

# **EQA Schemes in the pre-analytical phase: how they contribute to reduce laboratory errors**

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# External Quality Assessment/ Proficiency Testing

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Measurement alone does not result in improvement, but it is essential for identifying areas that need improvement and for monitoring improvement.

# EXTRA-ANALYTICAL PHASES: WHY ?

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- Current evidence on the *frequency and distribution of errors in laboratory medicine*
- *Requirements* for accreditation of laboratory services (according to the ISO 15189: 2007 International Standard)
- Change in the delivery of health care services according to a *patient-centered perspective*

# PRE-ANALYTICAL ISSUES

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- TEST REQUEST: APPROPRIATENESS
- PATIENT AND IDENTIFICATION
- BLOOD COLLECTION (prolonged tourniquet use, wrong tube and wrong sequence in sampling, sampling through catheters)
- SAMPLE HANDLING AND TRANSPORTATION
- ACCEPTABILITY (criteria for accepting/rejecting hemolysed, lipemic, clotted, underfilled samples).

# EXTRA-ANALYTICAL PHASES

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How has been possible to assess the activities concerning the extra-analytical phases by EQA organizers ?

**YESTERDAY**

# EXTRA-ANALYTICAL PHASES

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Specific trials by the use of:

→ questionnaire

→ samples

→ medical reports

AND

→ Working groups dedicated

**YESTERDAY**



# Trial on PRE-ANALYTICAL PHASE

## Results

### Questionnaire



	<u>Total</u>	Laboratories							
		A	B	C	D	E	F	G	H
CLINICAL REQUESTS ANALYSED	22907	1000	1000	1000	9041	1000	8110	756	1000
Percentage of Error									
PATIENT'S DATA (name and surname, data of birth, sex)									
Total	0.46	0.4	0.9		0.43		0.47		
TESTS									
-missing		2.7	2.4	3.2	2.5		0.1	5.7	0.6
-added		2.2	1.0		0.6	0.2	0.012	3.3	0.4
-misinterpreted		0.3	0.7	0.2	2.5	0.4		0.13	0.4
Total	3.15	5.2	4.1	3.4	5.6	0.6	0.12	9.1	1.4
INFORMATION MISSING									
Diagnostic suspicion		86.9	68.1	83.0	20.6	56.0			86.0
Data of requesting physician			0.4			2.8			0.6
Data to find out the patient						48.0			
Availability of the laboratory report			0.9		2.4	0.3			0

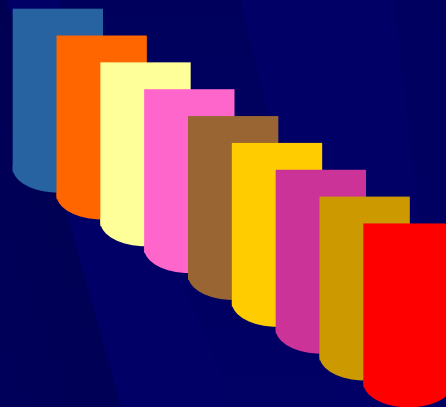
– Percentage of error regarding the transcription of clinical requests.

# Trial on PRE-ANALYTICAL PHASE

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Preparation and sending of samples with different degree of hemolysis, lipemia and icterus.





# Trial on PRE-ANALYTICAL PHASE

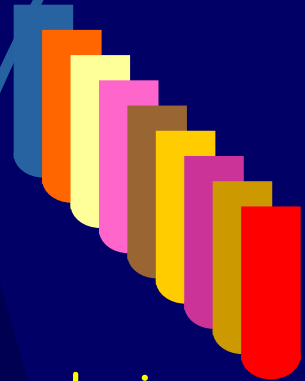
	Samples								
	A	B	C	D	E	F	G	H	I
	Icteric	Normal	Hemolyzed, lowly	Abnormal	Abnormal	Hemolyzed, moderately	Hemolyzed, markedly	Lipemic and icteric	Hemolyzed and lipemic
Classification of samples	Percentage of responses								
Normal	3	100	1						
Hemolyzed, lowly			86		13	1			
Hemolyzed, moderately				4	5	75	20		8
Hemolyzed, markedly				9	3	20	75		
Icteric, lowly	17								
Icteric, moderately	53								
Icteric, markedly	21								
Lipemic, lowly								10	1
Lipemic, moderately								20	
Lipemic, markedly								7	
Lowly lipemic and icteric	4					1	1	15	
Moderately lipemic and icteric								36	1
Markedly lipemic and icteric								11	1
Lowly hemolyzed and lowly lipemic									13
Lowly hemolyzed and moderately lipemic						1		1	7
Moderately hemolyzed and lowly lipemic				1		1	4		35
Moderately hemolyzed and moderately lipemic									20
Markedly lipemic and hemolyzed									5
Markedly hemolyzed and lipemic									4
Others	2		1	7	2	1			5
Abnormal			12	79	77				

