



Towards diagnostic quality control: *a pilot study on acquired inhibitors*

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External Quality Assessment

Pre-analytical phase

Analytical phase

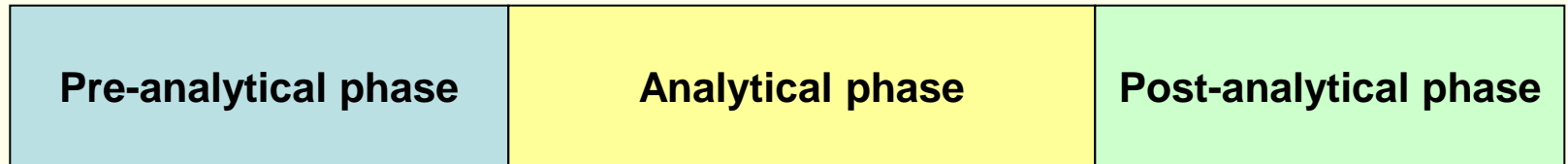
Post-analytical phase

Traditional
EQA

Analytical performance



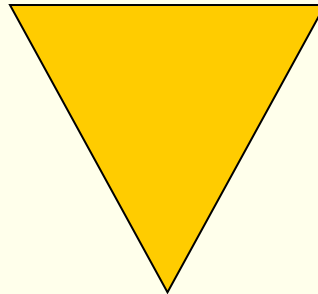
Laboratory Services



- Identification
- Collection
- Transportation
- Preparation

- Analysis

- Reporting
- Interpretation



External Quality Assessment



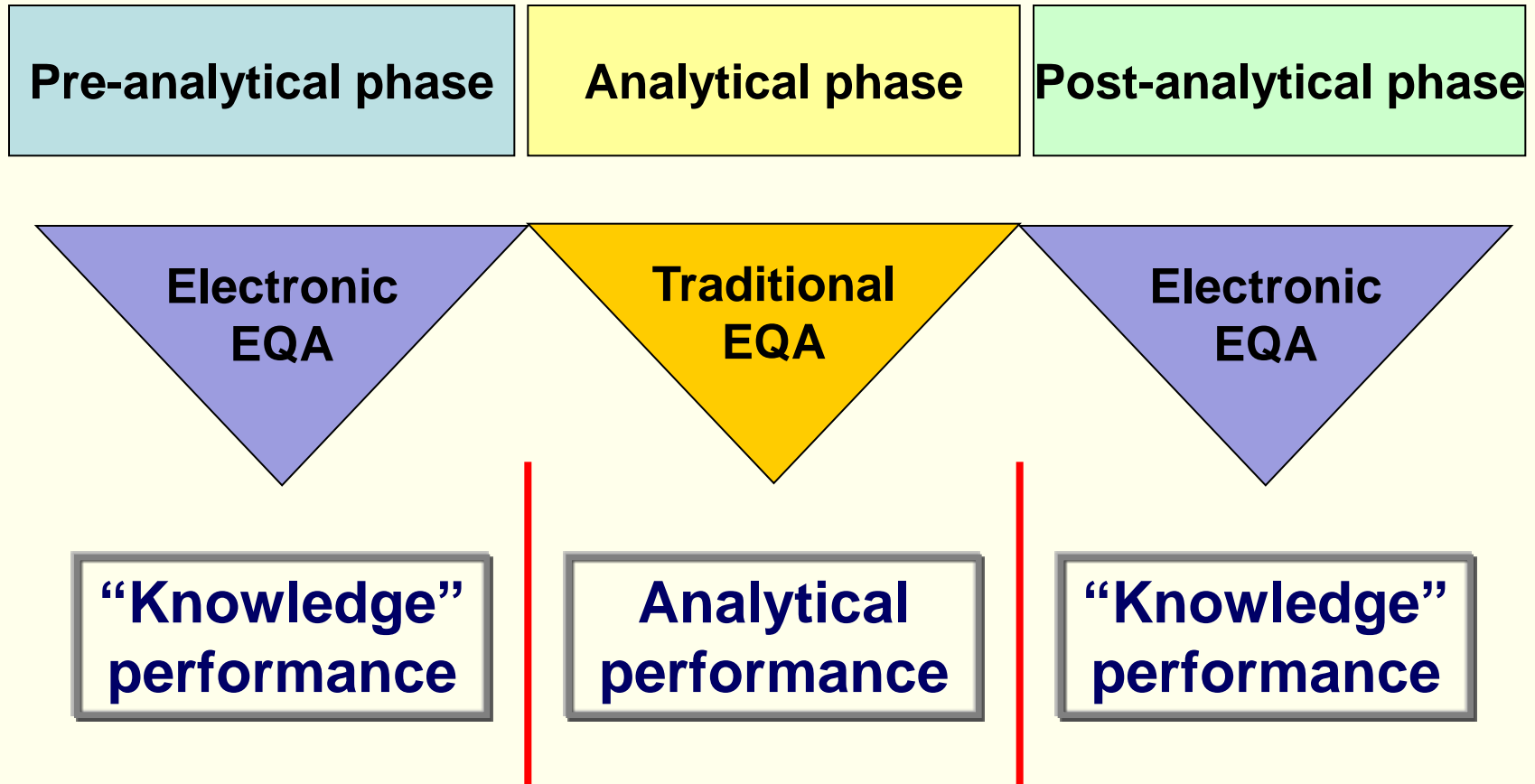
ISO STANDARD 15189

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 fulfilled.

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.



