



How to use EQA results in the Laboratory?

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What is External Quality Assessment?



Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

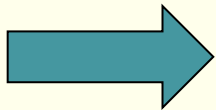
ISO 17043

In an external quality assessment program, a group of laboratories analyze the same specimens and submit their results to a central facility where the data are examined for outliers, and means and SDs are calculated to characterize the performance of the group of laboratories, and reports are generated to compare the performance of an individual laboratory to the peer group and sometimes to target values established by reference methods or reference laboratories.

James O. Westgard in “Basic QC Practices”



Objective assessment of a participants' performance for a particular laboratory method.



Deviation from the “true value”



Why External Quality Assessment?



ANALYTICAL PROCESS

	EXTERNAL	INTERNAL
PERMANENT	<p>ANALYTICAL PRINCIPLE METHOD EQUIPMENT CONSUMABLES (CALIBRATION)</p>	<p>CHOICE OF CONDITIONS INSTRUCTIONS IN-HOUSE REAGENTS IN-HOUSE EQUIPMENT (CALIBRATION)</p>
VARIABLE	<p>VARIATION IN BATCHES - REAGENTS - CONSUMABLES - (CALIBRATORS)</p>	<p>VARIATION IN PERFORMANCE/EXPERIENCE MAINTENANCE TRAINING TROUBLE SHOOTING</p>



External Quality Assessment is an indispensable part of the quality management in the medical laboratory.

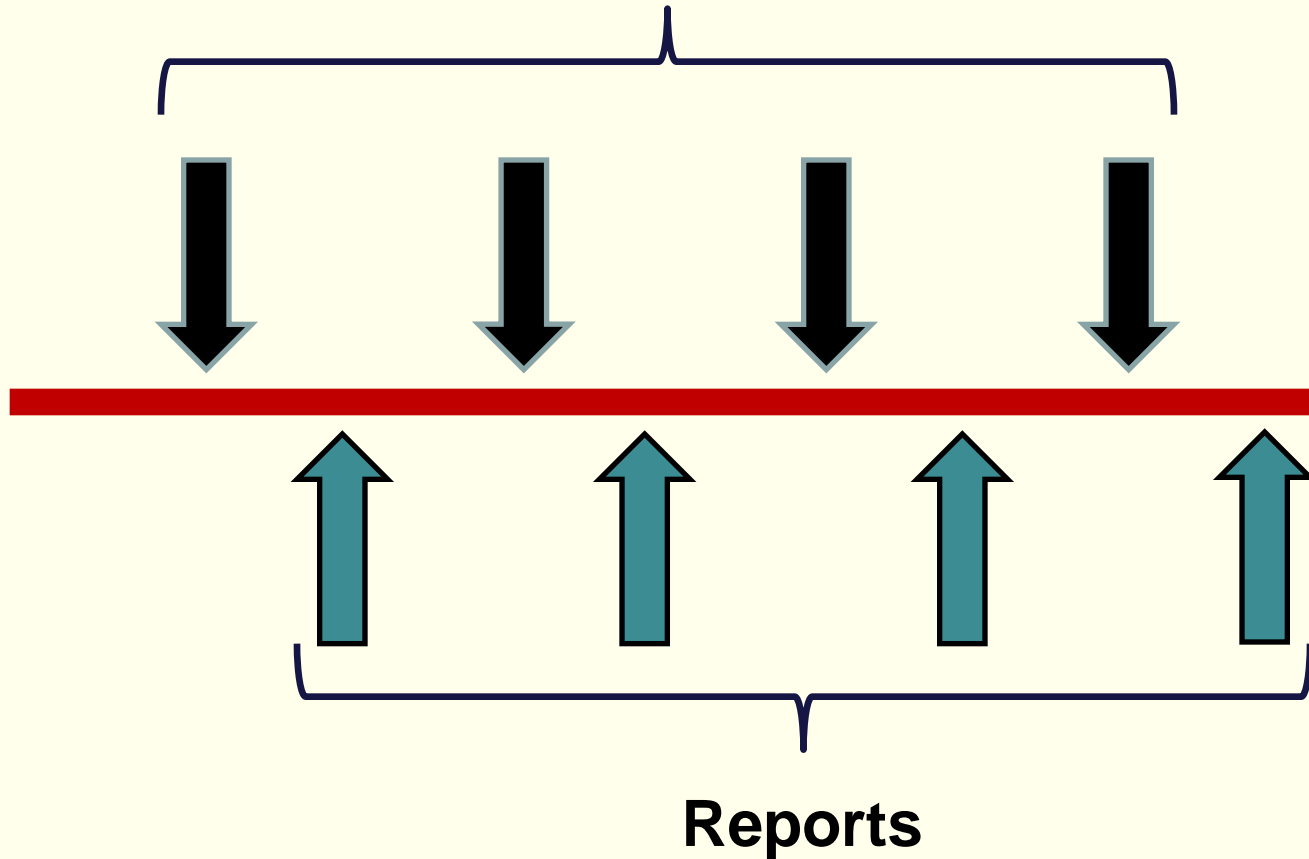


How to use EQA data?



