COBAS B 101

เครื่องตรวจวัดระดับ ฮีโมโกลบิน A1C และ LIPID PROFILE

HbA1c disc & lipid profile disc

คุณลักษณะทั่วไป-ทางเทคนิค

- เป็นเครื่อง point of care สำหรับตรวจวัดระดับ ฮีโมโกลบิน A1c และ Lipid profile ในเลือด โดยใช้เลือดจากปลายนิ้ว หยดลงในแผ่น disc และนำเข้าเครื่องอ่าน
- ใช้ Disc แยกตรวจ 2 ชนิด คือ HbA1c Disc และLipid Profile Disc [Triglyceride, Cholesterol, HDL and LDL (calculated)]
- Disc เป็นระบบ Sterile สามารถใช้ดูดเก็บตัวอย่างเลือดได้โดยตรงจากปลายนิ้ว ปริมาณเลือดที่ใช้ : HbA1c disc = 2 ไมโครลิตร

  Lipid profile disc = 19 ไมโครลิตร
- ตัวอย่างเลือดที่ใช้ capillary whole blood, venous whole blood, EDTA whole blood และ heparinized whole blood

TEST PRINCIPLE

- Blood sample is diluted and mixed with TRIS buffer to release Hb from the erythrocytes.
- A fraction of sample is conveyed into a reaction chamber where it mixed with sodium lauryl sulphate (SLS). SLS is used to form the SLS-Hb complex.
- The conc. of total Hb is calculated by measuring SLS-Hb complex with a wavelength 525 nm.

Hb A1c

- Hb A1c in another fraction of sample —(Potassium ferricyanide/ sucrose laurate)→ denatured HbA1c
- Denatured HbA1c + HbA1c Ab → latex agglutination
- Latex agglutination + agglutinator → agglutination inhibition reaction (wavelength 625 nm) → (conc. of HbA1c is calculated)

TEST PRINCIPLE

Lipid Panel

TC and HDL-chol: by an enzymatic method.

Cholesterol ester $\xrightarrow{\text{chol. esterase}}$ cholesterol + fatty acids

Cholesterol + NAD $^{+}$ $\xrightarrow{\text{chol DH}}$ cholestenone + NADH

NADH + WST8 $\xrightarrow{\text{diaphorase}}$ NAD^{+} + formazan dye (wavelength 460 nm)

Triglycerides: by enzymatic method

Triglycerides $\xrightarrow{\text{LPL}}$ glycerol + fatty acids

Glycerol + NAD^{+} $\xrightarrow{\text{Glycerol DH}}$ Dihydroxyacetone + NADH

NADH + WST8 $\xrightarrow{\text{diaphorase}}$ NAD^{+} + formazan dye (wavelength 460 nm.)

LDL-chol is calculated using Friedewald formula

(when TG $\geq$ 400mg/dl, the calculated LDL-chol is not reported)

Measuring range

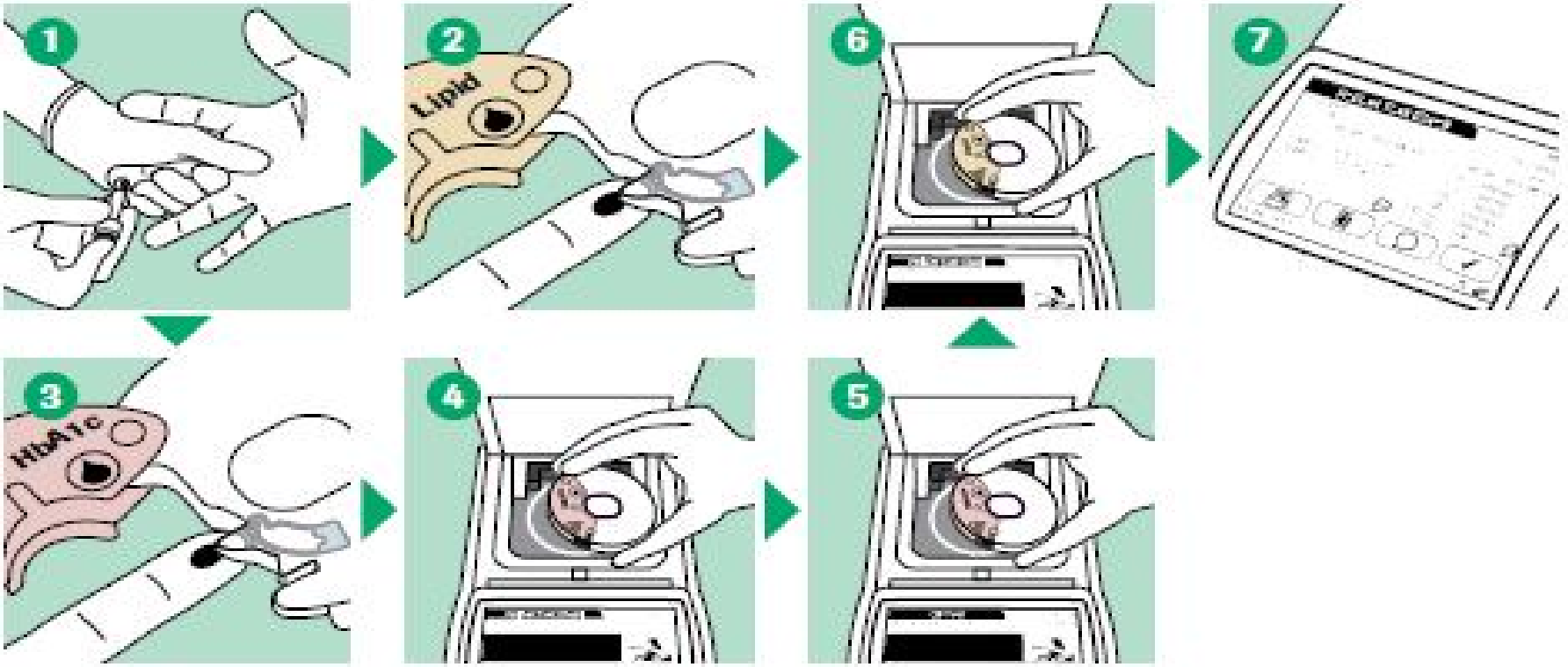
Parameter	CI unit	SI Unit
Total cholesterol	50-500 mg/dl	1.28 – 12.95 mmol/L
Triglycerides	45-650 mg/dl	0.50 – 7.35 mmol/L
HDL-cholesterol	15- 100 mg/dl	0.38 -2.60 mmol/L
LDL-cholesterol	Friedewald formula: LDL-chol = TC- HDL-TG/5	
HbA1c	20-130 mmol/mol (IFCC) 4% -14% (DCCT/NGSP)	

