METHOD CORRELATION OF SERUM, SODIUM CITRATE PLASMA, LITHIUM HEPARIN PLASMA AND K2-EDTA WHOLE BLOOD COLLECTED WITH VARIOUS COLLECTION TUBES AND COMPARED VIA SELECTED ICON CENTRAL LAB ASSAYS

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In this study we compare the results of blood sample analysis when blood samples are collected in different tubes from different manufacturers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53190

Source
ToetsingOnline

Brief title
Blood Sampling for Collection Tube Validation Study

Condition

- Other condition

Synonym
N/A

Health condition

lab-tube validation

Research involving
Human

Sponsors and support

Primary sponsor: ICON Clinical Research
Source(s) of monetary or material Support: Biotechnological Industry

Intervention

Keyword: blood sampling, collection tubes, validation

Outcome measures

Primary outcome

• Comparison of the results of 3 different parties

• Comparison of results between tubes of the same batch

• Comparison of repeated analyzes of the same tube

• Comparison of dipotassium ethylenediaminetetraacetic acid (K2EDTA) collection

tube results with repeat analysis on Day 0, Day 1, Day 2, Day 3 and Day 4

• Comparison of results from 3 different lots for SST and K2EDTA tubes

• Comparison of the results of 2 different lots for sodium citrate tubes

• Comparison of the results of 3 types of Li heparin tubes (3 ml, 4 ml and 7 ml)

• Comparison of results between tubes of the same batch

• Comparison of repeated analyzes of the same tube

• Comparison of the results of the K2EDTA collection of tubes with repeat

analysis on Day 0, Day 1, Day 2, Day 3 and Day 4

Secondary outcome

N/A

Study description

Background summary

Different types of collection tubes are required for different blood tests.
There are several manufacturers for each type of pipe. When tubes from another manufacturer are to be used, it is necessary to test them first to ensure that the results are the same as previously approved tubes. During this research, 4 types of tubes from 4 manufacturers are tested (a total of 17 to 21 different tubes).

Study objective

In this study we compare the results of blood sample analysis when blood samples are collected in different tubes from different manufacturers.

Study design

Are you participating in the research? Then the research will take 1 day (about 2 hours).
The test: are you suitable to participate?
We first want to know if you are suitable to participate. The researcher will first discuss this document with you.
If you decide to participate in the study, the researcher will sign this document together with you.
Then the researcher does the test. This consists of the following studies:
• Physical examination. The examiner measures your weight and height.
• We ask you about your medication use.

We also collect your demographic information, such as your age, gender, race and ethnicity. The
researcher will discuss the results, your medical history and medication use with you. .

It can also happen that you are healthy, but still not suitable to participate. For example, because you
are overweight or underweight according to the requirements of the examination. The researcher will tell you more about this.
How often do you visit the research center?
You will visit the research center 1 time in total:
• 1 time for the examination and the blood tests, both on Day 1

You will be told exactly what time you need to be there prior to arrival.
How much and how often is blood drawn for the test?
For the test, 17 or 21 tubes of blood are taken at once.

What investigations and measurements do we do?
During the investigation, we perform the following investigations and measurements:
• Blood test. For this, 17 or 21 tubes of blood are taken.
• We will ask you how you are feeling and if you have any special health concerns.

Study burden and risks

Blood collection
Blood tests may hurt or cause bruising. Occasionally a blood sample may be taken in some individuals: paleness, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

All in all, we will take approximately 80 milliliters (ml) of blood from you from the examination to the check-up. This amount does not cause problems in adults. For comparison: at the blood bank, 500 ml of blood is used in one go. If the researcher deems it necessary to guarantee the safety of the test subject, additional blood samples can be taken for any additional research. If this happens
then the total amount of blood drawn may be more than the amount indicated above.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Sex : male or female; females may be of childbearing potential, of nonchildbearing potential,
or postmenopausal.
2. Age : 18 years or older, at screening.
3. Body mass index (BMI) : 18.0 kg/m2 or higher, at screening
4. Status : healthy subjects.
5. Willing and able to sign the ICF.

Exclusion criteria

1. Previous participation in this study
2. Employee of ICON.
3. Donation or loss of more than 450 mL of blood within 60 days prior to the day of consent in the
current study.
4. Significant and/or acute illness within 5 days prior to the day of consent in the current study that
may impact safety, in the opinion of the Investigator.
5. Unsuitable veins for blood sampling.
6. Subjects who are, in the opinion of the Investigator, not suitable for enrolment for another
reason.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2023
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL84624.056.23