EQA Programme

4 surveys per year





EQA Programme

- **Assessment at a given moment**
- **Retrospective**

Evaluation:

per survey

long-term



Z-score:

Individual performance indicator:

A numerical indicator representing the performance of an individual participant in relation to the other participants.

Z-score = Standard Deviation Index

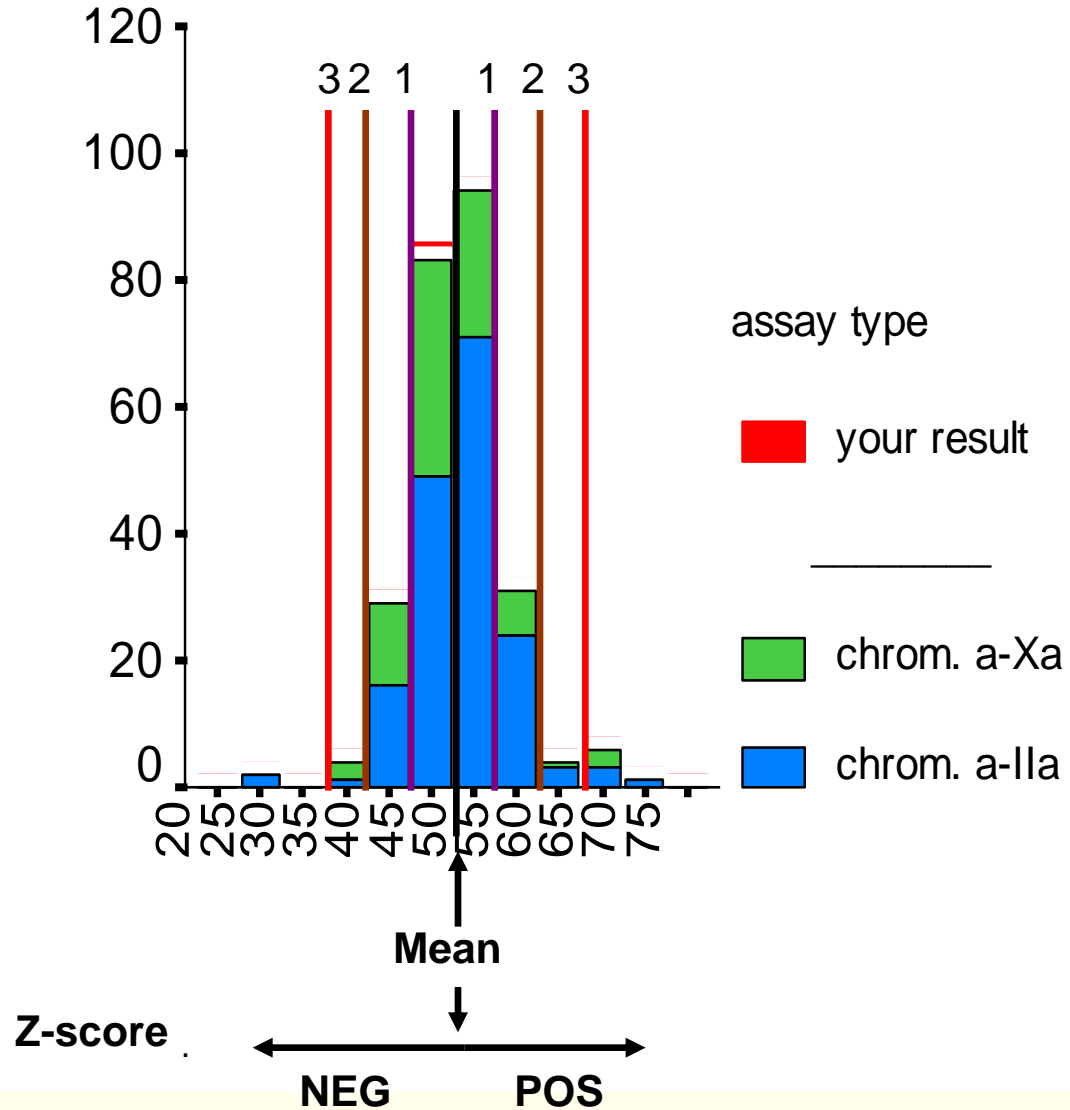
It describes the systematic error or bias of the individual result from the consensus value as a multiplier of the standard deviation.

