Il ruolo delle VEQ per la sicurezza trasfusionale

The role of EQA for transfusion safety

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Ist. Sup. Sanità

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Blood transfusion is an essential and life-saving support within the health care system

Threats associated with transfusion include:

- Inadequate supplies of blood and blood products to meet the needs of all patients requiring transfusion
- Inappropriate prescribing of blood and unnecessary transfusions
- Errors in the administration of blood and blood products.
- Technical and clerical errors in the processing and testing of blood
- Risk of transfusion-transmitted infections

The World Health Organization (WHO) advocates the following integrated strategy to national health authorities to promote the safety and accessibility of blood and reduce the risks associated with transfusion.

- Establishment of a well-organized, nationally-coordinated blood transfusion service (BTS) that can provide adequate and timely supplies of safe blood for all patients when needed.
- Collection of blood only from voluntary non-remunerated blood donors belonging to low-risk populations and selected using stringent criteria.
- Reduction in unnecessary transfusions through the appropriate clinical use of blood and the safe administration of blood and blood products.
- Quality-assured testing of all donated blood for transfusion transmissible infections, including HIV, hepatitis viruses, syphilis and other infectious agents, blood groups and compatibility.
- Implementation of effective **quality systems**, covering all aspects of BTS activities, including quality management, development and implementation of quality standards, effective documentation systems, training of all staff and regular quality assessment.

Blood Transfusion Safety
World Health Organization
Geneva

Errors in the laboratory may be due to:

- Incorrect storage or inappropriate use of reagents
- Equipment failure
- Technical failure in serological or NAT tests
- Inaccuracies in recording or transcription
- Misinterpretation of results

Errors often result from a combination of factors, with the original error being compounded by inadequate checking procedures in the laboratory

The aim of a blood transfusion laboratory in testing blood samples from patients and donors is to provide safe blood for transfusion.

The implementation of a quality system in the laboratory minimizes errors and ensures that:

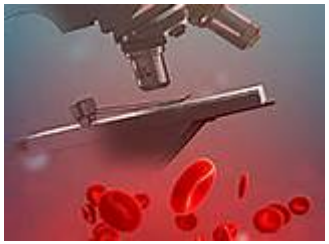
- Appropriate tests are performed on the correct samples
- Accurate results are obtained
- Correct blood product is provided for the correct patient at the correct time

Accurate results are essential

- **Serological test**
- **Molecular test**

infectious markers

- **Blood group serology tests**



It is important that the results are transcribed, collated and interpreted correctly so that safe and appropriate and compatible blood products are issued for transfusion.

Assessment of Quality System

Man-driven	Material-driven

• Audit – on site inspection
  • Internal
  • External
• Accreditation
	• Quality Assessement
	  • Internal
	  • External

External Quality Assessment (EQA)

External assessment of a laboratory's performance in testing samples and comparison with the performance of other laboratories

Information generated by EQA provides an opportunity for continuous quality improvement through the identification of laboratory errors and the implementation of measures to prevent their recurrence.

External quality assessment (EQA)

EQA in blood transfusion laboratory practice is an important component of a quality system for blood transfusion services.

EQA plays an important role in making blood safer (it **helps** to ensure the provision of appropriate, compatible blood and blood products for transfusion).

EQA Benefits to participating laboratories

- Access to a network of laboratories for the exchange of information
- Comparison of their own performance with the performance of other participating laboratories
- Identification of problems relating to laboratory processes, techniques and reagents
- Encouragement of best practice
- Opportunities to enhance the credibility of the laboratory and increase public confidence
- Provision of information and education to improve performance

EDUCATIONAL ROLE

- EQA schemes generate a large amount of data which can be used by scheme organizers to assist in the education of participants
- Improving quality
- Introducing IQC
- Training of operators
- Encouraged to use recommended methods

EQA Benefits to health and regulatory authorities

- Establishment of a network of blood transfusion laboratories with a known standard of performance
- It allow blood establishment to fulfill national and European requirements
- It ensure that the quality of blood and blood products is comparable within the country
- EQA facilitate the harmonization of practices and methods. Give an overview of current practice in the country → state-of-the-art methods and testing strategies
- It sensitizes blood establishment to a common QA practices

EQA Benefits to health and regulatory authorities

- Provision of useful information to assist in:

  — Setting standards

  — Reviewing testing strategies and technologies

  — Using resources effectively

  — Improving public confidence in the blood transfusion service

  — Supporting systems of accreditation.

