



Applicability of the new random access continuous loading analyser, RX modena, for the measurement of lipid profile tests



INTRODUCTION

Cardiovascular diseases (CVDs) are the number 1 cause of death globally, accounting for 17.3 million deaths per year, a number that is expected to grow to **23.6 million by 2030**. (1) Despite significant improvements in medical care over the past 25 years, cardiovascular disease remains a major public health challenge. With the increasing prevalence of obesity, metabolic syndrome, and type 2 diabetes mellitus, this burden is projected to escalate dramatically. (3)

CVDs refer to a group of disorders of the heart and blood vessels, including: coronary heart disease, stroke, cerebrovascular disease, peripheral arterial disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis and pulmonary embolism. (2)

There are a number of behavioural risk factors leading to CVD which include: **unhealthy diet, physical inactivity, tobacco use and harmful use of alcohol**. The effects of behavioural risk factors may show up in individuals as raised blood pressure, **raised blood glucose, raised blood lipids, and obesity**. These risks factors can be measured in primary care facilities and indicate an increased risk of developing a heart attack, stroke, heart failure and other complications. (2) In order to tackle the number of cardiovascular related deaths globally early detection of high risk patients is vital.

Early detection is key for people with cardiovascular disease or who are at high cardiovascular risk in order to ensure the correct treatment plan is issued and any risk of recurrence can be monitored effectively.

CVDs are diagnosed using an array of laboratory tests and imaging studies. The primary part of a patient diagnosis includes assessing the medical and family history of the patient, considering risk

factors and a physical examination. These findings will be coordinated with the results from tests and procedures that are carried out. Laboratory tests are used to detect the risk factors for heart diseases. These include detection of the fats, cholesterol and lipid components of blood including LDL, HDL, Triglycerides. (4)

LIPID PROFILE

The lipid profile, which includes a panel of tests, is used as part of a cardiovascular risk assessment and to monitor response to lipid modifying treatments. **Cholesterol, HDL, LDL and triglycerides** are among the analytes measured in this panel.

The average cholesterol in middle aged men and women in the UK is between 5.0mmol/L and 6.0mmol/L. Cholesterol experts agree that a total cholesterol of 5mmol/L or less, a non-HDL cholesterol of 4mmol/L or less and a LDL-cholesterol of 3mmol/L or less are considered healthy for most people. (5)

Cholesterol

Without cholesterol your body wouldn't work as it forms part of the outer shell of every cell. It is abundant in the brain, nervous tissue, skin and adrenal glands. However, **too much cholesterol in the blood can lead to increased risk of cardiovascular disease (CVD)**. (5) Cholesterol is transported from the liver to other tissues as a component of lipoproteins. Lipoproteins are defined as any of a group of soluble proteins that combine with and transport fat or other lipids in the blood plasma. (6) They are classified by density, the lower the density of the lipoprotein, the greater the amount of fats contained within it.(5)

Triglycerides

Triglycerides is another name for dietary fats. Like cholesterol, triglycerides also circulate blood around the body. The level of triglycerides in the blood will increase and slowly decrease after a meal as triglycerides are either used up or stored. Sometimes the removal of triglycerides from the blood is less efficient which can result in raised triglycerides and can have significant health implications. (5)

HDL

High Density Lipoprotein (HDL) is often referred to as the 'good' cholesterol. The role of HDL is to transport excess cholesterol from the tissues to the liver for disposal. Epidemiological studies show that **low levels of HDL-cholesterol are predictive of high risk of CVD.** In men, levels of HDL cholesterol below 1 mmol/L show an increased risk of CVD. In women, HDL cholesterol levels below 1.2 mmol/L increase risk of CVD. (5)

LDL

Low Density Lipoprotein (LDL) is involved in transporting cholesterol from the liver to the tissues where it is used. LDL is often referred to as the 'bad' cholesterol as too much of it is unhealthy. (7) **High levels of LDL-cholesterol in the blood are associated with an increased risk of CVD.** (5)

STUDY

A study was carried out by Randox Laboratories to evaluate four assays (cholesterol, HDL, LDL and triglycerides) applied to a newly developed fully automated, random access, floor standing clinical chemistry analyser, the RX modena. This instrument can complete 1,200 tests per hour, which combined with its continuous loading capability, means **instrument down time is reduced and cost effectiveness is increased.** The application of this

new instrument to the measurement of clinical chemistry parameters contributes to a **reliable analytical assessment of samples** thus benefiting the process of patient care.

Methodology

On-board calibration stabilities were tested by storing the reagents uncapped on the analyser for 28 days. Assay precision was assessed by testing patient samples at defined levels, 2 replicated twice a day for 20 days.

