ECAT FOUNDATION

External quality Control of diagnostic Assays and Tests
with a focus on Thrombosis and Haemostasis

PROGRAMME MANUAL 2024

ECAT FOUNDATION

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Dear sir, dear madam,

It is our pleasure to present you our Programme Manual 2024. This Programme Manual provides you with background information about our organisatiseon and the ECAT external quality assessment programme 2024.

The ECAT Foundation is an independent and impartial organization with the objective to provide an international External Quality Assessment Programme (EQAP) for laboratories working in the field of haemostasis and thrombosis.
The ECAT (External quality Control of diagnostic Assays and Tests) provides this international external quality control programme since 1994. It was started as a small-scale quality control programme only in Western Europe. Today more than 1800 laboratories from more than 50 different countries are participating in this worldwide programme.

Our primary aim is to contribute to quality assessment and improvement of clinical laboratories operating within the field of thrombosis and haemostasis with respect to the diagnosis and treatment of patients.

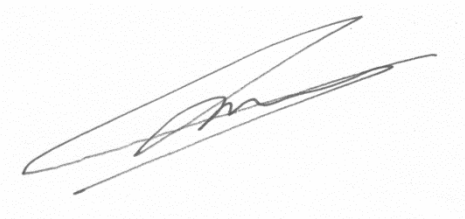
The ECAT Foundation is based in The Netherlands but provides EQAP for assays and tests in the field of thrombosis and haemostasis on an international scale. The programme is open for every laboratory providing services in the mentioned discipline.

In 2024 the ECAT programme includes 44 modules for regular laboratory tests, 2 modules for case studies and 1 electronic module for the pre- and post-analytical phase and a quality control programme for the CoaguChek INR monitors. Two new programmes are added to our programme in 2024, Factor VIII replacement products will be expanded with Esperoct and NovoEight (Novo Nordisk) and FIX product: Refixia (Novo Nordisk) and Fibrin(ogen) Degradation Products (FDP).

Via ECAT also 3 interpretative electronic modules on platelet testing of the NASCOLA (United States) are provided as well as 14 modules for molecular biology provided by the SPMD (Germany) and a homocysteine module provided by DEKS (Denmark). NASCOLA introduced a new electronical module on Whole Blood Impedance Platelet Aggregation.

We look forward to welcome you in our external quality assessment programme.

On behalf of the ECAT team,



Dr. Piet Meijer
Director

Since 25 April 2012 the EQA programme of the ECAT is accredited according to the international standard ISO/IEC 17043:2010 by the Dutch Council for Accreditation (RvA). For details see page 3.

CONTENT

GENERAL INFORMATION ECAT FOUNDATION

The ECAT is an independent and impartial organisation. Its legal entity is a foundation directed by the director, dr. P. Meijer. A Supervisory Board oversees the foundation and also serves as the Scientific Advisory Board. Members of the Supervisory Board are well experienced in the field of thrombosis and haemostasis.

Staff

Name	Position
Dr. P. Meijer	Director
Mrs. M. Van der Voorn	Operational Manager
Dr. M. van Essen	Programme Expert
Mrs.R. Stigter	Survey co-worker
Mrs. P. Paul	Customer Support
Mrs. G. Weise	Logistic co-worker
Mrs. A. Vledder	Logistic co-worker
Mrs. W. Hogenboom	Financial Manager
Mrs. B. de Jong-Vaane	Financial co-worker / Customer Support

Members of Supervisory Board

Name	Specialism	Position
Dr. W. van Gelder	Clinical chemist	Chair
Prof. Dr. M.P.M. de Maat	Biochemist/epidemiologists/clinical chemist	Member
Drs. N. Tuijn	Financial specialist	Member
Dr. F.J.M. van der Meer	Internist	Member
Prof. Dr. J.C.M. Meijers	Biochemist	Member

Members of Report Review Committee

Name	Specialism
Dr. A. Huisman	Clinical Chemist UMC - Utrecht
Dr. R.W.L.M. Niessen	Clinical Chemist OLVG Lab – Amsterdam
Dr. M. van Essen	Programme Expert ECAT Foundation
Dr. P. Meijer	Director ECAT Foundation

Accreditation

Since 25 April 2012 the EQA programme of the ECAT is accredited according to the international standard ISO/IEC 17043:2010 by the Dutch Council for Accreditation (RvA).

The following modules of ECATs' EQAP are part of the accreditation scope:

- Screen – I
- Screen - II
- Thrombophilia - I
- Thrombophilia - II
- Lupus Anticoagulant / Antiphospholipid Antibodies
- D-Dimer
- Coagulation Factor - I
- Coagulation Factor - II
- Von Willebrand Factor parameters
- Factor VIII inhibitor
- Thrombin Generation Test
- Factor XIII
- Fibrinolysis - I
- Fibrinolysis - II
- Monitoring for Anticoagulation Drugs (UFH, LMWH, Orgaran, Fondaparinux, Rivaroxaban, Apixaban, Argatroban, Dabigatran)

It is our intention to add new modules to the scope of the accreditation as soon as possible after the introduction. The latest version of the scope can always be found at our website.

Exclusive distributors

In some countries we have an exclusive distributor. If your laboratory is located in one of these countries and you are interested to participate in our EQA programme, please contact the ECAT office for contact details of your local distributor. The prices used by our distributors may differ from those indicated in the brochure due to local services, distribution costs etc.
The current countries with exclusive distributors are: Albania, Austria, Australia, Canada, Chile, Colombia, Costa Rica, Cyprus, Denmark, Greece, Israel, Malta, New Zealand, Norway, Peru, Portugal, Sri Lanka, Turkey/Middle-East countries, United States.

Products and services from third parties

ICT-related issues	Back-up services, web design and maintenance, web and database hosting, POCT application.	Health e.solutions – The Netherlands
	Participant management and survey evaluation software, web-based data submission.	KPMD – United Kingdom
Sample production	Sample production and testing for homogeneity and stability.	Affinity Biologicals – Canada Hyphen Biomed – France Nordic Haemostasis AB - Sweden Technoclone – Austria RCPA – Australia R^2 Diagnostics – United States
Laboratory testing	Reference laboratory for testing of homogeneity and stability.	Erasmus Medical Center – The Netherlands Radboud University Medical Center – The Netherlands

Confidentiality policy

1. ECAT is obliged to keep confidential any and all information they acquired from participants within the scope of their registration.
2. Any results from research conducted by ECAT within the scope of the programme offered by ECAT that can be traced to a certain participant shall be confidential and shall only be notified to the relevant participant.
3. If ECAT should, on the basis of a statutory provision or court decision, be obliged to disclose confidential information to a third party designated by the law or the competent court, and ECAT cannot in such case invoke the right of non-disclosure acknowledged or allowed under the law or by the competent court, ECAT shall not be obliged to pay compensation or damages, and the participant shall not have the right to dissolve the agreement on the basis of any resultant damage. ECAT is obliged to notify affected participants of this action in written.

(for further details see our general terms of delivery which can be found on our website)

Intellectual property rights and copyrights

1. ECAT reserves the rights and powers vested in ECAT pursuant to the intellectual property right.
2. The participant shall not be permitted to modify the items delivered or made available, unless the nature of the items delivered or made available should require otherwise or unless agreed otherwise.
3. Any designs, presentations, drawings, films, software or other material or files, whether electronic or otherwise, made by ECAT within the scope of the contract shall remain the property of ECAT, irrespective of whether they were handed over to the participant or to third parties, unless agreed otherwise.
4. Any and all documents provided by ECAT such as reports, advice, agreements, etc. shall exclusively be intended for use by the participant and they may not be reproduced, published or disclosed to third parties by the participant without ECAT's permission obtained in advance, unless the nature of the documents should dictate otherwise.
5. ECAT reserves the right to use the know-how acquired due to the carrying out of the work for other purposes, insofar as no confidential information is disclosed to third parties.

