External Quality Control

A new decade

Piet Meijer
ECAT Foundation
Leiden
The Netherlands

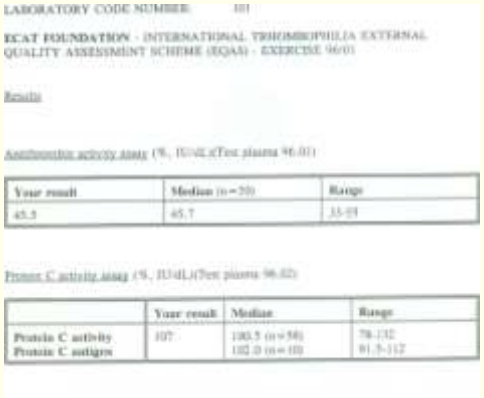
1994

Start of the ECAT Foundation as an independent organisation for external quality assessment in the field of thrombosis.

Thrombophilia module

- Antithrombin
- Protein C
- Protein S
- APC Resistance Testing

Approx. 50 participants in Europe


LABORATORY CODE NUMBER: 101

ECAT FOUNDATION - INTERNATIONAL THROMBOPHILIA EXTERNAL QUALITY ASSESSMENT SCHEME (EQAS) - EXERCISE 96/01

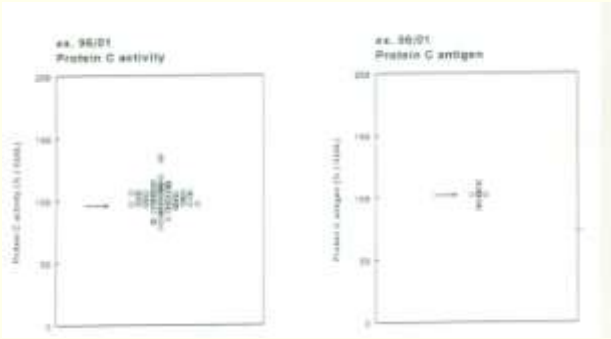
Results

Antithrombin activity assay (%, IU/dL)(Test plasma 96.01)

Your result	Median (n = 20)	Range
45.5	45.7	33-55

Protein C activity assay (%, IU/dL)(Test plasma 96.02)

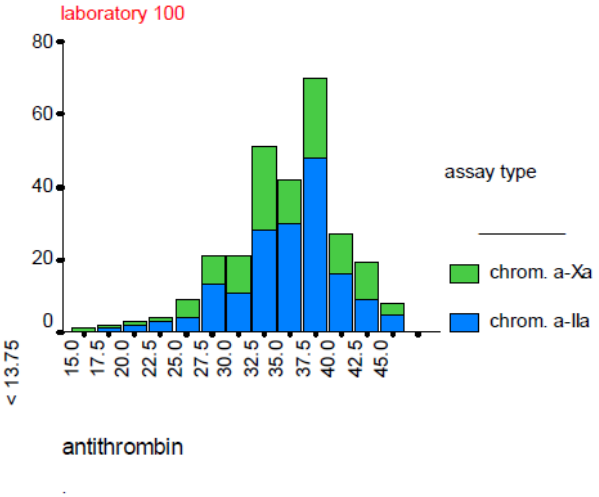
	Your result	Median	Range
Protein C activity	107	100.5 (n = 56)	78-132
Protein C antigen		102.0 (n = 10)	81.5-112