75 Laboratories : classification of samples (%)

# Trial on PRE-ANALYTICAL PHASE

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## Results

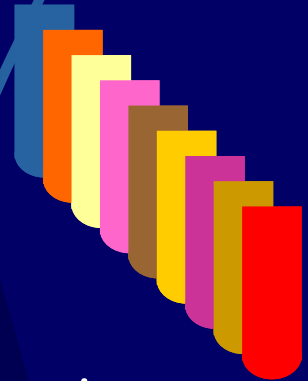


- ✓ The sample is **rejected *in toto*** by:
  - **42%** of the laboratories in the presence of **marked hemolysis**
  - **15%** in the presence of **moderate hemolysis**
  - **one** laboratory in the presence of **low hemolysis**.
- ✓ Most-commonly not performed tests: **ALT, AST, bilirubin, CK, iron, LDH, phosphate** and **potassium**.

# Trial on PRE-ANALYTICAL PHASE

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## Results

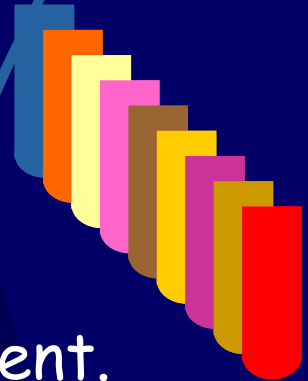


- ✓ Only a few laboratories *reject in toto* the sample.
- ✓ In presence of a moderate or marked icterus, the analyses not performed are mainly: **creatinine** and **total cholesterol**.

# Trial on PRE-ANALYTICAL PHASE

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## Results



- ✓ The answers of laboratories were in disagreement.
- ✓ The behaviour of participants seems to depend on the method utilized for each constituent.

2003

# Working Group

The impact on the **pre-analytical phase** on the quality of laboratory results: definition of a procedure to use in presence of samples with **interferences** such as hemolysis, jaundice and turbidity.





# Working Group

**26 laboratories** belonging to different Italian regions have been involved, on voluntary basis.

To each laboratory were sent:

1. a **questionnaire** concerning the presence of surveillance procedures within the pre-analytical phase
2. **10 samples of human plasma**, prepared from plasma pools, characterized by several degrees of interferences of **hemolysis**, **jaundice** and **turbidity**.

The laboratory had to indicate, for each sample, the **type** and the **degree of interference** and any **corrective action adopted**.

Among the 10 samples, moreover, **16 analytes** should have been determined (urea, glucose, AST, ALT, LDH, CK, total bilirubine, total cholesterol, triglycerides, total proteins, magnesium, sodium, potassium, troponine I and troponine T).

## INTERFERENZE DELLA FASE PREANALITICA

## Questionario

1 Esistono nel Tuo laboratorio procedure di sorveglianza della fase preanalitica, relativamente all'interferenza da emolisi, ittero e torbidità?

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

2 Se sì, potresti darne una breve descrizione seguendo queste indicazioni?

utilizzo di una procedura scritta

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

utilizzo di una scala cromatica visiva

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

utilizzo di indicatori del siero (Serum Index)

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

inserimento manuale dell'azione correttiva adottata

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

utilizzo del sistema gestionale per l'inserimento automatico

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

altro

*nel Sistema gestionale sono previsti  
commenti predefiniti che il tecnico  
inserisce all'occorrenza*

3 Quali settori analitici possiedono questo sistema di sorveglianza?

CHIMICA CLINICA

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

IMMUNOMETRIA

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

COAGULAZIONE

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

PROTEINE

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

4 Ritieni che il problema dell'interferenza debba essere implementato con opportune iniziative di standardizzazione?

<input checked="" type="checkbox"/>	no
<input type="checkbox"/>	si

5 Hai qualche suggerimento da dare?

*Prendere come campione da altri lab. i valori  
degli INDICI del SIERO se impiegano valori  
sbagliati per intervenire a dare un correttivo*