EQA Programme for Italian

Blood Establishments

Mandatory introduction of NAT in Italian Blood Centers:

- June 2002 → HCV RNA
- April 2008 →HIV RNA and HBV DNA

EQA schemes are organized and promoted by the

National Blood Centre in cooperation with the

National Centre for Immunobiologics Research and Evaluation of the ISS (CRIVIB)

National Centre for the Control and Evaluation of Medicines (CNCF)

Scope

EQA Programmes are aimed at assessing the performance of laboratories for the assays currently used for blood screening:

- **qualitative NAT assays** (HCV RNA, HIV RNA and HBV DNA)

  NAT- 3 Scheme

- **immunometric assays** (anti-HCV, anti-HIV, HBsAg and treponema)

  SIERO- 4 Scheme

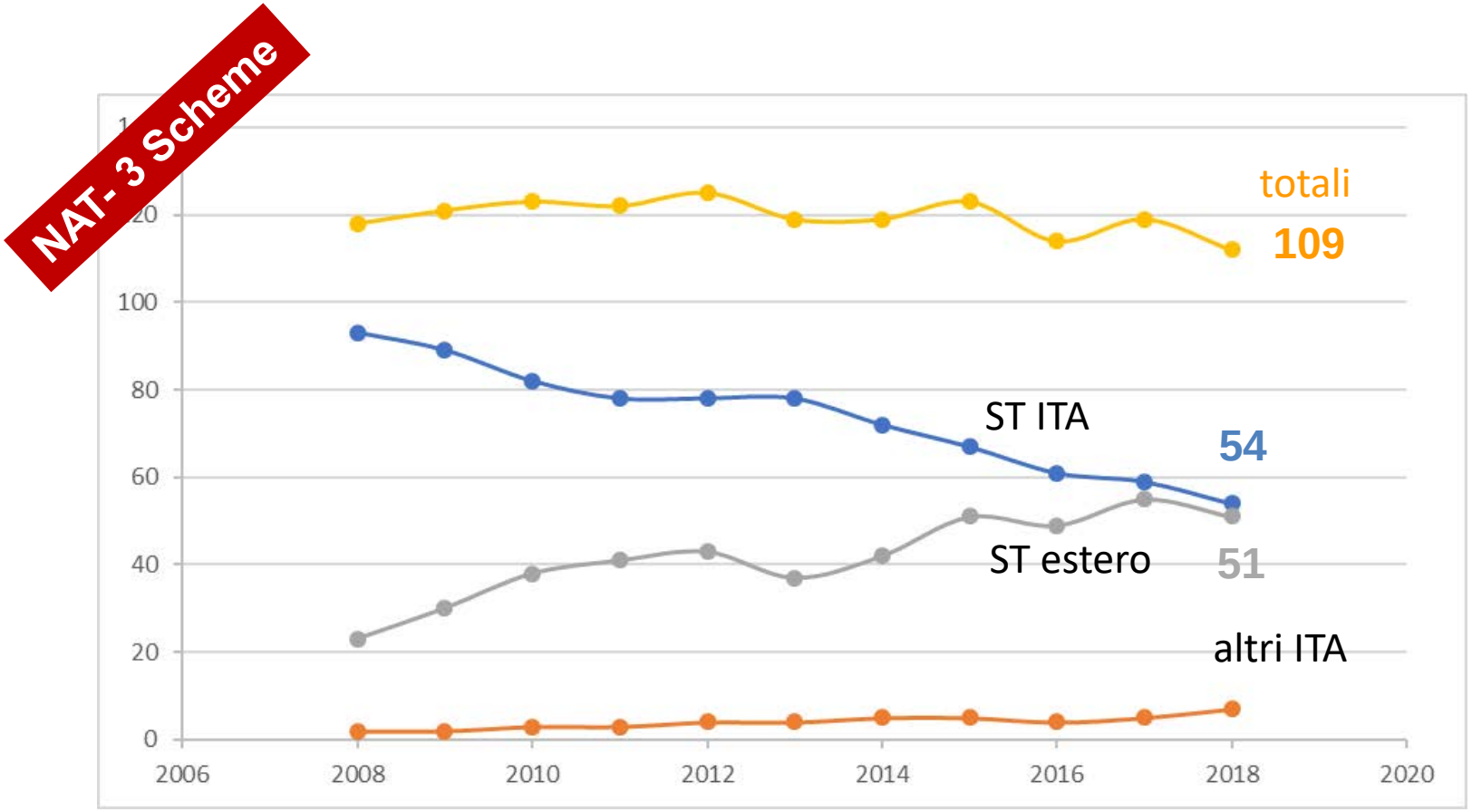
- **qualitative NAT assays** (WNV RNA)