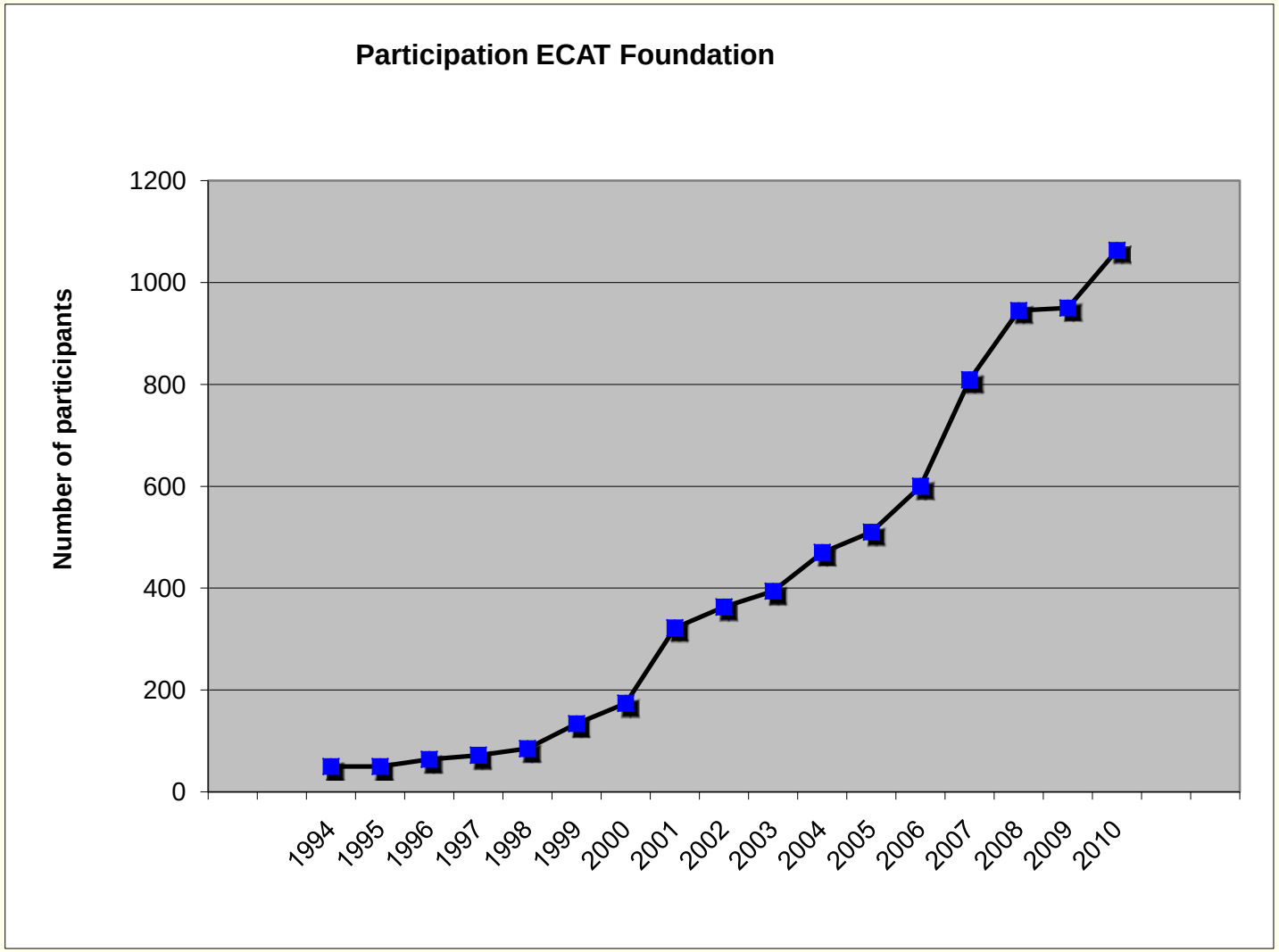
MAIN PROGRAMME

Description
Thrombophilia module Antithrombin (activity and antigen), Protein C (activity [chromogenic and clotting] and antigen), Protein S activity, Protein S antigen (total and free), APC Resistance
Protein C Pathway Test
Lupus Anticoagulant / Antiphospholipid Antibodies
D-Dimer
Coagulation Factor module I (Factor VIII, IX, XI and XII)
Coagulation Factor module II (Factor II, V, VII and X)
Von Willebrand Factor module (antigen, activity, collagen binding, multimers, Factor VIII)
Factor VIII inhibitor ##
Thrombin Generation Test ##
HIT – Immunological assays ##
HIT – Functional assays ##
Factor XIII
Fibrinolysis parameters I (Plasminogen, Antiplasmin)
Fibrinolysis parameters II (t-PA, PAI-1)
Unfractionated Heparin Monitoring (anti-Xa)
Low-Molecular Weight heparin Monitoring (anti-Xa)
Homocysteine
Post Analytical Platelet Function EQA (electronic survey) **$**
Pre- and post-analytical electronic surveys

ANTITHROMBIN (%, IU/dL)



ANTITHROMBIN	n	mean	CV	range	your result	z-score
Total group	**276**	**32.3**	**16.1%**	**16 – 42**		
Chromogenic - anti-IIa	**169**	**32.5**	**15.4%**	**17 – 42**		
Berichrom (Siemens)	64	32.3	13.7%	17 – 40		
Antithrombin Reagent (Siemens)	12	33.3	10.5%	28 – 40		
Stachrom / ATIII (Stago/Roche)	88	32.5	17.0%	17 – 42		
Chromogenic - anti-Xa	**107**	**32.2**	**17.4%**	**16 – 42**		
Coamatic (Chromogenix)	21	32.3	18.2%	18 – 42		
HemosIL liquid Antithrombin (IL)	42	31.2	17.2%	22 – 42		
Innovance Antithrombin (Siemens)	16	36.5	5.6%	32 – 40		

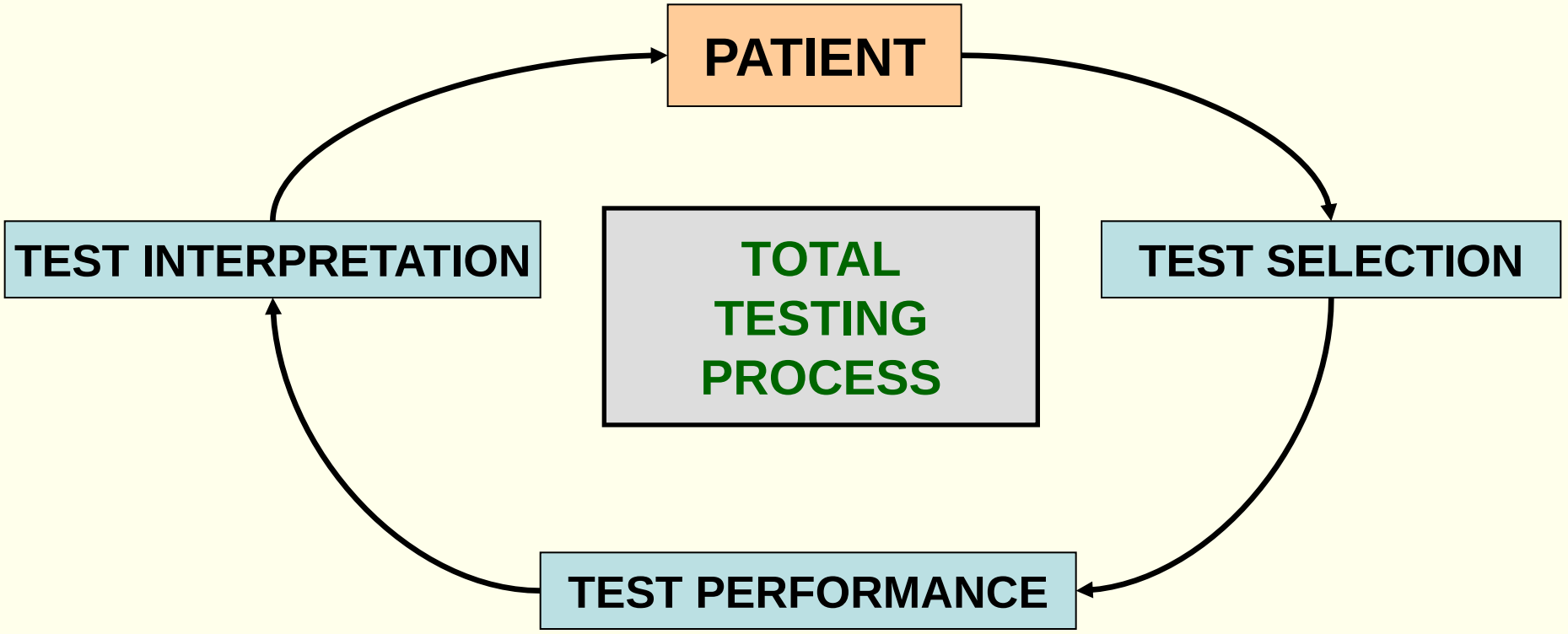


29 Countries Worldwide

One common approach since 1994

Assessment of analytical performance

LABORATORY SERVICE



"Brain-to-brain information loop" Lundberg GD, JAMA (1981);245: 1762 - 1763

Laboratory Services

Pre-analytical phase	Analytical phase	Post-analytical phase
• Question • Test solution • Ordering • Identification • Collection • Transportation • Preparation	• Analysis	• Reporting • Interpretation • Action