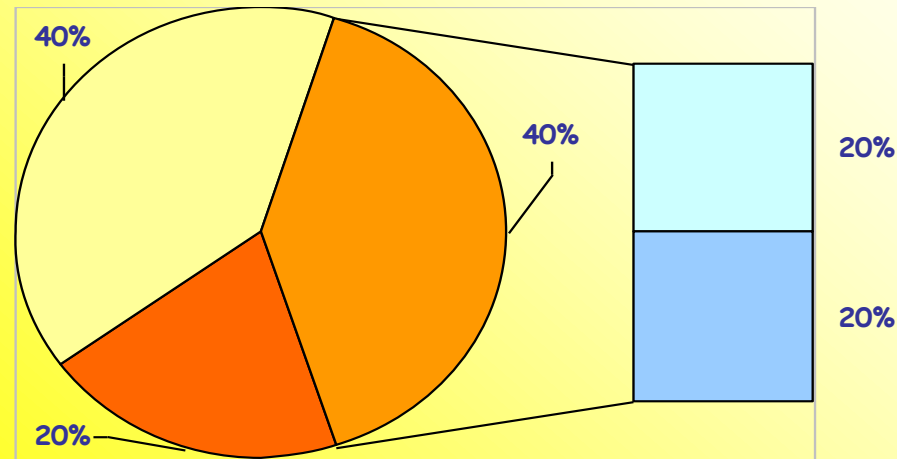
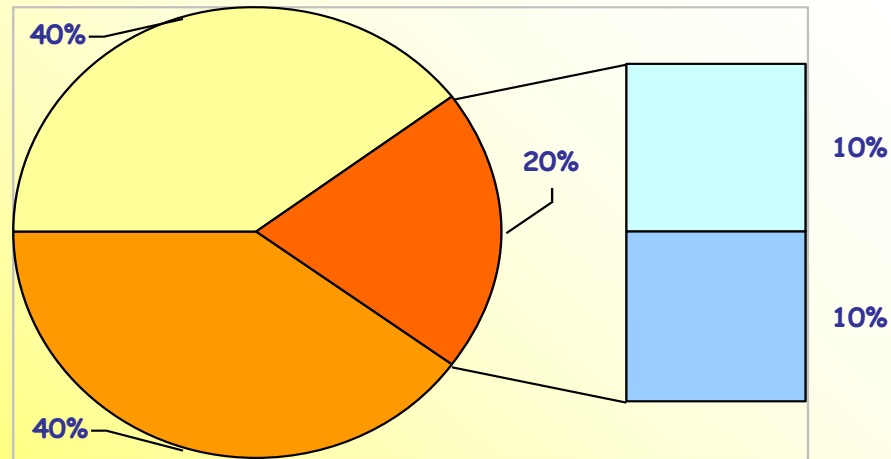
LABORATORIO  
REFERENTE