IFCC = International Federation of Clinical Chemistry & Laboratory Medicine

DCCT = Diabetic Control and Complication Trial

NGST = National Glycohaemoglobin Standardization Program

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

RELIABILITY TESTING

FOR COBAS B 101

The Integrated Cardiovascular Clinical Network CHSA

Integrated Cardiovascular Clinical Network CHSA

Roche cobas b 101 HbA1c and Lipids Evaluation

July 2013

Objective

- To determine the performance of Cobas b 101 instrument
- To test the suitability of instrument for the measurement of HbA1c and lipid profile in GP (precision and accuracy)

Method

- The instrument was evaluated in the iCCnet CHSA lab in Adelaide and in 10 primary health care centers in rural and remote South Australia during Feb - June 2013

- Precision testing was performed by medical scientist testing 30 replicates of both levels of QC material in a lab. setting.

- Lipids linearity was evaluated in 10 rural and remote PHC settings by testing cap. WB sample from 15 patients at each site on the Cobas b 101 in parallel with venous sample sent to the local laboratory. Both levels of QC material were tested in the morning of each day that patient testing was performed.

Quality Goals

Quality goals used in this study were taken from recommendations by the Standards for Point of Care testing in General Practice.[12] (Australian Government department for Health and Aging. Standards of Point of Care Testing in GP, 2004)

They are:

- PoCT device measuring HbA1c for use in General Practice in Australia should be able to achieve a minimum imprecision (CV%) of 4 % and ideally meet a desirable imprecision level of 3% or less
- PoCT device measuring cholesterol for use in General Practice in Australia should be able to achieve a minimum imprecision (CV%) of 5 % and ideally meet a desirable imprecision level of 3% or less
- PoCT device measuring triglycerides for use in General Practice in Australia should be able to achieve a minimum imprecision (CV%) of 7.5 % and ideally meet a desirable imprecision level of 5% or less
- PoCT device measuring HDL for use in General Practice in Australia should be able to achieve a minimum imprecision (CV%) of 6 % and ideally meet a desirable imprecision level of 4% or less

Precision

Analyte	Scientist Control Testing			Within-Practice Control Testing		
	Mean	SD	CV %	Mean	SD	Median CV % (mean)
HbA1c (mmol/mol)	39	0.77	2.0	39	1.05	2.7 (3.2)
CHOL (mmol/L)	3.75	0.06	1.6	3.63	0.06	1.6 (1.7)
TG (mmol/L)	1.11	0.01	1.4	1.11	0.02	1.5 (1.5)
HDL (mmol/L)	0.99	0.02	2.3	0.92	0.03	2.8 (2.9)

Table 2. cobas b 101 precision analysis for Quality Control Level 1

Analyte	Scientist Control Testing			Within-Practice Control Testing		
	Mean	SD	CV %	Mean	SD	Median CV % (mean)
HbA1c (mmol/mol)	87	1.36	1.6	87	1.48	1.7 (1.7)
CHOL (mmol/L)	6.8	0.12	1.8	6.74	0.11	1.6 (1.7)
TG (mmol/L)	4.4	0.04	0.9	4.38	0.05	1.2 (1.2)
HDL (mmol/L)	1.7	0.03	2.1	1.69	0.04	2.4 (2.6)

Table 3. cobas b 101 precision analysis for Quality Control Level 2

Analyte	Level 1 Control		Level 2 Control	
	cobas b 101 CV (%)	GP Trial CV (%)*	cobas b 101 CV (%)	GP Trial CV (%)*
HbA1c	2.7	2.7	1.7	3.1
CHOL	1.6	2.7	1.6	3.0
TG	1.5	4.5	1.2	4.6
HDL	2.8	6.1	2.4	4.4

* CV results for the GP trial were taken as an average across the two lot numbers used. Means for each control were not reported in the GP trial so could not be compared in this table

Table 4. Comparison of the median within-practice precision results obtained in this trial to the Australian Government's Point of Care Testing in General Practice Trial[15]

Further information: please see the report of

The integrated cardiovascular Clinical network CHSA
“ Roche Cobas b 101 HbA1c and Lipids evaluation, July 2013”

http://www.appn.net.au/Data/Sites/1/appn/05instrumentevaluations/02evaluationreports/aacbb101report.pdf


ติดต่อขอใช้เครื่องได้ที่ห้อง 433
(คุณเปรมมินทร์ ศรีศักดา โทร 408 ค่ะ)