External Quality Assessment

Pre-analytical phase	Analytical phase	Post-analytical phase

Traditional EQA

Analytical performance

LABORATORY PERFORMANCE ASSESSMENT

Individual Performance Indicator

Overall lab performance

ANTITHROMBIN	n	mean	CV	range	your result	z-score
Total group	248	47.9	10.2%	36 – 64	44	-0.80
Chromogenic - anti-IIa	165	48.4	9.4%	37 – 63	44	-0.98
Berichrom (Dade-Behring)	72	48.3	7.8%	39 – 56		
Stachrom (Stago/Roche)	48	47.8	8.7%	40 – 57	44	-0.90
ATIII (Stago/Roche)	29	50.1	11.2%	40 - 63		

Performance per assay type

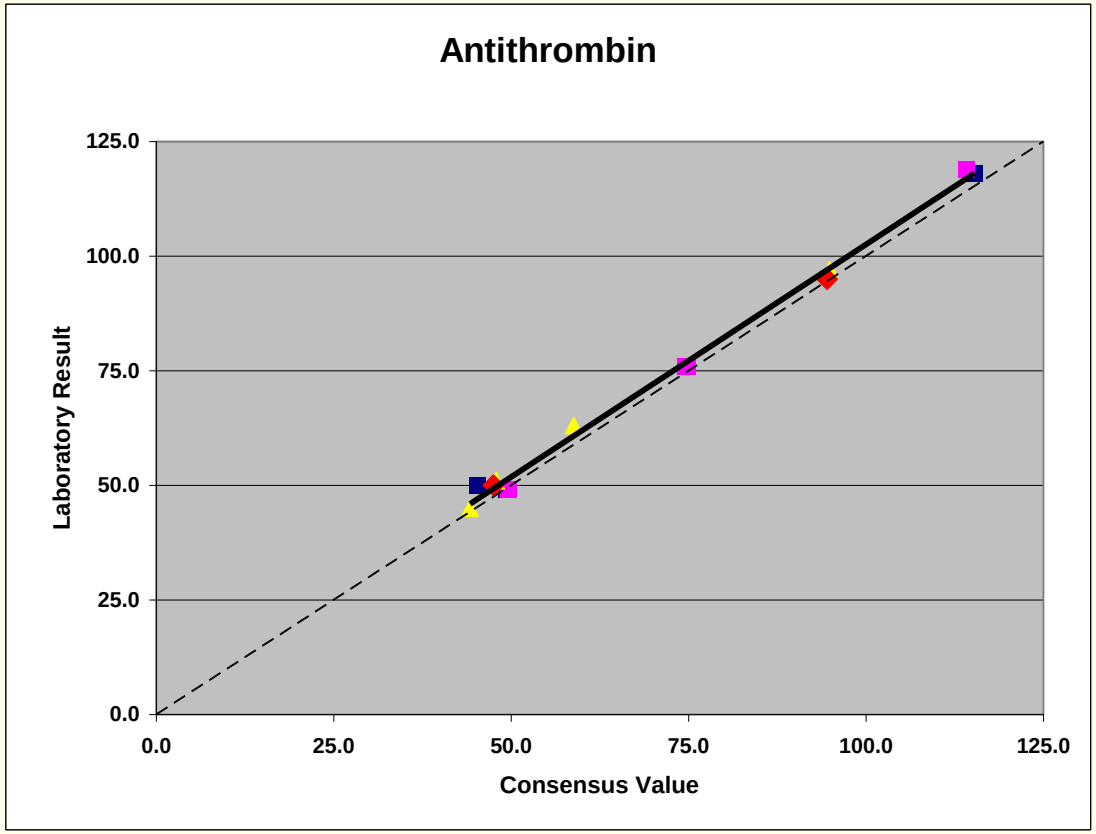
Performance per method

ANTITHROMBIN

Labcode: **0**

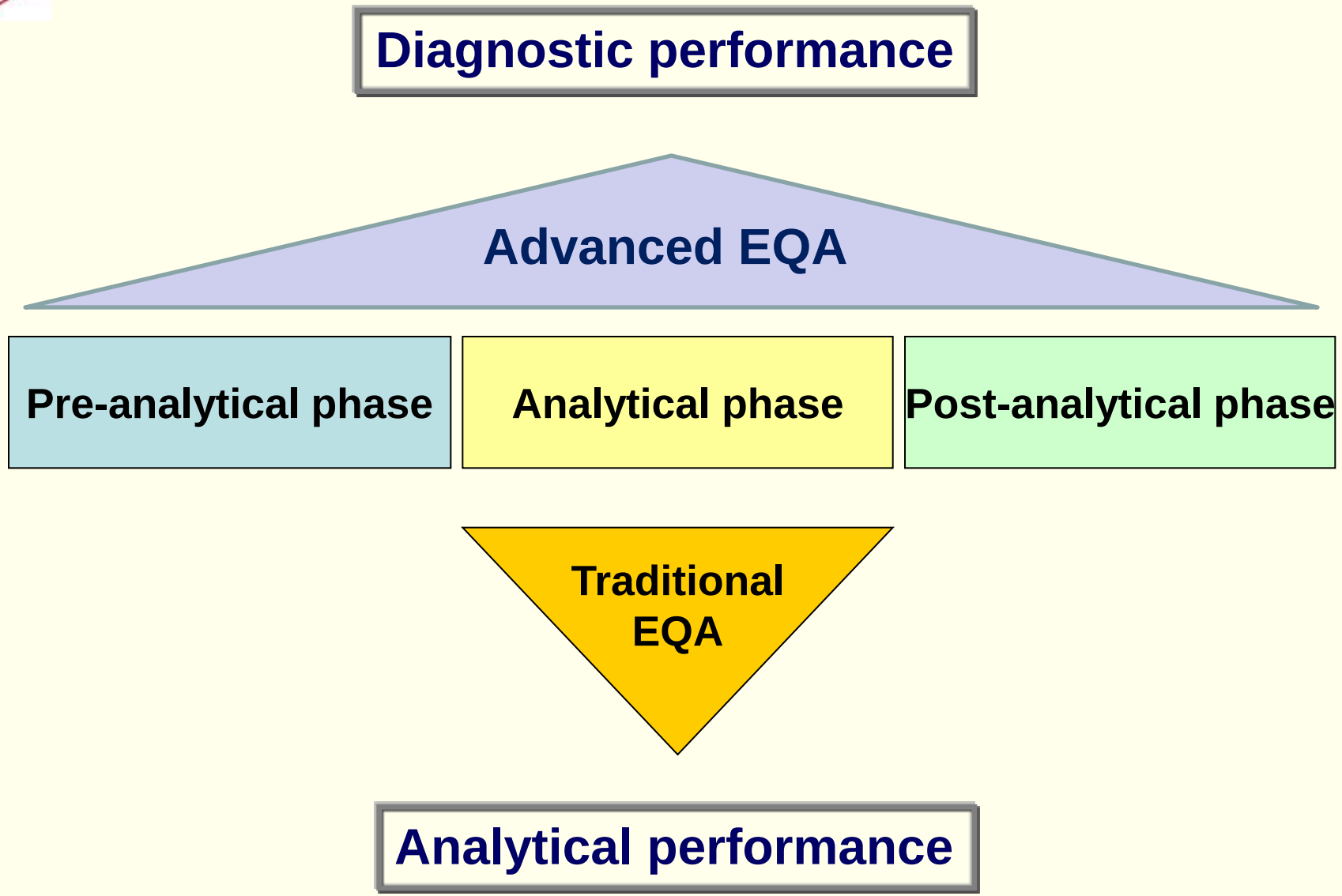
Name
Hospital
Department
City
Country

Exercise	Y (Lab Result)	X (Cons. Value)
	0	0
	125	125
2005-1		49.8
2005-2	50.0	45.3
2005-3	118.0	115.3
2005-4	49.0	49.3
2006-1	76.0	74.8
2006-2	119.0	114.1
2006-3	49.0	49.6
2006-4	76.0	74.5
2007-1	97.0	94.9
2007-2	51.0	47.9
2007-3	45.0	44.2
2007-4	63.0	58.8
2008-1	50.0	47.5
2008-2	95.0	94.5
2008-3		
2008-4		
Mean	72.2	68.6