Questionnaire



# Surveillance procedures in the pre-analytical phase

Results



- No indicator
- Automated detection
- Visual detection

- Written procedures
- No written procedures

# Identification and classification of interferences

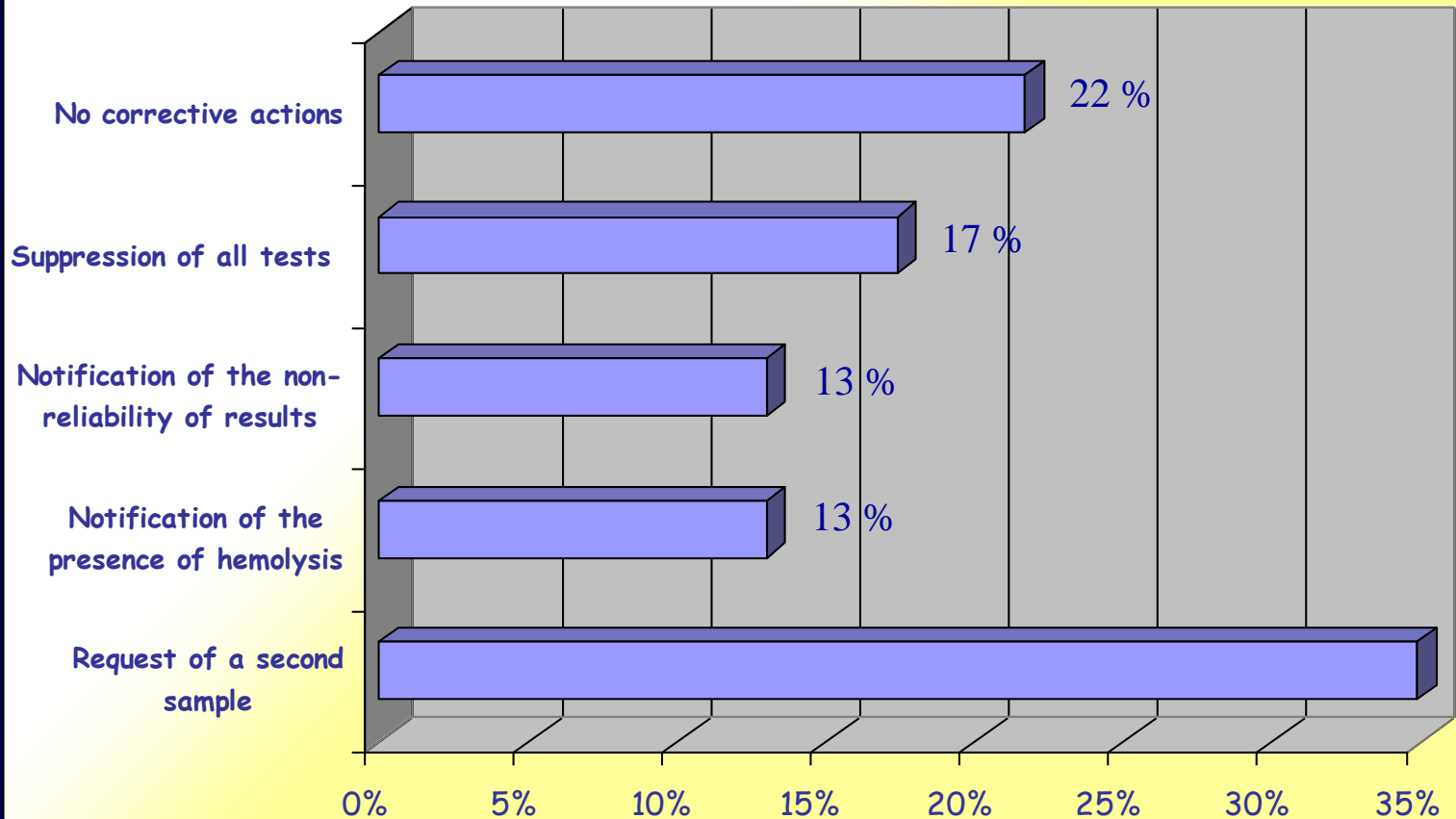
**Results**

Sample	Type of interference	Lab (%)
H1	hemolysis	100%
H2	hemolysis	100%
H3	hemolysis	52%
H3	lipemia/turbidity	4%
H3	none	44%
H4	hemolysis	100%
I1	jaundice	91%
I1	none	9%
I2	jaundice	96%
I2	none	4%
I3	jaundice	87%
I3	none	13%
L1	lipemia/turbidity	100%
L2	lipemia/turbidity	100%
L3	lipemia/turbidity	100%

