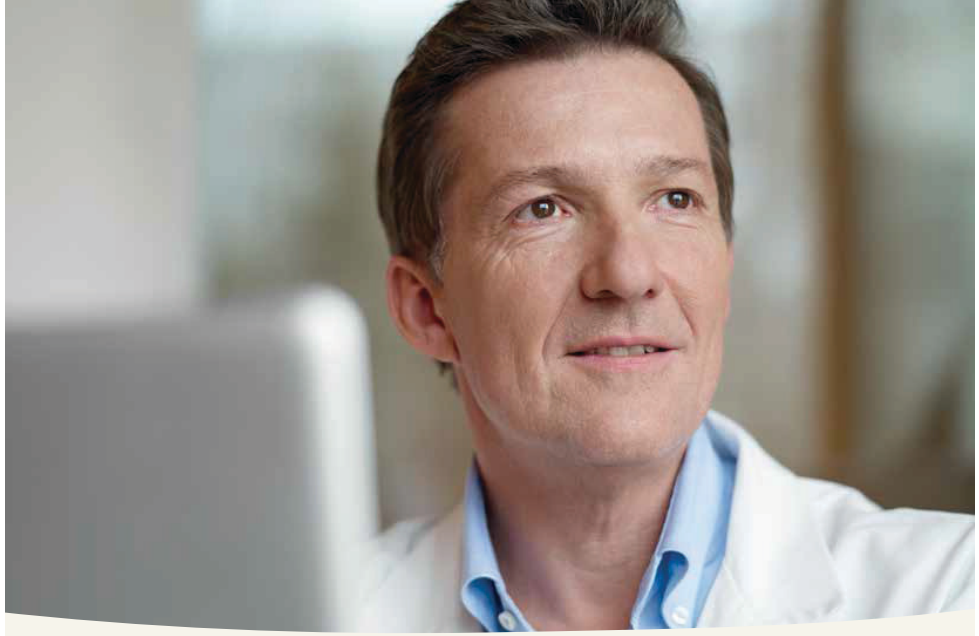
cobas b 101 system

Enhancing patient care at the point of need with combined HbA1c and lipid panel testing

Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland
www.cobas.com

Roche

cobas®
Life needs answers



Diabetes and dyslipidemia

Two growing global health issues that significantly increase the risk of cardiovascular disease (CVD)

Both diabetes and dyslipidemia are growing in prevalence every year, yet only 50 % of people who have either disease are diagnosed.[1,2]

A challenge to global healthcare

By 2012 the number of people living with diabetes reached 371 million worldwide.[1] In this year alone 4.8 million people died as a result of having the disease.[1] If left untreated, increased blood glucose levels may lead to serious complications affecting the heart and blood vessels, eyes, kidneys, and nerves.[1] Type 2 diabetes, characterised by insufficient insulin production or cellular response to it, is the most common type, affecting 90 – 95 % of people with diabetes.[3] Dyslipidemia is a disorder of lipoprotein metabolism that affects over 300 million people worldwide and leads to the development of atherosclerosis and other related diseases.[2] Both diabetes and dyslipidemia are growing in prevalence every year, yet only 50 % of people who have either disease are diagnosed.[1,2]

Major risk factors for CVD

In people aged 50 years and above, diabetes increases the lifetime risk for CVD above that of any other single risk factor.[4] Type 2 diabetes is also considered a coronary heart disease (CHD) risk-equivalent condition,[5] as people with type 2 diabetes have as high a risk for myocardial infarction (MI) as those with previous MI.[6] Similarly, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglycerides are independent risk factors for CVD.[7-10]

CVD is the leading cause of death globally

In 2010 there were a total of 62.5 million worldwide cases of CHD, congestive heart failure and stroke.[11] By 2030 this number is expected to increase by a third to 83.9 million.[11] More people die annually from CVD than from any other cause.[12] In 2008 there were 17.3 million deaths attributed to CVD.[12] By 2030 deaths from CVD are expected to increase 35 % to 23.3 million.[12] In 2010, the global cost of CVD was USD 863 billion and it is estimated to rise to USD 1,044 billion in 2030 – an increase of 22 %.[11] Early identification and treatment of CVD risk factors is essential for reducing the global burden of this often deadly disease.

