ECAT FOUNDATION

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



PROGRAMME MANUAL 2018

ECAT FOUNDATION

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BIC code: INGBNL2A

Dear sir, dear madam,

It is our pleasure to present you our Programme Manual 2018. This Programme Manual provides you with background information about our organisation and the ECAT external quality assessment programme 2018.

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 1500 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 2017 the ECAT programme includes 28 modules for regular laboratory tests, 1 module for case studies and 1 electronic module for the pre- and post-analytical phase. ECAT provides also quality control for the CoaguChek XS/XS Pro INR monitor. 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.



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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 1992.

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 Office Manager

Mrs. A. Veninga Scheme Manager / Quality Manager

Mrs. M. Van der Voorn Survey Manger Mrs. W. Hogenboom Financial Manager

Mrs. G. Zandbergen Financial Officer / Survey Assistant

Mrs. A. de Haan Survey Assistant

Members of Supervisory Board

Name Specialism Position Prof. Dr. C. Kluft Biochemist Chairman Dr. M.P.M. de Maat Biochemist/epidemiologists/clinical chemist Secretary/Deputy chairman Ir. D.C. van Cuilenburg Accountant Member Clinical chemist Member Dr. F. Haas Member Dr. H.W. Verbruggen **Biochemist** Member Dr. F.J.M. van der Meer Internist Dr. J. Ruinemans-Koerts Clinical chemist 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
- 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.



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GENERAL INFORMATION ECAT FOUNDATION

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, Israel, New Zealand, Norway, Portugal, Turkey/Middle-East countries, United States.



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)	87.50	101					
Annual Subscription Fee (result submission via internet / survey report via internet + by post)	137.50	102					

	MAIN P	ROGRAM	ME				
Pagarintian	Number		Surv	Price	Product		
Description	Surveys	2018-M1	2018-M2	2018-M3	2018-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	355.00	402
Thrombophilia - II APC Resistance	4	V	√	√	$\sqrt{}$	137.50	417
Lupus Anticoagulant / Antiphospholipid Antibodies	4	V	√	√	V	137.50	404
Coagulation Factor - I Factor VIII, IX, XI and XII	4	√	√	√	V	125.50	406
Coagulation Factor - II Factor II, V, VII and X	4	√	√	√	V	125.50	407
Von Willebrand Factor parameters (antigen, activity, collagen binding, multimers, Factor VIII)	4	√	V	V	V	125.50	408
ADAMTS13 - I (activity and antigen)	4	V	√	√	√	162.50	409
ADAMTS13 - II (antibodies)	2		V		√	85.00	410
Factor XIII (activity and antigen)	4	V	√	√	√	125.50	411
Fibrinolysis - I Plasminogen, Antiplasmin	4	√	√	√	V	125.50	412
Fibrinolysis - II t-PA, PAI-1	4	√	√	√	V	125.50	413
Factor VIII inhibitor	2		$\sqrt{}$		$\sqrt{}$	142.50	202
Factor IX Inhibitor	2			$\sqrt{}$		142.50	201
Thrombin Generation Test	2		$\sqrt{}$		$\sqrt{}$	135.00	203
HIT - I (immunological testing)	1			$\sqrt{}$		85.00	204
Unfractionated Heparin Monitoring (anti-Xa)	4	V	√	√	√	116.50	414
Low-Molecular Weight Heparin Monitoring (anti-Xa)	4	√	√	√	√	116.50	415
Orgaran (anti-Xa)	2		V		√	59.00	205
Fondaparinux (anti-Xa)	2		V		√	59.00	206
Rivaroxaban (anti-Xa)	2		V		√	59.00	207
Apixaban (anti-Xa)	2		V		√	59.00	208
Argatroban (anti-IIa, dTT)	2		√		√	59.00	209
Dabigatran (anti-Ila, dTT)	2		√		√	59.00	210
Homocysteine	4	V	V	√	V	98.50	416

ROTEM/TEG PROGRAMME							
Description	Number of	Sur	veys	Price	Product		
Description	Surveys	2018-T1	2018-T2	(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	2	V	√	140.00 237.50 336.00	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	2	V	V	140.00 237.50 336.00	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	2	V	V	140.00 237.50 336.00	218 219 220		