(for further details see our general terms of delivery which can be found on our website)

Provision of global survey reports

ECAT may provide to third parties, like distributors of the ECAT programme or diagnostic companies, global survey reports which only demonstrate the overall statistical analysis without any traceable results to a specific participant.

PROGRAMME AND PRICES

Annual Subscription

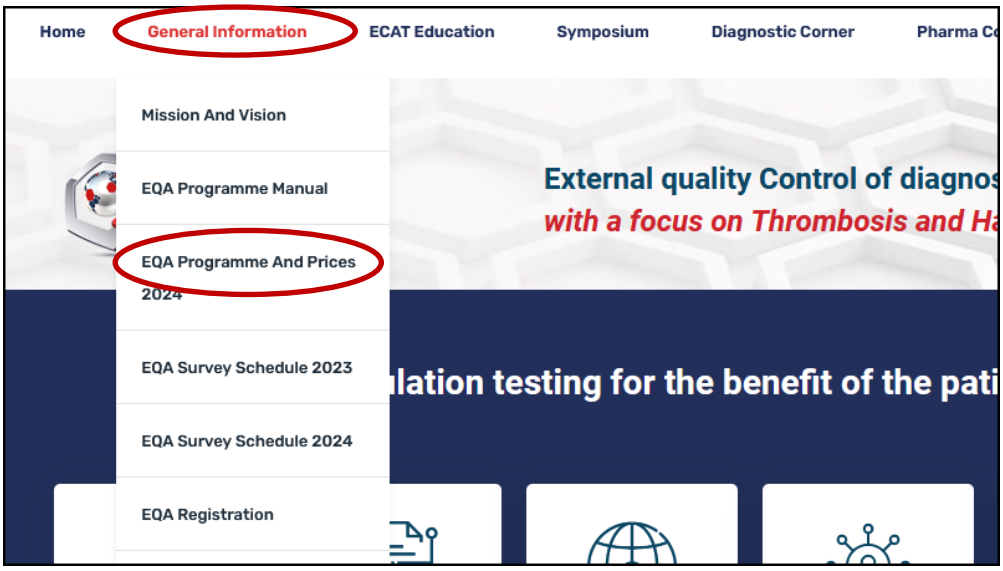
The annual subscription fee is mandatory for each participant and will be added to the fee for the selected modules.

Programme and prices

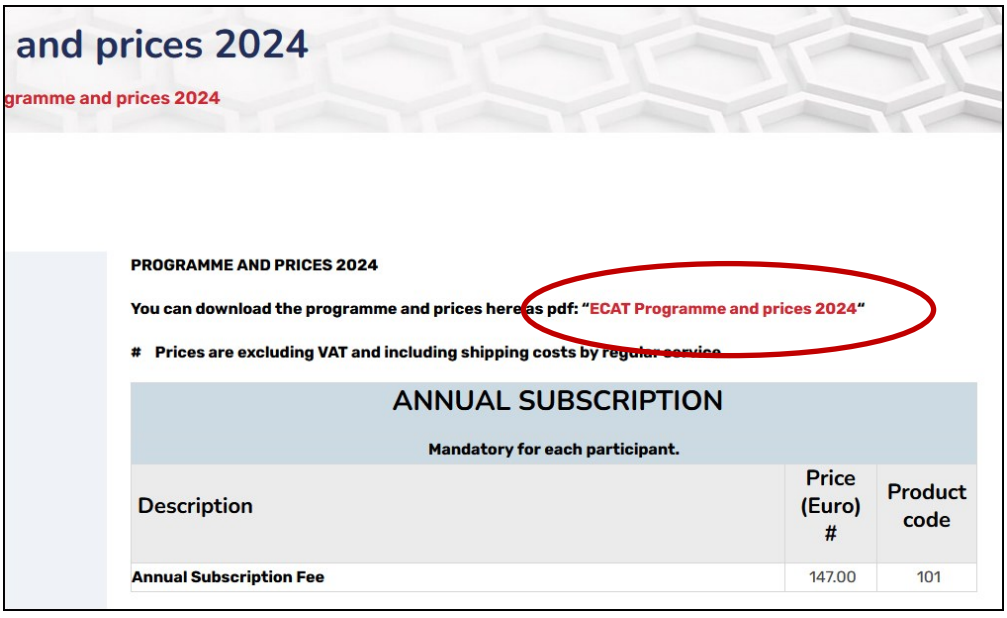
Our programme and prices can be found and downloaded on our website www.ecat.nl.

- Click on the Programme button on our homepage

- Or select in the menu “General Information” followed by “EQA Registration”



- You can download and print the programme and prices as PDF if needed.



DETAILED SAMPLE INFORMATION				
Description	**Survey Code**	**Number of different samples per survey**	**Number of vials per sample code**	**Component**
Thrombophilia - I: Antithrombin (activity and antigen), Protein C (activity [chromogenic and clotting] and antigen), Protein S activity, Protein S antigen (total and free)	M	2	2	Plasma, lyophilised
Thrombophilia - II APC Resistance	M	2	1	Plasma, lyophilised
Coagulation Factor - I Factor VIII (clot and chromogenic activity), IX (clot and chromogenic activity), XI:C and XII:C	M	2	2	Plasma, lyophilised
Coagulation Factor - II Factor II:C, V:C, VII:C and X:C	M	2	2	Plasma, lyophilised
Von Willebrand Factor parameters (antigen, ristocetin cofactor activity, activity, collagen binding, multimers, Factor VIII)	M	2	2	Plasma, lyophilised
ADAMTS13 - I (activity and antigen)	M	2	1	Plasma, lyophilised
ADAMTS13 - II (antibodies)	M	2	1	Plasma, lyophilised
ADAMTS13 - III (functional inhibitor)	M	2	1	Plasma, lyophilised
Factor XIII (activity and antigen)	M	2	1	Plasma, lyophilised
Fibrinolysis - I Plasminogen, Antiplasmin	M	2	1	Plasma, lyophilised
Fibrinolysis - II t-PA, PAI-1	M	2	1	Plasma, lyophilised
Haemophilia Factor VIII / Factor IX (clot and chromogenic activity)	H	2	1	Plasma, lyophilised
Factor VIII inhibitor	H	2	1	Plasma, lyophilised
Factor IX Inhibitor	H	2	1	Plasma, lyophilised
Emicizumab	H	2	1	Plasma, lyophilised
Kovaltry	H	2	1	Plasma, lyophilised
Jivi	H	2	1	Plasma, lyophilised
Esperoct	H	2	1	Plasma, lyophilised
NovoEight	H	2	1	Plasma, lyophilised
Refixia	H	2	1	Plasma, lyophilised
Lupus Anticoagulant / Antiphospholipid Antibodies	L	1	2	Plasma, lyophilised
Unfractionated Heparin Monitoring (anti-Xa)	A	2	1	Plasma, lyophilised
Low-Molecular Weight Heparin Monitoring (anti-Xa)	A	2	1	Plasma, lyophilised
Orgaran (anti-Xa)	A	2	1	Plasma, lyophilised
Fondaparinux (anti-Xa)	A	2	1	Plasma, lyophilised
Rivaroxaban (anti-Xa)	A	2	1	Plasma, lyophilised
Apixaban (anti-Xa)	A	2	1	Plasma, lyophilised
Edoxaban (anti-Xa)	A	2	1	Plasma, lyophilised
Argatroban (anti-IIa/dTT)	A	2	1	Plasma, lyophilised
Dabigatran (anti-IIa/dTT)	A	2	1	Plasma, lyophilised
D-Dimer	D	2	1	Plasma, lyophilised
Screen - I APTT, PT/INR and Fibrinogen	S	2	1	Plasma, lyophilised
Screen - II Thrombin Time, Reptilase Time	S	2	1	Plasma, lyophilised
Thrombin Generation Test	TG	3	1	Plasma, lyophilised
PFA-100/200	P	2	2	tubes ± additives
ROTEM delta (samples per set)	T	2	1	Plasma, lyophilised
ROTEM sigma (samples per set)	T	2	1	Plasma, lyophilised
TEG (samples per set)	T	2	1	Plasma, lyophilised
CLOT-PRO (samples per set)	T	2	1	Plasma, lyophilised
HIT - I (immunological testing)	HIT	2	1	Plasma or serum, lyophilised
POCT INR QC Programme	Q	4	1	Plasma, lyophilised
APTT / PT Mixing Test Programme	MIX	2	1	Plasma, lyophilised
Activated Clotting Time	ACT	2	1	Artificial whole blood
FDP	F	2	1	Plasma, lyophilised
Homocysteine		2	1	Plasma, liquid
Post Analytical Platelet Function EQA (electronic survey)		-	-	-
Platelet Dense Granule exercise (electronic survey)		-	-	-