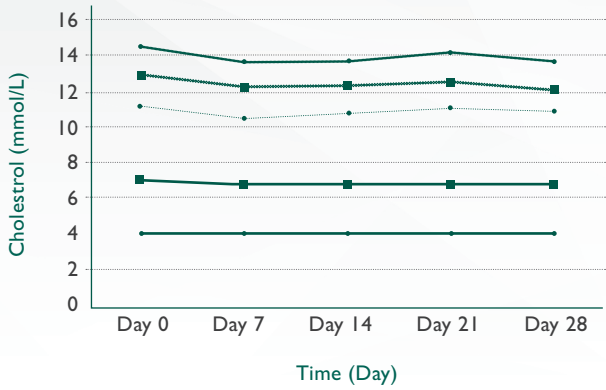
Results

Assay	Limit of quantitation (mmol/L)	Linearity (mmol/L)
Cholesterol	0.58	15.94
HDL	0.1	3.6
LDL	0.75	20.57
Triglycerides	0.4	11.11

ON-BOARD STABILITY

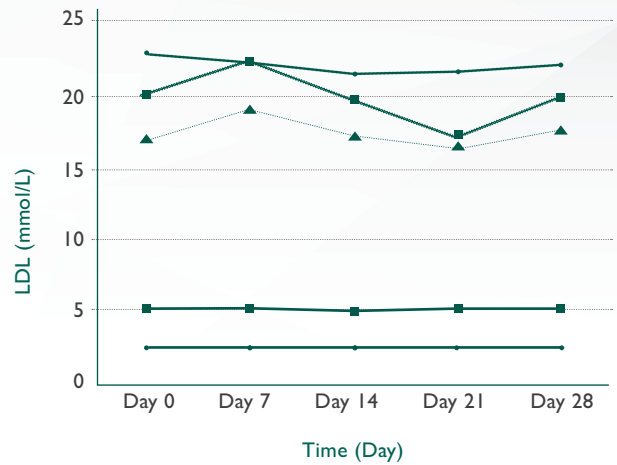
The reagents presented an on-board stability and calibration frequency of 28 days.

Cholesterol assay on RX modena: on-board stability



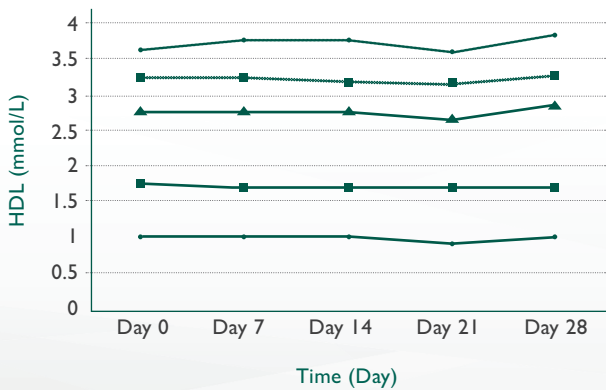
- Control 1
- Control 2
- Linearity L7
- Linearity L8
- Linearity L9

LDL assay on RX modena: on-board stability



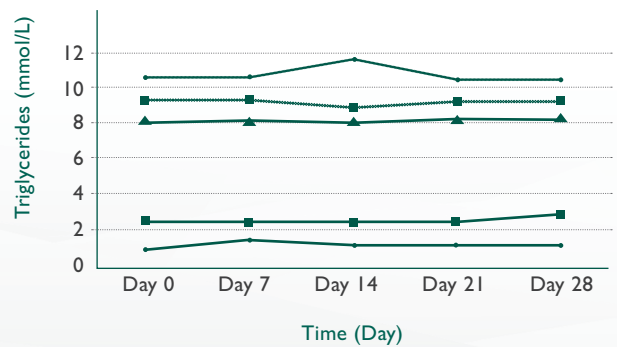
- Control 1
- Control 2
- Linearity L8
- Linearity L9
- Linearity L10

