ECAT FOUNDATION

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



PROGRAMME MANUAL 2019

ECAT FOUNDATION

Postal address

ECAT Foundation P.O. BOX 107 2250 AC Voorschoten The Netherlands

Contact details (general)

T. +31 71 3030910 F. +31 71 3030919 E. info@ecat.nl W. www.ecat.nl Visiting address

ECAT Foundation Dobbeweg 1 2254 AG Voorschoten The Netherlands

Contact details (financial department)

T. +31 71 3030911 F. +31 71 3030919 E. finance@ecat.nl

Registration no. at the Chamber of Commerce: 41174102

VAT number: NL802836872B01

IBAN no.: NL38 INGB 0006 9304 71

BIC code: INGBNL2A

Dear sir, dear madam,

It is our pleasure to present you our Programme Manual 2019. This Programme Manual provides you with background information about our organisation and the ECAT external quality assessment programme 2019.

The ECAT Foundation is an independent and impartial organisation 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 1650 laboratories from over 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 2019 the ECAT programme includes 31 modules for regular laboratory tests, 1 module for case studies and 1 electronic module for the pre- and post-analytical phase and a quality control programme for the CoaguChek INR monitors. Via ECAT also 2 interpretative electronic modules on platelet testing of the NASCOLA (United States) are provided as well as 14 modules for molecular biology provided by the DGKL (Germany).

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

Dr. Piet Meijer Director Mrs. Aletta Veninga Scheme Manager

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	3
Mission	3
Staff	3
Members of Supervisory Board (2019)	3
Accreditation	3
Exclusive distributors	4
Products and services from third parties	4
Confidentiality policy	4
Intellectual property rights and copyrights	4
Provision of global survey reports	
PROGRAMME AND PRICES	
ANNUAL SUBSCRIPTION	
MAIN PROGRAMME	
ROTEM/TEG PROGRAMME	
D-DIMER PROGRAMME	6
SCREEN PROGRAMME	
POCT INR QC PROGRAMME	6
OTHER SURVEYS	
MOLECULAR BIOLOGY (In co-operation with the DGKL, Germany)	
DETAILED SAMPLE INFORMATION	
POCT FOR COAGUCHEK MONITORS	
POCT INR QC Programme	
POCT INR QC Single kits	
How to order POCT Quality Control Single Kits	12
SURVEY SCHEDULE 2019REGISTRATION	
Registration	
Terms of delivery	
Confirmation of registration	
Survey Manual	
Annual subscription	
Payment	
Cancellation policy	
INFORMATION ECAT SURVEYS	
Samples	
Survey Instructions	
Result submission	
Statistical evaluation	
Performance evaluation	
Survey reports	
Report set-up	
Additional use of results	
OTHER ACTIVITIES	
ECAT Education	
Workshops and courses	20
Biennial participants' meeting	20

GENERAL INFORMATION ECAT FOUNDATION

The ECAT is an independent and impartial organization. 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.

Mission

The ECAT Foundation has been operating External Quality Assessment Programmes (EQAP) in the field of thrombosis and haemostasis since 1994.

The primary aim of the ECAT Foundation 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.

Staff

Name Position
Dr. P. Meijer Director

Mrs. J. Hooijmans Administrative co-worker

Mrs. A. Veninga Scheme Manager / Quality Officer

Mrs. C. Brasjen Assistant Quality Officer / Administrative co-worker

Mrs. M. Van der Voorn
Mrs. A. de Haan
Mrs. W. Hoogenboom
Survey Manager
Survey Assistant
Financial Manager

Mrs. G. Zandbergen Financial co-worker / Survey Assistant

Members of Supervisory Board (2019)

<u>Name</u>	<u>Specialism</u>	<u>Position</u>
Prof. Dr. M.P.M. de Maat	Biochemist/epidemiologists/clinical chemist	Chair
Drs. F. van den Hurk	Financial specialist	Member
Dr. W. van Gelder	Clinical chemist	Member
Dr. F.J.M. van der Meer	Internist	Member
Dr. J. Ruinemans-Koerts	Clinical chemist	Member
Prof. Dr. J.C.M. Meijers	Biochemist	Member

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)
- Homocysteine

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.



Page 3

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, Argentina, Australia, Canada, Colombia, Cyprus, Greece, Israel, New Zealand, Norway, Peru, Portugal, Turkey/Middle-East countries, United States.