DETAILED SAMPLE INFORMATION				
Description	**Survey Code**	**Number of different samples per survey**	**Number of vials per sample code**	**Component**
Whole Blood Impedance Platelet Aggregation (electronic survey)		-	-	-
Case study on bleeding disorders		1	1 or 2	Plasma, lyophilised
Case study on anticoagulation bridging		1	1	Plasma, lyophilised
Pre- and post-analytical electronic surveys in haemostasis		-	-	-
Molecular Genetics MG1		2	1	DNA preparation, lyophilised
Molecular Genetics MG2		2	1	DNA preparation, lyophilised
DNA Sequencing		5	1	DNA preparation, lyophilised
DNA Isolation		2	1	Full blood, K-EDTA

LIST OF PARAMETERS		
Parameter	**Module**	**Survey Code**
Activated Clotting Time	Activated Clotting Time	ACT
ADAMTS-13 activity	ADAMTS13 - I	M
ADAMTS-13 antigen	ADAMTS13 - I	M
ADAMTS-13 antibodies	ADAMTS13 - II	M
ADAMTS-13 functional antibodies	ADAMTS13 - III	M
Anticardiolipin antibodies (IgG, IgM)	Lupus Anticoagulant / Antiphospholipid Antibodies	L
Antithrombin activivty	Thrombophilia - I	M
Antithrombin antigen	Thrombophilia - I	M
APC Resistance	Thrombophilia - II	M
Apixaban (anti-Xa)	Apixaban	A
APTT (clotting time / ratio)	Screen – I	S
APTT Mixing Test	APTT / PT Mixing Test	Mix
Argatroban (anti-IIa / dTT)	Argatroban	A
CLOT-PRO	CLOT-PRO	T
Dabigatran (anti-IIa / dTT)	Dabigatran	A
D-Dimer	D-Dimer	D
Edoxaban (anti-Xa)	Edoxaban	A
Emicizumab	Emicizumab	M
Esperoct	Esperoct	H
Factor II:C	Coagulation Factor - II	M
Factor V:C	Coagulation Factor - II	M
Factor VII:C	Coagulation Factor - II	M
Factor VIII (clot and chromogenic)	Coagulation Factor - I / Haemophilia	M / H
Factor VIII Inhibitor	Factor VIII Inhibitor	H
Factor IX (clot and chromogenic)	Coagulation Factor - I / Haemophilia	M / H
Factor IX Inhibitor	Factor IX Inhibitor	H
Factor X:C	Coagulation Factor - II	M
Factor XI:C	Coagulation Factor - I	M
Factor XII:C	Coagulation Factor - I	M
Factor XIII activity	Factor XIII	M
Factor XIII antigen	Factor XIII	M
Fibrinogen (Clauss)	Screen – I	S
Fibrinogen (Derived)	Screen – I	S
Fibrin(ogen) Degradation Products	Fibrin(ogen) Degradation Products	F
Fondaparinux (anti-Xa)	Fondaparinux	A
ß2-Glycoprotein I antibodies (IgG, IgM)	Lupus Anticoagulant / Antiphospholipid Antibodies	L
HIT (immunological testing)	HIT – I	HIT
Homocysteine	Homocysteine	-
INR	Screen – I	S
INR POCT	POCT INR QC Programme	Q
Jivi	Jivi	H
Kovaltry	Kovaltry	H
Low-Molecular Heparin (anti-Xa)	Low-Molecular Heparin Monitoring	A
Lupus Anticoagulant	Lupus Anticoagulant / Antiphospholipid Antibodies	L
NovoEight	NovoEight	H
Orgaran (anti-Xa)	Orgaran	A
PAI-1 activity	Fibrinolysis - II	M
PAI-I antigen	Fibrinolysis - II	M
PFA-100/200	PFA-100/200	P

LIST OF PARAMETERS		
Parameter	**Module**	**Survey Code**
Plasminogen activity	Fibrinolysis - I	M
Plasmin Inhibitor (antiplasmin) activity	Fibrinolysis - I	M
Protein C acivity (chromogenic / clotting)	Thrombophilia - I	M
Protein C antigen	Thrombophilia - I	M
Protein S activity	Thrombophilia - I	M
Protein S antigen (total and free)	Thrombophilia - I	M
PT (clotting time, percentage)	Screen – I	S
PT Mixing Test	APTT / PT Mixing Test	Mix
Refixia	Refixia	H
Reptilase Time (clotting time / ratio)	Screen – II	S
Rivaroxaban (anti-Xa)	Rivaroxaban	A
ROTEM delta	ROTEM delta	T
ROTEM sigma	ROTEM sigma	T
TEG	TEG	T
Thrombin Generation Test	Thrombin Generation Test	TG
Thrombin Time (clotting time / ratio)	Screen – II	S
t-PA antigen	Fibrinolysis - II	M
Unfractionated Heparin (anti-Xa)	Unfractionated Heparin Monitoring	A
Von Willebrand Factor antigen	Von Willebrand Factor Parameters	M
Von Willebrand Factor ristocetin cofactor activity	Von Willebrand Factor Parameters	M
Von Willebrand Factor activity	Von Willebrand Factor Parameters	M
Von Willebrand Factor collagen binding	Von Willebrand Factor Parameters	M
Von Willebrand Factor multimers	Von Willebrand Factor Parameters	M
Von Willebrand Factor / Factor VIII	Von Willebrand Factor Parameters	M

Part of the samples used in the surveys is from commercial source. For abnormal samples real patient plasma is used when appropriate. Samples are provided as lyophilized material.

Instructions for use of the samples will be given in the Survey Manual and the Survey Instructions.

Molecular Biology

In co-operation with the SPMD in Germany several EQA programmes related to Molecular Biology are provided.

Molecular Diagnostic Testing
Twice a year an EQA programme for Molecular Diagnostic Testing is provided. There are two modules on molecular genetic testing (MG1 and MG2), each including 6 sets with different genetic defects to be tested. Within a module the relevant sets for participation should be selected. For details please go to our website programme and prices page. The material provided is purified DNA. Detailed information about these two modules can be found on our website under General Information – EQA Progamme and Prices.

DNA isolation
Twice a year an EQA programme for DNA isolation is provided. Here whole EDTA-blood is provided. These surveys focus on the determination of concentration of DNA, ratio 260/280, method of identification and defined genotypes.

DNA sequencing
Twice a year an EQA programme for DNA sequencing is provided. Purified DNA is provided. DNA sequencing should be performed and corresponding diagnostic interpretation should be given.

Special surveys

Electronic post-analytical platelet function survey:
In co-operation with the NASCOLA in the United States twice a year a post-analytical survey for platelet function testing is provided. These surveys focus on the interpretation of aggregation patterns in combination with a case description.

Platelet Dense-Granule Survey:
In co-operation with the NASCOLA in the United States twice a year a platelet dense-granule survey is provided. This is an electronic challenge in which electron microscopy images have to be evaluated.

Whole Blood Impedance Platelet Aggregation survey:
Whole blood impedance platelet function testing is provided in co-operation with the NASCOLA. These surveys focus on interpretation of whole blood impedance aggregation patterns. Surveys are offered electronically twice a year and include aggregation tracings and case descriptions.