SD		26.1
Number	13.0	



Intercept	1.08	**Variability**	1.84
Slope	1.01	**Corr. Coeff**	0.9958

Long-term $CV_{analytical}$	**2.6%**
Bias	**5.2%**


Diagnostic performance
Advanced EQA
Pre-analytical phase
Analytical phase
Post-analytical phase
Traditional EQA
Analytical performance

ISO STANDARD 15189

5.6.4 The laboratory shall participate in interlaboratory comparisons such as those organized by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not furfilled.

External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.

Pre-analytical

CASUS ? Hilfe × Vorschau schliessen

Experte | Clipboard | ← Zurück | → Weiter | Karte 1 von 21 | Plättchenarmes Plasma

Die meisten Gerinnungsparameter werden in plättchenarmem Plasma gemessen. Aber es gibt Ausnahmen – welche?

i | Bild 1 von 1 | ← | →

Aufgabe

Bitte markieren Sie in der folgenden Liste die Parameter, die **nicht** in zellarmem Plasma gemessen werden!

Multiple Choice-Antwort:

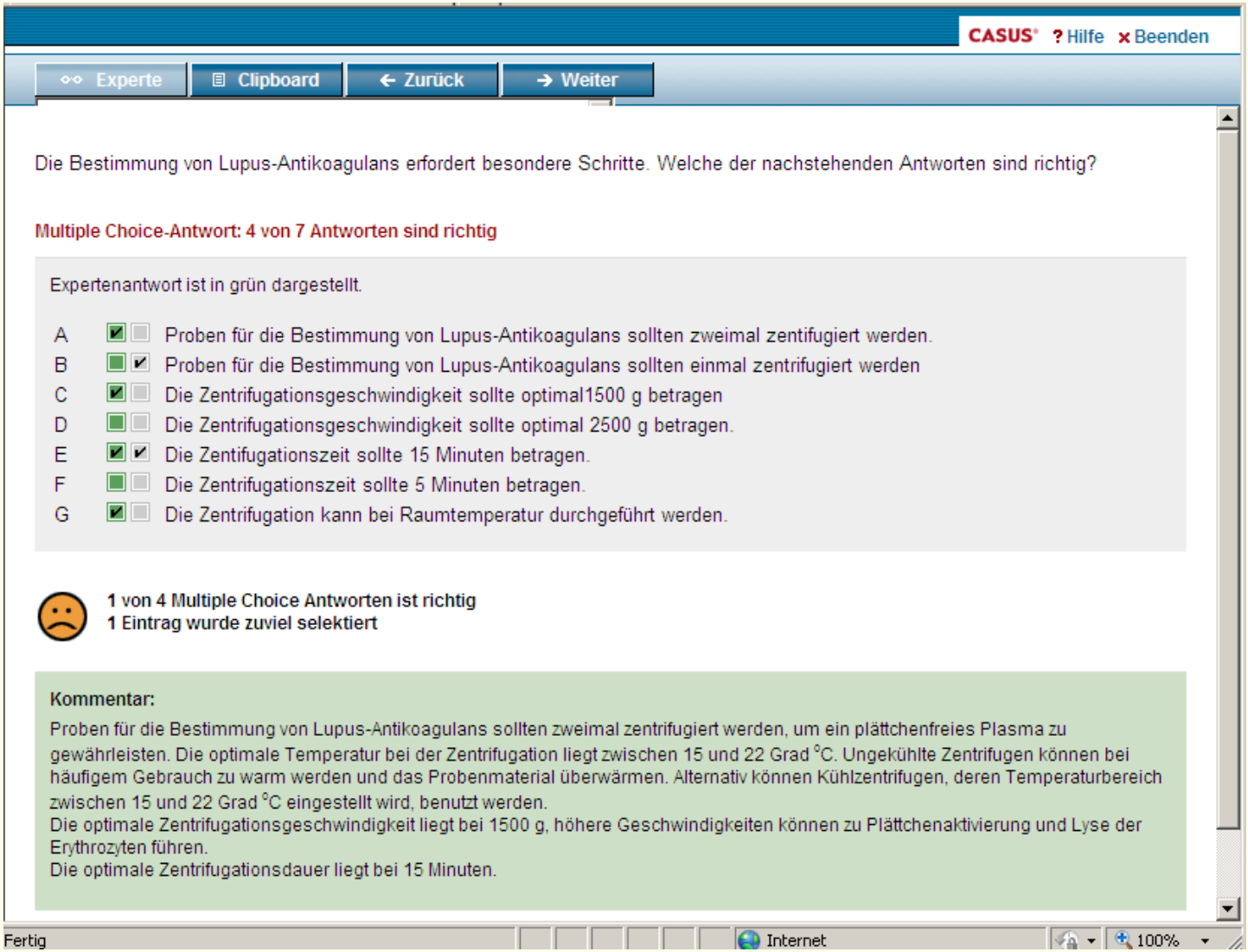
Bitte wählen Sie die entsprechende(n) Antwort(en) aus.