Products and services from third parties

<u>ICT-related issues</u> Back-up services, web design and Health e.solutions – The

maintenance, web and database hosting, Netherlands

POCT application.

Participant management and survey KPMD – United Kingdom evaluation software, web-based data

submission.

Sample production and testing for Affinity Biologicals – Canada

homogeneity and stability. Hyphen Biomed – France

Technoclone – Austria MCA – The Netherlands Klinikum Augsburg – Germany

Laboratory testing Reference laboratory for testing of Erasmus Medical Center – The

homogeneity and stability. 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

Prices are excluding VAT

Annual Subscription

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

The following options are available for the annual subscription fee:

- internet result submission, survey report only via internet as PDF
- internet result submission, survey report via internet as PDF and a printed copy by postal service

ANNUAL SUBSCRIPTION							
Description	Price (Euro) #	Product code					
Annual Subscription Fee (result submission via internet / survey report via internet)	112.50	101					
Annual Subscription Fee (result submission via internet / survey report via internet + by post)	200.50	102					

	MAIN P	ROGRAM	ME				
Passaintian	Number		Surv	Price	Product		
Description	of Surveys	2019-M1	2019-M2	2019-M3	2019-M4	(Euro) #	code
Thrombophilia - I Antithrombin (activity and antigen), Protein C (activity [chromogenic and clotting] and antigen), Protein S activity, Protein S antigen (total and free)	4	V	V	V	V	345.00	402
Thrombophilia - II APC Resistance	4	V	√	√	V	140.00	417
Lupus Anticoagulant / Antiphospholipid Antibodies	4	√	√	√	√	157.50	404
Coagulation Factor - I Factor VIII (clot and chromogenic activity),	4	√	√	√	√	160.00	406
Coagulation Factor - II Factor II:C, V:C, VII:C and X:C	4	V	√	√	√	160.00	407
Von Willebrand Factor parameters (antigen, activity, collagen binding, multimers, Factor VIII)	4	√	√	√	√	135.00	408
ADAMTS13 - I (activity and antigen)	4	V	V	V	√	180.00	409
ADAMTS13 - II (antibodies)	2		V		√	115.00	410
Factor XIII (activity and antigen)	4	V	V	√	√	127.50	411
Fibrinolysis - I Plasminogen, Antiplasmin	4	V	V	V	√	125.50	412
Fibrinolysis - II t-PA, PAI-1	4	V	√	√	√	125.50	413
Factor VIII inhibitor	2		V		√	165.00	202
Factor IX Inhibitor	2	V		√		165.00	201
Thrombin Generation Test	2		V		$\sqrt{}$	137.50	203
HIT - I (immunological testing)	1			V		95.00	204
Unfractionated Heparin (anti-Xa)	4	V	V	V	√	112.50	414
Low-Molecular Weight Heparin (anti-Xa)	4	V	V	√	√	112.50	415
Orgaran (anti-Xa)	2		V		√	57.50	205
Fondaparinux (anti-Xa)	2		V		√	57.50	206
Rivaroxaban (anti-Xa)	2		V		√	57.50	207
Apixaban (anti-Xa)	2		V		√	57.50	208
Edoxaban (anti-Xa)	2		V		√	57.50	221
Argatroban (anti-lla/dTT)	2		V		V	57.50	209
Dabigatran (anti-Ila/dTT)	2		V		√	57.50	210
Homocysteine	4	V	V	√	√	110.00	416

ROTEM/TEG PROGRAMME							
	Number of	Surveys					Product
Description	Surveys	2019-T1	2019-T2	2019-T3	2019-T4	(Euro) #	code
ROTEM delta 1 instrument / 1 set of samples ROTEM 2 instruments / 2 sets of samples ROTEM 3 instruments / 3 sets of samples ROTEM	4	√	√	V	V	282.50 480.25 678.00	212 213 214
ROTEM sigma 1 instrument / 1 set of samples ROTEM 2 instruments / 2 sets of samples ROTEM 3 instruments / 3 sets of samples ROTEM	4	V	V	V	V	307.50 522.75 738.00	215 216 217
TEG □ 1 instrument / 1 set of samples TEG □ 2 instruments / 2 sets of samples TEG □ 3 instruments / 3 sets of samples TEG	4	√	√	√	√	282.50 480.25 678.00	218 219 220