Case study on bleeding disorders:
Case study on bleeding disorders is a combination of analytical aspects as well as case-based interpretation of the laboratory results. The participant will receive plasma to perform laboratory tests, which can be selected based on a given case description. Genetic testing will be included as an option. In addition a questionnaire on the interpretation of test results has to be completed as well. The scope of this case studies is to investigate the ability of proper interpretation of the clinical case description and the obtained laboratory test results, resulting in the correct diagnosis.

Case study on anticoagulation bridging:
In certain clinical situations (e.g. surgery) patients on DOACS need to be bridged with Low-Molecular Weight Heparin (LMWH). Measuring anti-Xa in such patient samples maybe hampered by the residual effect of rivaroxaban in the LMWH assay and vice versa. The scope of the case study on anticoagulation bridging is to investigate the presence and type of anticoagulant(s) taking into account the clinical case description.

Pre- and post-analytical survey:
This is an electronic survey in which multiple choice questions with respect to aspects of the pre- and post-analytical phase have to be answered. Comments on the given answers are shown and an overview of the score is given.

Disclaimer:

The ECAT Foundation is not responsible for either the content or the evaluation of the test results of surveys provided either by the NASCOLA or SPMD.

POCT FOR COAGUCHEK MONITORS

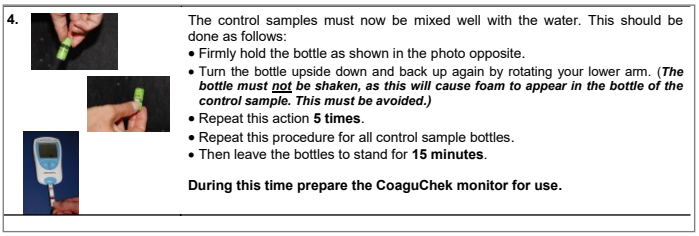
Introduction

The ECAT Foundation provides an external quality control kit for CoaguChek INR monitors. It can be used for quality control of reference monitors in coagulation clinics, monitors used in hospital settings, medical centres etc. as well as individual monitors of patients.
It is possible to evaluate more than one monitor (max. approx. 5) at the same time with one quality control kit. Because of the use of a set of 4 certified plasma samples it is possible to get, within a certain confidence interval, insight in the correctness of INR measurement within the therapeutic interval. The results can be evaluated via an online evaluation tool and the evaluation report per monitor is immediately available.
It is advisable to evaluate the performance of each monitor at least twice a year or after the change of a lot number of test strips.

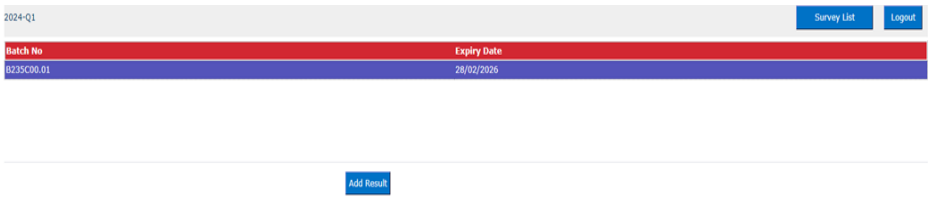
Examples of QC kit and evaluation tool

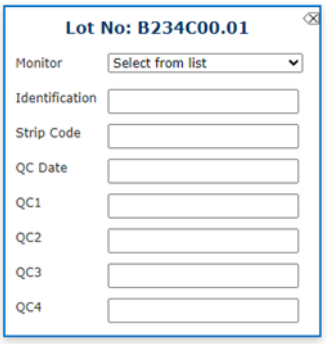
- Ready-to-use QC kit (excl. test strips):

- Clear instructions:



- Online evaluation tool:
  (evaluation report immediately available)





- Clearly structured and informative evaluation report:

POCT INR QC 2024

For 2024 the ECAT offers the following options:

POCT INR QC Programme

Samples are provided as QC kit 4 times per year. Each quarter you will receive a different lot-number of the quality control kit. For evaluation the webtool is available and the reports per monitor are generated immediately. You will receive an overall evaluation report after each quarter.
More information about the dispatch date of the kits and survey period can be found in the online Survey Schedule. Information about the cost is given in our Programme and Prices 2024.

Registration POCT INR QC Programme:
Registration for this POCT INR QC Programme is included in the online subscription form 2024.

POCT INR QC Single kits

The single kits can be ordered and evaluated at any time. For evaluation the webtool is available and the reports per monitor are generated immediately.

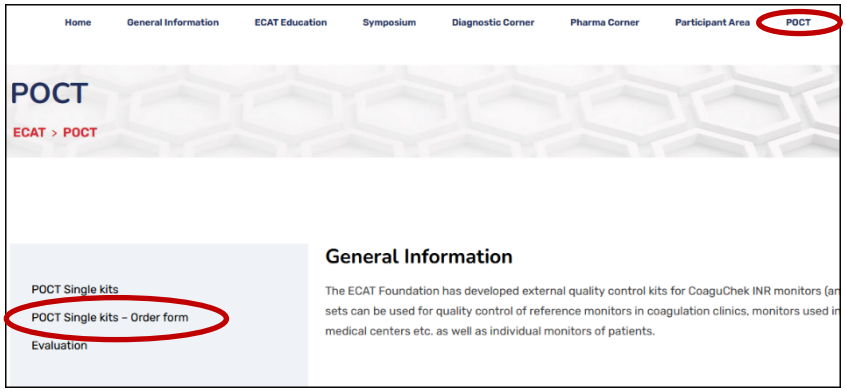
Description	Price (Euro) Excl. VAT and shipment cost **	Product code
ECAT INR Quality Control single kit	83.25	ECAT11001

** Shipping and handling costs per order:
- within the Netherlands: € 14,50
- within Europe: € 27,50
- outside Europe: price on request

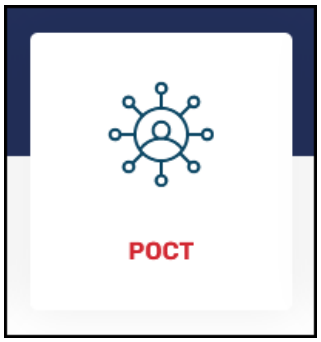
For orders of more than 25 sets at once a special price can be provided.
Orders for these POCT quality control kits will be separately invoiced from the regular EQA programme.

How to order POCT Quality Control Single Kits

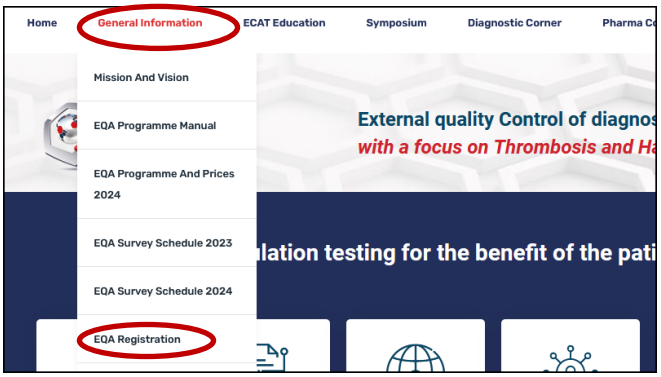
In the POCT section at the ECAT website (POCT → POCT single kit - order form) a special order form can be found for ordering POCT QC kits. This online order form can only be used to order a number of single kits, Product code ECAT11001.

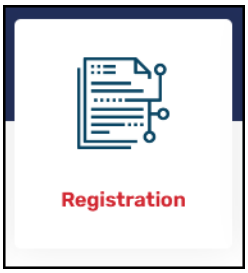


You can also use the shortcut by clicking on the POCT logo on the homepage.



REGISTRATION





Registration

The available modules and corresponding prices are updated annually. Either combination of modules can be selected. It is possible to start any time during the year. The registration will start the first survey scheduled after the registration is received and will continue until the end of the year.

