Abbott

Afinion™ Lipid Panel

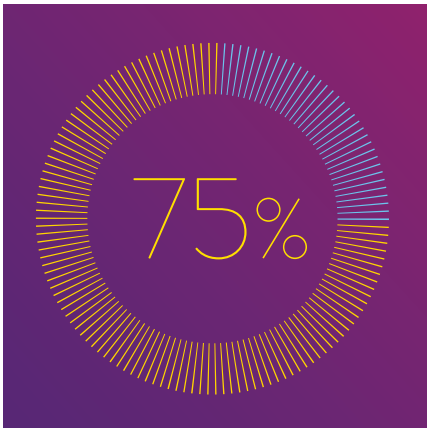
MAKE EVERY MINUTE COUNT

CARDIOVASCULAR DISEASE

Cardiovascular Disease (CVD) is already the **leading cause of death in the world**[1], and given current lifestyle and environmental factors, the CVD epidemic shows no signs of slowing. You are therefore likely to see a large number of patients at risk of developing CVD in your practice. In addition, **people with diabetes are 2-3 times more likely to develop CVD.**[2]

CVD can often be prevented before it takes hold. According to the WHO, **80% of premature deaths from heart attack and stroke could be avoided** through controlling blood pressure, quitting smoking, reducing high cholesterol, monitoring diabetes, becoming more physically active and adopting a healthy diet.[3] Early assessment, efficient diagnosis and ongoing monitoring are all vital to achieving positive outcomes.

It is now established that increased **LDL cholesterol (LDL-C) values are causally related to atherosclerotic CVD.** Lowering LDL-C and other ApoB-containing lipoproteins significantly reduces CV events.[4] As a risk predictor, the relationship between **non-HDL-Cholesterol (non-HDL-C)** and CV risk has however emerged as a comparably strong predictor as LDL-C, leading to increased focus of both measures in current risk assessment strategies, particularly in people with high Triglyceride (TG) levels, Diabetes Mellitus (DM), obesity, or very low LDL-C levels.[4]



"COMBINED REDUCTION IN HbA1c, SYSTOLIC BLOOD PRESSURE AND LIPIDS DECREASE CARDIOVASCULAR EVENTS BY 75%."[5]

CVD RISK ESTIMATION

The recently updated algorithms for the projection of the **10-year CVD risk,** SCORE2 and SCORE2-OP (SCORE2-Older Persons), estimates an individual's 10-year risk of both fatal and non-fatal CVD events in apparently healthy people aged **40-69 years and ≥ 70 years** respectively.[6] The risk estimation is based on the risk factors: age, sex, smoking, systolic blood pressure and non-HDL-C. Both algorithms are available in four geographical regions. with low, moderate, high, and very high CVD risk.[6]

ESTIMATION OF LIFETIME BENEFIT

There are new tools to motivate patients (especially younger people), to improve their long term health. These include ways of estimating the life-time benefit to them of positive behavioural change, such as smoking cessation, reducing their LDL-C (by 1 mmol/L) or their systolic blood pressure (by 10 mmHG).[6]

The lifetime benefit is expressed as 'years of median life expectancy free from myocardial infarction or stroke'. The estimation is based on the same risk factors as the SCORE2 / SCORE2-OP algorithms and include the non-HDL-C.[6]

CV RISK CATEGORIES BASED ON SCORE2 AND SCORE2-OP IN APPARENTLY HEALTHY PEOPLE ACCORDING TO AGE[6]

	<50 years	50-69 years	≥70 years*
VERY HIGH CVD RISK risk factor treatment generally recommended*	≥7.5%	≥10%	≥15%
HIGH CVD RISK risk factor treatment should be considered	2.5 to <7.5%	5 to <10%	7.5 to <15%
LOW-TO-MODERATE CVD RISK risk factor treatment generally not recommended	<2.5%	<5%	<7.5%

* In apparently healthy people >70 years old, the treatment recommendation for lipid-lowering drugs is Class IIb ('may be considered').
Adapted from 2021 ESC Guidelines on cardiovascular disease prevention in clinical practice[6]

The division of the population into three distinct age groups (<50, 50-69, and ≥70 years) results in a discontinuous increase in risk thresholds for low-to-moderate, high, and very high risk.

