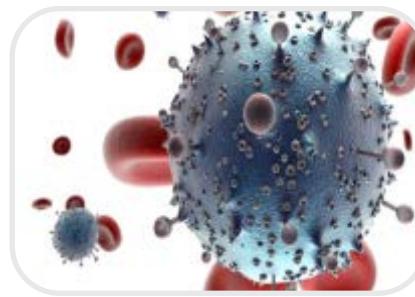


An International and leading provider of external quality assessment services within the UK and to over 50 countries worldwide

HOW TO BE A GOOD PARTICIPANT

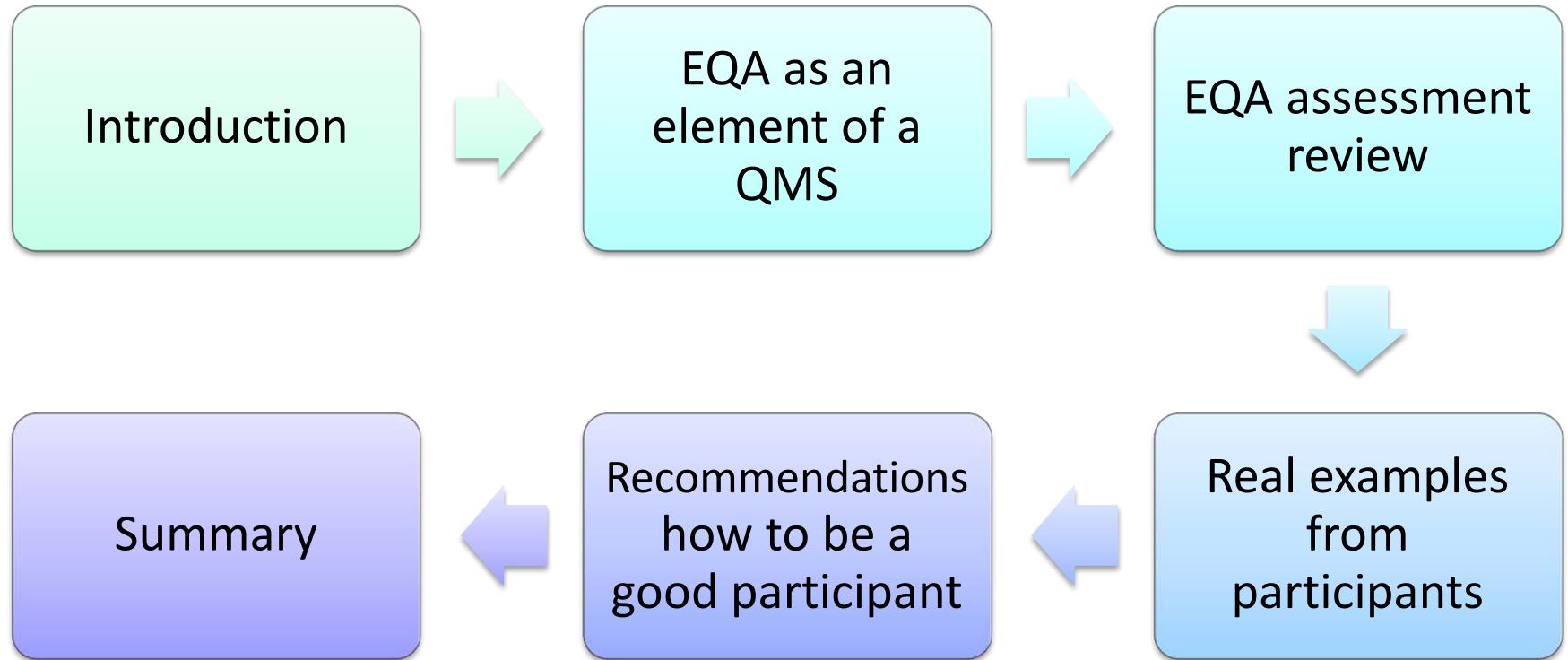
Scientific Meeting



Sérgio Bio Fernandes

User Day | 29th November 2013 | London

Overview



Quality Management System - Laboratory



CPA
Accreditation

ISO 15189:2012

ISO 17025:2005

ISO 9001:2008

All based in
process approach

Management of the EQA process

The laboratory should develop a **process** for the management of the EQA



Primary objective: to assure that all EQA samples are **treated in the same manner** as other samples tested

*Procedures
should be
developed*

Handling of samples

Analyses of samples

Appropriate record keeping

Investigation of any failures

Taking corrective action

Effective Communication

The moment: receiving the report!



**100% correct
results**



**EQA performance
problem**



EQA Failure Checklist – Assessment Review 1



Recommended APPROACH

- Any EQA report should have a methodic and audit-like approach
- We could apply a model like “EQA Failure Checklist – Assessment Review”

Overview

YES NO N/A

A single sample fails on several analytes (swap, clot, ...)

All samples failed for the analyte (reconstitution, ...)

First time or recurrent situation?



