Performance Evaluation cobas click for HbA1c and Lipid panel

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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
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CH
Scientific
Roche Diagnostics International Ltd

Forrenstrasse 2
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CH

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
Type:	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	ID
CCMO	NL82547.000.22