D-DIMER PROGRAMME							
Description	Number Surveys			Price	Product		
2000	Surveys	2019-D1	2019-D2	2019-D3	2019-D4	(Euro) #	code
D-Dimer	4	√	√	V	V	125.00	405

SCREEN PROGRAMME									
	Number	Number Surveys					Price	Product	
Description	of Surveys	2019 S1	2019 S2	2019 S3	2019 S4	2019 S5	2019 S6	(Euro) #	code
Screen - I: APTT, PT/INR and Fibrinogen	6	√	√	√	√	$\sqrt{}$	√	165.00	501
Screen - II: Thrombin Time, Reptilase Time	6	V	√	√	√	√	√	165.00	502

POCT INR QC PROGRAMME No annual subscription fee applicable if only participating in the POCT INR QC Programme.							
Number Surveys					Price (Euro)	Product	
Description	of Surveys	2019-Q1	2019-Q2	2019-Q3	2019-Q4	Excl. VAT *	code
POCT INR QC Programme for CoaguChek INR monitors (any type) 4							
* Annual shipping costs for countries outside Europe: on request.							

OTHER SURVEYS								
Description	Organised by	Number of Surveys	Survey period(s)	Price (Euro) #	Product code			
Post Analytical Platelet Function EQA (electronic survey)	Nascola, USA	2	Spring, Autumn	150.00	701			
Platelet Dense Granule exercise (electronic survey)	Nascola, USA	2	Spring, Autumn	150.00	704			
Case studies on bleeding disorders (distribution separately from the regular surveys)	ECAT/ INSTAND	2	Spring, Autumn	200.00	703			
Pre- and post-analytical electronic surveys in haemostasis	ECAT	1	Autumn	75.00	705			

	MOLECULAR BIOLOGY (In co-op	eration wi	th the DG	(L, Germar	ny)	
MOLECULAR G	ENETICS MG1					
Survey	ırvey Description		Surveys		Price	Product
		surveys	MG1 1/19	MG1 2/19	(Euro) #	code
MG1 Set A	FV-Leiden, Prothrombin, MTHFR (C677T, A1298C), PAI-I 4G5G	2	√	√	**	601
MG1 Set B	FXIII V34L, GPIIIa, βFib (g455a), VKORC1 (G-1639A/C1173T), FXII c46t, FV-H1299R	2	√	√	**	602
MG1 Set C	a1 PI, Apo E, ApoB100, ACE, CETP	2	$\sqrt{}$	\checkmark	**	603
MG1 Set D	Aldo B (149,174,334), HFE (H63D, C282Y, S65C), LCT c-13910t, NOD2 (R702W, G908R, L1007fins C)	2	√	V	**	604
MG1 Set E	M. Wilson (ATP7B-C3207A), FSAP (Marburg-I), ITGA2 Gplalla C807T, Col1A1 SP1, VDR (Bsml/Apal,TaqI)	2	√	V	**	605
MG1 Set F	Faktor VII (R353Q), AT3 Cambridge Typ I/II, CYP3A5*3	2	√	√	**	606
MOLECULAR G	ENETICS MG2					
Survey	Description	Number	Sur	veys	Price	Product
ou. voy	2000 paon	surveys	MG2 1/19	MG2 2/19	(Euro) #	code
MG2 Set A	TPMT, CYP2C8 (K399R), CYP2C9 *2/*3, UGT1A1 (*28), DPYD *2A (Ex 14 skipping), BCHE A/K, DPYD *13, DPYD D949V (rs67376798)	2	V	V	**	801
MG2 Set B	K-Ras: Codon 12/13/61, BRAF V600E, BRAF V600K, cKit D816V	2	√	V	**	802
MG2 Set C	HLA-B27, TNF alpha (238, 308)	2	√	√	**	803
MG2 Set D	CYP2D6, CYP2C19 (*2/*17), CYP2C19*3	2	√	√	**	804
MG2 Set E	HLA B*5701, CYP2B6*6, ABCB1 (MDR1) c.3435>T, CCR5-del-32bp	2	$\sqrt{}$	√	**	805
MG2 Set F	IL28B (C/T Polymorphismus), IL6 (G174C), CYP3A4*22	2	\checkmark	\checkmark	**	806
PRICES MG1 or	MG2					
	32: One set : € 110.00 Three sets: Two sets: € 170.00 Four sets:	€ 230.00 € 290.00	Five sets Six sets:			
DNA SEQUENC	ING SQ	· · ·				
Description		Number of surveys		veys SQ 2/19	Price (Euro) #	Product code
	g (Sequencing and corresponding diagnostic	2	SQ 1/19 √	√ √	248.00	901
interpretation)	u Di					
DNA ISOLATION	N DI	Number of	Sur	veys	Price	Product
Description	Description		DI 1/19	DI 2/19	(Euro) #	code
The FV genotyping FV-H1299R (HIS12	DNA isolation and FV genotyping) <u>i includes:</u> FV-Leiden (ARG506GLN), 299ARG), FV-Cambridge (ARG306THR), RG306GLY), FII g20210a, MTHFR C677T, Y S65C)	2	V	V	124.00	902