# Corrective actions following the identification of hemolysis

Results

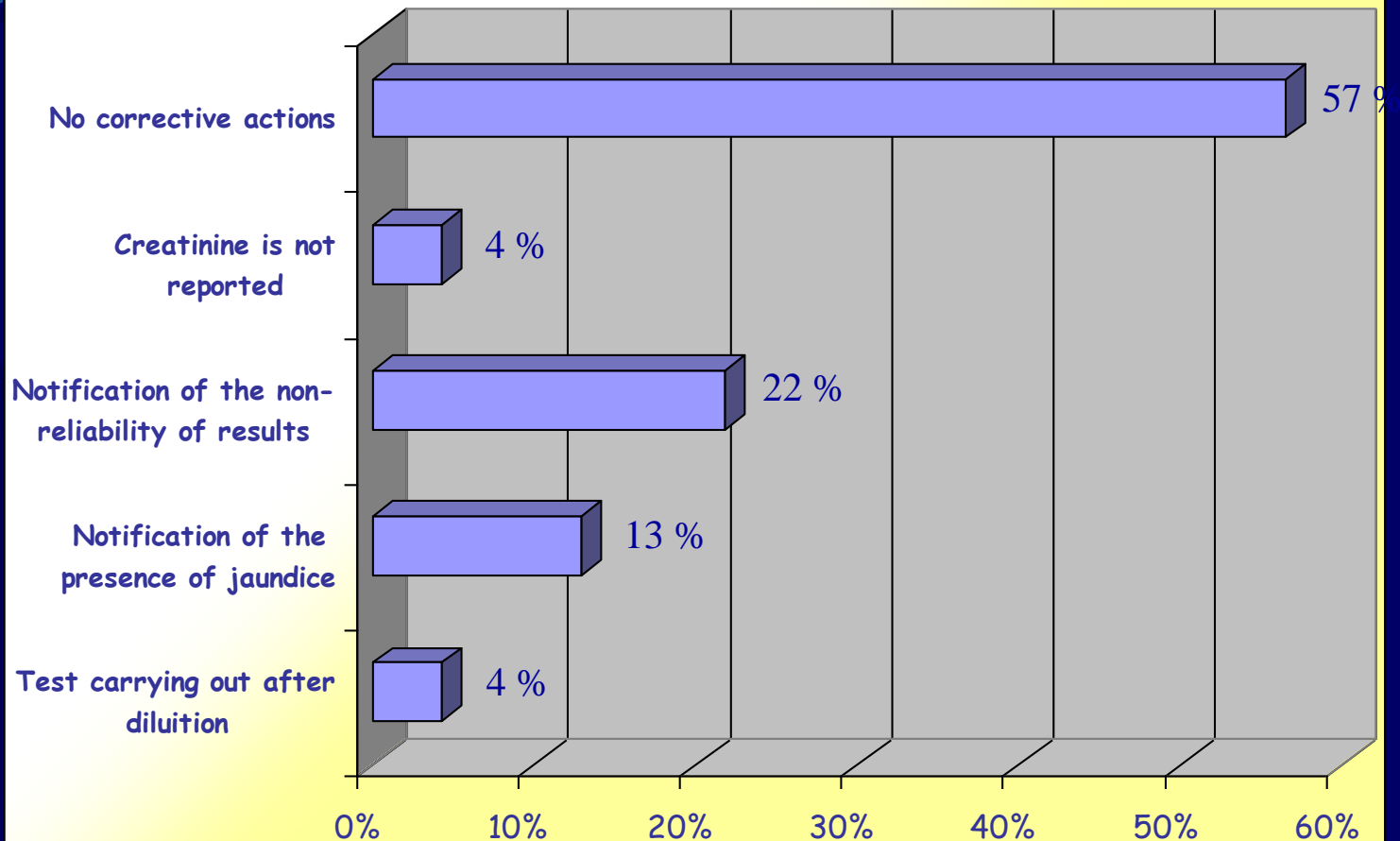
**SAMPLE I2: HIGH DEGREE OF HEMOLYSIS**



# Corrective actions following the identification of jaundice

Results

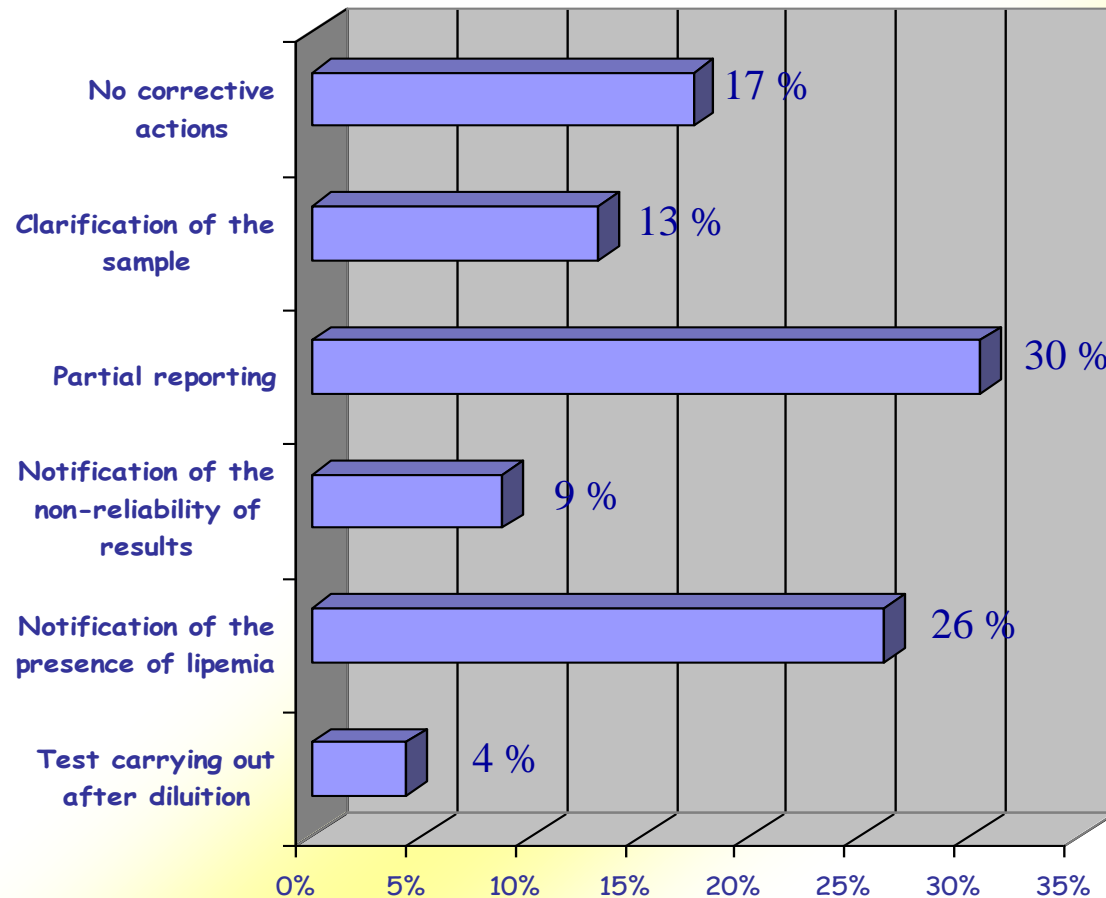
**SAMPLE I2: HIGH DEGREE OF JUNDICE**



# Corrective actions following the identification of lipemia

Results

**SAMPLE LI: HIGH DEGREE OF LIPEMIA**



Results

# Working Group



- ✓ The investigation demonstrates the necessity to improve the agreement among laboratories in the classification of the interferences, obtaining more objective and effective processes for systematically identifying unsuitable specimens
- ✓ The variability of the corrective actions, adopted in presence of interference, shows the necessity to define a **standardized process** for the management of unsuitable samples, in relation to the analyte and to the used method.



**Need of recommendations for detection and management of unsuitable samples in clinical laboratories**

# The Haemolytic, Icteric and Lipemic Sample Recommendations Regarding their Recognition and Prevention of Clinically Relevant Interferences

Recommendations of the Working Group on Preamerical Variables of the German  
Society for Clinical Chemistry and the German Society for Laboratory Medicine

W.G. Guder, Munich (chairman), F. da Fonseca-Wollheim, Berlin, W. Heil, Wuppertal,  
Y. M. Schmitt, Darmstadt, G. Töpfer, Götting, H. Wisser, Mannheim, B. Zawta, Mannheim

J Lab Med 2000; 24 (8): 357-364

Clin Chem Lab Med 2007;45(6):728-736 © 2007 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2007.174