- A ☑ Faktor XIII
- B ☑ Partielle Thromboplastinzeit (PTT)
- C ☐ Prothrombinvariante G20210A
- D ☐ Thrombozytenaggregation
- E ☑ Prothrombin

Abschicken

Instruct AG (dbg: id=121716)

Pre-analytical



Pre-analytical

Zusammenfassung Ihrer Fallsitzung

Wollen Sie einen neuen Fall beginnen oder das Programm beenden?

Beenden | Abbrechen | Fallauswahl

Fallenname: Instand-VR-Hämostaseologie
Score: 93%

	Kartenname	Kartenkommentar	Antworttyp	Erfolg
1	Antikoagulanzienkunde		Sortier-/Zuordnungsantwort	100%
2	Antikoagulanzien		Sortier-/Zuordnungsantwort	100%
3	Antikoagulanzien als Störfaktoren 1		Multiple Choice-Antwort	
4	Neue Antikoagulanzien		Multiple Choice-Antwort	100%
5	Neue Antikoagulanzien, Wirkungsweise		Multiple Choice-Antwort	66%
6	Neue Antikoagulanzien - Störfaktoren 2		Multiple Choice-Antwort	100%
7	Thrombozytenarmes Plasma - Zentrifugation		Multiple Choice-Antwort	100%
8	Thrombozytenarmes Plasma Zentrifugation Temperatur		Multiple Choice-Antwort	100%
9	Temperaturabhängige Stabilität		Multiple Choice-Antwort	
10	Plasma auftauen		Multiple Choice-Antwort	100%
11	Plättchenarmes Plasma		Multiple Choice-Antwort	
12	Die häufigsten Fehler		Multiple Choice-Antwort	100%
13	Füllungszustand der Röhrchen		Multiple Choice-Antwort	
14	Problem des halbvollen Gerinnungsröhrchens		Multiple Choice-Antwort	100%
15	Ergebnisverfälschung		Multiple Choice-Antwort	100%
16	Qualitätskontrolle		Multiple Choice-Antwort	100%
17	Referenzwerte		Sortier-/Zuordnungsantwort	100%
18	Referenzbereiche		Sortier-/Zuordnungsantwort	67%
19	Probenmaterial für molekulare Diagnostik		Multiple Choice-Antwort	20%
20	Indikationen		Multiple Choice-Antwort	100%
21	Geeignete Methoden		Multiple Choice-Antwort	100%

Post-analytical

Kristoffersen AH *et al Clin Chem (2006); 52*:1871-8.

Postanalytical External Quality Assessment of Warfarin Monitoring in Primary Healthcare

Ann-Helen Kristoffersen,[1*] Geir Thue,[2] and Sverre Sandberg[1,2]

Questionnaire

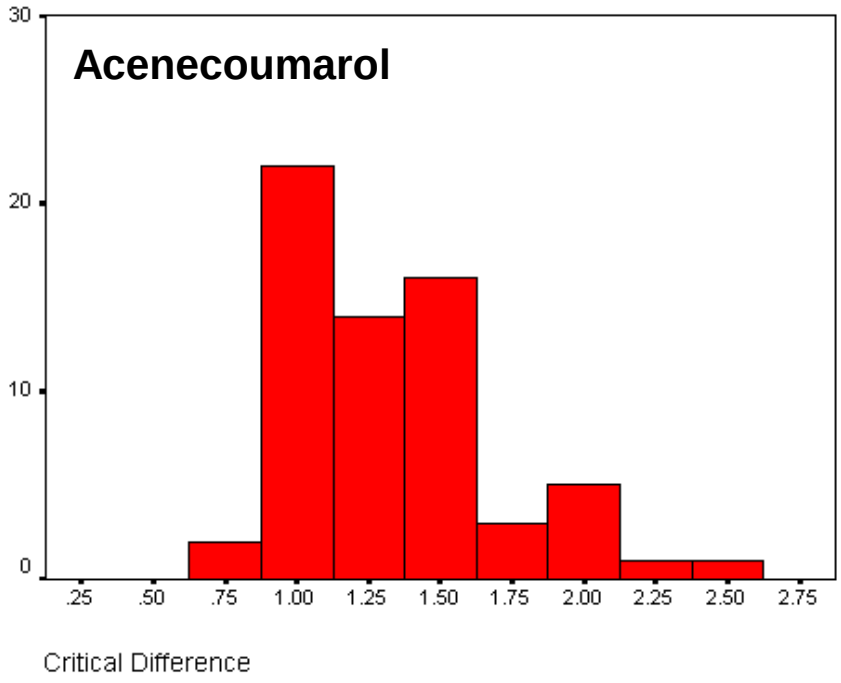
Patient A is a 72 year-old man, otherwise healthy, who had an operation two years earlier for aortic stenosis with a mechanical heart valve prosthesis. You have taken over his treatment with Marevan (warfarin). During the last months, his INR value have ranged from 3.0 to 3.5. The last result you received was 3.3 INR. His Marevan dosing has been unchanged during this time.