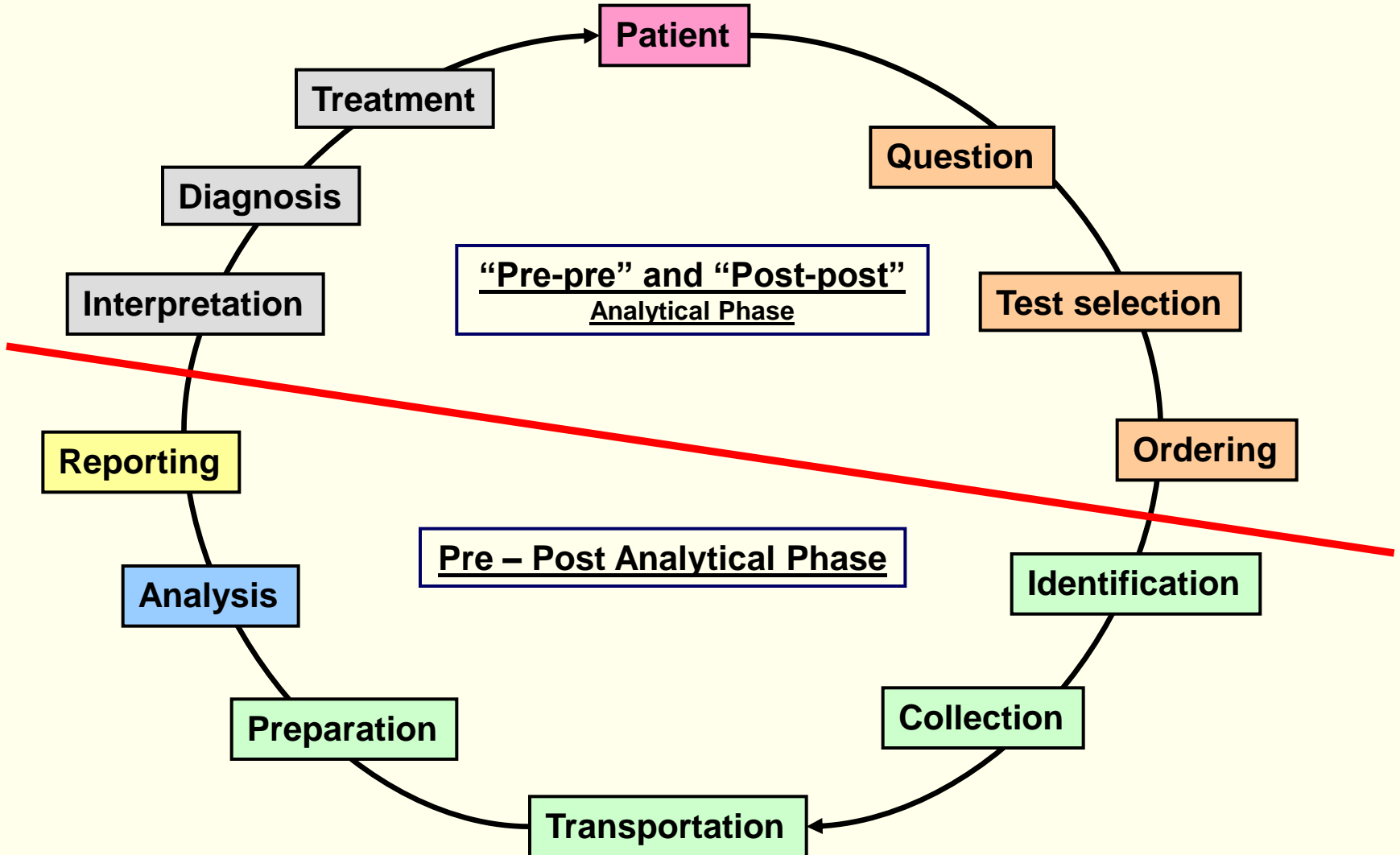
External Quality Assessment

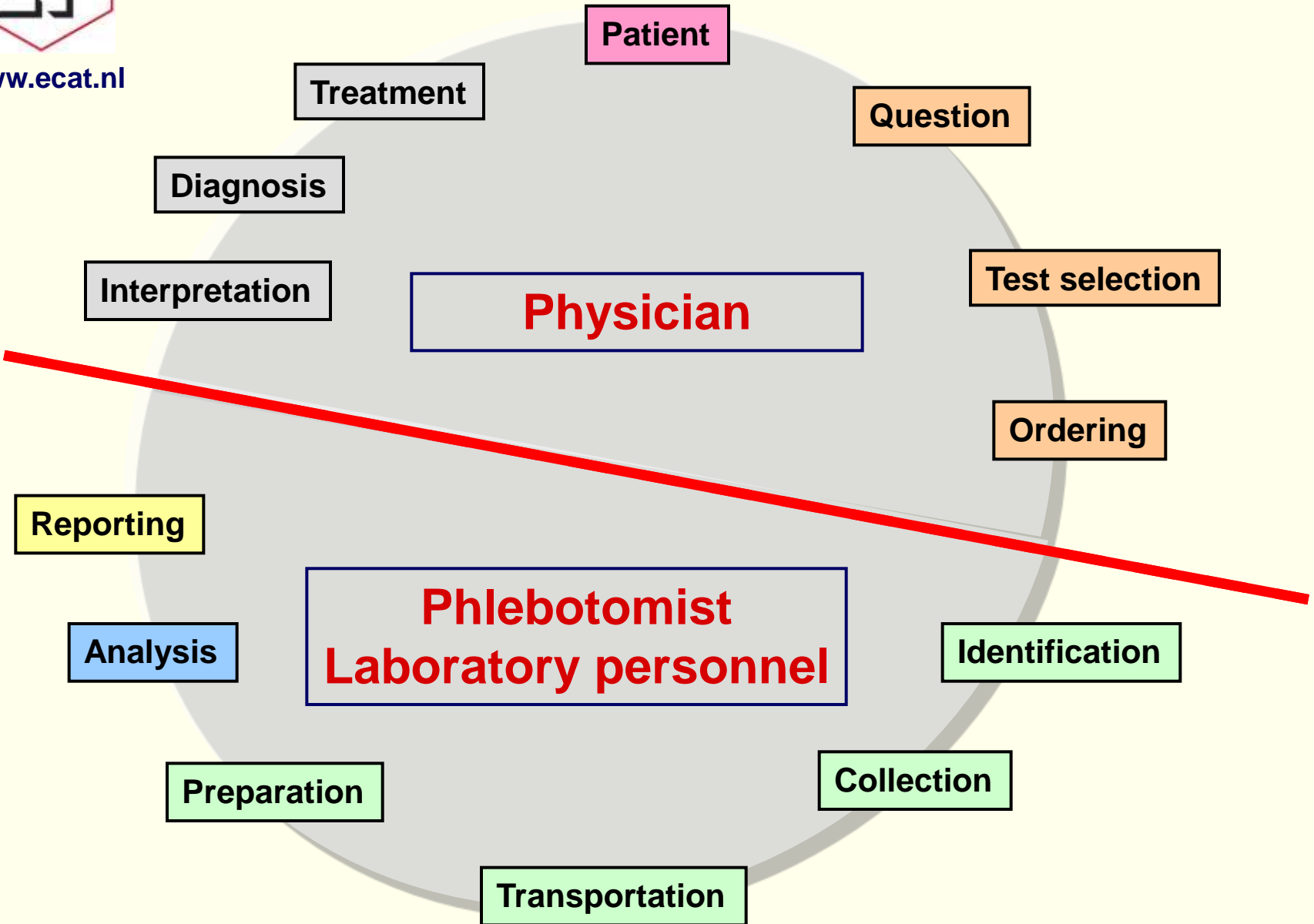


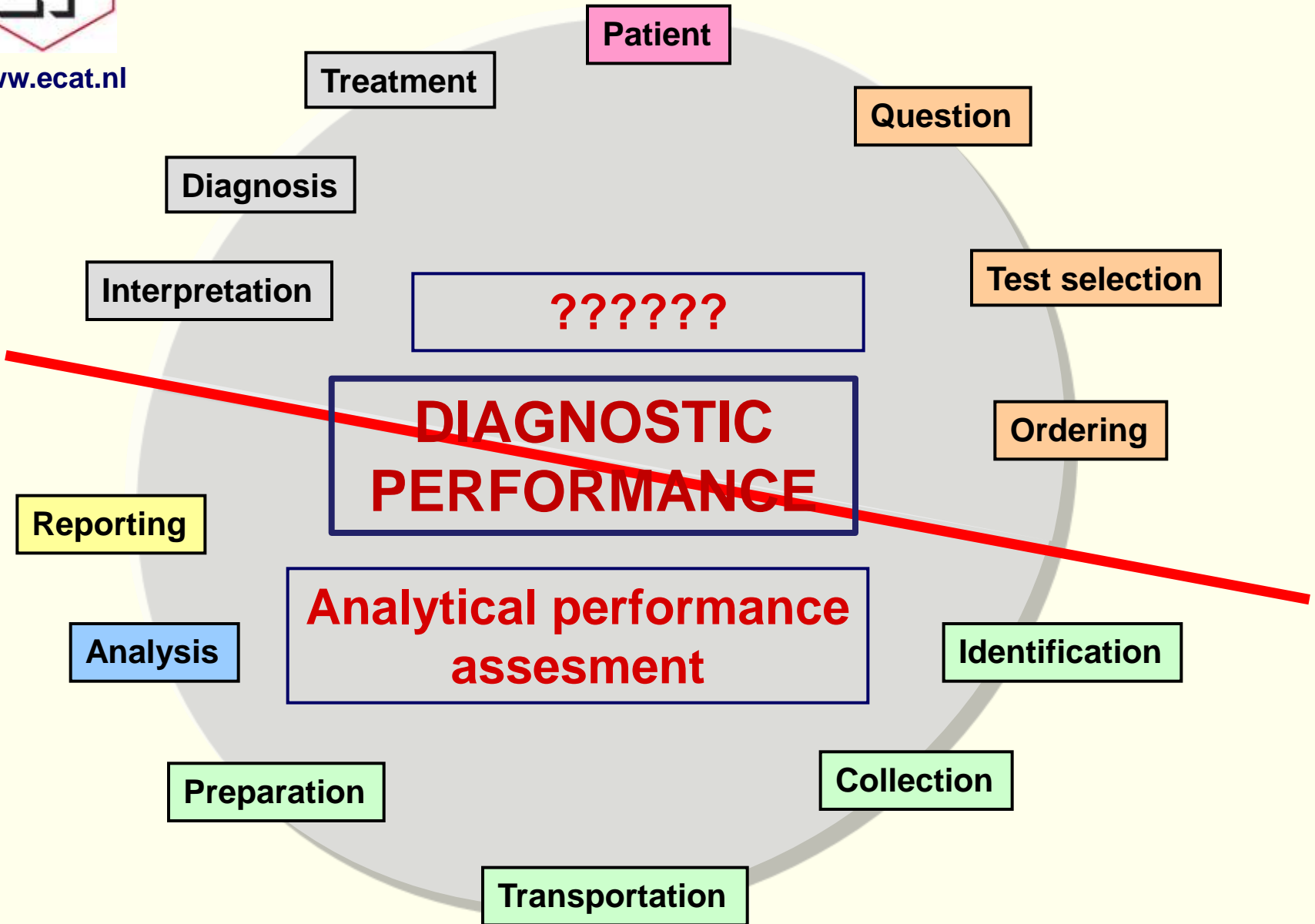


Total Testing Process

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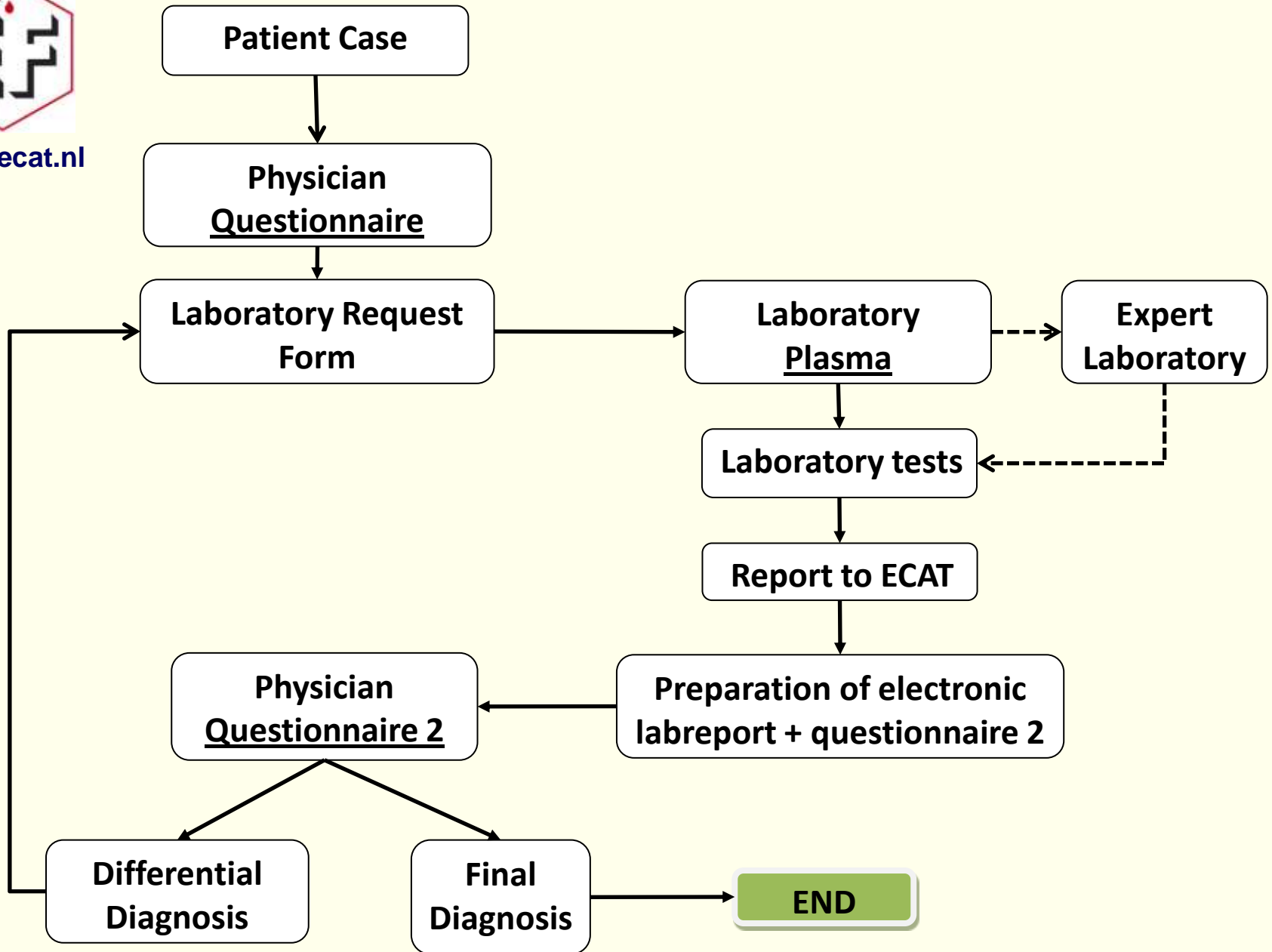
Case-based EQA

- Patient oriented
- Includes both analytical and diagnostic aspects