Review

## Recommendations for detection and management of unsuitable samples in clinical laboratories

Giuseppe Lippi<sup>1,\*</sup>, Giuseppe Banfi<sup>2</sup>, Mauro  
Buttarelli<sup>3</sup>, Ferruccio Ceriotti<sup>4</sup>, Massimo  
Daves<sup>5</sup>, Alberto Dolci<sup>6</sup>, Marco Caputo<sup>7</sup>, Davide  
Giavarina<sup>8</sup>, Massimo Messori<sup>9</sup>, Massimo  
Miconi<sup>9</sup>, Bruno Nanni<sup>10</sup>, Margherita  
Salvagno<sup>1</sup> for the SIMeL-CISM  
analytical Variables Working Group

20-06-2011

**Raccomandazioni di consenso SIBioC – SIMeL per la rilevazione e la gestione dei  
campioni emolizzati e l'utilizzo dell'indice di emolisi**

a cura del GdS intersocietario SIBioC - SIMeL sulla variabilità extra-analitica



## **Preamalytical quality control program – an overview of results (2001–2005 summary)**

**M<sup>o</sup> Jesús Alsina, Virtudes Álvarez, Nùria Barba, Sandra Bullich, Mariano Cortés, Irene Escoda and Cecilia Martínez-Brú\***

SEQC Committee for the Quality of the Extraanalytical Phase, Spain

### **Short Communication**

## **National survey on the pre-analytical variability in a representative cohort of Italian laboratories**

**Giuseppe Lippi<sup>1,\*</sup>, Martina Montagnana<sup>1</sup> and Davide Giavarina, on behalf of the SIBioC (Italian Society of Clinical Biochemistry and Clinical Molecular Biology) – SIMEL (Italian Society of Laboratory Medicine) – CISMEL (Italian Committee for Standardisation of Laboratory and Haematological Methods) Inter-associative Study Group on the Extra-Analytical Variability of Laboratory Testing<sup>2</sup>**