D-DIMER PROGRAMME							
Description	Number of		Surveys			Price	Product
2000. р. 1011		2018-D1	2018-D2	2018-D3	2018-D4	(Euro) #	code
D-Dimer 1 set of samples / max. 3 instruments	4	√	√	$\sqrt{}$	$\sqrt{}$	120.00	405

SCREEN PROGRAMME									
Description	Number of Surveys	Number Surveys				Price	Product		
		2018 S1	2018 S2	2018 S3	2018 S4	2018 S5	2018 S6	(Euro) #	code
Screen - I: APTT, PT/INR and Fibrinogen 1 set of samples / max. 3 instruments	6	V	V	√	V	V	√	161.00	501
Screen - II: Thrombin Time 1 set of samples / max. 3 instruments	6	√	√	√	√	√	$\sqrt{}$	161.00	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	2018-Q1	2018-Q2	2018-Q3	2018-Q4	Excl. VAT *	code	
POCT INR QC Programme for CoaguChek INR monitors (any type)	4	√	√	√	√	350.00	301	
* 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 DGK	(I German	nv)	
MOLECULAR G	<u> </u>	Cration W		te, commu	· y /	
	-	Number	Sur	veys	Price	Product
Survey	Description	of surveys	MG1 1/18	MG1 2/18	(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	√	√	**	603
MG1 Set D	Aldo B (149,174,334), HFE (H63D, C282Y, S65C), LCT c-13910t, NOD2 (R702W, G908R, L1007fins C)	2	√	√	**	604
MG1 Set E	M. Wilson (ATP7B-C3207A), FSAP (Marburg-I), ITGA2 Gplalla C807T, Col1A1 SP1, VDR (Bsml/Apal,TaqI)	2	√	√	**	605
MG1 Set F	Faktor VII (R353Q), AT3 Cambridge Typ I/II, CYP3A5*3	2	√	√	**	606
MOLECULAR G	ENETICS MG2					
Cumian	Description	Number	Sur	veys	Price	Product
Survey	Description	of surveys	MG2 1/18	MG2 2/18	(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	√	**	801
MG2 Set B	K-Ras: Codon 12/13/61, BRAF V600E, BRAF V600K, cKit D816V	2	√	√	**	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	√	√	**	805
MG2 Set F	IL28B (C/T Polymorphismus), IL6 (G174C), CYP3A4*22	2	√	√	**	806
PRICES MG1 or	MG2					
** <u>MG1 or MC</u>	32: One set : € 106.00 Three sets: T wo sets: € 162.00 Four sets:	€ 218.00 € 274.00	Five sets Six sets:			
DNA SEQUENC	ING SQ					
Description		Number of	Sur	veys	Price	Product
Description		surveys	SQ 1/18	SQ 2/18	(Euro) #	code
DNA Sequencin interpretation)	g (Sequencing and corresponding diagnostic	2	√	√	248.00	901
DNA ISOLATION	N DI					
Description		Number of	Sur	veys	Price	Product
Description		surveys	DI 1/18	DI 2/18	(Euro) #	code
The FV genotyping FV-H1299R (HIS12	DNA isolation and FV genotyping) <u>Includes:</u> FV-Leiden (ARG506GLN), 299ARG), FV-Cambridge (ARG306THR), RG306GLY), FII g20210a, MTHFR C677T, Y, S65C)	2	V	V	116.00	902



