

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2020-M1

Main

Labcode 99906936

Date of Issue : 28-May-2020

Survey : 2020-M1

Report : Main

Note:

In the Survey Manual 2020 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2020 should be considered as an integral part of this survey report.

Please notice the information regarding the homogeneity of samples used and the between-laboratory variation on page 21 of the Survey Manual.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before July **8th, 2020**. Complaints received after this date will not be taken into consideration.

Multiple instruments

From 2019 you have the possibility to submit per parameter results for three different instruments and/or methods. However, some participants have submitted two or three times the same results, suggesting that this are separate results. Only results clearly marked with different instruments or different methods are included as additional result. Duplicated results, which are probably **no** separate results are excluded in the statistical analysis. We have excluded the results from the second and third test system in the statistical analysis. Do not submit multiple times the same results anymore in future surveys.

Exclusion of results

Results < [value] or > [value] are excluded from the statistical analysis.

When other results (e.g. deviating results) are excluded from the statistical analysis, these results are placed between brackets.

This report is authorized by:

Dr. M.J. van Essen-Hollestelle
Programme Expert

Note: A printed version of the actual Survey Manual is provided to all participants once a year. This manual can also be downloaded from the member section of the ECAT website.

ECAT Foundation

Director: Dr. P. Meijer
ECAT Office
P.O. Box 107
2250 AC Voorschoten, The Netherlands
phone +31 (0) 71 3030 910; fax + 31 (0) 71 3030 919
E-mail: info@ecat.nl
Website: www.ecat.nl
VAT number: NL802836872B01

Registration number with the Chamber of Commerce (KvK) Gouda : 41174102
General terms of delivery are applicable to all our services.

All rights reserved. No part of this report may be reproduced, stored in a retrieval system, or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior permission from the ECAT Foundation.

Appendices are an integral part of the total report.

OVERVIEW Z-SCORES

Satisfactory ($-2 \leq Z\text{-score} \leq 2$)
 Need attention ($-3 \leq Z\text{-score} < -2$ or $2 < Z\text{-score} \leq 3$)
 Unsatisfactory ($Z\text{-score} < -3$ or > 3)

| Module | Parameter | Sample | Test System | Total | Assay | Method |
|---------------------|---------------------|--------|-------------|-------|-------|--------|
| Factor IX Inhibitor | Factor IX Inhibitor | 20.60 | 1 | -0.03 | 0.06 | -0.17 |
| | | 20.61 | 1 | 0.10 | 0.14 | -0.08 |

| | |
|----------------------------|----------------------------|
| Factor IX Inhibitor | Factor IX Inhibitor |
|----------------------------|----------------------------|

Sample No 20.60
Sample Details Plasma with a Factor IX Inhibitor level of approx. 12.5 BU/mL
Prior Use Prior Use: None
Unit Units:
Expiry Date 31-October-2022
Homogeneity 5.8 % **Homogeneity Parameter** FIX inhibitor
 For any method used for the measurement of this parameter with a CV ≤ 19.3% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

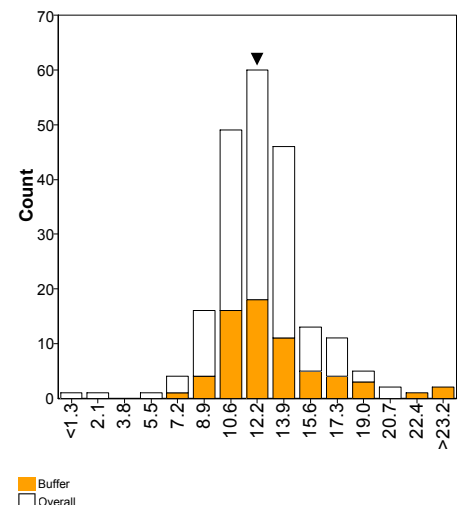
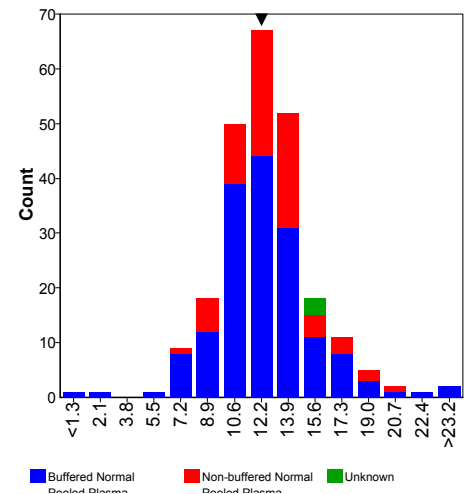
Number of Participants 266
Number of Responders 231 **Response Rate** 87 %
Comments One participant (labcode 9059), reported a result for factor VIII inhibitor (0.0) instead of a factor IX inhibitor. This result was excluded in the statistical evaluation.

