

# Validation of a novel capillary bloodsampling kit (Demecal) for the detection of HIV antibodies

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Technical validation of HIV antibody detection in capillary blood sampled with the Demecal set.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON31729

### Source

ToetsingOnline

### Brief title

Home sampling of capillary blood for HIV antibody detection

### Condition

- Viral infectious disorders

### Synonym

nvt

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Demecal Europe BV ([www.demecal.eu](http://www.demecal.eu))

**Source(s) of monetary or material Support:** Demecal en Streeklab Haarlem (volledig uit eigen middelen)

## Intervention

**Keyword:** Capillary blood, Demecal, HIV, Homesampling

## Outcome measures

### Primary outcome

Measured HIV-antibody detection levels in capillary plasma will be compared with venous blood. Tests in both blood samples should be 100% comparable.

### Secondary outcome

none

## Study description

### Background summary

There is a growing demand by epidemiologists as well as individuals for home screening of HIV as part of sexual transmitted diseases. A new blood sampling device makes it possible to do home sampling of capillary (fingerprick) blood and additionally sending to a laboratory for analysis.

### Study objective

Technical validation of HIV antibody detection in capillary blood sampled with the Demecal set.

### Study design

Twenty HIV positive patients visiting the HIV outpatient clinic for routine bloodsampling will be asked to participate in the study. Upon informed consent an extra tube of blood will be drawn during routine venous blood sampling subsequently a capillary blood will be sampled by the Demecal device. In the Demecal device cells and plasma will be separated. In the laboratory HIV antibodies will be measured in the Demecal obtained plasma as well as the extra drawn venous blood sample. Both will be compared by statistical analyses.

### Study burden and risks

none

## Contacts

### Public

Demecal Europe BV ([www.demecal.eu](http://www.demecal.eu))

Surinameweg 8  
2035 VA Haarlem  
Nederland

### Scientific

Demecal Europe BV ([www.demecal.eu](http://www.demecal.eu))

Surinameweg 8  
2035 VA Haarlem  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Routine blood sampling requested for HIV positive patient.

### Exclusion criteria

Younger than 18 years of age

No venal blood drawing possible

## 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): 10-12-2008

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 20-05-2008

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL14310.029.07