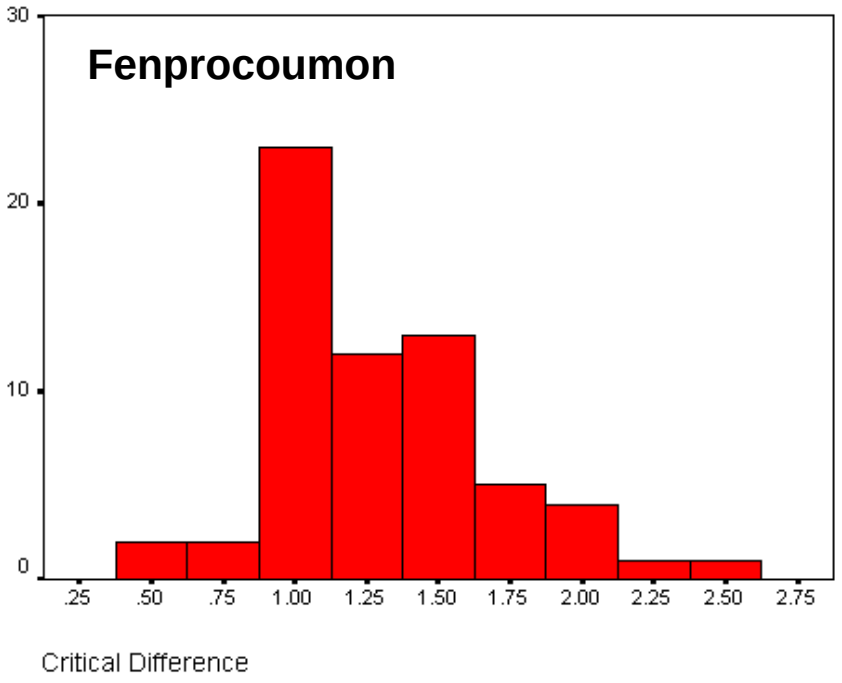
- Give the time in weeks until the next INR measurement:
  at least ___ week(s), but not more than ___ weeks.
- If you were to increase his Marevan dose, how low must this INR value be? ___.
- If you were to decrease his Marevan dose, how high must the INR value be? ___.
- In your opinion, what is the therapeutic range for this patient?:
  INR value between ___ and ___.

Post-analytical

Results

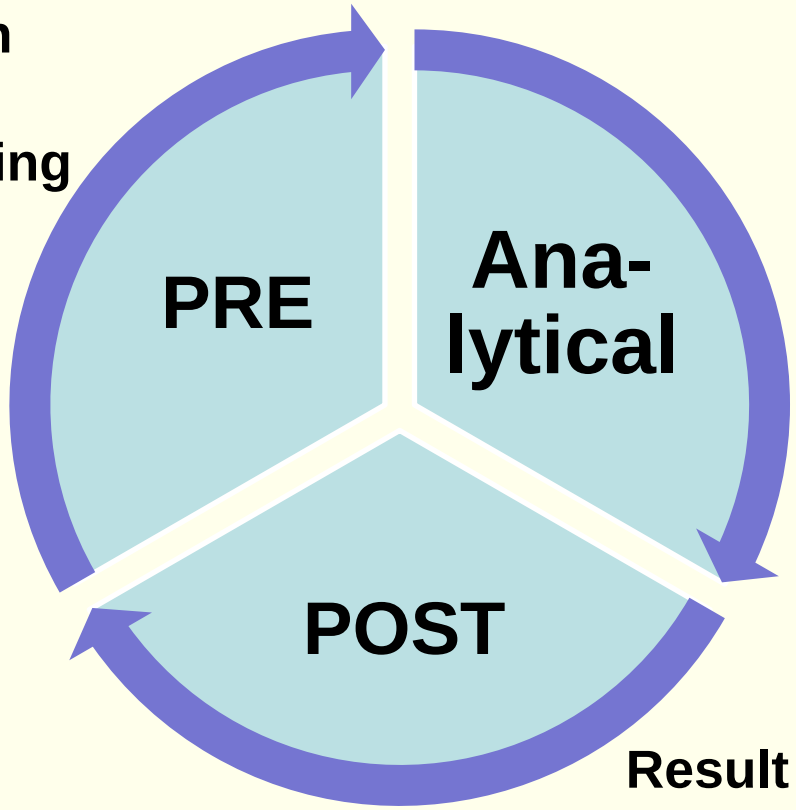
INR range	Range	10%	25%	50%	75%	90%	CV
Acenocoumarol	0.8 – 2.5	1.0	1.0	1.2	1.6	2.0	28%
Fenprocoumon	0.6 – 2.5	0.9	1.0	1.2	1.6	1.9	30%