Own Reagent

| | n | assigned value | Uncert. | CV (%) | Range | your result | z-score | your result | z-score | your result | z-score |
|--------------------------------------|-----|----------------|---------|--------|------------|-------------|---------|-------------|---------|-------------|---------|
| Total Group | 238 | 12.5 | 0.21 | 20.7 | 0.9 - 30.0 | 12.4 | -0.03 | | | | |
| Buffered Normal Pooled Plasma | 163 | 12.2 | 0.27 | 22.3 | 0.9 - 30.0 | 12.4 | 0.06 | | | | |
| Buffer | 65 | 12.9 | 0.45 | 22.3 | 8.0 - 30.0 | 12.4 | -0.17 | | | | |

Other Reagents

| | n | assigned value | Uncert. | CV (%) | Range |
|--|-----|----------------|---------|--------|-------------|
| Total Group | 238 | 12.5 | 0.21 | 20.7 | 0.9 - 30.0 |
| Unknown | 3 | 15.7 | | | 15.4 - 16.0 |
| Buffer | 2 | 15.6 | | | 15.4 - 15.7 |
| Factor IX deficient plasma | 1 | 16.0 | | | - |
| Buffered Normal Pooled Plasma | 163 | 12.2 | 0.27 | 22.3 | 0.9 - 30.0 |
| Buffer + Albumin | 15 | 11.2 | 0.88 | 24.3 | 0.9 - 14.6 |
| Factor IX deficient plasma | 65 | 12.3 | 0.41 | 21.5 | 1.5 - 20.6 |
| Heat-inactivated normal plasma | 8 | 12.3 | | | 6.5 - 14.5 |
| Other | 8 | 11.4 | | | 6.5 - 14.4 |
| Unknown | 2 | 10.2 | | | 8.8 - 11.5 |
| Non-buffered Normal Pooled Plasma | 72 | 12.8 | 0.32 | 16.9 | 7.4 - 21.0 |
| Buffer | 42 | 12.7 | 0.29 | 11.7 | 9.1 - 16.8 |
| Buffer + Albumin | 2 | 13.0 | | | 12.9 - 13.2 |
| Factor IX deficient plasma | 15 | 14.2 | 1.43 | 31.3 | 7.4 - 21.0 |
| Heat-inactivated normal plasma | 2 | 15.0 | | | 14.0 - 16.0 |
| Other | 10 | 11.5 | 0.94 | 20.7 | 8.5 - 14.4 |
| Unknown | 1 | 16.0 | | | - |



| | |
|----------------------------|----------------------------|
| Factor IX Inhibitor | Factor IX Inhibitor |
|----------------------------|----------------------------|

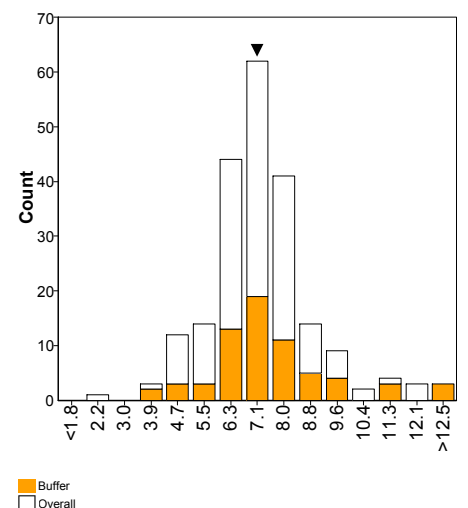
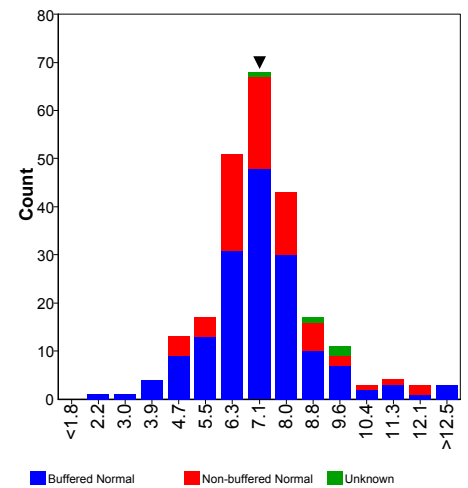
| | | | |
|-------------------------------|--|------------------------------|---------------|
| Sample No | 20.61 | | |
| Sample Details | Plasma with a Factor IX Inhibitor level of approx. 7.5 BU/mL | | |
| Prior Use | Prior Use: None | | |
| Unit | Units: | | |
| Expiry Date | 31-October-2022 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | FIX inhibitor |
| Number of Participants | 266 | Response Rate | 87 % |
| Number of Responders | 231 | | |
| Comments | One participant (labcode 9059), reported a result for factor VIII inhibitor (0.0) instead of a factor IX inhibitor. This result was excluded in the statistical evaluation. | | |