$$\mathbf{Z\text{-score} = (lab - cons)/s}$$



Z-score:

laboratory 102





Descriptive statistics after removal of outliers

$$\text{Z-score} = (44 - 47.9) / 4.9 = -0.80$$

Negative
Z-Score



<u>ANTITHROMBIN</u>	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		
Chromogenic - anti-Xa	83	46.9	11.6%	36 - 64		
Coamatic (Chromogenix)	31	45.6	13.1%	36 – 64		
Coamatic LR (Chromogenix)	12	48.9	13.4%	42 – 63		
HemosIL Antithrombin (IL)	21	47.2	10.4%	40 - 62		



Analyte	Consensus Sample 1	Z-score Sample 1	Consensus Sample 2	Z-score Sample 2
FVIII	95%	0.45	70%	- 0.95
FIX	105%	- 0.25	53%	0.33
FXI	87%	0.15	65%	-1.17
FXII	100%	0.75	43%	- 2.65



INTERNATIONAL
STANDARD

ISO/IEC
17043

First edition
2010-02-01

Conformity assessment — General
requirements for proficiency testing

*Évaluation de la conformité — Exigences générales concernant les
essais d'aptitude*

$-2 \leq Z\text{-score} \leq 2$

Satisfactory

$-3 \leq Z\text{-score} < -2$

$2 < Z\text{-score} \leq 3$

Questionable

$Z\text{-score} < -3$

$Z\text{-score} > 3$

Unsatisfactory



$-2 \leq Z\text{-score} \leq 2$

Satisfactory

No signal

**$-3 \leq Z\text{-score} < -2$
 $2 < Z\text{-score} \leq 3$**

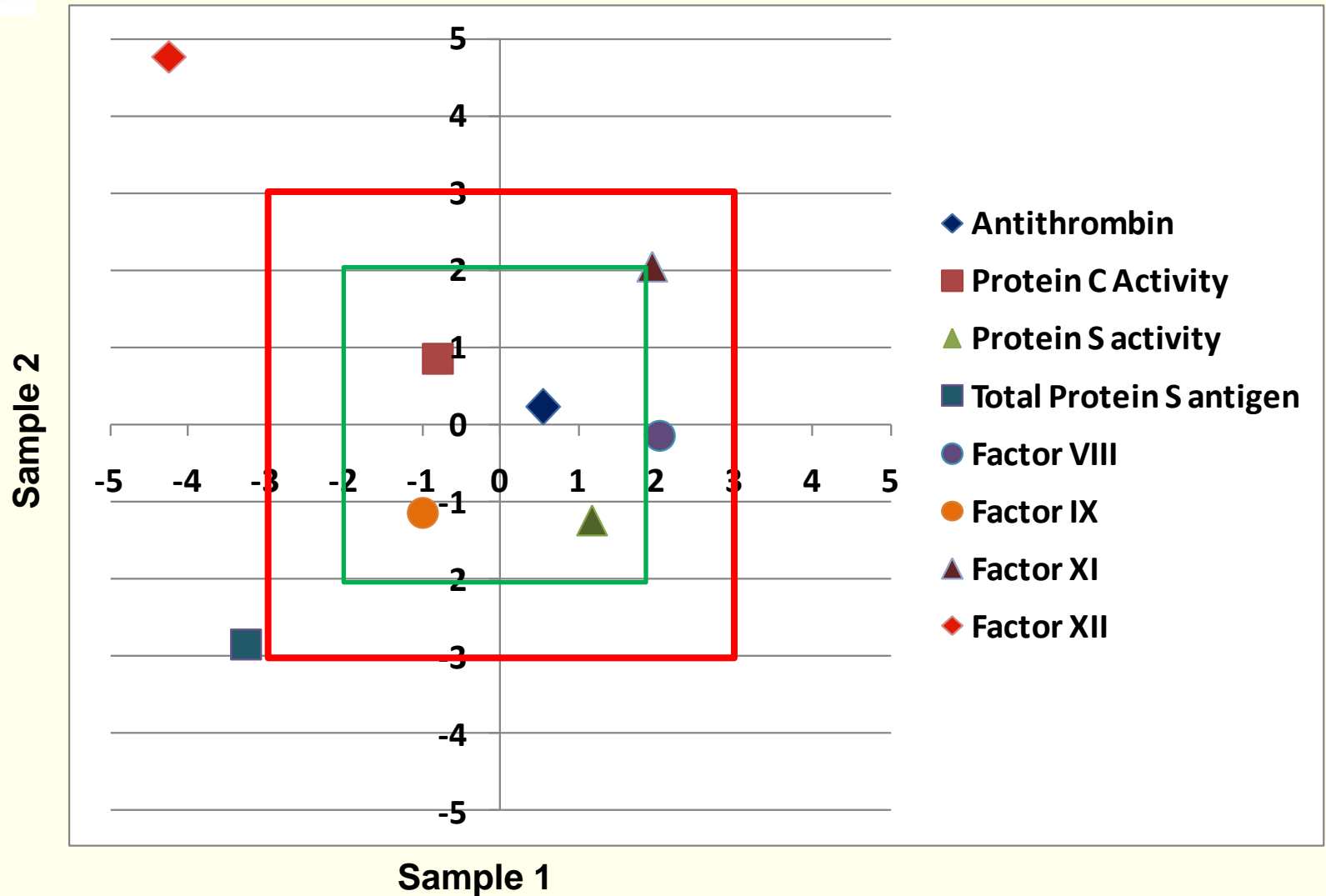
Questionable

Warning signal

**$Z\text{-score} < -3$
 $Z\text{-score} > 3$**

Unsatisfactory

Action signal





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.