  NAT- WNV RNA Scheme

Participant

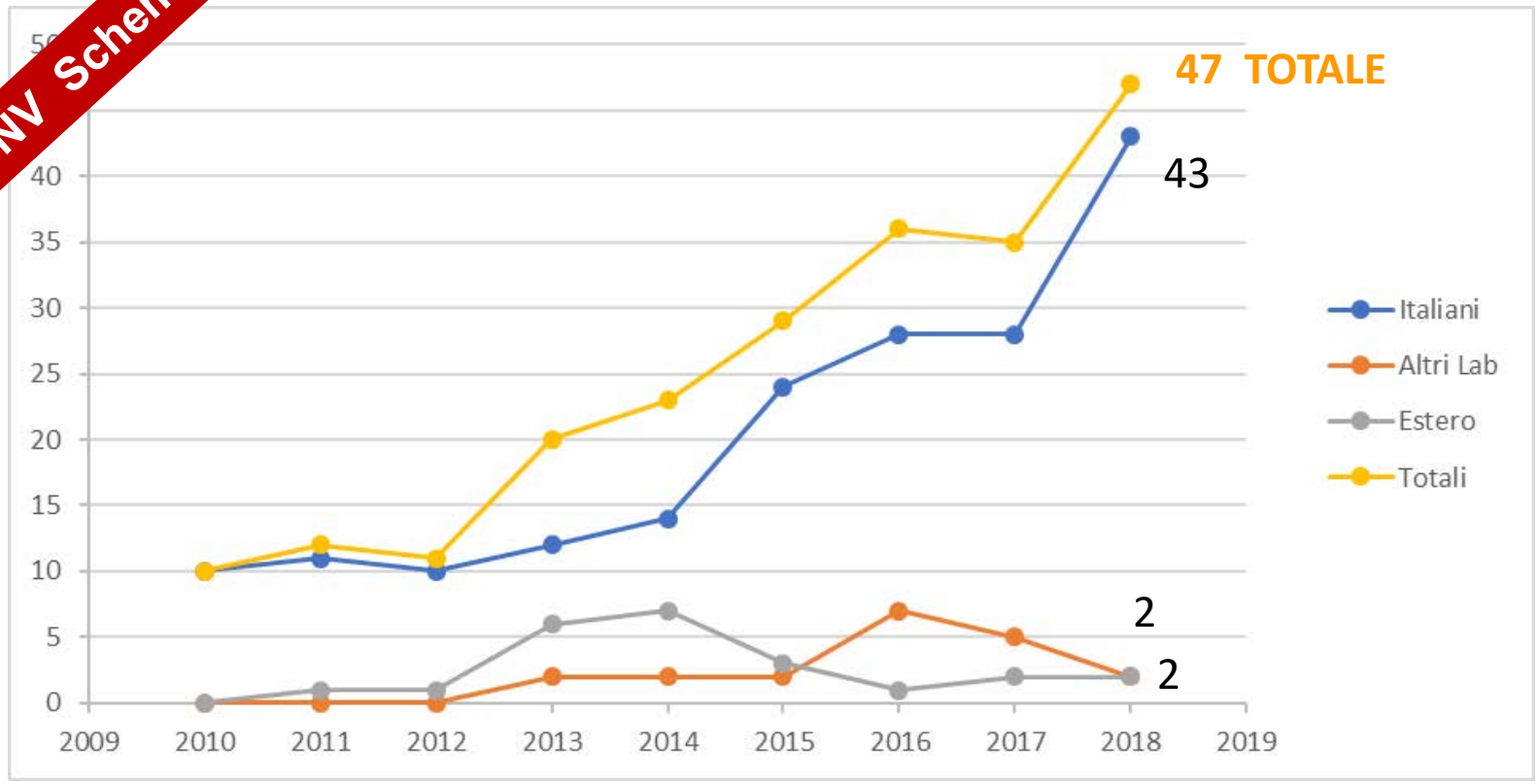
Italian Blood Centres and….