Established 1922

Medical and Surgical Requisites Pty Ltd

Call within Brisbane 07 3859 2900 33 Fulcrum Street Richlands Queensland 4077 www.medsurg.com.au
Phone 1300medsurg (1300 633 787) **Email** medical@medsurg.com.au **Fax** 07 3859 2995

Metabolic syndrome
Driving a new global CVD epidemic

Metabolic syndrome identifies those at high risk of developing CVD and diabetes
Most individuals with CVD have multiple risk factors, of which several are interrelated and cluster together.[13,14] The presence of multiple risk factors adds substantial CVD risk over and above the sum of the risk associated with each individual risk factor.[13]

Around 20 – 25 % of the world's adults have metabolic syndrome, a term used to describe a group of such risk factors (Fig. 1).[13] People with metabolic syndrome have a three-fold higher risk of heart attack or stroke and a two-fold risk of mortality from these conditions.[13] They also have a five-fold greater risk of developing type 2 diabetes.[13]

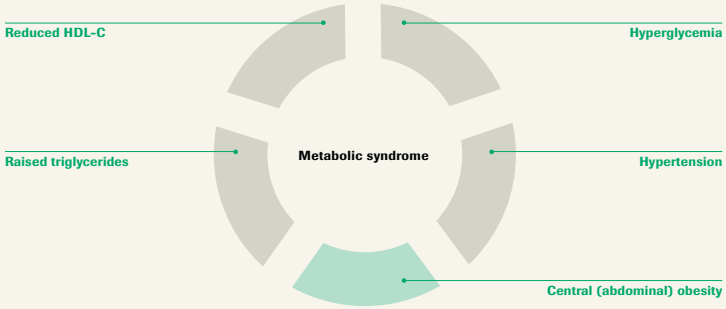


Figure 1: Clinical components of metabolic syndrome. According to the new International Diabetes Federation (IDF) definition, for a person to be defined as having the metabolic syndrome they must have central obesity plus any two of the other four factors.[13]

Point-of-care HbA1c and lipid panel testing at the physician's office
Supporting early detection and management of metabolic syndrome, dyslipidemia and diabetes

Supporting early diagnosis of metabolic syndrome at the physician's office
Glycated hemoglobin (HbA1c) concentrations reflect average glycemia over the preceding 2 – 3 months.[15] Point-of-care HbA1c and lipid panel testing, in combination with blood pressure and waist circumference measurements, allow physicians to diagnose patients with metabolic syndrome within the timeframe of the consultation. Because many people who are tested for metabolic syndrome are likely to already be affected by diabetes and/or CVD without knowing it,[1,2] it is important that these individuals are identified early so that lifestyle interventions and/or treatment can be initiated as early as possible to minimise complications.[16]

Optimising management of patients with dyslipidemia at the physician's office
Point-of-care lipid panel testing has been shown to result in a higher percentage of patients with either total cholesterol or triglyceride levels within the target range,[17] and enhanced medication adherence and treatment satisfaction.[18,19] Point-of-care lipid panel testing has also been shown to improve cholesterol risk management in high-risk patients,[20] and to improve LDL-C, non-HDL-C and total cholesterol goal attainment.[21,22] Similarly, physicians performed a higher number of patient risk assessments for CHD when patient results were available during the same office visit, compared with cases where patient results were only available after the office visit (68 % vs. 19 %).[23]

Point-of-care testing … has the potential to improve monitoring of chronic conditions, therapeutic control and clinical efficiency, and to enhance clinical decision making within the timeframe of the consultation.[17]

Optimising management of patients with diabetes at the physician's office

Immediate feedback of HbA1c results can improve patients' glycemic control (Fig. 2) and increase the percentage of patients within their HbA1c target range.[17,24-28] Rapid availability of HbA1c results also enhances clinical decision making in terms of appropriate intensification of therapy,[29,30] improves medication adherence[18] and patient satisfaction,[19] and may potentially reduce diabetes-related expenses and patient-borne costs (UK-based studies).[25,31] Furthermore, patients with diabetes who receive point-of-care testing are more likely to be motivated to look after their condition and to view their relationship with their physician as being strengthened.[19]

Immediate feedback of HbA1c results using a point-of-care device can improve patients' glycemic control