Shipment Costs:

Prices includes delivery of samples by regular postal service.

When delivery of samples by courier service is required, additional costs have to be paid. These costs depend on the country of delivery. For questions about delivery by courier service, please contact the ECAT office.



DETAILED SAMPLE INFORMATION

lyophilised lyophilised
lyophilised
<u> </u>
vonhilised
yopiilliseu
lyophilised
um, lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
lyophilised
-
lyophilised
-
tion, lyophilised
tion, lyophilised
tion, lyophilised
tion, lyophilised



DETAILED SAMPLE	INFORMATION	
Description	Measuring range (approx.)	Number of participants (approx.)
Thrombophilia - I:		
Antithrombin (activity and antigen), Protein C (activity [chromogenic and clotting] and antigen), Protein S activity,	20 – 120%	385
Protein S antigen (total and free)		
Thrombophilia - II	normal / FV Leiden	270
APC Resistance Lupus Anticoagulant / Antiphospholipid Antibodies	negative - positive	600
Coagulation Factor - I		
Factor VIII, IX, XI and XII	0 – 200%	345
Coagulation Factor - II	0 – 200%	250
Factor II, V, VII and X Von Willebrand Factor parameters		
(antigen, activity, collagen binding, multimers, Factor VIII)	0 – 125%	360
ADAMTS13 - I (activity and antigen)	0 – 125%	110
ADAMTS13 - II (antibodies)	0 – 10 BU/mL	65
Factor XIII (activity and antigen)	0 – 120%	170
Fibrinolysis - I		
Plasminogen, Antiplasmin	0 – 120%	145
Fibrinolysis - II t-PA, PAI-1	0 – 50 ng/mL	65
Factor VIII inhibitor	0 – 15 BU/mL	345
Factor IX Inhibitor	0 – 15 BU/mL	250
Thrombin Generation Test	normal / abnormal	55
HIT - I (immunological testing)	negative / positive	400
Unfractionated Heparin Monitoring (anti-Xa)	0 – 1.25 IU/mL	155
Low-Molecular Weight Heparin Monitoring (anti-Xa)	0 – 1.25 IU/mL	280
Orgaran (anti-Xa)	therapeutic range	130
Fondaparinux (anti-Xa)	therapeutic range	120
Rivaroxaban (anti-Xa)	therapeutic range	240
Apixaban (anti-Xa)	therapeutic range	210
Edoxaban (anti-Xa)	therapeutic range	New
Argatroban (anti-lla, dTT)	therapeutic range	45
Dabigatran (anti-lla, dTT)	therapeutic range	200
Homocysteine	0 – 100 μmol/L	50
ROTEM delta	normal - pathological	80
ROTEM sigma	normal - pathological	20
TEG	normal - pathological	20
D-Dimer	normal - elevated	650
Screen - I:		
APTT, PT	normal – prolonged	310
INR Fibringen	1.0 - 5.0	
Fibrinogen Screen - II: Thrombin Time, Reptilase Time	1.0 – 4.0 g/L normal – prolonged	80
POCT INR QC Programme	2 – 4.5	35
Post Analytical Platelet Function EQA (electronic survey)	-	95
Platelet Dense Granule exercise (electronic survey)	-	15
· · · · · · · · · · · · · · · · · · ·	-	
Case studies on bleeding disorders	-	75
Pre- and post-analytical electronic surveys in haemostasis	-	60

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.



PROGRAMME DETAILS

Instructions for use of the samples will be given in the Survey Manual (provided at the beginning of 2019) and the Survey Instructions (provided with each survey).