Registration to the ECAT EQAP can be done via our website (www.ecat.nl).
Select in the menu "General Information" followed by "EQA Registration" or click on the shortcut registration button on the homepage. Follow the instructions given at webpage.
The registration forms are only accepted when a new participant confirms to agree with our "terms of delivery".
During the registration process you are asked to select:

1) Country
2) Contact details
3) Modules

Terms of delivery

The terms of delivery of the ECAT Foundation can be found on our website.

Confirmation of registration

After completion of the online registration an automatically generated confirmation e-mail will be received, including an overview for which modules you have registered. From our office you will receive an e-mail with information about the survey you will start.
With the first samples more detailed information about the registration, an unique laboratory code and the website login code will be received.

Survey Manual

Each year the Survey Manual will be updated. This Manual gives instructions how to perform the surveys. This includes:

- information about the reconstitution and measurement of samples
- instructions how to report results with the report forms on the website
- explanation of the survey reports
- instructions non-ECAT programmes

The annual Survey Manual will become online available before the start of the first survey.

Annual subscription

Annually participants receive information about the programme for the next year and instructions how to subscribe. This ensures that all participants are informed about added or deleted modules in the ECAT programme.

Payment

Participants annually receive an invoice for their participation. The invoice for new participants is sent after the registration process is completed.
Payment should be done by bank transfer. Cheques are not accepted.

For participants of one of the EMU countries we ask for a VAT number. If the VAT number of your organisation is not available at our Financial Department, the ECAT is legally obliged to add 21% VAT to the invoice.

Details ECAT bank account:

Bank office : ING
Address:P.O. Box 94780, 1090 GT Amsterdam, The Netherlands
Account no. : 6930471
IBAN no. : NL38 INGB 0006 9304 71
BIC code : INGBNL2A

Cancellation policy

Cancellation is only accepted at the end of a year by a written confirmation. If no cancellation is received, the ECAT will continue the subscription profile of the laboratory into the new year. Cancellation during the year is not possible.

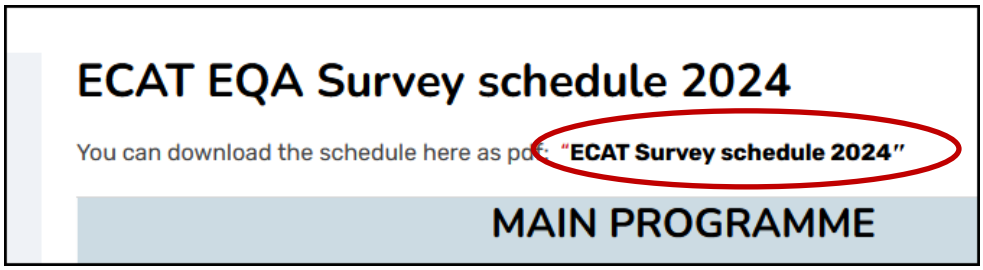
SURVEY SCHEDULE 2024

The survey schedule can be found and downloaded on the website www.ecat.nl.

- Click on the Programme button on our homepage

- Click on Survey Schedule 2024

- Download the survey schedule



INFORMATION ECAT SURVEYS

Samples

Samples are sent to participants according to the survey schedule and survey composition. The frequency is clearly indicated on the subscription and registration forms.

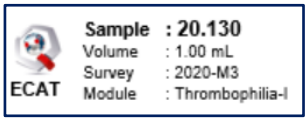
Samples used in the surveys are human-based plasmas. To maintain stability and for practical purposes during the distribution process, the samples are lyophilized.

The plasma samples have been tested by an FDA approved method for the presence of HIV antigen, hepatitis B surface antigen as well as for hepatitis C antigen and have been found to be negative. As with all preparations of human origin, suitable precautions should be taken in the handling and disposal.

The samples are packed in plastic bubble bags and carton boxes to prevent damage during transport. After receipt the samples should be stored at 2-8 °C until use.

Each vial has a label with the ECAT logo, survey number, sample code, volume for reconstitution and module. This code corresponds with a code in the sample list on the survey instruction. This sample code is also the identification code when results are reported.

Example label:



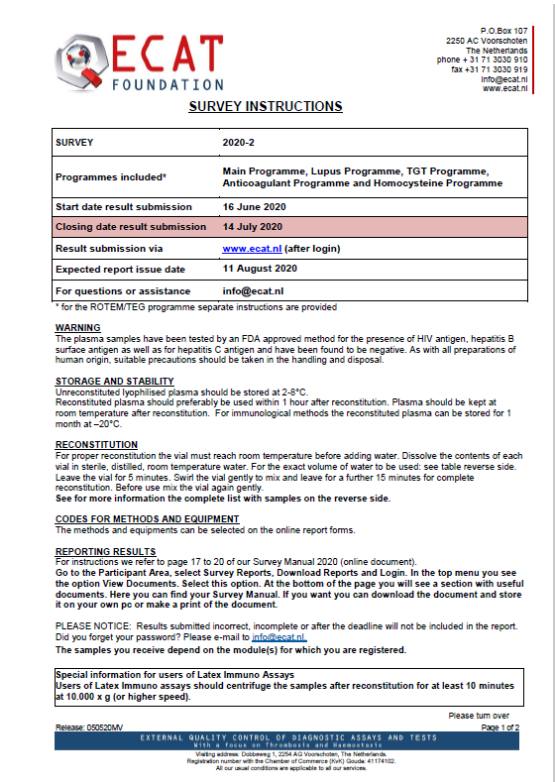
Survey Instructions

Together with the samples the detailed Survey Instructions are provided. These instructions include:

- information about the samples of each module
- the volume of reconstitution
- safety matters

Participants can also download the Survey Instructions as well as the Survey Manual from the member section at the website.

Example survey instructions:



ECAT FOUNDATION

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2250 AC Voorschoten
The Netherlands
phone +31 71 3030 910
fax +31 71 3030 919
info@ecat.nl
www.ecat.nl

SURVEY INSTRUCTIONS

SURVEY	2020-2
Programmes included*	Main Programme, Lupus Programme, TGT Programme, Anticoagulant Programme and Homocysteine Programme
Start date result submission	16 June 2020
Closing date result submission	14 July 2020
Result submission via	www.ecat.nl (after login)
Expected report issue date	11 August 2020
For questions or assistance	info@ecat.nl

* for the ROTEM/TEG programme separate instructions are provided

WARNING
The plasma samples have been tested by an FDA approved method for the presence of HIV antigen, hepatitis B surface antigen as well as for hepatitis C antigen and have been found to be negative. As with all preparations of human origin, suitable precautions should be taken in the handling and disposal.

STORAGE AND STABILITY
Unreconstituted lyophilised plasma should be stored at 2-8°C.
Reconstituted plasma should preferably be used within 1 hour after reconstitution. Plasma should be kept at room temperature after reconstitution. For immunological methods the reconstituted plasma can be stored for 1 month at –20°C.

RECONSTITUTION
For proper reconstitution the vial must reach room temperature before adding water. Dissolve the contents of each vial in sterile, distilled, room temperature water. For the exact volume of water to be used: see table reverse side. Leave the vial for 5 minutes. Swirl the vial gently to mix and leave for a further 15 minutes for complete reconstitution. Before use mix the vial again gently.
See for more information the complete list with samples on the reverse side.

CODES FOR METHODS AND EQUIPMENT
The methods and equipments can be selected on the online report forms.

REPORTING RESULTS
For instructions we refer to page 17 to 20 of our Survey Manual 2020 (online document).
Go to the Participant Area, select Survey Reports, Download Reports and Login. In the top menu you see the option View Documents. Select this option. At the bottom of the page you will see a section with useful documents. Here you can find your Survey Manual. If you want you can download the document and store it on your own pc or make a print of the document.

PLEASE NOTICE: Results submitted incorrect, incomplete or after the deadline will not be included in the report. Did you forget your password? Please e-mail to info@ecat.nl.
The samples you receive depend on the module(s) for which you are registered.