all testing labs and blood establishments/centres wishing to participate in the program, from all over Europe and the world (only for **NAT-3 scheme**)



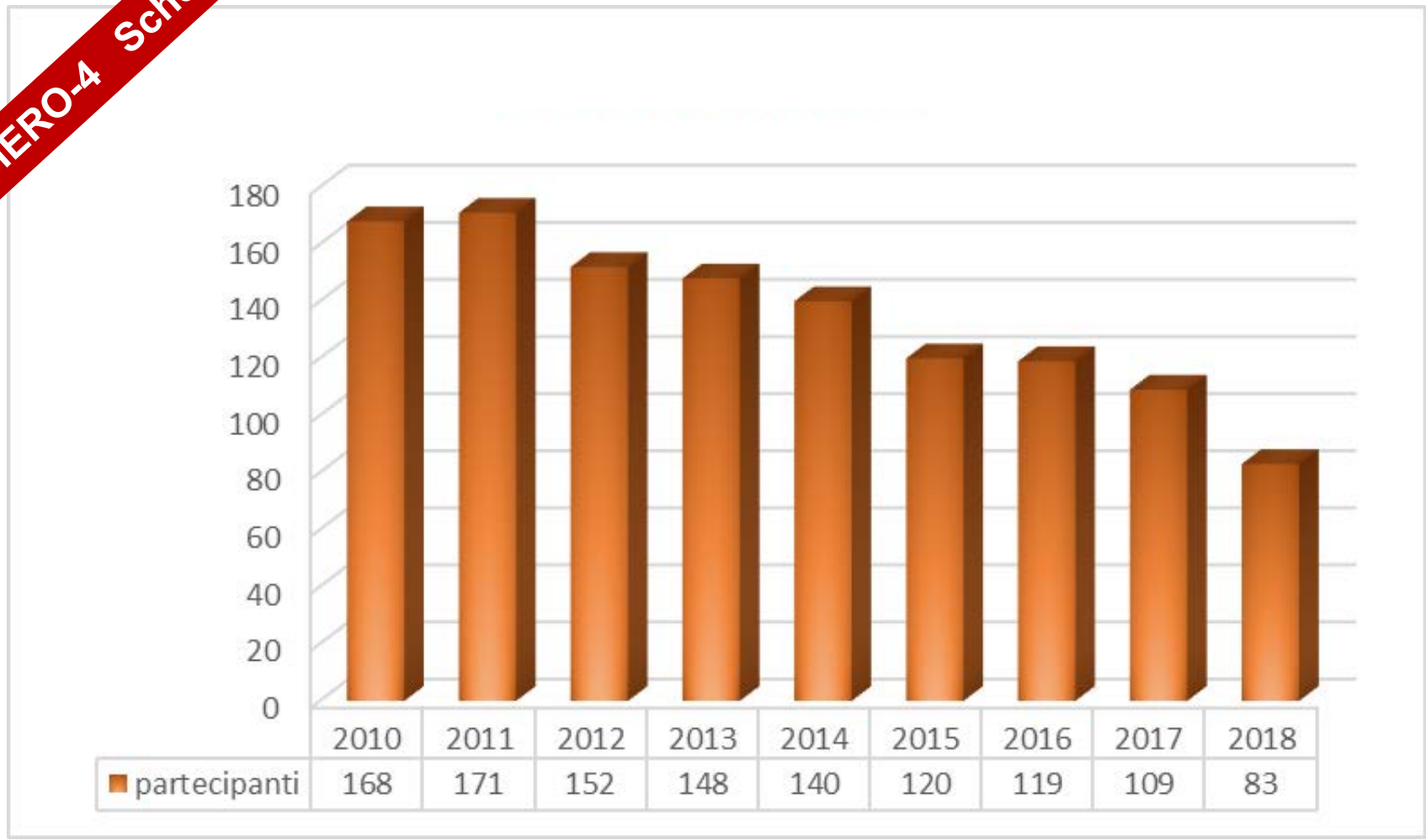
Participant

WNV Scheme



Participant

SIERO-4 Scheme



Management of IT-EQA

Scientif Advisory Group

Coordinator(s) of EQA

Biological Material to be used

Production of EQA samples
Preparation of EQA Panels

Protocol for participants

Opening of the website

Shipment EQA samples to Participants

Evaluation of Results

REPORT

Study outline

Project