CV RISK CATEGORIES AND TREATMENT GOALS[4,6]

	LOW RISK	MODERATE RISK	HIGH RISK	VERY HIGH RISK
LDL-C	<3.0 mmol/L (<116 mg/dL)	<2.6 mmol/L (<100 mg/dL)	<1.8 mmol/L (<70 mg/dL) and ≥ 50% reduction from baseline	<1.4 mmol/L (<55 mg/dL) and ≥ 50% reduction from baseline
non-HDL-C		<3.4 mmol/L (<130 mg/dL)	<2.6 mmol/L (<100 mg/dL)	<2.2 mmol/L (<85 mg/dL)

LDL-C AND NON-HDL-C AS RISK FACTORS FOR ASCVD[6]

Results of randomized controlled trials indicate that lowering LDL-C safely reduces CVD risk even at low LDL-C levels.

- The relative reduction in CVD risk is proportional to the absolute size of the change in LDL-C, irrespective of the drug(s) used to achieve such change.
- Even a small absolute reduction in LDL-C may be beneficial in a high or very-high-risk patient.

Non-HDL-C encompasses all atherogenic (apo-B-containing) lipoproteins, and is calculated as: TC - HDL-C = non-HDL-C

- The relationship between non-HDL-C and CV risk is at least as strong as the relationship with LDL-C.
- Non-HDL-C is used as an input for SCORE2 and SCORE2-OP risk algorithms.

EXPECTED LDL-C REDUCTIONS FOR COMBINATION THERAPIES[6]

Intensity of lipid-lowering treatment

TREATMENT	AVERAGE LDL-C REDUCTION
Moderate-intensity statin	≈30%
High-intensity statin	≈50%
High-intensity statin plus ezetimibe	≈65%
PCSK9 inhibitor	≈60%
PCSK9 inhibitor plus high-intensity statin	≈75%
PCSK9 inhibitor plus high-intensity statin plus ezetimibe	≈85%

Adapted from 2021 ESC Guidelines on cardiovascular disease prevention in clinical practice[6]

FASTING OR NON-FASTING LIPID PROFILE?

Historically, lipid-profiles have been recommended to be measured in a fasting state. New evidence however shows that Lipids and lipoproteins only change minimally in response to normal food intake and that non-fasting triglycerides have been shown to be superior in predicting cardiovascular risk.[7]

For general risk screening, ESC recommends non-fasting sampling of lipid parameters.[4,6]

Even if **non-fasting sampling can be used in most cases**, calculated LDL-C from non-fasting samples should be interpreted with caution in patients with metabolic syndrome, diabetes mellitus, or hypertriglyceridaemia.[4,6]

NON-FASTING LIPID PROFILES	FASTING LIPID PROFILES
EVIDENCE-DRIVEN	**BELIEF-DRIVEN**
• Prospective evidence on >300,00 persons	• We have always done it that way!
• New guidelines	• Old guidelines
• Practical	• Impractical
• Safe	• Risk of hypoglycemia
• Cost saving	• Cost increasing
• Same vsit	• Unnecessary return visits
• Time efficient and patient-friendly, laboratory-friendly, and physician friendly	• Diverts time, energy, and resources from patient care

Most people will eat regularly throughout the day, so they are only in a fasting state (without food intake for 8 hours or more) for a few hours in the morning before breakfast. This natural mini-fast can be extended until noon, before blood is drawn for the test.