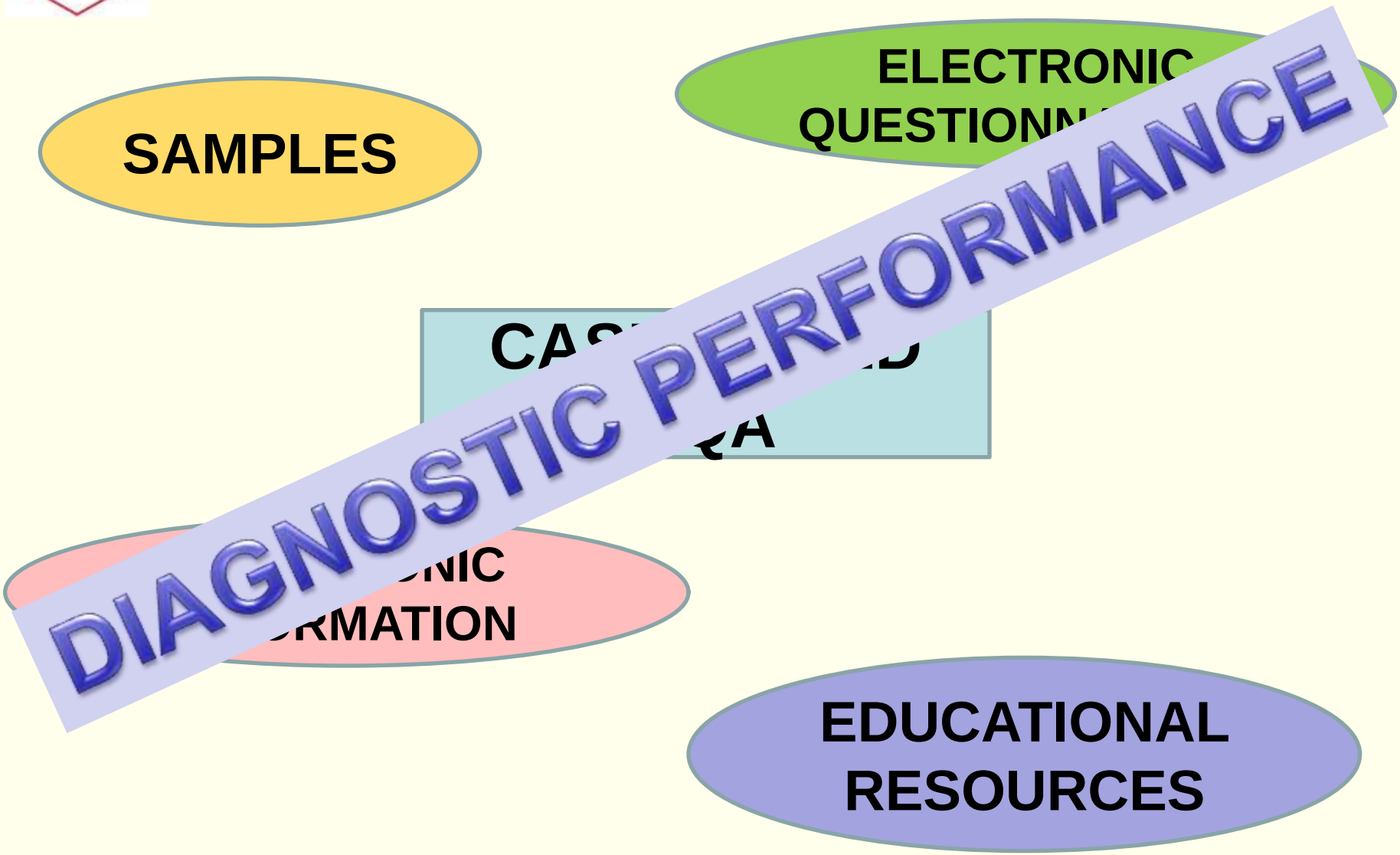
Case-based EQA

Case description
Test selection
Sample processing
Etc.



Test performance
Performance
evaluation
Etc.

Result evaluation
Result interpretation
Etc.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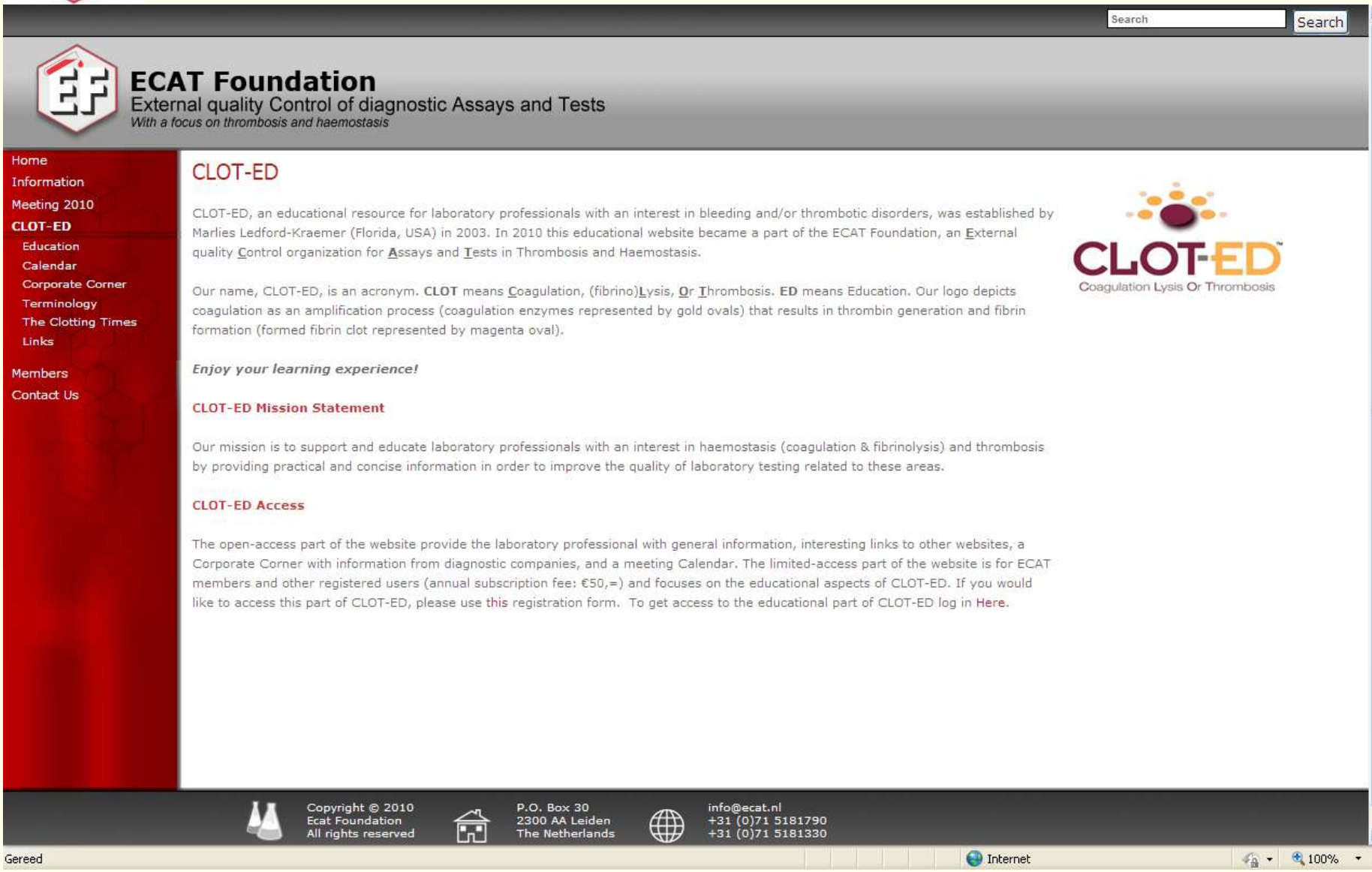
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CLOT-ED, an educational resource for laboratory professionals with an interest in bleeding and/or thrombotic disorders, was established by Marlies Ledford-Kraemer (Florida, USA) in 2003. In 2010 this educational website became a part of the ECAT Foundation, an External quality Control organization for Assays and Tests in Thrombosis and Haemostasis.
Our name, CLOT-ED, is an acronym. CLOT means Coagulation, (fibrino)Lysis, Or Thrombosis. ED means Education. Our logo depicts coagulation as an amplification process (coagulation enzymes represented by gold ovals) that results in thrombin generation and fibrin formation (formed fibrin clot represented by magenta oval).
CLOT-ED
Coagulation Lysis Or Thrombosis
Enjoy your learning experience!
CLOT-ED Mission Statement
Our mission is to support and educate laboratory professionals with an interest in haemostasis (coagulation & fibrinolysis) and thrombosis by providing practical and concise information in order to improve the quality of laboratory testing related to these areas.
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Corporate Corner