Own Reagent

| | n | assigned value | Uncert. | CV (%) | Range | your result | z-score | your result | z-score | your result | z-score |
|--------------------------------------|-----|----------------|---------|--------|------------|-------------|---------|-------------|---------|-------------|---------|
| Total Group | 239 | 7.2 | 0.11 | 18.7 | 1.9 - 18.0 | 7.3 | 0.10 | | | | |
| Buffered Normal Pooled Plasma | 163 | 7.1 | 0.13 | 18.8 | 1.9 - 18.0 | 7.3 | 0.14 | | | | |
| Buffer | 66 | 7.4 | 0.23 | 20.2 | 4.0 - 18.0 | 7.3 | -0.08 | | | | |

Other Reagents

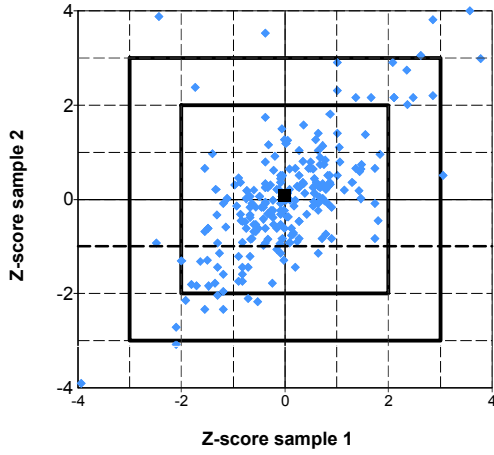
| | n | assigned value | Uncert. | CV (%) | Range |
|--|-----|----------------|---------|--------|------------|
| Total Group | 239 | 7.2 | 0.11 | 18.7 | 1.9 - 18.0 |
| Unknown | 4 | 9.4 | | | 7.2 - 10.0 |
| Buffer | 3 | 9.2 | | | 7.2 - 10.0 |
| Factor IX deficient plasma | 1 | 9.6 | | | - |
| Buffered Normal Pooled Plasma | 163 | 7.1 | 0.13 | 18.8 | 1.9 - 18.0 |
| Buffer + Albumin | 14 | 7.3 | 0.28 | 11.6 | 5.5 - 12.3 |
| Factor IX deficient plasma | 65 | 6.9 | 0.20 | 18.7 | 1.9 - 10.2 |
| Heat-inactivated normal plasma | 8 | 6.7 | | | 3.0 - 8.4 |
| Other | 8 | 6.3 | | | 3.5 - 10.3 |
| Unknown | 2 | 6.2 | | | 5.6 - 6.7 |
| Non-buffered Normal Pooled Plasma | 72 | 7.2 | 0.19 | 17.9 | 4.4 - 12.1 |
| Buffer | 42 | 7.2 | 0.25 | 18.3 | 4.4 - 9.5 |
| Buffer + Albumin | 2 | 6.5 | | | 6.2 - 6.7 |
| Factor IX deficient plasma | 15 | 8.3 | 0.82 | 30.3 | 5.5 - 12.1 |
| Heat-inactivated normal plasma | 2 | 7.1 | | | 7.0 - 7.2 |
| Other | 10 | 6.6 | 0.25 | 9.7 | 5.5 - 7.5 |
| Unknown | 1 | 8.0 | | | - |