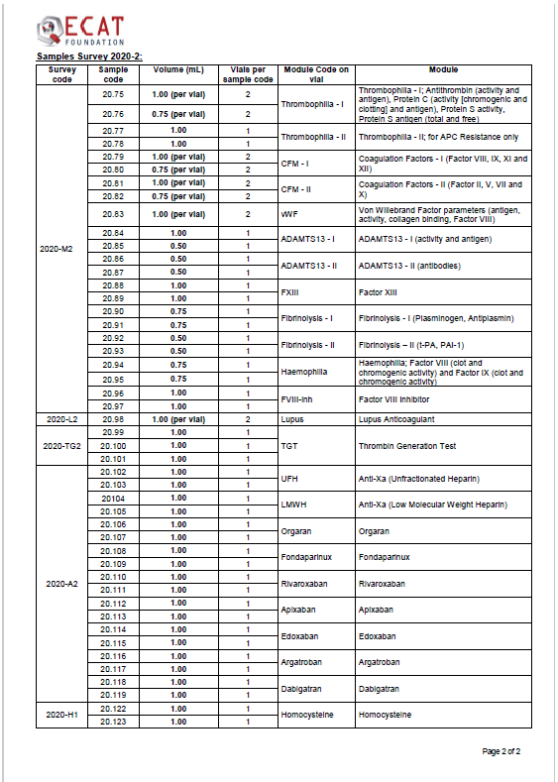
Special information for users of Latex Immuno Assays
Users of Latex Immuno assays should centrifuge the samples after reconstitution for at least 10 minutes at 10.000 x g (or higher speed).

Please turn over

Release: 050520MV Page 1 of 2

EXTERNAL QUALITY CONTROL OF DIAGNOSTIC ASSAYS AND TESTS
With a focus on Thrombosis and Haemostasis

Visiting address: Dobbeweg 1, 2254 AG Voorschoten, The Netherlands.
Registration number with the Chamber of Commerce (KvK) Dordts 41174102.
All our usual conditions are applicable to all our services.



ECAT FOUNDATION

Samples Survey 2020-2:

Survey code	Sample code	Volume (mL)	Vials per sample code	Module Code on vial	Module
2020-M2	20.75	1.00 (per vial)	2	Thrombophilia - I	Thrombophilia - I; Antithrombin (activity and antigen), Protein C (activity [chromogenic and clotting] and antigen), Protein S activity, Protein S antigen (total and free)
	20.76	0.75 (per vial)	2		
	20.77	1.00	1	Thrombophilia - II	Thrombophilia - II; for APC Resistance only
	20.78	1.00	1		
	20.79	1.00 (per vial)	2	CFM - I	Coagulation Factors - I (Factor VIII, IX, XI and XII)
	20.80	0.75 (per vial)	2		
	20.81	1.00 (per vial)	2	CFM - II	Coagulation Factors - II (Factor II, V, VII and X)
	20.82	0.75 (per vial)	2		
	20.83	1.00 (per vial)	2	vWF	Von Willebrand Factor parameters (antigen, activity, collagen binding, Factor VIII)
	20.84	1.00	1	ADAMTS13 - I	ADAMTS13 - I (activity and antigen)
	20.85	0.50	1		
	20.86	0.50	1	ADAMTS13 - II	ADAMTS13 - II (antibodies)
	20.87	0.50	1		
	20.88	1.00	1	FXIII	Factor XIII
	20.89	1.00	1		
	20.90	0.75	1	Fibrinolysis - I	Fibrinolysis - I (Plasminogen, Antiplasmin)
	20.91	0.75	1		
	20.92	0.50	1	Fibrinolysis - II	Fibrinolysis – II (t-PA, PAI-1)
	20.93	0.50	1		
	20.94	0.75	1	Haemophilia	Haemophilia; Factor VIII (clot and chromogenic activity) and Factor IX (clot and chromogenic activity)
	20.95	0.75	1		
	20.96	1.00	1	FVIII-Inh	Factor VIII Inhibitor
	20.97	1.00	1		
2020-L2	20.98	1.00 (per vial)	2	Lupus	Lupus Anticoagulant
2020-TG2	20.99	1.00	1	TGT	Thrombin Generation Test
	20.100	1.00	1		
	20.101	1.00	1		
2020-A2	20.102	1.00	1	UFH	Anti-Xa (Unfractionated Heparin)
	20.103	1.00	1		
	20104	1.00	1	LMWH	Anti-Xa (Low Molecular Weight Heparin)
	20.105	1.00	1		
	20.106	1.00	1	Orgaran	Orgaran
	20.107	1.00	1		
	20.108	1.00	1	Fondaparinux	Fondaparinux
	20.109	1.00	1		
	20.110	1.00	1	Rivaroxaban	Rivaroxaban
	20.111	1.00	1		
	20.112	1.00	1	Apixaban	Apixaban
	20.113	1.00	1		
	20.114	1.00	1	Edoxaban	Edoxaban
	20.115	1.00	1		
	20.116	1.00	1	Argatroban	Argatroban
	20.117	1.00	1		
	20.118	1.00	1	Dabigatran	Dabigatran
	20.119	1.00	1		
2020-H1	20.122	1.00	1	Homocysteine	Homocysteine
	20.123	1.00	1		

Page 2 of 2

Instructions for testing

The ECAT plasmas should be treated as regular patient plasmas and included in the normal daily analytical process in the laboratory. The regularly used methods should be applied. No special treatment of the samples is allowed. Results should be reported similar as a result of a patient is reported.

Result submission

Survey results are reported via our web-based result submission facility in the participant area of our website. This facility is password-protected. The password is provided to the participant during the registration procedure. In the Survey Manual detailed instructions are given how to use this web-based result submission facility.

Besides the test results on the ECAT samples and the unit in which the result is expressed, information should be given on the assay principle, methodology and equipment used. For most of the parameters also a clinical classification of the samples is asked. Pull down menu's will show the different options for assay type, method, equipment and classification.

Inappropriate completion of the report forms may lead to exclusion of the results from the statistical evaluation.

Results returned after the survey closing date will not be included in the statistical evaluation.

Statistical evaluation

For the external quality assessment programme of the ECAT the robust average of the results reported by all participants in the survey is used as the assigned value (= consensus value).
The reason for the use of the consensus value as the assigned value is the fact that within the field of laboratory diagnosis of Thrombosis and Haemostasis no reference measurement procedure and certified reference materials exist.
In accordance with ISO standard 17043:2010 and ISO standard 13528:2022 Algorithm A is used as a robust statistical algorithm for the calculation of the consensus value and the standard deviation.

The standard procedure for the evaluation of quantitative test results is as follows:

- Results are harmonised to the same unit (% / U/dL).
- The consensus value and standard deviation (SD) are calculated using Algorithm A.
- Based on this consensus value and SD the between-laboratory variation is calculated.

Algorithm A is applied on the total group and the level of assay type and method if there are at least 10 participants included in the same group (for CLOT-PRO a minimum of 5 participants is used). If the group size is less than 10 participants (in the case of CLOT-PRO less than 5 participants) the median is used.

Performance evaluation

As an individual performance indicator the Z-score is used. The Z-score indicates the distance between the participants' result and the consensus value expressed as a ratio of the standard deviation. The Z-score can be either positive or negative depending whether the participants' results is higher or lower than the consensus value.

The z-score is calculated as follows:

[(laboratory result) - (mean result of all laboratories)] / (standard deviation of all results)

The Z-score is also calculated for groups on the level of assay type and method with at least 10 participants. (for CLOT-PRO a minimum of 5 participants is used).

Acceptance criteria
Each participants should carefully evaluate the Z-scores given in the report.
In accordance with ISO guideline 17043 and ISO guideline 13528 the following acceptance criteria are used:

$-2 \leq$ Z-score ≤ 2	:	The result is acceptable
$-3 <$ Z-score < -2 or $2 <$ Z-score < 3	:	The results is questionable (warning signal)
Z-score ≤ -3 or Z-score ≥ 3	:	The result is unacceptable (action signal)

A single action signal or two warning signals in consecutive surveys shall be taken as evidence that an anomaly has occurred that requires investigation by the laboratory.