DETAILED SAMPLE INFORMATION

DETAILED SAMPLE INFORMATION					
Description	Number of different samples per survey	Number of vials per sample code	Component		
Thrombophilia - I:					
Antithrombin (activity and antigen), Protein C (activity	2	2	Plasma, lyophilised		
[chromogenic and clotting] and antigen), Protein S activity, Protein S antigen (total and free)					
Thrombophilia - II APC Resistance	2	1	Plasma, lyophilised		
Lupus Anticoagulant / Antiphospholipid Antibodies	1	2	Plasma, lyophilised		
Coagulation Factor - I	2				
Factor VIII, IX, XI and XII	2	2	Plasma, lyophilised		
Coagulation Factor - II Factor II, V, VII and X	2	2	Plasma, lyophilised		
Von Willebrand Factor parameters	1	2	Plasma, lyophilised		
(antigen, activity, collagen binding, multimers, Factor VIII) ADAMTS13 - I (activity and antigen)					
· · · · · · · · · · · · · · · · · · ·	2	1	Plasma, lyophilised		
ADAMTS13 - II (antibodies)	2	1	Plasma, lyophilised		
Factor XIII (activity and antigen)	2	1	Plasma, lyophilised		
Fibrinolysis - I Plasminogen, Antiplasmin	2	1	Plasma, lyophilised		
Fibrinolysis - II t-PA, PAI-1	2	1	Plasma, lyophilised		
Factor VIII inhibitor	2	1	Plasma, lyophilised		
Factor IX Inhibitor	2	1	Plasma, lyophilised		
Thrombin Generation Test	3	1	Plasma, lyophilised		
HIT - I (immunological testing)	2	1	Plasma or serum, lyophilised		
Unfractionated Heparin Monitoring (anti-Xa)	2	1	Plasma, lyophilised		
Low-Molecular Weight Heparin Monitoring (anti-Xa)	2	1	Plasma, lyophilised		
Orgaran (anti-Xa)	2	1	Plasma, lyophilised		
Fondaparinux (anti-Xa)	2	1	Plasma, lyophilised		
Rivaroxaban (anti-Xa)	2	1	Plasma, lyophilised		
Apixaban (anti-Xa)	2	1	Plasma, lyophilised		
Argatroban (anti-lla, dTT)	2	1	Plasma, lyophilised		
Dabigatran (anti-Ila, dTT)	2	1	Plasma, lyophilised		
Homocysteine	2	1	Plasma, lyophilised		
ROTEM delta (per sample set)	2	2	Plasma, lyophilised		
ROTEM sigma (per sample set)	2	3	Plasma, lyophilised		
TEG (per sample set)	2	2	Plasma, lyophilised		
D-Dimer	2	1	Plasma, lyophilised		
Screen - I: APTT, PT/INR and Fibrinogen	2	1	Plasma, lyophilised		
Screen - II: Thrombin Time	2	1	Plasma, lyophilised		
POCT INR QC Programme	4	1	Plasma, lyophilised		
Post Analytical Platelet Function EQA (electronic survey)	-	-	-		
Platelet Dense Granule exercise (electronic survey)	-	-	-		
Case studies on bleeding disorders	1	1 or 2	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	DNA preparation, lyophilised		
ואוסוומנוטוו		I	DINA preparation, tyophilised		



PROGRAMME DETAILS

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, Protein S antigen (total and free)	20 – 120%	375			
Thrombophilia - II APC Resistance	normal / FV Leiden	260			
Lupus Anticoagulant / Antiphospholipid Antibodies	negative - positive	575			
Coagulation Factor - I Factor VIII, IX, XI and XII	0 – 200%	280			
Coagulation Factor - II Factor II, V, VII and X	0 – 200%	235			
Von Willebrand Factor parameters (antigen, activity, collagen binding, multimers, Factor VIII)	0 – 125%	320			
ADAMTS13 - I (activity and antigen)	0 – 125%	100			
ADAMTS13 - II (antibodies)	0 – 10 BU/mL	65			
Factor XIII (activity and antigen)	0 – 120%	155			
Fibrinolysis - I Plasminogen, Antiplasmin	0 – 120%	140			
Fibrinolysis - II t-PA, PAI-1	0 – 50 ng/mL	70			
Factor VIII inhibitor	0 – 15 BU/mL	285			
Factor IX Inhibitor	0 – 15 BU/mL	175			
Thrombin Generation Test	normal / abnormal	50			
HIT - I (immunological testing)	negative / positive	370			
Unfractionated Heparin Monitoring (anti-Xa)	0 – 1.25 IU/mL	145			
Low-Molecular Weight Heparin Monitoring (anti-Xa)	0 – 1.25 IU/mL	255			
Orgaran (anti-Xa)	therapeutic range	115			
Fondaparinux (anti-Xa)	therapeutic range	115			
Rivaroxaban (anti-Xa)	therapeutic range	230			
Apixaban (anti-Xa)	therapeutic range	195			
Argatroban (anti-Ila, dTT)	therapeutic range	45			
Dabigatran (anti-Ila, dTT)	therapeutic range	200			
Homocysteine	0 – 100 μmol/L	60			
ROTEM delta	normal - pathological	50			
ROTEM sigma	normal - pathological	15			
TEG	normal - pathological	15			
D-Dimer	normal - elevated	700			
Screen - I: APTT, PT INR Fibrinogen	normal – prolonged 1.0 – 5.0 1.0 – 4.0 g/L	300			
Screen - II: Thrombin Time	normal – prolonged	55			
POCT INR QC Programme	2 – 4.5	35			
Post Analytical Platelet Function EQA (electronic survey)	-	90			
Platelet Dense Granule exercise (electronic survey)	-	10			
Case studies on bleeding disorders	-	70			
Pre- and post-analytical electronic surveys in haemostasis	_	45			
		.~			