- Assessment of analytical and diagnostic performance
- Electronic and practical surveys

DIAGNOSTIC PERFORMANCE ASSESSMENT SURVEYS



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Scope project:

- **Correct diagnosis based on both clinical information and laboratory data.**
- Interpretation of clinical information.
- Evaluation of test request
- Test performance
- Interpretation of laboratory data (incl. comments)



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10 participating centers

Reference center:
Erasmus MC Rotterdam

A center can only participate
if both the clinicians and
clinical chemist are willing
to participate.





Naam	Labnaam	Waarde	Referentiebereik
Mr. J. J. J.	Hemoglobin	13,3	13,0 - 16,0
Mr. J. J. J.	Hematocrit	39,0	37,0 - 47,0
Mr. J. J. J.	Plateleten	152	150 - 400
Mr. J. J. J.	PT	11,2	10,0 - 12,0
Mr. J. J. J.	APTT	28,0	25,0 - 35,0
Mr. J. J. J.	Fibrinogen	3,80	2,00 - 4,00
Mr. J. J. J.	D-Dimeren	0,10	< 0,50
Mr. J. J. J.	PT/APTT	1,14	0,80 - 1,20
Mr. J. J. J.	PT/APTT	0,81	0,70 - 1,00
Mr. J. J. J.	PT/APTT	0,72	0,60 - 0,80

Case description

On your consultation a blank man, 63 years old, appeared.