Survey reports

From each survey a report of the evaluation of the results is prepared. The survey reports are electronically available in PDF-format. The evaluation report includes those modules for which a participant is registered.
The reports include the results of all participants. The position of the participants' own results in relation to all results are clearly presented both in the statistical tables as well as in histograms.

The participants' performance is presented by the Z-score (see above) both in the statistical tables as well as in Z-score plots (only when two samples are distributed per survey) and Z-score history plots.

The following survey reports are produced:

- Screen assays
- APTT/PT Mixing Test
- D-Dimer
- Lupus Anticoagulant
- Thrombin Generation Test
- HIT
- Thromboelastography
- Anticoagulation
- PFA
- Activated Clotting Time
- Haemophilia
- Fibrin(ogen) Degradation Products
- POCT INR
- Main (including all modules not mentioned above)

Report set-up

For each analyte a participant has subscribed for in the ECAT programme a report is given.
The report consists of the following parts:

1. Module / Parameter
2. Information
3. Classification
4. Own reagent
5. Other reagents
6. Graphs
7. Z-score plot
8. Z-score history plot

Module / Parameter

At the top of each report page the name of the module (left) and the parameter (right) is indicated. See example below.

Screen - I	APTT (clotting time)

Information

Next, information is given regarding the sample used, number of participants and responders, response rate and general comments. An example is given below.

Sample Number	18.21		
Sample Details	Control plasma from a pool of anticoagulated patients (INR approx. 2.5)		
Prior Use	2018-S2		
Unit	Seconds		
Expiry Date	30-November-2019		
Homogeneity	1.8 %	**Homogeneity Parameter**	APTT
	For any method used for the measurement of this parameter with a **CV ≤ 6.0%** 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	302		
Number of Responders	227	**Response Rate**	75 %
Comments	For the most frequently used reagents (n>=10) the results of sample 18.21 are good comparable with those of sample 18.05 in survey 2018-S2. The following participants reported deviating results which were excluded from the statistical evaluation: **582** : 527 / 610 **3189** : 263 **7770105** : 3.34		

Classification

When appropriate an overview of the clinical classification is given in a separate table and separately your own classification given. See example below:

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	3	0	3	319	4

Your Classification Abnormal

Own reagent

A table is given showing the descriptive statistics for the own reagent used (eventually in combination with the equipment used) as well the own results and Z-score for the different instruments for which results have been submitted. The assigned value represent the consensus value as calculated by Algorithm A. The between-laboratory variation (CV) and Z-score are only given when at least 10 participants belong to the same group (for derived fibrinogen and fibin(ogen) degradation products this number is 5).See example below:

Own Reagent

						STA1		STA2		STAv	
	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Stago PTT Autom./STA APTT	27	64.6	1.03	6.6	58.7 - 72.4	62.8	-0.43	62.1	-0.59	61.6	-0.71
Stago/Roche STA (all types)	25	64.8	1.06	6.5	59.2 - 72.4	62.8	-0.48	62.1	-0.65	61.6	-0.76

Other reagents

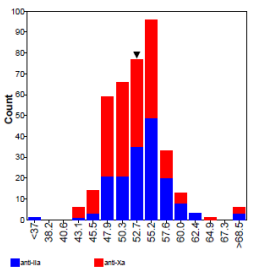
A table is given showing the descriptive statistics of the other reagents used by the participants (eventually including the descriptive statistics for the assay). See example below:

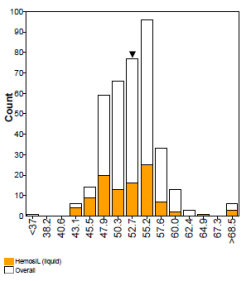
Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Beijing Succeeder Fibrinogen	2	3.3			3.2 - 3.3
DIAgam Fibrinogen	1	3.1			
Hyphen Biomed Fibrinogen	1	3.4			
I.L. HemosIL Fibrinogen- C	18	2.9	0.07	8.6	2.4 - 3.3
I.L. HemosIL Q.F.A. Thrombin	40	2.9	0.04	7.8	2.4 - 3.5
Labexpert Fibrinogen LX	3	3.3			3.3 - 3.6
Other	4	3.4			2.5 - 3.7
Roche Fibrinogen	3	2.3			2.3 - 2.3
Sekisui Coagpia Fibrinogen	2	2.9			2.6 - 3.2
Siemens Multifibrin-U	42	3.4	0.06	9.4	2.4 - 3.9
Siemens Thrombin Reagent	50	2.7	0.04	7.9	2.2 - 3.1
Stago STA Fib2	2	3.2			3.1 - 3.2
Stago STA Fibri Prest	1	3.5			
Stago STA Fibrinogen-5	2	3.0			3.0 - 3.1
Tcoag TriniCLOT Fibrinogen	9	2.9			2.6 - 3.8

The graph

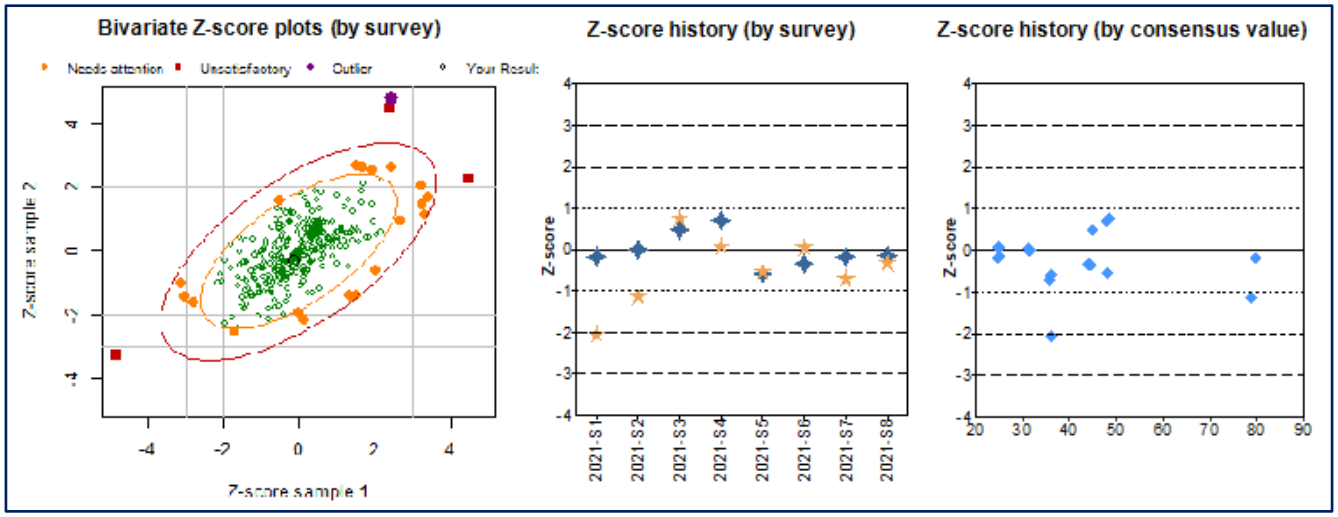
The distribution of the results is represented in a histogram.
Depending of the parameter the results are grouped based on the assay principle or the method used.
The position of your own result within the distribution is indicated by a black arrow on top of the bar in question in the histogram.
A separate graph is given where the own used method is presented within the whole distribution.





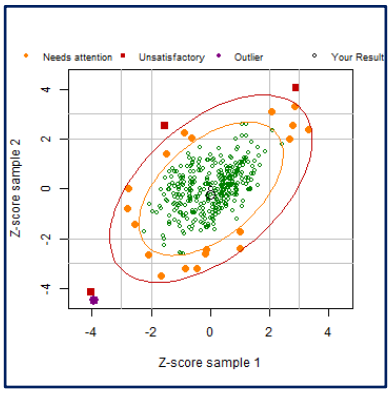
Z-score plots

Per instrument three different types of Z-score related plots are presented.