Molecular Biology

In co-operation with the DGKL 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 see page 8. The material provided is purified DNA.

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-Granual Survey:

In co-operation with the NASCOLA in the United States twice per year a platelet dense-granule survey is provided. This is a paper or electronic challenge in which electron microscopy images have to be evaluated.

Case studies on bleeding disorders:

Case studies 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.

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 DGKL.

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:



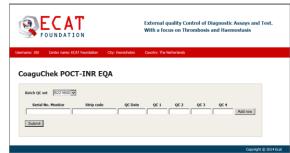
The control samples must now be mixed well with the water. This should be

- Firmly hold the bottle as shown in the photo opposite.

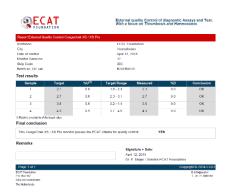
 Turn the bottle upside down and back up again by rotating your lower arm. (The bottle must not be shaken, as this will cause foam to appear in the bottle of the control sample. This must be avoided.)
- · Repeat this action 5 times.
- Repeat this procedure for all control sample bottles.
 Then leave the bottles to stand for 15 minutes.

During this time prepare the CoaguChek monitor for use.

• Online evaluation tool: (evaluation report immediately available)



• Clearly structured and informative evaluation report:



POCT INR QC 2019

For 2019 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 on page 13. Information about the cost is given on page 6.

Registration POCT INR QC Programme:

Registration for this POCT INR QC Programme is included in the online registration form 2019.

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	67.50	ECAT11001	

^{**} Shipping and handling costs per order:

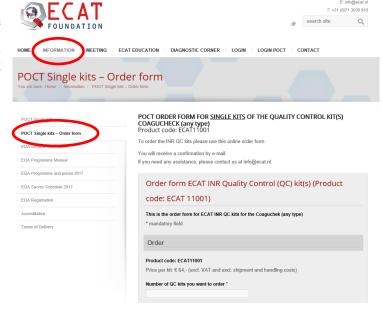
- within the Netherlands: € 10.=
- within Europe: € 20,=
- outside Europe: price on request

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 (Information \rightarrow 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.





SURVEY SCHEDULE 2019

MAIN PROGRAMME								
Survey	Survey Sample dispatch date Survey period start Survey period end Survey report availa							
2019 - M1	5 March	5 March	2 April	30 April				
2019 - M2	4 June	4 June	2 July	30 July				
2019 - M3	27 August	27 August	24 September	22 October				
2019 - M4	12 November	12 November	10 December	14 January 2020				

ROTEM/TEG PROGRAMME							
Survey	Survey Sample dispatch date Survey period start Survey period end Survey report available						
2019 - T1	5 March	5 March	2 April	30 April			
2019 - T2	4 June	4 June	2 July	30 July			
2019 – T3	27 August	27 August	24 September	22 October			
2019 – T4	12 November	12 November	10 December	14 January 2020			

D-DIMER PROGRAMME							
Survey	vey Sample dispatch date Survey period start Survey period end Survey report av						
2019 - D1	February 2019	11 March	19 March	29 March			
2019 - D2		17 June	25 June	5 July			
2019 - D3		9 September	17 September	27 September			
2019 - D4		25 November	3 December	13 December			

SCREEN PROGRAMME						
Survey	Sample dispatch date	Survey report available				
2019 - S1		18 February	22 February	4 March		
2019 - S2	Early February 2019	8 April	12 April	23 April		
2019 - S3		17 June	21 June	1 July		
2019 - S4		19 August	23 August	2 September		
2019 - S5		14 October	18 October	28 October		
2019 - S6		2 December	6 December	16 December		

POCT INR QC PROGRAMME							
Quarter Sample dispatch date Survey period start Survey period end Survey report available							
2019 - Q1	19 February	19 February	31 March	30 April			
2019 - Q2	2 April	2 April	30 June	31 July			
2019 - Q3	2 July	2 July	30 September	31 October			
2019 - Q4	1 October	1 October	31 December	31 January 2020			

OTHER SURVEYS					
Survey	Period				
Post Analytical Platelet Function EQA (electronic survey)	Spring, Autumn (2 surveys per year)				
Platelet Dense Granule exercise (electronic survey)	Spring, Autumn (2 surveys per year)				
Case studies on bleeding disorders	Spring, Autumn (2 surveys per year)				
Pre- and post-analytical electronic surveys in haemostasis	Autumn (1 survey per year)				