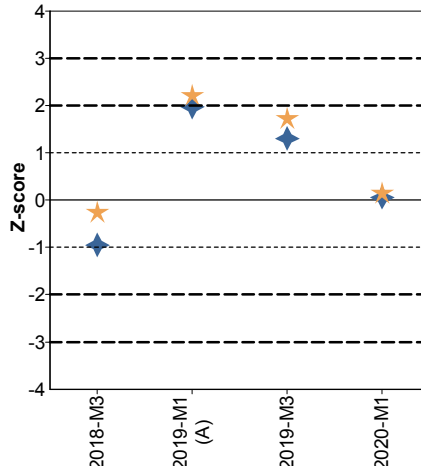
Factor IX Inhibitor

Instrument ID

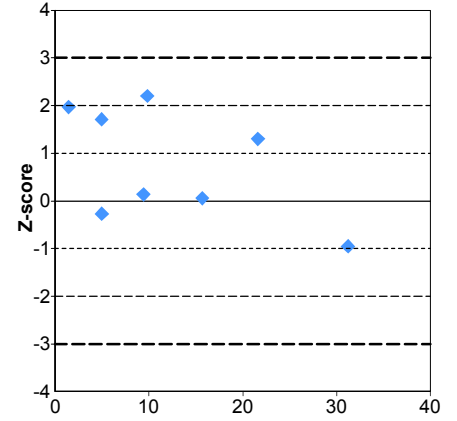
Z-score plot



Z-score history (by survey)

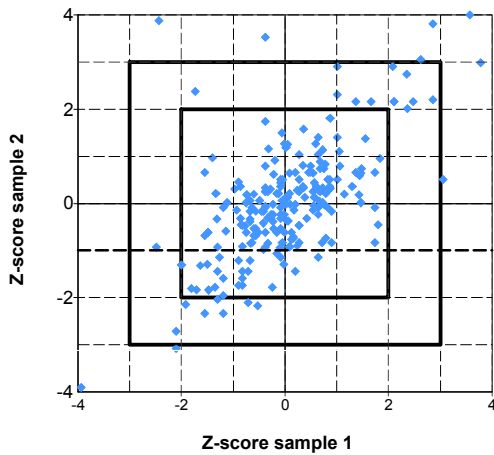


Z-score history (by consensus value)

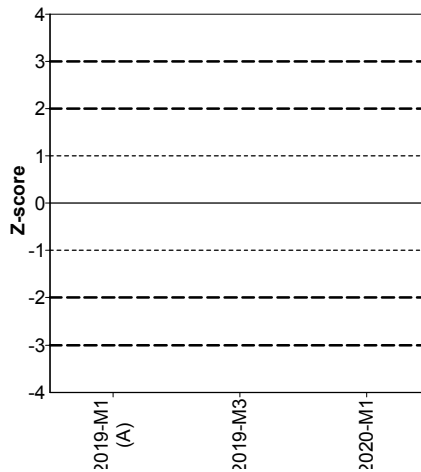


Instrument ID

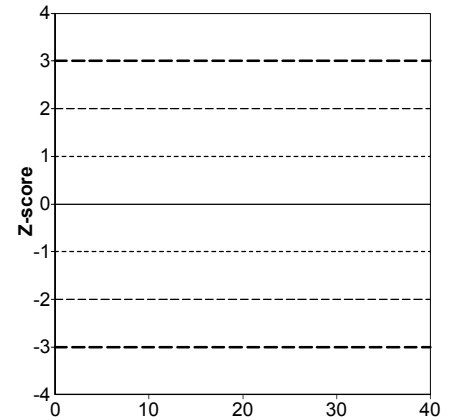
Z-score plot



Z-score history (by survey)

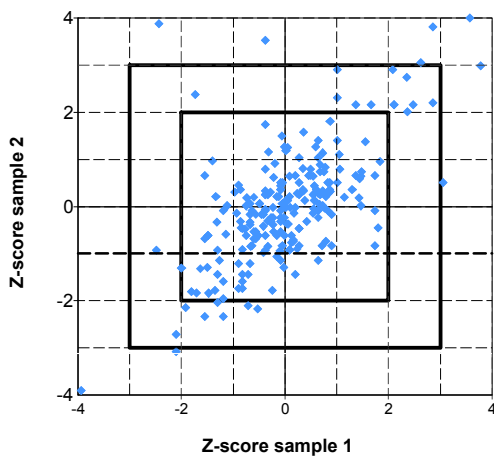


Z-score history (by consensus value)

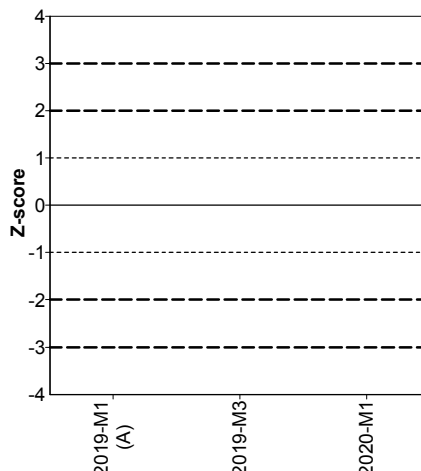


Instrument ID

Z-score plot



Z-score history (by survey)



Z-score history (by consensus value)