The referral of the GP include the following information:

- since some days growing bruising is observed.
- no trauma
- clotting disorder?

Haematological parameters are normal as well as the PT.

Physical examination shows several purpura and ecchymoses at the back and the left side of the patient.

This bruising appeared spontaneously since a couple of days and are growing. The largest one is now about 15 cm.

This phenomenon was not shown previously with this patient.



Case Study Close this Case

VRAAG

*2. Wat zou u nog meer willen weten ten aanzien van de historie van deze patiënt?
(meerdere keuzes zijn mogelijk)

Familie anamnese

Is er eerder wel eens een overvloedige of langdurige bloeding geweest, bij bv operatie of tandheelkundige ingreep

Heeft patiënt gemakkelijk bloedwonden of tandvleesbloedingen

Zijn er andere aandoeningen waaraan patiënt nu behandeld wordt

Geen van deze

De afbeelding is niet beschikbaar.
Dit kan zijn omdat de afbeelding niet is gevonden.

Kijk op de pagina Internet 100%

Questionnaire includes questions on:

- patient history
- clinical symptoms
- physical examination
- potential differential diagnosis



Differential diagnosis after first investigations:

- **Trauma** 4 / 10
- **Primary Haemostasis**
 - **acquired VWD** 9 / 10
- **Thrombocytopathy**
 - **thrombocytopathy e.c.i.** 8 / 10
 - **drug-induced dysfunction** 7 / 10
 - **Uremia** 3 / 10
 - **VWD** 3 / 10



Differential diagnosis after first investigations:

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- **Vasculair**

- **Vitamine C deficiency** 3 / 10
- **Amyloidosis** 5 / 10

- **Secundairy Haemostasis**

- **Sec. Haemostasis disorder e.c.i.** 4 / 10
- **Vitamine K deficiency** 3 / 10
- **Lupus** 3 / 10
- **Clotting Factor deficiency** 5 / 10
- **Clotting Factor Inhibitor** 8 / 10



Secondary Haemostasis

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HOSPITAL	Secondary Haemostasis Disorder e.c.i.	Vitamine K deficiency	Liver disease	DIC	Lupus	Clotting Factor Deficiency	Clotting Factor Inhiibitor
1		v				v	v
2		v	v				v
3	v						v
4							v
5		v					
6	v				v	v	v
7	v		v			v	
8					v	v	v
9					v		v
10	v					v	v



Lab results (first round):

APTT	:	prolonged (2 – 3 times)
PT / INR	:	normal
Fibrinogen	:	normal
Thrombin Time	:	normal
APTT Mix (without)	:	normal – slightly prolonged
APTT Mix (with)	:	prolonged
Factor VIII	:	1 – 5%
Factor VIII Mix (without)	:	44 – 57%
Factor VIII Mix (with)	:	10 – 11%



Differential diagnosis after second round:

• Trauma	-	(4/10)
• Primary Haemostasis		
➤ acquired VWD	2 / 4	(9/10)
• Thrombocytopathy		
➤ thrombocytopathy e.c.i.	1 / 4	(8/10)
➤ drug-induced dysfunction	1 / 4	(7/10)
➤ Uremia	-	(3/10)
➤ VWD	2 / 4	(3/10)



Differential diagnosis after second round:

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- **Vasculair**

- **Vitamine C deficiency** 1 / 4 (3/10)
- **Amyloidosis** 1 / 4 (5/10)

- **Secundairy Haemostasis**

- **Sec. Haemostasis disorder e.c.i.** - (4/10)
- **Vitamine K deficiency** - (3/10)
- **Lupus** 1 / 4 (3/10)
- **Clotting Factor deficiency** 2 / 4 (5/10)
- **Clotting Factor Inhibitor** 4 / 4 (8/10)

All physicians ask for additional laboratory investigations



Future plans:

- **Completion of pilot study (till the end of 2012)**
- **Extension to a national project in 2013**
- **International (?)**



Strength:

- Evaluation of the entire diagnostic process including both the physician and the laboratory.

Weaknesses:

- Not all aspects of the total testing process can be included (e.g. sample collection and preparation).
- The physician is “guided” by an electronic questionnaire and not completely “self-supporting”.



Diagnostic EQA:

A new tool to examine the entire diagnostic process