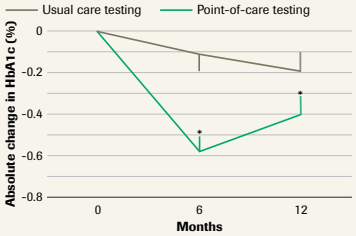
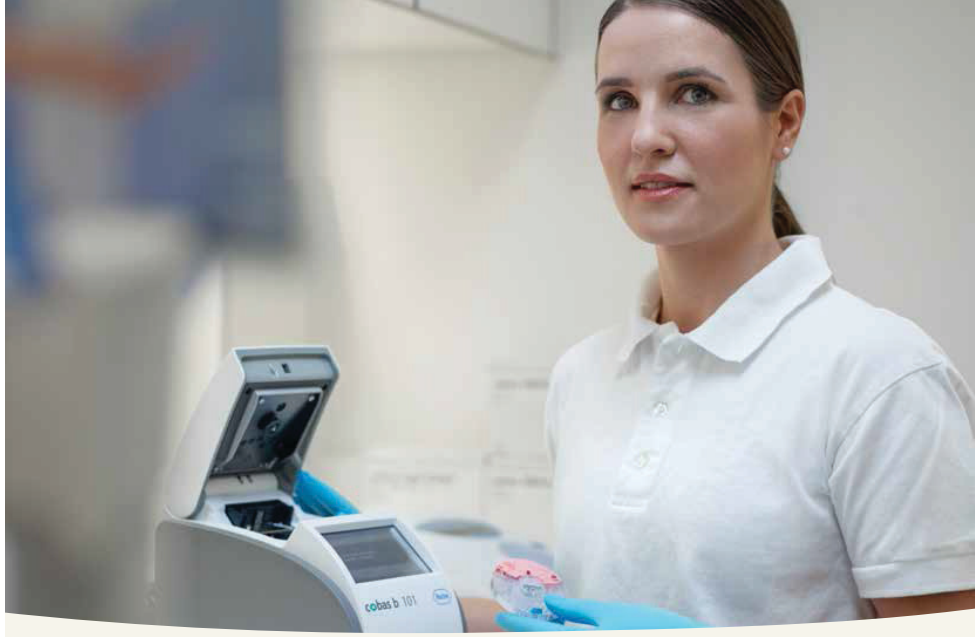


Figure 2: Changes in HbA1c levels (%) from baseline at 6- and 12-month follow-up in point-of-care testing and usual care groups.[28] **p < 0.05 vs. baseline.*

In the management of diabetes, HbA1c measurement is the gold-standard for long-term follow-up of glycemic control and is complementary to patient self-monitoring of blood/interstitial glucose.[15,16] HbA1c testing has many benefits for patients and their physicians (Table 1).[32,33]

HbA1c testing is convenient for the patient	Fasting is not required prior to taking sample
	Sample may be taken at any time of day
	Minimal preparation required by the patient
HbA1c test results are reliable	Low biological variability
	High sample stability
	Reproducible test results
	Greater pre-analytical stability than glucose
	Not affected by acute factors (e.g., stress, exercise)
HbA1c test results are related to the progression of disease complications	Reflects long-term glycemic control
	Better predicts the development of CVD than glucose
	May identify individuals with greater susceptibility to protein glycation
	May identify individuals with higher complication rates

Table 1: The benefits of HbA1c testing.[32,33]



cobas b 101 system

Enhancing patient care at the point of need with combined HbA1c and lipid panel testing

The cobas b 101 system can support physicians to optimise the management of patients with diabetes and dyslipidemia, and support the early diagnosis of patients with metabolic syndrome who are at high risk of developing CVD and diabetes.

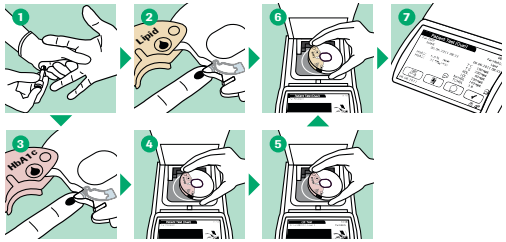
The cobas b 101 system is a point-of-care device offering combined HbA1c and lipid panel* testing on one platform.

The **cobas b** 101 system offers single testing (HbA1c or lipid panel, separately) as well as dual testing (HbA1c and lipid panel, consecutively) with fast turnaround time:

- Single HbA1c test result in less than 6 minutes
- Single lipid panel result in approximately 6 minutes
- Dual HbA1c test and lipid panel results in 15 minutes

** Lipid panel testing includes:*
Total cholesterol (measured)
Triglycerides (measured)
HDL-C (measured)
LDL-C (calculated)
non-HDL-C (calculated)
Total cholesterol/HDL-C ratio (calculated)

From patient preparation to the display of HbA1c test and lipid panel results in one 15-minute workflow



1. Simultaneous loading of both discs from a single finger prick
2. Fill lipid disc. Put aside lipid disc (max. 8 min.)
3. Fill HbA1c disc (60 – 90 sec. [max. transfer time])
4. Insert HbA1c disc right away (6 min.)
5. Remove HbA1c disc when test is finished
6. Insert lipid disc (6 min.)
7. **cobas** HbA1c test and lipid panel results are shown together at the end

