# **Cobas b 101 CRP Performance Evaluation**

Published: 22-06-2017 Last updated: 12-04-2024

Evaluation of the point of care CRP test

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeAncillary infectious topicsStudy typeObservational invasive

## **Summary**

#### ID

NL-OMON45337

Source

ToetsingOnline

**Brief title** 

Cobas b 101 CRP Performance Evaluation

#### **Condition**

Ancillary infectious topics

#### **Synonym**

blood infection parameters, infection

#### **Research involving**

Human

### **Sponsors and support**

**Primary sponsor:** Roche Diagnostic International Ltd.

Source(s) of monetary or material Support: Roche Diagnostics international Ltd.

### Intervention

Keyword: CRP, diagnostic, point of care

#### **Outcome measures**

### **Primary outcome**

Analytical performance, reliability and robustness

#### **Secondary outcome**

Interference

# **Study description**

#### **Background summary**

In current medical practice, the CRP test is taken by venous sampling and analysed in the laboratory. A new point of care CRP test is developed that needs onlt capillary blood sampling.

#### Study objective

Evaluation of the point of care CRP test

#### Study design

Diagnostic cohort study

#### Study burden and risks

Blood sampling at a single occation, including 2 fingerpricks and 1 venous blood draw.

## **Contacts**

#### **Public**

Roche Diagnostic International Ltd.

Forrenstrasse 2 Rotkreuz CH6343 CH

#### **Scientific**

Roche Diagnostic International Ltd.

Forrenstrasse 2 Rotkreuz CH6343 CH

### **Trial sites**

### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

> 18 years of age clinical patients with (known) raised CRP levels, and/or patients who requier blood sampling within standard care

### **Exclusion criteria**

contra-indication for blood drawing pregnancy breast feeding

# Study design

## **Design**

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled
Primary purpose: Diagnostic

#### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-06-2017

Enrollment: 160

Type: Actual

## **Ethics review**

Approved WMO

Date: 22-06-2017

Application type: First submission

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 NL61250.100.17