HDL assay on RX modena: on-board stability



- Control 1
- Control 2
- Linearity L7
- Linearity L8
- Linearity L9

Triglycerides assay on RX modena: on-board stability



- Control 1
- Control 2
- Linearity L7
- Linearity L8
- Linearity L9

WITHIN RUN PRECISION

ASSAYS				
Cholesterol	Level 1 (n=80) (4.94 mmol/L)	Level 2 (n=80) (4.09 mmol/L)	Level 3 (n=80) (6.58 mmol/L)	Level 4 (n=80) (7.85 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	2.6	2.2	1.6	1.6
HDL	Level 1 (n=80) (0.51 mmol/L)	Level 2 (n=80) (1.52 mmol/L)	Level 3 (n=80) (2.20 mmol/L)	Level 4 (n=80) (2.63 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	1.9	1.7	1.4	1.7
LDL	Level 1 (n=80) (1.42 mmol/L)	Level 2 (n=80) (3.31 mmol/L)	Level 3 (n=80) (4.53 mmol/L)	Level 4 (n=80) (8.51 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	2.8	2.0	2.0	2.0
Triglycerides	Level 1 (n=80) (1.22 mmol/L)	Level 2 (n=80) (2.56 mmol/L)	Level 3 (n=80) (3.43 mmol/L)	Level 4 (n=80) (5.19 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	1.8	1.9	1.4	1.9

ASSAYS				
Cholesterol	Level 1 (n=80) (4.94 mmol/L)	Level 2 (n=80) (4.09 mmol/L)	Level 3 (n=80) (6.58 mmol/L)	Level 4 (n=80) (7.85 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	3.7	2.5	2.0	2.2
HDL	Level 1 (n=80) (0.51 mmol/L)	Level 2 (n=80) (1.52 mmol/L)	Level 3 (n=80) (2.20 mmol/L)	Level 4 (n=80) (2.63 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	2.5	2.4	1.9	1.9
LDL	Level 1 (n=80) (1.42 mmol/L)	Level 2 (n=80) (3.31 mmol/L)	Level 3 (n=80) (4.53 mmol/L)	Level 4 (n=80) (8.51 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	5.7	3.5	3.6	3.2
Triglycerides	Level 1 (n=80) (1.22 mmol/L)	Level 2 (n=80) (2.56 mmol/L)	Level 3 (n=80) (3.43 mmol/L)	Level 4 (n=80) (5.19 mmol/L)
	CV(%)	CV(%)	CV(%)	CV(%)
	2.7	2.2	2.1	2.4

Correlation

In the correlation studies serum patient samples ($n \geq 100$) were tested and compared against an existing method. Slopes fell within 0.90 – 1.10 and correlation coefficients were > 0.95 .

Correlation studies were conducted using another commercially available clinical chemistry analyser ($n \geq 100$ serum samples).

Findings

The results from this evaluation of cholesterol, HDL, LDL and triglycerides assays on the new RX modena analyser indicate optimal analytical performance and overall the system represents a rapid, user friendly, cost effective analytical tool with reduced down time for the clinical chemistry laboratory.

References

1. SMITH ET AL (2012) Our Time: A Call to Save Preventable Death From Cardiovascular Disease (Heart Disease and Stroke). [Online] Available from - http://www.world-heart-federation.org/fileadmin/user_upload/documents/Publications/OurTimeACalltoSavePreventableDeathFromCVD.pdf [Accessed: 16th May 2017]
2. WHO Media Centre (2017) Cardiovascular Diseases (CVDs) [Online] Available at: <http://www.who.int/mediacentre/factsheets/fs317/en/> [Accessed: 15th May 2017]
3. European Heart Journal (2011) Triglyceride-rich lipoproteins and high-density lipoprotein cholesterol in patients at high risk of cardiovascular disease: evidence and guidance for management [Online] Available at: <https://academic.oup.com/eurheartj/article/32/11/1345/2398402/Triglyceride-rich-lipoproteins-and-high-density> [Accessed: 16th May 2017]
4. News Medical Life Sciences (2012) Cardiovascular disease diagnosis [Online] Available at: <http://www.news-medical.net/health/Cardiovascular-Disease-Diagnosis.aspx> [Accessed: 17th May 2017]
5. Heart UK Fact Sheet (2015) Cholesterol and lipoproteins [Online] Available at: (https://heartuk.org.uk/files/uploads/documents/huk_fs_mfsA_cholesterollipoproteins_v2.pdf) [Accessed: 16th May 2017]
6. Oxford Dictionaries Online (2017) [Online] Available at: <https://en.oxforddictionaries.com/definition/lipoprotein> [Accessed: 16th May 2017]
7. Heart UK [Online] Available at: (<https://heartuk.org.uk/health-and-high-cholesterol>) [Accessed: 17th May 2017]

Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
+44 (0) 28 9442 2413 • marketing@randox.com • randox.com/clinical-chemistry-analysers/

Information correct at time of print. Randox Laboratories Ltd is a subsidiary of Randox Holdings Limited a company registered within Northern Ireland with company number N.I. 614690. VAT Registered Number: GB 151 6827 08. Product availability may vary from country to country. Please contact your local Randox representative for information. Products may be for Research Use Only and not for use in diagnostic procedures in the USA.