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 2018) 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 once 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.

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.



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:



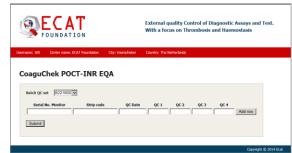
The control samples must now be mixed well with the water. This should be

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

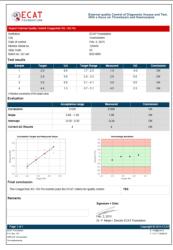
 Turn the bottle upside down and back up again by rotating your lower arm. (The bottle must not be shaken, as this will cause foam to appear in the bottle of the control sample. This must be avoided.)
- · Repeat this action 5 times.
- Repeat this procedure for all control sample bottles.
 Then leave the 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 2018

For 2018 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 5. Information about the cost is given on page 7.

Registration POCT INR QC Programme:

Registration for this POCT INR QC Programme is included in the online registration form 2018.

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	65.50	ECAT11001	

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

- within Europe: € 20,=
- outside Europe: price on request

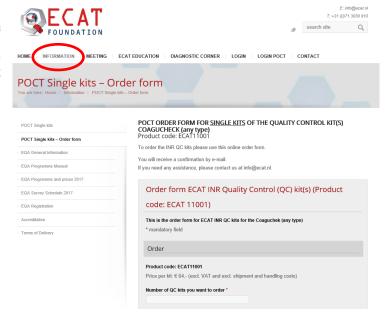
- within the Netherlands: € 10,=

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 2018

	MAIN PROGRAMME							
Survey	Survey Sample dispatch date Survey period start Survey period end Survey report available							
2018 - M1	27 February	27 February	27 March	1 May				
2018 - M2	29 May	29 May	26 June	31 July				
2018 - M3	28 August	28 August	25 September	30 October				
2018 - M4	13 November	13 November	11 December	22 January 2019				

	ROTEM/TEG PROGRAMME							
Survey	Survey Sample dispatch date Survey period start Survey period end Survey report available							
2018 - T1	27 February	27 February	27 March	1 May				
2018 - T2	28 August	28 August	25 September	30 October				

D-DIMER PROGRAMME							
Survey	Survey Sample dispatch date Survey period start Survey period end Survey report available						
2018 - D1	February 2018	12 March	20 March	30 March			
2018 - D2		11 June	19 June	29 June			
2018 - D3		10 September	18 September	28 September			
2018 - D4		26 November	4 December	14 December			

	SCREEN PROGRAMME							
Survey	Sample dispatch date	Survey report available						
2018 - S1		12 February	16 February	23 February				
2018 - S2	Early February 2018	9 April	13 April	20 April				
2018 - S3		11 June	15 June	22 June				
2018 - S4		20 August	24 August	31 August				
2018 - S5		15 October	19 October	26 October				
2018 - S6		3 December	7 December	14 December				

POCT INR QC PROGRAMME							
Quarter	arter Sample dispatch date Survey period start Survey period end Survey report available						
2018 - Q1	14 February	14 February	31 March	30 April			
2018 - Q2	4 April	4 April	30 June	31 July			
2018 - Q3	4 July	4 July	30 September	31 October			
2018 - Q4	3 October	3 October	31 December	31 January 2019			