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Siemens Healthcare Diagnostics

technoclone
Highlights of Technoclone are indicated on the next page ...

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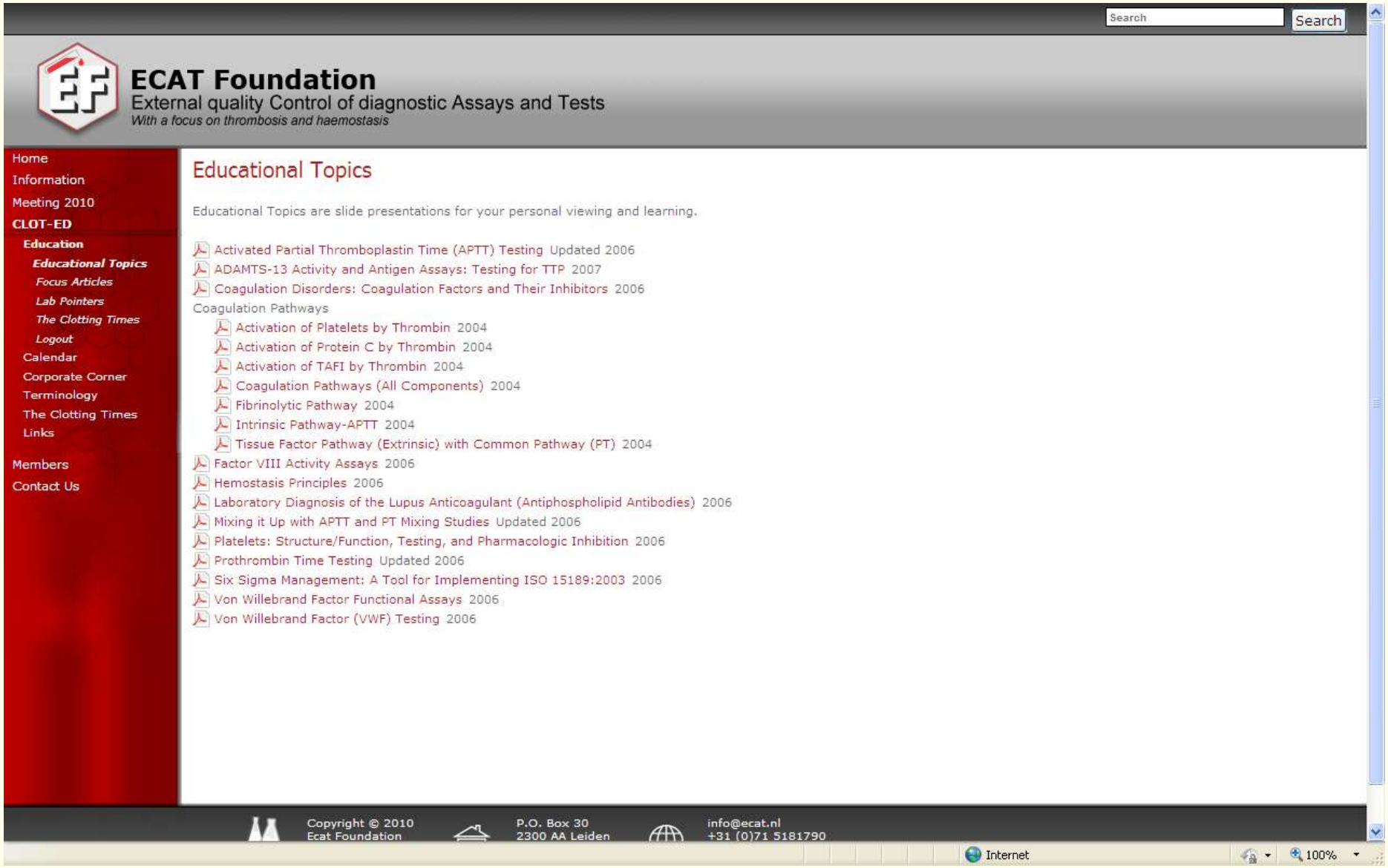
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Activated Partial Thromboplastin Time (APTT) Testing Updated 2006
ADAMTS-13 Activity and Antigen Assays: Testing for TTP 2007
Coagulation Disorders: Coagulation Factors and Their Inhibitors 2006
Coagulation Pathways
Activation of Platelets by Thrombin 2004
Activation of Protein C by Thrombin 2004
Activation of TAFI by Thrombin 2004
Coagulation Pathways (All Components) 2004
Fibrinolytic Pathway 2004
Intrinsic Pathway-APTT 2004
Tissue Factor Pathway (Extrinsic) with Common Pathway (PT) 2004
Factor VIII Activity Assays 2006
Hemostasis Principles 2006
Laboratory Diagnosis of the Lupus Anticoagulant (Antiphospholipid Antibodies) 2006
Mixing it Up with APTT and PT Mixing Studies Updated 2006
Platelets: Structure/Function, Testing, and Pharmacologic Inhibition 2006
Prothrombin Time Testing Updated 2006
Six Sigma Management: A Tool for Implementing ISO 15189:2003 2006
Von Willebrand Factor Functional Assays 2006
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External Quality Control in the New Decade:

- New challenges
- Analytical Performance / Diagnostic Performance
- Education
- Workshops
- ???

To work with you together on further quality improvement in the haemostasis laboratory!

THANK YOU FOR YOUR ATTENTION