A lipid profile measured in the fasting state will not reflect the true lipid and lipoprotein composition and concentration in the blood present throughout the day.[7]

Adapted from Langsted A, Nordestgaard BG. Pathology 2019[7]

FAMILIAL HYPERCHOLESTEROLAEMIA (FH)

FH is a significantly underdiagnosed and undertreated dyslipidaemia, particularly in children. With a prevalence of 1 per 200-250 persons, 14-34 million people worldwide are currently suffering from FH.[5] **Coronary artery disease** typically develops early in people with FH if left untreated, but **can be dramatically reduced through early diagnosis and appropriate treatment.**[4]

Universal lipid screening in children between the ages of 9 to 11 years, as recommended by the National Heart, Lung, and Blood Institute, American Academy of Pediatrics, American Heart Association, National Lipid Association, and the American College of Cardiology, has the potential to substantially improve case finding.[8]

It is crucial to consider the diagnosis of FH in children with LDL-C persistently >160 mg/dL (4.1 mmol/L) and in adults with LDL-C >190 mg/dL (4.9 mmol/L)4, especially if there is a family history of early-onset coronary artery disease (CAD).[8]

HOW OFTEN SHOULD LIPIDS BE TESTED?[4]

- **Before starting a lipid-lowering drug treatment:** Twice, with an interval of 1-12 weeks (unless a condition requires prompt drug treatment, such as ACS and very high-risk patients).
- **Once treatment begins:** 8 (±4) weeks.
- **After adjusting treatment:** 8 (±4) weeks until the goal is achieved.
- **Once target level is achieved:** Annually (unless there are adherence problems, etc.).

HbA1c AND BLOOD GLUCOSE LEVEL TESTING[4]

1. Because of the increased frequency of DM during statin treatment, regular HbA1c checks should be considered in patients at high-risk of developing DM and those undergoing high-dose statin treatment.

2. The elderly or those with metabolic syndrome, obesity or signs of insulin resistance should be considered for glucose control.

ALBUMIN/CREATININE RATIO (ACR) AND eGFR TESTING TO PREDICT CARDIOVASCULAR RISK

- Routine assessment of microalbuminuria is indicated to identify patients with DM at risk of developing renal dysfunction or at high risk of future CVD.[5]
- Screening for kidney disease in patients with DM requires the calculation of eGFR and urine tests of albumin excretion.[5]

Albuminuria is the earliest marker of kidney disease in diabetes.[9] At any eGFR, the degree of albuminuria is associated with the risk of cardiovascular disease (CVD), CKD progression, and mortality.[10]

Both, albuminuria and eGFR independently improve the prediction of incident cardiovascular events beyond traditional risk factors as found in a big meta-analysis.[11] In the general population, the improvement was greater with ACR than with eGFR or dipstick proteinuria.[11]

KDIGO recommends a comprehensive CKD staging that incorporates albuminuria at all stages of eGFR.[12]

BENEFITS OF TESTING LIPIDS AT POINT-OF-CARE

Point-of-care (POC) Lipid Panel testing, can **quickly help screen** your patients to identify if they may need a referral, on-going monitoring, or a discussion around lifestyle factors. With the new recommendations of non-fasting sampling for general CVD risk screening, you can get even greater flexibility with your POC testing practices.

Having accurate POC results has been shown to **save time while reducing costs and the total number of GP appointments required.**[13] This helps you and your patient make progress with every consultation.

Learn more on

MYPOCACADEMY
CPD Certified

COMPARED TO POINT-OF-CARE TESTING (POCT), PATIENTS ON A **TRADITIONAL LABORATORY-LED PATHWAY ARE AT LEAST 3 TIMES MORE LIKELY TO MISS** AN NHS HEALTH CHECK OR EXIT THE CARE PATHWAY ALTOGETHER.[13]

3x

INTRODUCING
AFINION™ LIPID PANEL

The Afinion™ Lipid Panel assay is a simple and highly accurate fingerstick test providing a full lipid panel that may be used in the diagnosis and treatment of lipid disorders: total cholesterol (Chol), high density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol, triglycerides (Trig), non-HDL-C and Chol/HDL-C ratio.

It helps make every moment matter during the patient consultation, by quickly determining your patients' lipid levels.