	MOLECULAR BIOLOGY (via DGKL, Germany)								
Survey	Sample dispatch date	Survey period start	Survey period end						
MG1 1/19	13 March	18 March	6 April						
MG1 2/19	4 September	9 September	28 September						
MG2 1/19	13 March	18 March	6 April						
MG2 2/19	4 September	9 September	28 September						
SQ 1/19	6 March	11 March	6 April						
SQ 2/19	28 August	2 September	28 September						
DI 1/19	6 March	11 March	6 April						
DI 2/19	28 August	2 September	28 September						



REGISTRATION

Registration

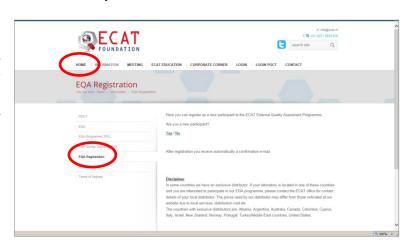
The available modules and corresponding prices are updated annually. Either combination of modules can be selected. It is possible to start any time during the year. The registration will start the first survey scheduled after the registration is received and will continue until the end of the year.

Registration to the ECAT EQAP can be done via our website (www.ecat.nl). Select in the menu "Information" followed by "EQA Registration". Follow 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) Type of annual subscription
- 2) Modules
- 3) Contact details



Terms of delivery

The terms of delivery of the ECAT Foundation can be found on our website. If you want a printed copy, please contact our office.

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 receipt of the first samples a Survey Manual is supplied, as well as more detailed information about the registration, an unique laboratory code and the website login code.

Survey Manual

Every year all participants receive an updated Survey Manual. This Manual gives instructions how to perform the surveys. This includes:

- the survey schedule
- 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

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. When the invoice is not paid in due time the registration will be cancelled.

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.



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:

ECAT N

Sample : 13.03Volume : 0.75 mL
Survey : 2013-1

Module : Thrombophilia

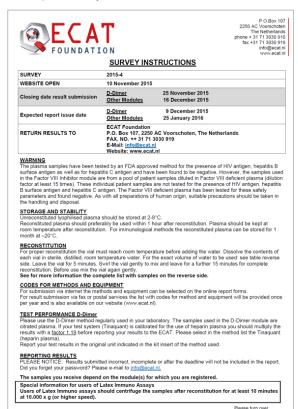
Survey Instructions

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:



Page 1 of 2

Samples	Survey 2015-4:			
Sample code	Volume (mL)	Vials per sample	Module Code on vial	Module
15.124	0.75 (per vial)	code 2	Thrombophilia	Thrombophilia Module; Antithrombin (activity and antigen) Protein C (activity [chromogenic and clotting] and antigen Protein S activity, Protein S antigen (total and free)
15.125	1.00 (per vial)	2	Thrombophilia	Thrombophilia Module (see above)
15.126	1.00	1	APCR	Thrombophilia Module; for APC Resistance only
15.127	0.75	1	APCR	Thrombophilia Module; for APC Resistance only
15.128	0.75 (per vial)	2	Lupus	Lupus Anticoagulant
15.129	1.00	1	D-Dimer	D-Dimer
15.130	1.00	1	D-Dimer	D-Dimer
15.131	0.75 (per vial)	2	CFM I	Coagulation Factors Module I (Factor VIII, IX, XI and XII)
15.132	1.00 (per vial) 1.00 (per vial)	2	CFM I	Coagulation Factors Module I (Factor VIII, IX, XI and XII) Coagulation Factors Module II (Factor II, V, VII and X)
15.133 15.134	1.00 (per vial) 0.75 (per vial)	2	CFM II	Coagulation Factors Module II (Factor II, V, VII and X) Coagulation Factors Module II (Factor II, V, VII and X)
15.135	0.75 (per vial)	2	VWF	Von Willebrand Factor
15.136	0.75 (per viai)	1	ADAM act/ag.	ADAMTS-13 (activity and antigen)
15.137	1.00	1	ADAM act/ag.	ADAMTS-13 (activity and antigen)
15.138	0.50	1	ADAM inh.	ADAMTS-13 (inhibitor)
15.139	0.50	1	ADAM inh.	ADAMTS-13 (inhibitor)
15.140	1.00	1	FXIII	Factor XIII
15.141	1.00	1	FXIII	Factor XIII
15.142	1.00	1	Fibrinolysis I	Fibrinolysis Parameters I (Plasminogen, Antiplasmin)
15.143	1.00	1	Fibrinolysis I	Fibrinolysis Parameters I (Plasminogen, Antiplasmin)
15.144	0.50	1	Fibrinolysis II	Fibrinolysis Parameters II (t-PA, PAI-1)
15.145	1.00	1	Fibrinolysis II	Fibrinolysis Parameters II (t-PA, PAI-1)
15.146	1.00	1	UFH	Anti-Xa (Unfractionated Heparin)
15.147 15.148	1.00	1	LMWH	Anti-Xa (Unfractionated Heparin) Anti-Xa (Low Molecular Weight Heparin)
15.149	1.00	1	LMWH	Anti-Xa (Low Molecular Weight Heparin) Anti-Xa (Low Molecular Weight Heparin)
15.150	1.00	1	Homocysteine	Homocysteine
15,151	1.00	1	Homocysteine	Homocysteine
15.152	0.75	1	FVIII-inh	Factor VIII Inhibitor
15.153	0.75	1	FVIII-inh	Factor VIII Inhibitor
X	(Only survey 1+3)	1	FIX-inh	Factor IX Inhibitor
Х	(Only survey 1+3)	1	FIX-inh	Factor IX Inhibitor
15.154	0.75	1	TGT	Thrombin Generation Test
15.155 15.156	1.00	1	TGT	Thrombin Generation Test
10:100	1100	1	TGT	Thrombin Generation Test
X	(Only survey 3)	1	HIT	HIT (immunological test) HIT (immunological test)
15.157	1.00	1	Orgaran	Organan Organia
15.158	1.00	1	Orgaran	Orgaran
15.159	1.00	1	Fondaparinux	Fondaparinux
15.160	1.00	1	Fondaparinux	Fondaparinux
15.161	1.00	1	Rivaroxaban	Rivaroxaban
15.162	1.00	1	Rivaroxaban	Rivaroxaban
15.163	1.00	1	Apixaban	Apixaban
15.164	1.00	1	Apixaban	Apixaban
15.165	1.00	1	Argatroban	Argatroban
15.166	1.00	1	Argatroban	Argatroban
15.167	1.00	1	Dabigatran	Dabigatran
15.168	1.00	1	Dabigatran	Dabigatran

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). In accordance with ISO standard 17043:2010 and ISO standard 13528:2015 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 the screening assays and homocysteine a minimum of 5 participants is used). If the group size is less than 10 participants (in the case of the screening assays and homocysteine 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 the screening assays and homocysteine 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 15328 the following acceptance criteria are used:

-2 < 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 a 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. A printed example can be provided on request (extra costs). 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.



INFORMATION ECAT SURVEYS

The following survey reports are produced:

- Screen assays
- D-Dimer
- Lupus Anticoagulant
- Thrombin Generation Test
- HIT
- ROTEM/TEG
- 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. The header
- 2. The graph
- 3. The table
- 4. Z-score plot
- 5. Z-score history plot

The header

The header of each report sheet consist of two parts. At the top of each page the survey number, number of pages of the report, the date the report is issued and the labcode is indicated. Also the name of the module and the analyte is indicated.



External quality Control for Assays and Tests With a focus on Thrombosis and Haemostasis Survey: 2017-M1 Page 4 of 115 01-May-2017 Labcode: 100

Thrombophilia - I

Antithrombin activity

In addition, information about the number of responders, the sample used, the units in which the results are reported, the stability and homogeneity of the sample are given

Example of general information

Sample No 17.28

Sample Details Normal Coagulation Control Plasma

 Prior Use
 Prior Use: None

 Unit
 Units: % or IU/dL

 Expiry Date
 30-November-2018

Homogeneity 1.9 % Homogeneity Parameter Antithrombin

Number of Participants 362

Number of Responders 320 Response Rate 88 %

Comments

When appropriate the clinical classification is given in a separate table.

Example of classification table

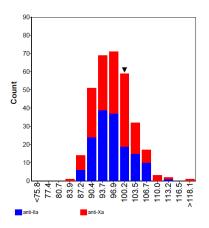
Classification	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	311	1	1	3	4

The graph

The distribution of the results is represented in a histogram.

