

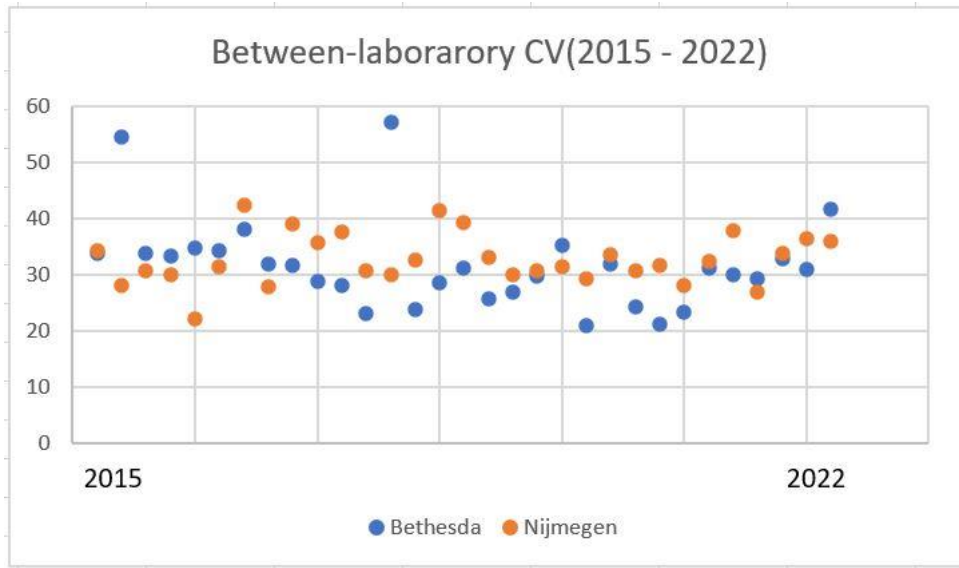
ECAT Information:

Guideline for Factor VIII and Factor IX Inhibitor-type testing

It is well known that the laboratory testing of Factor VIII (FVIII) and Factor IX (FIX) inhibitors is hampered by a large between-laboratory variability.

In figure 1 you can appreciate that in the period 2015 – 2022 the between-laboratory variation for FVIII inhibitor was on average 30%.

Figure 1. The between-laboratory variation (%) for FVIII Inhibitor testing in the period 2015 – 2022



Although the between-laboratory variation for the FIX inhibitor is slightly lower (approx. 20%) than for the FVIII inhibitor, a considerable between-laboratory variation was still observed.

In addition, a wide variation in methodology was used. This can be observed from the information on the methodology used, submitted by the participants in the ECAT surveys (see fig. 2 for a list of combinations between the type of normal pooled plasma and the type of control mixture used, taken from a survey report from the ECAT surveys for FVIII inhibitor).

Figure 2. List of combinations between the type of normal pooled plasma and the type of control mixture used in the ECAT surveys

	n
<b>Total Group</b>	334
<b>Non-Buffered Normal Pooled Plasma</b>	106
Buffer	66
Buffer + Albumin	2
Factor VIII Deficient Plasma	18
Heat-activated normal plasma	4
Other	15
Unknown	1
<b>Buffered Normal Pooled Plasma</b>	228
Buffer	92
Buffer + Albumin	19
Factor VIII Deficient Plasma	85
Heat-inactivated normal plasma	20
Other	9
Unknown	3

--

For this reason the International Council for Standardisation in Haematology (ICSH) has decided to establish a writing group for a laboratory guideline on the measurement of FVIII and FIX type 1 Inhibitors. The director of ECAT, dr. Piet Meijer, has chaired this writing group which included a number of well-known international researchers (drs. Flora Peyvandi, Silmara de Lima Montalvão, Guy Young, Rajiv Pruthi and Steve Kitchen).

Recently this laboratory guideline was published in the International Journal for Laboratory Haematology (IJLH). This publication can be reached by the following link: <http://doi.org/10.1111/ijlh.14109> It is an open-access publication and therefore can be downloaded free of charge.

This guideline includes a lot of background information on inhibitor testing and describes in detail how an inhibitor test should be performed.