Evaluation of survey results

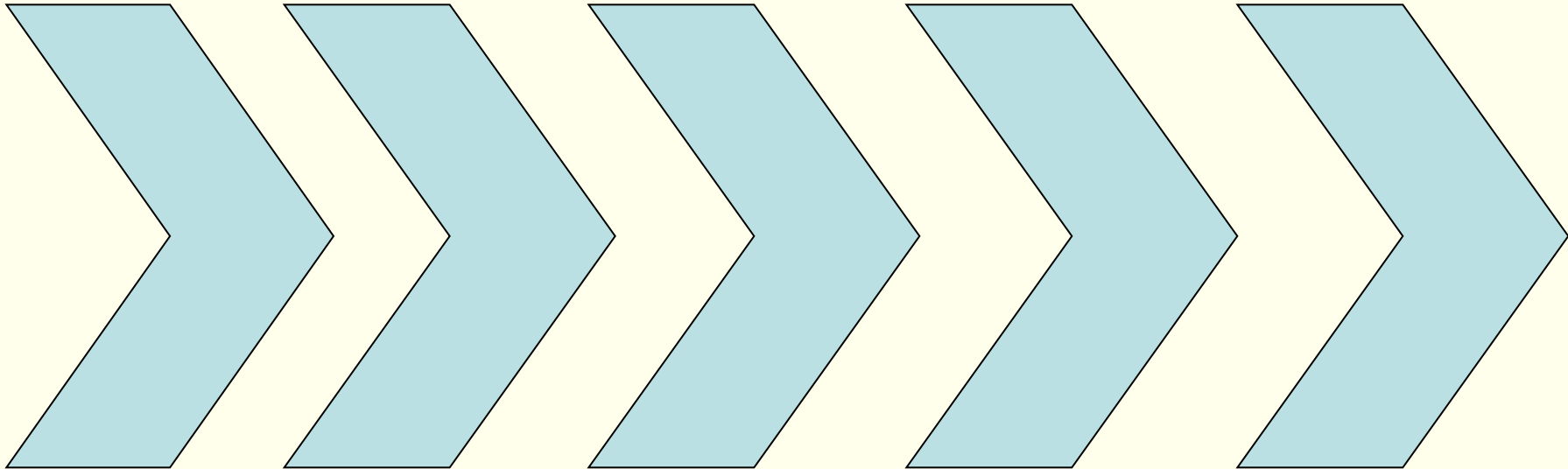
**Receipt
report**

**Evaluation
report**

**Corrective
actions**

Implementation

**Documentation
Storage**





-3 > Z-score > 3

INTERNAL

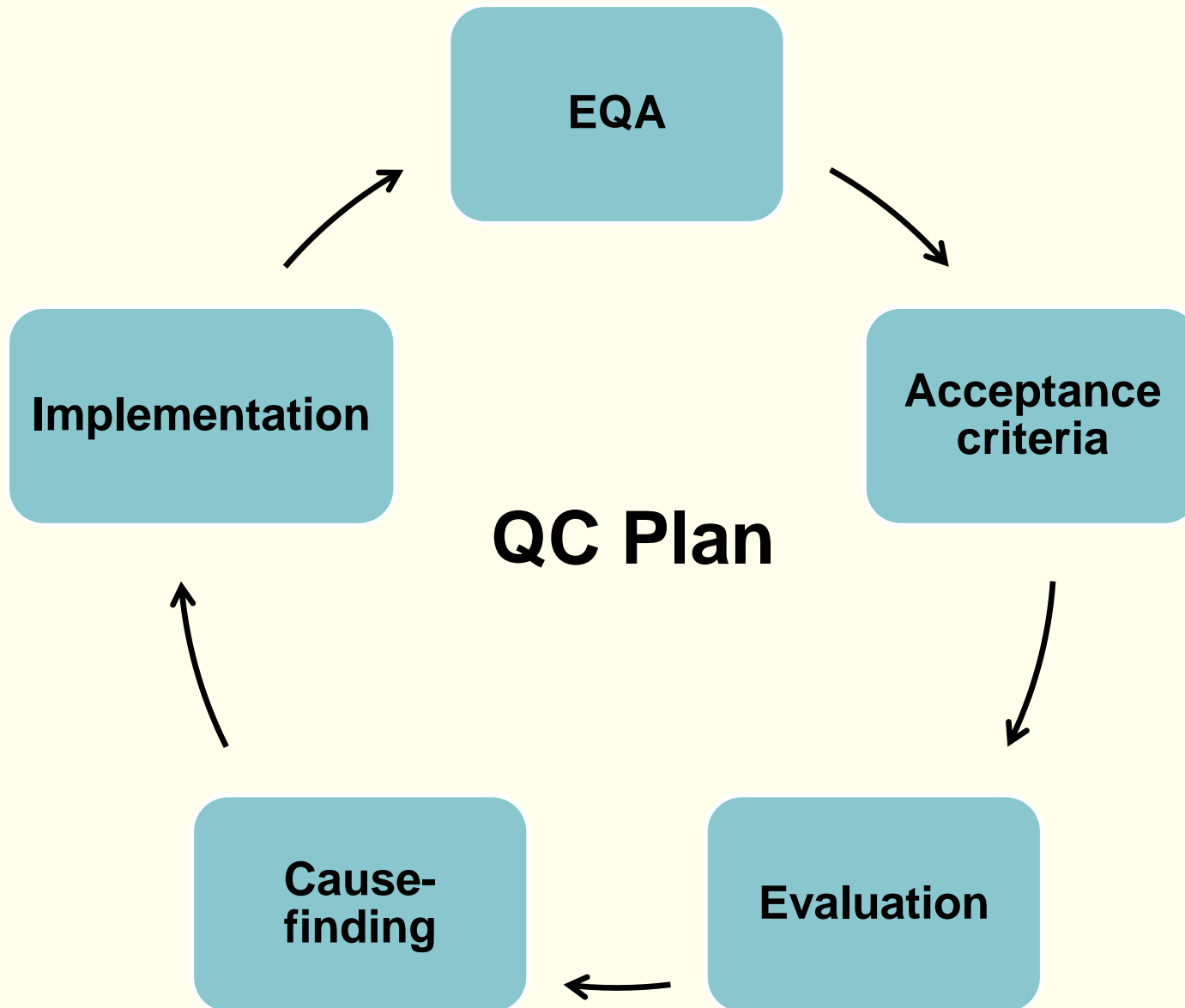
- Internal QC
- Reagents
- Calibration
- Instructions EQA organiser
- Test instructions
- Etc.

EXTERNAL

- Sample condition
- Instruction letter
- Deviation method group
- Large variation in method group
- Etc.

BOTH

- Results correctly submitted/registered
- All samples deviate
- Change in method
- Accordance with previous EQA results
- Etc.





Analyte	Consensus Sample 1	Z-score Sample 1	Consensus Sample 2	Z-score Sample 2
FVIII	97%	-4.25	45%	3.85
FIX	105%	- 3.33	53%	4.00
FXI	107%	-5.08	35%	6.30
FXII	95%	-4.80	43%	4.85



THANK YOU FOR YOUR ATTENTION