# Performance Evaluation cobas click for HbA1c and Lipid panel

Published: 28-06-2023 Last updated: 18-01-2025

The objectives of this multicenter performance evaluation study comprise an assessment of the analytical performance, the reliability and robustness of the system to obtain a CE mark.

Ethical review	Approved WMO
Status	Completed
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

## **Summary**

### ID

NL-OMON53795

**Source** ToetsingOnline

**Brief title** Cobas click

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders

#### Synonym

Diabetes mellitus (person with high glucose level) and dyslipidemia (imbalance of lipids)

#### **Research involving**

Human

### **Sponsors and support**

**Primary sponsor:** Roche Diagnostics International Ltd **Source(s) of monetary or material Support:** Roche Diagnostics

### Intervention

Keyword: HbA1c, lipids, Point of care (POC)

### **Outcome measures**

#### **Primary outcome**

- Method comparison between HbA1c and Lipid panel test: capillary vs venous whole blood (EDTA K2 and K3) on cobas click system vs. laboratory reference equipment.

- Method comparison between HbA1c and Lipid panel test: capillary vs venous whole blood (EDTA K2 and K3) on cobas b 101/alpha software vs. laboratory reference equipment.

Method comparison acceptance criteria for HbA1c:

-Slope: 1.000±0.060

-Intercept: <=0.500% HbA1c

-Pearson: r>=0.980

Bias on medical decision points:

On 5.0% HbA1c: <=6.0%

On 5.7% HbA1c: <=6.0%

On 6.5% HbA1c: <=6.0%

On 8.0% HbA1c: <=6.0%

On 12.0% HbA1c: <=6.0%

Method comparison for Lipid panel:

-Slope: 1.00±0.100

-Pearson: r>=0.975

Intercept:

Total Cholesterol: <11.7 mg/dL (0.3 mmol/L)

Triglycerides: <13.3 mg/dL (0.15 mmol/L)

HDL: <5.80 mg/dL (0.15 mmol/L)

Bias on medical decision points:

Total Cholesterol:

On 200 and 240 mg/dL: <=3.0%

Triglycerides:

On 150 and 200 mg/dL:  ${<}{=}5.0\%$ 

HDL:

On 40 and 60 mg/dL: <=5.0%

#### Secondary outcome

n/a

# **Study description**

#### **Background summary**

HbA1c (glycated hemoglobin) can be determined by using samples from capillary whole blood directly from the fingertip or from EDTA (K2/K3) venous whole blood. Equal to the cobas b 101 HbA1c test, the new cobas HbaA1c test Gen. 2 uses a latex agglutination-inhibition immunoassay on a disc format with an onboard dilution container.

The cobas Lipid Panel Gen. 2 measures total cholesterol, triglycerides, and high density lipoprotein cholesterol from capillary blood from the fingertip or from venous whole blood with EDTA (K2/K3) anticoagulant. Low density lipoprotein is calculated using the Friedewald formula. The cobas click system provides the lipid panel assay on a disc format with on onboard dilution container.

### **Study objective**

The objectives of this multicenter performance evaluation study comprise an assessment of the analytical performance, the reliability and robustness of the system to obtain a CE mark.

### Study design

Method comparison HbA1c test and Lipid Panel: capillary whole blood and venous whole blood (EDTA K2 and K3) on cobas click vs. reference instrument measurements.

Method comparison HbA1c test and Lipid Panel: capillary whole blood and venous whole blood (EDTA K2 and K3) on cobas b 101/software alpha vs. reference instrument measurements.

Matrix comparison between HbA1c test and Lipid Panel test: EDTA (K2) whole blood will be compared with EDTA (K3) whole blood and capillary whole blood on cobas click system and cobas b 101 with alpha software.

#### Study burden and risks

The burden for subjects will consist of a maximum of 2 extra venapunctures and a minimum of 2 (maximum of 4) capillary punctures without hospitalization. The only risks for this study are the possible side effects for capillary and venous blood draw.

# Contacts

#### Public Roche Diagnostics International Ltd

Forrenstrasse 2 Rotkreuz 6343 CH **Scientific** Roche Diagnostics International Ltd

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Informed consent signed. Subject is >= 18 years old at the time of enrollment.

### **Exclusion criteria**

Subjects for whom informed consent is not signed before sample collection. Subjects whom the attending physician has determined that the health status of the subject is at risk and/or may be compromised if a blood draw is performed. Subjects who have received an intravenous lipid emulsion injection within 5 days of the study blood draw. Pregnant subjects.

# Study design

# Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	19-04-2024
Enrollment:	360
Туре:	Actual

# Medical products/devices used

Generic name:	cobas click instrument;cobas b 101 (alpha software) instrument;cobas HbA1c Test Gen. 2;cobas Lipid p
Registration:	No

# **Ethics review**

Approved WMO	
Date:	28-06-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	16-02-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	11-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register** CCMO **ID** NL82547.000.22