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	Survey Sample dispatch date Survey period start							
MG1 1/18	14 March	19 March	7 April					
MG1 2/18	19 September	24 September	13 October					
MG2 1/18	14 March	19 March	7 April					
MG2 2/18	19 September	24 September	13 October					
SQ 1/18	7 February	12 February	3 March					
SQ 2/18	29 August	3 September	22 September					
DI 1/18	7 March	12 March	31 March					
DI 2/18	29 August	3 September	29 September					

REGISTRATION

Registration

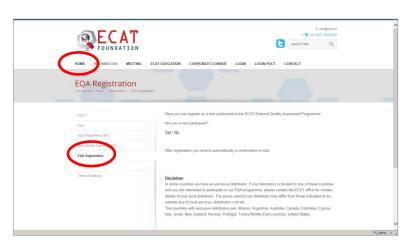
The available modules and corresponding prices are updated annually. Either combination of modules can be selected. It is possible to start any time during the year. The registration will start the first survey scheduled after the registration is received and will continue until the end of the year.

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 :13.03
Volume :0.75 mL
Survey :2013-1
Module :Thrombophilia

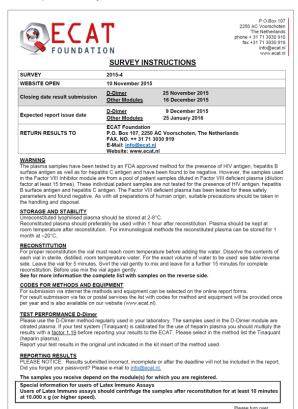
Survey Instructions

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 15.133	1.00 (per vial) 1.00 (per vial)	2	CFM II	Coagulation Factors Module I (Factor VIII, IX, XI and XII) Coagulation Factors Module II (Factor II, V, VII and X)
15.133	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) Anti-Xa (Unfractionated Heparin)
15.148	1.00	1	LMWH	Anti-Xa (Untractionated Heparin) Anti-Xa (Low Molecular Weight Heparin)
15.149	1.00	1	LMWH	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
X 15 154	(Only survey 1+3) 0.75	1	FIX-inh	Factor IX Inhibitor
15.154	1.00	1	TGT	Thrombin Generation Test Thrombin Generation Test
15.155	1.00	1	TGT	Thrombin Generation Test Thrombin Generation Test
X	(Only survey 3)	1	HIT	HIT (immunological test)
χ	(Only survey 3)	1	HIT	HIT (immunological test)
15.157	1.00	1	Orgaran	Organan
15.158	1.00	1	Orgaran	Organan
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
15.166	1.00	1	Argatroban Argatroban	Argatroban Argatroban
15.167	1.00	1	Argatroban Dabigatran	Argatroban Dabigatran
15.168	1.00	1	Dabigatran	Dabigatran
10.100	1	1.	Duoigundii	Davigation

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

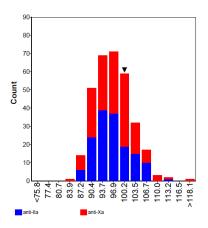
Classification	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	311	1	1	3	4

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).

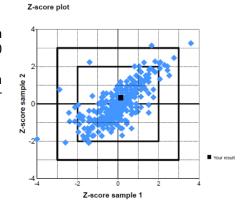
The group(s) to which your results belongs are highlighted in grey.

		value	(,,,		result	
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.

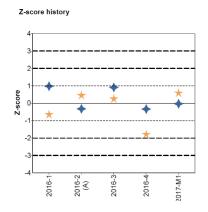
The relationship of both Z-scores gives an indication if the deviation from the mean value of your particular method is caused by systematic and/or random errors.



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 2016 the theme of special issue was "Quality in the Coagulation Laboratory". The issue that will appear by the end of 2017 is entitled "Factor XIII, clinical, laboratory and quality aspects".

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.

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 **8 and 9 November 2018**. All participants are informed in advance about the details of the programme as well as registration procedure.