BSI Group - The Netherlands B.V
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body No.: 2797

Conformity Assessment Route: Regulation (EU) 2017/746 Annex IX

QMS certificate No.: IVDR 728551

EC Certificate No.: IVDR 738185

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

On behalf of the Manufacturer I hereby declare that the devices listed above fulfil the requirements specified in Regulation (EU) 2017/746 and is in conformity with this Regulation.

Claire Dora

Claire Dora
Associate Director, Regulatory Affairs
Abbott Diagnostics Technologies AS

Oslo, 2024-09-06

Place/Date (yyyy-mm-dd)

Abbott Diagnostics Technologies AS