Sample Stability Elecsys Troponin T hs Gen 6

Published: 27-01-2023
Last updated: 19-10-2024

Primary objectiveThe objective of this study is to demonstrate the 12 month stability of cTnT in native serum, Li-heparin plasma and K2-EDTA plasma samples at -20 ± 5 °C, > 4 hours at 15 to 25 °C, > 24 hours at 2 to 8°C and > 12 months for…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON53855

Source
ToetsingOnline

Brief title
Sample Stability Elecsys Troponin T hs Gen 6

Condition

- Coronary artery disorders

Synonym
acute myocardial infarction, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostics GmbH
Source(s) of monetary or material Support: Roche Diagnostics GmbH

Intervention

Keyword: analytical study, sample stability, Troponin Ths

Outcome measures

Primary outcome

Sample stability acceptance criteria:

All measurements will be visualized in a scatter plot over time, as relative/absolute change from baseline T0. Regression will be performed per matrix. A linear regression analysis will be conducted to determine an appropriate equation that models the percent recovery or absolute deviation as a function of time. The best-fit model determined will be plotted on the scatterplot and the regression equation, coefficient of determination (R2), and one-sided 95% confidence limits for the model at each time point will be reported.

Regression analyses will yield an estimation for slope and intercept as well as one-sided 95% confidence intervals. Acceptance is assessed via the intercept of the confidence interval of linear regression and the 90% or 110% limit (100% +- most conservative acceptance limit).

Additional analysis as outlined above might be required for registration by authority (FDA). As these requirements will become clarified after study end these additional analysis will be conducted during registration phase of the product under investigation.

Freeze and thaw acceptance criteria:

Mean measuring value of the four repetitions will be compared for each sample

using T0 (fresh never frozen) as well as T1 (sample stress period start) time point. This comparison will refer to a one time freeze and thaw cycle including a limited sample storage time. Based on the analyte concentration the following acceptance criteria will be applied: LEoMR to 24.0 ng/L: <= 2.40 ng/L deviation, >24.0 ng/L to HEoMR: <= 10 % deviation.

Secondary outcome

Prolonged sample stability evaluation for frozen storage conditions of up to 7 years.

Study description

Background summary

Sample stability information is part of the information provided in the method sheet. Although it is required for the launch of the product, the requirements for its determination vary from country to country. In the US, several specific requirements apply as samples need to be native, fresh never frozen, and determination of sample stability needs to be performed separately for each sample type.
Therefore, a sample stability study will be performed to verify the stability of cTnT for use with the Elecsys Troponin T hs Gen 6 assay. The MDPs for use with the Elecsys Troponin Gen 6 hs has not yet been determined and will be determined as part of the Reference Range Study (CIM RD005476). However, a method comparison of the current Elecsys Troponin hs as well as the new assay under investigation allow to estimate the future MDP range that is used in this study to predominantly select samples within or around this important value range. Furthermore the samples for sample stability testing should cover the measuring range. The study will comprise data that should be used for the Method Sheet showing sample stability for up to 12 months. Remaining samples will be transferred to Roche for further evaluation of sample stability of frozen specimens for up to 7 years.

Study objective

Primary objective
The objective of this study is to demonstrate the 12 month stability of cTnT in native serum, Li-heparin plasma and K2-EDTA plasma samples at -20 ± 5 °C, > 4

hours at 15 to 25 °C, > 24 hours at 2 to 8°C and > 12 months for < -60°C as well as - 15°C to - 25°C storage. Stability will be determined for each sample type separately.

Additional Objective
For long term sample stability testing (up to 7 years) done at -15°C to -20°C as well as < -60°C remaining samples will be shipped to Roche for further analysis in a separate study setting.

Study design

Study Familiarization
In this part of the Study Protocol the site personnel should get acquainted with the system and reagents, the experimental design and/or WebCAEv. If the experiments performed in the Study Familiarization do not meet the target acceptance criteria, the root cause has to be found before the other study parts can start. The data of the Study Familiarization experiments are not used for evaluation of performance claims.

Main Trial (sample collection)
Sample collection as outlined in section 9.2. of the research protocol.

Main Trial (sample measurement / stability evaluation)
Sample measurement as outlined in section 9.2 of the research protocol.

Intervention

For investigation of TnT hs levels (stability over time at various storage conditions) up to 70 ml of blood will be taken one time.

Study burden and risks

This study is a non-interventional evaluation of an investigational in-vitro diagnostic product and results will not influence any treatment decision. Therefore, for purposes of this study the definition of an adverse event (AE) is restricted to such related to the blood draw. The sites performing the blood draw are experienced in their day-to-day use following the manufacturer*s instructions of CE labelled routine equipment. Therefore, no AEs (except those relating to the blood draw) are anticipated for this study.

The determination of troponine T helps cardiologists to predict and diagnose heart diseases. A constant improvement of such assays helps to improve medical decision making for upcoming patient generations. Since sample stability data is a pre-requisite for product registration the risk of the participating subjects might be justified by the future benefit of patients by an improved

troponine T assay.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Lower end of the Measuring range to 4.8 ng/L; >= 3 samples
>4.8 to 7.2 ng/L, >= 2 samples
19.2 to 18.8 ng/L, >= 2 samples
113.6 to 170.4 ng/L, >= 2 samples
>4.8 to 170.4 ng/L, >= 3 samples
>170.4 to 3000 ng/L, >= 1 sample
>3000 to 6000 ng/L, >= 1 sample
8550 to 9500 ng/L (upper 10% of the measuring range), >= 1 sample

Sample appearance: non-hemolytic, non-icteric, non-lipemic
Written Informed consent given.
Subject age >= 21 years

Exclusion criteria

-Subject age < 21 years
-No written informed consent.
-Not able to provide 20 to 30 ml of blood (depending on the blood collection tube type used), most preferred 2 or 3 times 20 to 30ml of blood to collect more than one specimen type.
-Sample do not match requested analyte concentration.
-Sample do not match quality requirements (i.e. icteric, lipemic, hemolytic)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2023
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	Elecsys® Troponin T hs Gen 6
Registration:	No

Ethics review

Approved WMO Date:	27-01-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-07-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL81841.058.22