- Aim of the Study
- Material
- Study design
- Evaluation of participants

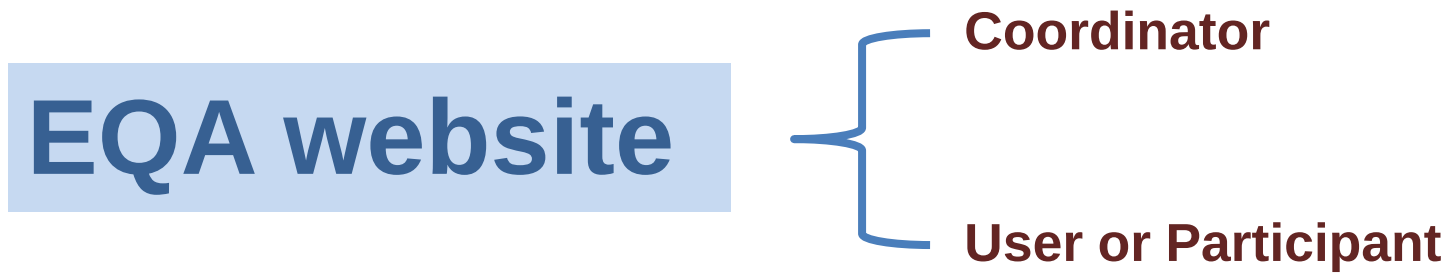
Participants' adhesion to EQA Scheme

Experimental Phase of EQA study (generally 1 month)

Test of EQA samples - Results

EQA WebSite

The EQA website was established by an external Company ALMAVIVA



Registration Form

Laboratory	○ Italian ◉ International		
Laboratory Type			
Country			
Name of the Laboratory			
First Name		Surname	
Address (where to deliver samples)			
City		Postcode	
Work Phone		Work Phone	
Mobile		E-Mail	
Fax		Fax	