Depending of the analyte 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.



The table

The table given in the report show the descriptive statistics for all results and for each assay principle and method.

The target 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 the screen assay and homocysteine this number is 5).

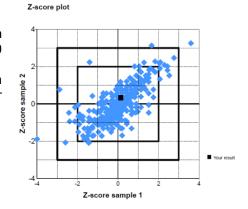
The group(s) to which your results belongs are highlighted in grey.

		value	(70)	range	result	2 000.0
Total Group	320	97	5.3	84 - 122	100	0.66
Chromogenic, anti-lla	151	96	5.0	86 - 112		
Homemade	1	97				
Hyphen Biophen AT (anti-IIa)	1	102				
Other	1	100				
Siemens Antithrombin III	49	95	5.1	86 - 112		
Stago Stachrom ATIII	98	97	4.9	88 - 107		
Tcoag TriniCHROM Antithrombin IIa	1	98				
Chromogenic, anti-Xa	169	97	5.5	84 - 122	100	0.58
Chromogenix Coamatic Antithrombin	15	98	5.0	92 - 107		
Chromogenix Coamatic LR Antithrombin	2	99		93 - 105		
Hyphen Biophen Antithrombin (anti-Xa)	3	97		92 - 104		
Hyphen Biophen AT (LRT)	2	96		90 - 101		
I.L. HemosIL Antithrombin	5	102		91 - 114		
I.L. HemosIL liquid Antithrombin	82	98	5.0	84 - 122	100	0.41
Sekisui Coagpia Antithrombin	1	92				
Siemens Innovance AT	58	95	5.4	86 - 111		
Sysmex L system AT	1	93				

Z-score plot

The relationship of the Z-scores of the two different samples are plotted in a Z-score plot. The Z-score plot only includes methods with at least 10 participants.

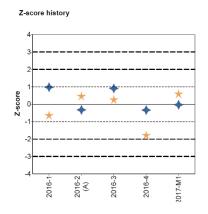
The relationship of both Z-scores gives an indication if the deviation from the mean value of your particular method is caused by systematic and/or random errors.



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 overview

At the front of the main 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 give. An example of such a summary table is given below.

	OVERVIEW Z-SCORES								
Satisfactory (-2 ≤ Z-score ≤ 2) Need attention (-3 ≤ Z-score < -2 to ≤ -3 or 2 to ≤ 3) Unsatisfactory (Z-score < -3 or > 3)									
Module	Parameter	Sample	Total	Assay	Method				
Thrombophilia - I	Antithrombin activity	17.27	-0.17	-0.03	-0.09				
		17.28	0.66	0.58	0.41				
	Protein C clotting activity	17.27	1.31	1.31	1.02				
		17.28	-0.62	-0.62	-0.69				
	Free Protein S antigen	17.27	0.48	0.52	0.18				
		17.28	0.98	0.98	0.27				
Thrombophilia - II	APC Resistance (with FV deficient	17.29			-1.24				
		17.30			-1.68				
Coagulation Factor - I	Factor VIII (clotting activity)	17.32	-0.58	-0.58	0.33				
		17.33	-1.26	-1.27	-1.21				
	Factor XII	17.32	0.86	0.84					
		17.33	0.28	0.28					
Coagulation Factor - II	Factor V	17.34	1.20	1.20	1.75				
		17.35	2.19	2.19	2.11				
LMWH Heparin	ANTI-Xa (Low Molecular Weight He	17.47	-0.75	-0.75	-0.45				
		17.48	-0.34	-0.34	-0.39				

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.

Each year also a special issue is composed on a specific theme. For instance in 2018 the theme of special issue was "Platelet Function Disorders".

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' meeting

Every even year the ECAT organises a participants' meeting in Leiden, The Netherlands. The programme of this meeting focuses on laboratory-related topics in the field of thrombosis and haemostasis. This participants' meeting is free-of-charge for participants in the ECAT External Quality Assessment Programme.

In conjunction with the participants' meeting the ECAT organises frequently special courses with topics related to the laboratory diagnosis of haemostasis and/or quality of laboratory diagnosis. For these course a fee will be charged.

Further information can be found on our website.

The next ECAT Participants' Meeting will be on **5 and 6 November 2020**. All participants are informed in advance about the details of the programme as well as registration procedure.