MSR
Established 1922

Medical and Surgical Requisites Pty Ltd

Call within Brisbane 07 3859 2900 33 Fulcrum Street Richlands Queensland 4077 www.medsurg.com.au
Phone 1300medsurg (1300 633 787) **Email** medical@medsurg.com.au **Fax** 07 3859 2995

Easy and safe handling of samples and test discs

- Direct sample application from a single finger prick and no capillaries, tubes or pipettes are needed for sample collection
- Requires only very small sample volumes (2 µL for HbA1c, 19 µL for lipids) with self-filling discs
- Discs can be stored for more than 13 months from production at room temperature (2 – 30 °C)

Comprehensive connectivity and data management

- IT connectivity solutions are available with the **cobas IT** 1000 application
- **cobas b** 101 supports POCT1A interface protocol and can be connected to Data Management Systems, Laboratory Information Systems (LIS) or Hospital Information Systems (HIS)
- External devices such as a printer and a barcode scanner are available
- Large data storage with 5,000 patient results, 500 quality control results, and 50 operator IDs

User-friendly, robust and service-free

- Large touchscreen, full keyboard on display, and multiple language support
- Menus integrate text and graphical guidance for simplified use
- Reference ranges are configurable and individual results comments can be added
- No calibration is needed, samples and discs are checked for integrity, and all steps of the process are controlled
- Quality control menu features configurable test intervals, target ranges and QC lockout

Confirmed performance with full compliance to guidelines

- External multicenter studies[34] performed under Clinical and Laboratory Standards Institute (CLSI) guidelines have shown that both the **cobas** HbA1c test and **cobas** lipid panel met high standards for precision and accuracy derived from the National Glycohemoglobin Standardization Program (NGSP) and National Cholesterol Education Program (NCEP)

References

1 International Diabetes Federation. (2012). Diabetes atlas, 5th edition – 2012 update. Available at http://www.idf.org/diabetesatlas. Last accessed March 2013.

2 Decision Resources. (2007). Cardium study 4, Dyslipidemia, Inc. Waltham, MA.

3 American Diabetes Association. (2013). Diagnosis and classification of diabetes mellitus. *Diabetes Care 36 Suppl 1,* 67-74.

4 Lloyd-Jones, D.M., Leip, E.P., Larson, M.G., D'Agostino, R.B., Beiser, A. et al. (2006). Prediction of lifetime risk for cardiovascular disease by risk factor burden at 50 years of age. *Circulation 113,* 791-798.

5 National Cholesterol Education Program. (2002). 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 106,* 3143-3421.

6 Haffner, S.M., Lehto, S., Ronnemaa, T., Pyorala, K., & Laakso, M. (1998). Mortality from coronary heart disease in subjects with type 2 diabetes and in nondiabetic subjects with and without prior myocardial infarction. *N Engl J Med 339,* 229-234.

7 Hopkins, P.N., Wu, L.L., Hunt, S.C., & Brinton, E.A. (2005). Plasma triglycerides and type III hyperlipidemia are independently associated with premature familial coronary artery disease. *J Am Coll Cardiol 45,* 1003-1012.

8 Hokanson, J.E. (2002). Hypertriglyceridemia and risk of coronary heart disease. *Curr Cardiol Rep 4,* 488-493.

9 Di Angelantonio, E., Sarwar, N., Perry, P., Kaptoge, S., Ray, K.K. et al. (2009). Major lipids, apolipoproteins, and risk of vascular disease. *JAMA 302,* 1993-2000.

10 Grundy, S.M., Cleeman, J.I., Merz, C.N., Brewer, H.B. Jr., Clark, L.T. et al. (2004). Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. *Circulation 110,* 227-239.

11 Bloom, D.E., Jané-Llopis, E., Abrahams-Gessel, S., Bloom, L.R., Fathima, S. et al. (2011). The global economic burden of noncommunicable diseases. Geneva: World Economic Forum. Available at http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf. Last accessed March 2013.

12 World Health Organization. (2013). Cardiovascular diseases (CVDs). Available at http://www.who.int/mediacentre/factsheets/fs317/en/index.html. Last accessed March 2013.

13 International Diabetes Federation. (2006). The IDF consensus worldwide definition of the metabolic syndrome. Available at http://www.idf.org/metabolic-syndrome. Last accessed March 2013.

14 Grundy, S.M., Brewer, H.B. Jr., Cleeman, J.I., Smith, S.C. Jr., & Lenfant, C. (2004). Definition of metabolic syndrome: Report of the National Heart, Lung, and Blood Institute/American Heart Association conference on scientific issues related to definition. *Circulation 109,* 433-438.