☐ Replacing the former Contact Person

First Name		Surname	

Security Code [ ] Please enter the verification code hidden in the image

Confirm Cancel

UserID e Password

REPORTING THE RESULTS

an example

Dettaglio Risultato

Anno: 2018/4 **Responsabile:**

Metodica: cobas MPX test (cobas® 6800 / 8800 Systems) **Data Invio:** 21/11/2018

Programma: Programma Italiano di Valutazione Esterna di Qualità (VEQ) delle tecniche diagnostiche di amplificazione genomica (NAT) finalizzate alla qualificazione biologica dei prodotti ad uso trasfusionale (sangue, emocomponenti, prodotti plasma derivati). Target virali: HCV-RNA, HIV-RNA ed HBV-DNA Schema VEQ NAT-3 2018

Laboratorio:

Risultati laboratorio

Campione	Interpretazione	Risultato Grezzo	Note	Lotto/Scadenza	Operatore	Tipo di Campione	Esito
1	Reattivo	37.14	HCV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HCV	
2	Reattivo	32.33	HBV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HBV	
3	Non reattivo			MPX lotto n°E08514 01/11/2020	A	Non reattivo	
4	Reattivo	35.52	HIV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HIV	
5	Reattivo	36.41	HIV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HIV	
6	Non reattivo			MPX lotto n°E08514 01/11/2020	A	Non reattivo	

REPORTING THE RESULTS

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Laboratorio:

Risultati laboratorio								Performance	
Campione	Interpretazione	Risultato Grezzo	Note	Lotto/Scadenza	Operatore	Tipo di Campione	Esito	Metodica [1]	Complessivi [2]
1	Reattivo	37.14	HCV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HCV		43/43	110/110
2	Reattivo	32.33	HBV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HBV		43/43	110/110
3	Non reattivo			MPX lotto n°E08514 01/11/2020	A	Non reattivo		43/43	110/110
4	Reattivo	35.52	HIV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HIV		43/43	110/110
5	Reattivo	36.41	HIV	MPX lotto n°E08514 01/11/2020	A	Reattivo - HIV		43/43	110/110
6	Non reattivo			MPX lotto n°E08514 01/11/2020	A	Non reattivo		43/43	110/110

Risultati convalidati dal coordinatore: ESITO FAVOREVOLE

REPORTING THE RESULTS

an example

Dettaglio Risultato

Anno: **Responsabile:**

Metodica: cobas MPX test (cobas® 6800 / 8800 Systems) **Data Invio:**

Programma: Programma Italiano di Valutazione Esterna di Qualità (VEQ) delle tecniche diagnostiche di amplificazione genomica (NAT) finalizzate alla qualificazione biologica dei prodotti ad uso trasfusionale (sangue, emocomponenti, prodotti plasma derivati). Target virali: HCV-RNA, HIV-RNA ed HBV-DNA Schema VEQ NAT-3 2018

Laboratorio:

Risultati laboratorio

Campione	Interpretazione	Risultato Grezzo	Note	Lotto/Scadenza	Operatore	Tipo di Campione	Esito
1	Non reattivo	0		ROCHE cobas 6800 215549 31/07/2018	A	Non reattivo	
2	Reattivo	1		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HIV	
3	Reattivo	1		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HCV	
4	Non reattivo	0		ROCHE cobas 6800 215549 31/07/2018	A	Non reattivo	
5	Non reattivo	0		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HBV	
6	Reattivo	1		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HCV	

REPORTING THE RESULTS

an example

Dettaglio Risultato

Anno: **Responsabile:**

Metodica: cobas MPX test (cobas® 6800 / 8800 Systems) **Data Invio:**

Programma: Programma Italiano di Valutazione Esterna di Qualità (VEQ) delle tecniche diagnostiche di amplificazione genomica (NAT) finalizzate alla qualificazione biologica dei prodotti ad uso trasfusionale (sangue, emocomponenti, prodotti plasma derivati). Target virali: HCV-RNA, HIV-RNA ed HBV-DNA Schema VEQ NAT-3 2018

Laboratorio:

Risultati laboratorio								Performance	
Campione	Interpretazione	Risultato Grezzo	Note	Lotto/Scadenza	Operatore	Tipo di Campione	Esito	Metodica [1]	Complessivi [2]
1	Non reattivo	0		ROCHE cobas 6800 215549 31/07/2018	A	Non reattivo		36/36	111/111
2	Reattivo	1		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HIV		37/37	112/112
3	Reattivo	1		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HCV		37/37	112/112
4	Non reattivo	0		ROCHE cobas 6800 215549 31/07/2018	A	Non reattivo		37/37	112/112
5	Non reattivo	0		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HBV		36/37	110/112
6	Reattivo	1		ROCHE cobas 6800 215549 31/07/2018	A	Reattivo - HCV		37/37	112/112

Risultati convalidati dal coordinatore: ESITO NON FAVOREVOLE

Campione 5 non identificato correttamente

Red light – error

Review all documentation relating to the result of "non-compliant" (raw data, computer records …). Participant is asked to :

a) verification of any transcription errors

b) evaluate results of the internal quality controls

c) verification of the calibration / maintenance of the instrument,

d) verification of any instruments' alarms

Red light – error

Try to evaluate the type of error occurred :

a) pre-analytical error;

b) analytical error (instrument failure, instrument calibration, method used not suitable, contamination)

c) post -analytical error

Red light – error

	Perfomed	Not performed	Not applicable
Collection and review of data	☑	☐	☐
Evaluation of results	☑	☐	☐
Classification of the error	☑	☐	☐
Corrective actions	☑	☐	☐

EQA Programme for European Blood Establishments

edqm
European Directorate for the
Quality of Medicines & HealthCare

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Blood Proficiency Testing Scheme (B-PTS)

European Scheme Open to European Blood Transfusion Screening Laboratories

PTS activity is co-ordinated by the EDQM and co-funded by the EU Commission and the Council of Europe

Scientific Advisory Group

It is composed of experts in the field of blood transfusion.
It supports the EDQM in co-ordinating the B-PTS activity

Scientific Advisor for <u>each</u> B-PTS study. He/she is responsible for:

- writing a study outline (e.g. materials, tests, concentrations of samples, limitations statistical evaluation);
- giving advice on the procurement of suitable materials for the B-PTS study;
- assessing the feasibility of the study and writing the feasibility report;
- giving advice on the protocol for the study;
- providing technical and scientific assistance during the studies;
- advising the DBO on setting the assigned and target values of standard deviation for the statistical evaluation of the study results, where necessary

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

YEAR	PTS code	no of participants
2010	B-PTS001 HCV-NAT	38
2011	B-PTS003 HIV-NAT	33
2011	B-PTS006 HCV-NAT	33
2012	B-PTS008 HIV-NAT	34
2013	B-PTS010 HIV-NAT	34
2013	B-PTS012 HBV & HCV NAT	33
2014	B-PTS014 HBV & HCV NAT	38
2015	B-PTS018 HBV/HCV/HIV NAT	43
2016	B-PTS024 HBV/HCV/HIV NAT	40
2017	B-PTS030 HBV/HCV/HIV NAT	40
2018	B-PTS037 HBV/HCV/HIV NAT	44
2019	B-PTS038 HBV/HCV/HIV NAT	on going

CONCLUSIONS

- EQAs are important tools for monitoring the quality of laboratories
  - ✓ Provide labs with an objective means of assessing and documenting the reliability of the data
- EQA can result in a significant benefit for laboratories
  - ✓ Allow participants to become aware of unsuspected errors or problems
  - ✓ Policy for participation should be defined
  - ✓ Evaluation of results and corrective actions are crucial

What are the limitations of EQA studies?

- EQA cannot be used a substitute for routine internal QC.
- EQA is not a means of training individual analysts, nor (for the participant laboratory) a way of validating analytical methods.
- EQA provides a participant laboratory only with an indication of problems if they are present.
- EQA does not provide any diagnostics help to solve the problem.
- Success in a EQA for one analyte does not indicate that a laboratory is equally competent in determining an unrelated analyte

GRAZIE PER L'ATTENZIONE