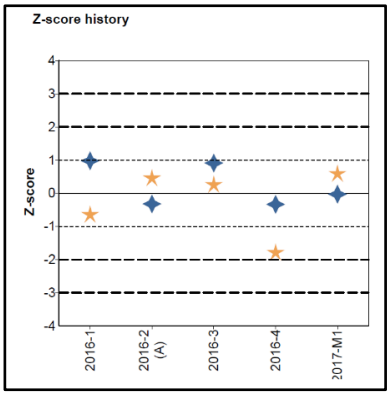
Z-score plot

The relationship of the Z-scores of the two different samples are plotted in a Z-score plot. The correlation between the Z-scores is evaluated by a bivariate Z-score analysis.
The Z-score plot only includes methods with at least 10 participants.
The relationship of both Z-scores gives an indication if the deviation from the mean value of your particular method is caused by systematic and/or random errors.



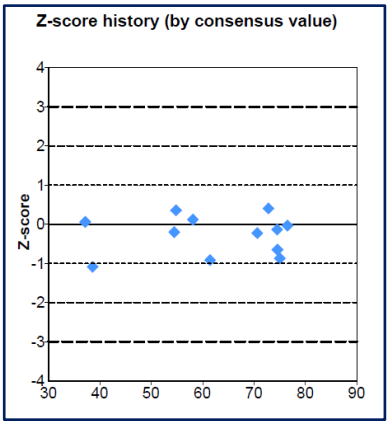
Z-score history plot

The history of the Z-score for a period of one year is given in a Z-score history plot.
The dashed lines in the Z-score history plot indicates the level of -1/1 , -2/2 and -3/3.



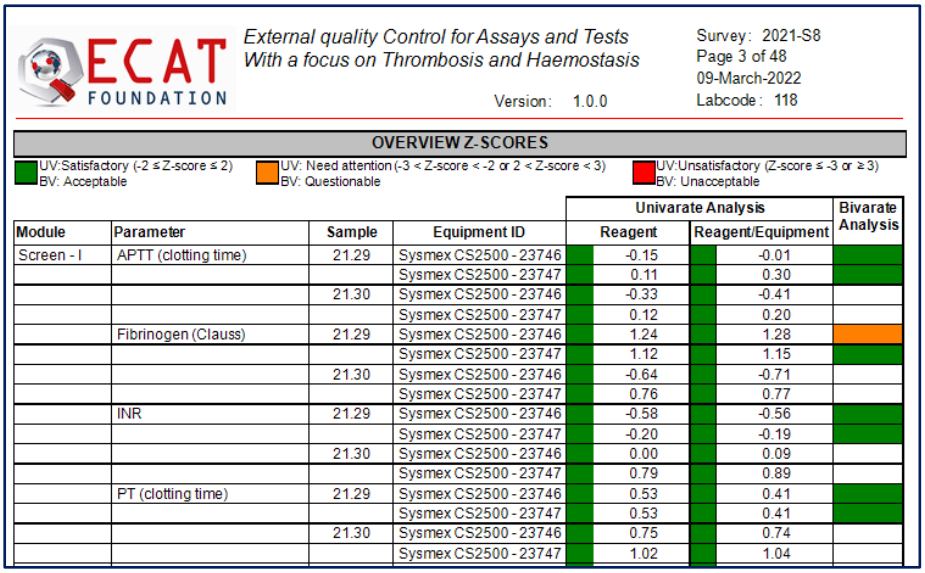
Z-score history plot by consensus value

In the Screen, D-Dimer, Main, Haemophilia and Anticoagulation report also a Z-score history plot is presented by consensus (= assigned) value.
This provides the participant with insight in their longitudinal deviation from the assigned value in time and concentration/activity of the parameter.
The dashed lines in the Z-score history plot indicates the level of -1/1 , -2/2 and -3/3.



Z-score overview

At the front of the Main, Anticoagulation, Haemophilia and Screen survey report is for those parameters where results are reported and a Z-score can be calculated an overview of the Z-scores given. An example of such a summary table is given below.



ECAT FOUNDATION

External quality Control for Assays and Tests
With a focus on Thrombosis and Haemostasis

Version: 1.0.0

Survey: 2021-S8
Page 3 of 48
09-March-2022
Labcode: 118

OVERVIEW Z-SCORES

UV:Satisfactory (-2 ≤ Z-score ≤ 2) BV: Acceptable
UV: Need attention (-3 < Z-score < -2 or 2 < Z-score < 3) BV: Questionable
UV:Unsatisfactory (Z-score ≤ -3 or ≥ 3) BV: Unacceptable

Module	Parameter	Sample	Equipment ID	Univarate Analysis		Bivarate Analysis
				Reagent	Reagent/Equipment	
Screen - I	APTT (clotting time)	21.29	Sysmex CS2500 - 23746	-0.15	-0.01	
			Sysmex CS2500 - 23747	0.11	0.30	
		21.30	Sysmex CS2500 - 23746	-0.33	-0.41	
			Sysmex CS2500 - 23747	0.12	0.20	
	Fibrinogen (Clauss)	21.29	Sysmex CS2500 - 23746	1.24	1.28	
			Sysmex CS2500 - 23747	1.12	1.15	
		21.30	Sysmex CS2500 - 23746	-0.64	-0.71	
			Sysmex CS2500 - 23747	0.76	0.77	
	INR	21.29	Sysmex CS2500 - 23746	-0.58	-0.56	
			Sysmex CS2500 - 23747	-0.20	-0.19	
		21.30	Sysmex CS2500 - 23746	0.00	0.09	
			Sysmex CS2500 - 23747	0.79	0.89	
	PT (clotting time)	21.29	Sysmex CS2500 - 23746	0.53	0.41	
			Sysmex CS2500 - 23747	0.53	0.41	
		21.30	Sysmex CS2500 - 23746	0.75	0.74	
			Sysmex CS2500 - 23747	1.02	1.04	

Additional use of results

Survey results may be used for scientific purposes. In this case anonymous use of results will be guaranteed. Individual survey results will never be provided to commercial parties without permission of the participant.

OTHER ACTIVITIES

ECAT Education

The mission of ECAT Foundation is to support and educate laboratory professionals with an interest in haemostasis and thrombosis by providing practical and concise information in order to improve the quality of laboratory testing related to these areas. ECAT Education is a specific part at the ECAT website. There is an open-access part, containing for instance an international meeting calendar, terminology used in the field of thrombosis and haemostasis, ECAT newsletters and assays, where background information regarding reagents for laboratory testing in haemostasis is available.
The password-protected area contains the annual special issues (see below) and the abstracts and presentations of previous ECAT Meetings. The part of this website with other educational resources is currently under reconstruction and therefore not available at the moment.

The ECAT Foundation provides a newsletter with a variety of background information on quality and laboratory testing related issues in the field of thrombosis and haemostasis.

Workshops and courses

On a regular basis the ECAT organises workshops and courses on topics related to our programme. For example, workshops were organised on thrombin generation testing, inhibitor testing, platelet function testing, dealing with an prolonged APTT. Courses were, for instance, organised for quality planning, interpretation of EQA results and troubleshooting, Lupus Anticoagulant testing, quality assurance according to ISO 15189.

Biennial participants' symposium

The ECAT organises every two years a participants' meeting in Leiden, The Netherlands. The programme of this symposium focuses on laboratory-related topics in the field of thrombosis and haemostasis.
In conjunction with the participants' symposium the ECAT organises frequently special courses with topics related to the laboratory diagnosis of haemostasis and/or quality of laboratory diagnosis.
Further information can be found on our website.
The next ECAT Participants' Symposium will be held on **26 and 27 September 2024**. All participants are informed in advance about the details of the programme as well as registration procedure. See for details about the programme and registration: https://www.ecat.nl/meeting-2/symposium/