15 Hanas, R., & John, G. (2010). 2010 consensus statement on the worldwide standardization of the hemoglobin A1C measurement. *Diabetes Care 33,* 1903-1904.

16 American Diabetes Association. (2013). Standards of medical care in diabetes – 2013. *Diabetes Care 36 Suppl 1,* 11-66.

17 Bubner, T.K., Laurence, C.O., Gialamas, A., Yelland, L.N., Ryan, P. et al. (2009). Effectiveness of point-of-care testing for therapeutic control of chronic conditions: results from the PoCT in General Practice Trial. *Med J Aust 190,* 624-626.

18 Gialamas, A., Yelland, L.N., Ryan, P., Willson, K., Laurence, C.O. et al. (2009). Does point-of-care testing lead to the same or better adherence to medication? A randomised controlled trial: the PoCT in General Practice Trial. *Med J Aust 191,* 487-491.

19 Laurence, C.O., Gialamas, A., Bubner, T., Yelland, L., Willson, K. et al. (2010). Patient satisfaction with point-of-care testing in general practice. *Br J Gen Pract 60,* e98-104.

20 Tsuyuki, R.T., Johnson, J.A., Teo, K.K., Simpson, S.H., Ackman, M.L. et al. (2002). A randomized trial of the effect of community pharmacist intervention on cholesterol risk management: the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP). *Arch Intern Med 162,* 1149-1155.

21 Gerrald, K.R., Dixon, D.L., Barnette, D.J., & Williams, V.G. (2010). Evaluation of a pharmacist-managed lipid clinic that uses point-of-care lipid testing. *J Clin Lipidol 4,* 120-125.

22 Bozovich, M., Rubino, C.M., & Edmunds, J. (2000). Effect of a clinical pharmacist-managed lipid clinic on achieving National Cholesterol Education Program low-density lipoprotein goals. *Pharmacotherapy 20,* 1375-1383.

23 Ruffin, D.M., & McKenney, J.M. (2012). Office-based cholesterol testing: impact on process-of-care in patients with a pilot study. *J Pharm Technol 13,* 75-79.

24 Kennedy, L., Herman, W.H., Strange, P., & Harris, A. (2006). Impact of active versus usual algorithmic titration of basal insulin and point-of-care versus laboratory measurement of HbA1c on glycemic control in patients with type 2 diabetes: the Glycemic Optimization with Algorithms and Labs at Point of Care (GOAL A1C) trial. *Diabetes Care 29,* 1-8.

25 Grieve, R., Beech, R., Vincent, J., & Mazurkiewicz, J. (1999). Near patient testing in diabetes clinics: appraising the costs and outcomes. *Health Technol Assess 3,* 1-74.

26 Ferenczi, A., Reddy, K., & Lorber, D. L. (2001). Effect of immediate hemoglobin A1c results on treatment decisions in office practice. *Endocr Pract 7,* 85-88.

27 Petersen, J.R., Finley, J.B., Okorodudu, A.O., Mohammad, A.A., Grady, J.J. et al. (2007). Effect of point-of-care on maintenance of glycemic control as measured by A1C. *Diabetes Care 30,* 713-715.

28 Cagliero, E., Levina, E.V., & Nathan, D.M. (1999). Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. *Diabetes Care 22,* 1785-1789.

29 Miller, C.D., Barnes, C.S., Phillips, L.S., Ziemer, D.C., Gallina, D.L. et al. (2003). Rapid A1c availability improves clinical decision-making in an urban primary care clinic. *Diabetes Care 26,* 1158-1163.

30 Thaler, L.M., Ziemer, D.C., Gallina, D.L., Cook, C.B., Dunbar, V.G. et al. (1999). Diabetes in urban African-Americans. XVII. Availability of rapid HbA1c measurements enhances clinical decision-making. *Diabetes Care 22,* 1415-1421.

31 Khunti, K., Stone, M.A., Burden, A.C., Turner, D., Raymond, N.T. et al. (2006). Randomised controlled trial of near-patient testing for glycated haemoglobin in people with type 2 diabetes mellitus. *Br J Gen Pract. 56,* 511-517.

32 Sacks, D.B. (2011). A1C versus glucose testing: a comparison. *Diabetes Care 34,* 518-523.

33 Bonora, E., & Tuomilehto, J. (2011). The pros and cons of diagnosing diabetes with A1C. *Diabetes Care 34 Suppl 2,* 184-190.

34 Roche data on file.