ACCURATE
RESULTS[19,20]

EASY
TO USE[14-18]

AFINION™ LIPID PANEL TEST CARTRIDGE

7–8 MIN

ACCURATE RESULTS IN 7–8 MINUTES

15 µL

WHOLE BLOOD, SERUM OR PLASMA

Since launching in 2012, the Afinion™ Lipid Panel has been regularly certified by the Cholesterol Reference Method Laboratory Network (CRMLN)[21]

GOLD STANDARD ACCURACY

Accuracy is a vital consideration for your testing method. It is a commonly held perception that point-of-care testing produces less accurate results than lab testing, and therefore results can be unreliable or need confirmation. The Afinion™ Lipid Panel is certified and accurate to CRMLN standards[21] – considered the gold standard for commercial labs – giving you the confidence of having reliable results that can inform vital clinical decisions within the consultation, without needing to send samples to the lab.

MONITOR YOUR STATIN PATIENTS IN-CONSULTATION

For patients with established CVD, the Afinion™ Lipid Panel can be effective for the ongoing monitoring of their treatment. Immediate results within a single consultation can inform whether a patient's medication is working optimally or needs to be changed.

When you make every minute count, your patients will benefit sooner.

STREAMLINE AND SIMPLIFY THE CARE PATHWAY[13,22-24]

In comparison to the traditional care pathway of laboratory testing – which requires more time, resources and appointments, and leaves room for patients to exit the care pathway – point-of-care testing offers efficient care with fewer steps.

POINT-OF-CARE VS. CENTRAL LAB

- **Streamlined and efficient** with no patients lost in the process
- Better **patient understanding**
- Better clinician/patient **relationship**
- Better **control of cardiovascular risk**

- **Many steps** can take several days with multiple visits, calls and follow-ups
- **Patients can get 'lost'** along the way
- **Inconvenient** for the patient and provider
- **Extra work** for the practice

30 MINUTES VS. DAYS

TEST TIME:

• **Afinion HbA1c**	3 min
• **Afinion ACR**	5 min
• **Afinion LIPID PANEL**	7-8 min
• **Afinion CRP**	3-4 min

ACCURACY AND SPEED PROVEN IN THE COMMUNITY[19]

In individuals attending a community CVD risk screening in North London, a clinical assessment with fingerstick capillary blood was performed. Their lipid profile, HbA1c and urinary ACR tests were performed using the Afinion™ AS100 analyser and the Cholestech LDX™ system.

RESULTS

1. Good agreement between laboratory results and the Afinion™ AS100 analyser for TC, HDL-C and TG results.

2. Good agreement between laboratory results and the Afinion™ AS100 analyser for HbA1c and urinary ACR.

3. All laboratory personnel and other operators noted that the Afinion™ AS100 analyser is easy to use.

CONCLUSIONS

"POCT CAN SUPPORT A '**ONE STOP SHOP**' APPROACH BY PROVIDING **RAPID, RELIABLE RESULTS.** THE AFINION™ AS100 ANALYSER PROVIDES A **MULTI-ANALYTE PLATFORM** AND **COMPARES WELL WITH LABORATORY-BASED METHODS** AND ANOTHER WELL-ESTABLISHED POCT ANALYSER (CHOLESTECH LDX™ SYSTEM)."[19]

BUILT-IN CONNECTIVITY

The Afinion™ 2 analyser's direct network gives it built-in connectivity. It transfers a variety of data – including results, sample types and analytes, to a centralised, secure network.

This allows you to:

- Access data at any time
- Transfer and email results
- Manage patients seamlessly
- Monitor misidentified patients and out-of-range QC results

FOUR TESTS ON ONE PLATFORM

CARDIOVASCULAR RISK

AFINION™ Lipid Panel

Product code: 1116801

DIABETES

AFINION™ HbA1c

Product code: 1116795

KIDNEY

AFINION™ ACR

Product code: 1116781

RESPIRATORY

AFINION™ CRP

Product code: 1116787

ABBREVIATIONS

ACR: albumin/creatinine ratio
ASCVD: Atherosclerotic Cardiovascular Disease
CAD: Coronary Artery Disease
DM: Diabetes Mellitus
eGFR: estimated Glomerular Filtration Rate
HDL-C: High Density Lipoprotein Cholesterol
FH: Familial Hypercholesterolaemia
LDL-C: Low Density Lipoprotein Cholesterol
TG: Triglyceride
SCORE: Systemic Coronary Risk Estimation

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