EQA Failure Checklist – Assessment Review 2

Report reviewed for clerical errors	YES	NO	N/A
EQA evaluation results match the copy of submitted results			
Incorrect Data Entered			
Incorrect Units Reported (log and copies/mL; HCV Ag pg/mL vs fmol/L)			
Use of points and commas in quantitative results (use point only to indicate decimal place)			

EQA Failure Checklist – Assessment Review 3

Specimens Handling	YES	NO	N/A
Specimens stored at correct temperature between receipt and analysis			
Sample reconstituted properly			
Sample thoroughly mixed before testing			
Staff read the information sheet and web instructions carefully (special procedures and any changes from previous distributions)			
Unexpected delays in receiving specimens			

EQA Failure Checklist – Assessment Review 4

Testing Procedure	YES	NO	N/A
Staff competent to perform testing			
Manufacturer's package insert testing respected (reconstitution, expiration date, kit components mixed from different batches)			
Sample mix-up (decanting to a secondary cup)			
Instrument maintenance up-to-date			
Instrument calibration? (due / recent calibration)			
New lot number of reagents or calibrators used			
Internal kit controls: criteria passed			
IQC within acceptable range			
Multi-step process: all steps investigated? Eg: extraction			

Root
Cause
Analysis!

ASK FOR
REPEATS!

EQA performance problems – real examples

The examples given are mostly from virology but the basic principles are applicable to other areas



Error-based learning

One of the objectives of the schemes is to give participants the opportunity to **learn from failures**



Error is part of the growing process. Identify your
LESSON LEARNED!

Recurrent mistakes and inefficient corrective actions are against the process of **continuous improvement!**

Wimbledon & unforced errors & EQA



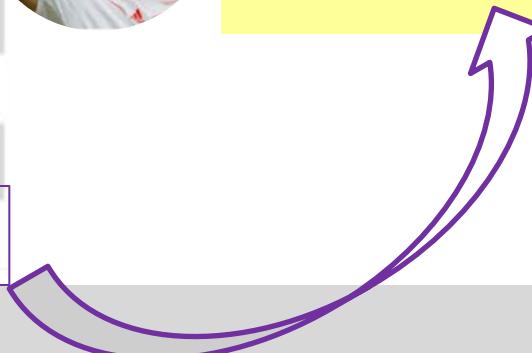
Unforced error occurs when it is judged a tennis player has full control over his /her swing and commits an error.

Participants have some “distractions” that can be considered unforced errors

Set	1	2	3
Breaks	4	2	1
1st Serve Points Won	42.9%	57.7%	63.6%
2nd Serve Points Won	25.0%	42.9%	50.0%
First Serve Speed (MPH)	96.9	94.4	90.7
Unforced Errors	14	10	4



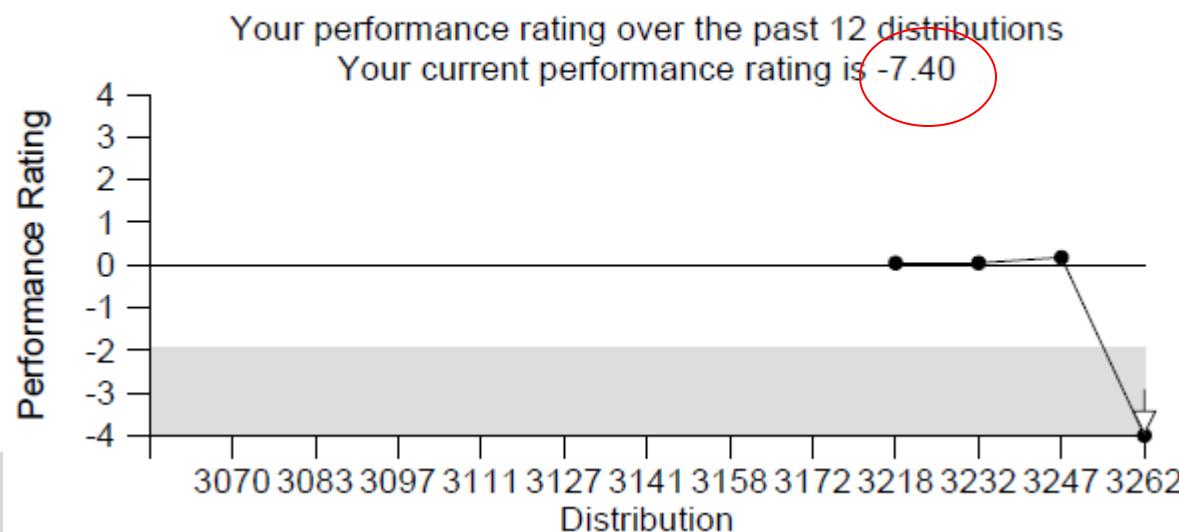
Strategy: improve your performance by **minimizing unforced errors**



Swapping specimens

Intended Result	Your Report	Your Score
Specimen 1537 HBsAg positive Anti-HCV negative Anti-HIV negative	HBsAg negative Anti-HCV negative Anti-HIV presumptive positive	-1 2 -1
Specimen 1538 HBsAg negative Anti-HCV positive Anti-HIV negative	HBsAg negative Anti-HCV positive Anti-HIV negative	2 2 2
Specimen 1539 HBsAg negative Anti-HCV negative Anti-HIV presumptive positive	HBsAg positive Anti-HCV negative Anti-HIV negative	-1 2 -1

Your performance rating indicates possible poor performance



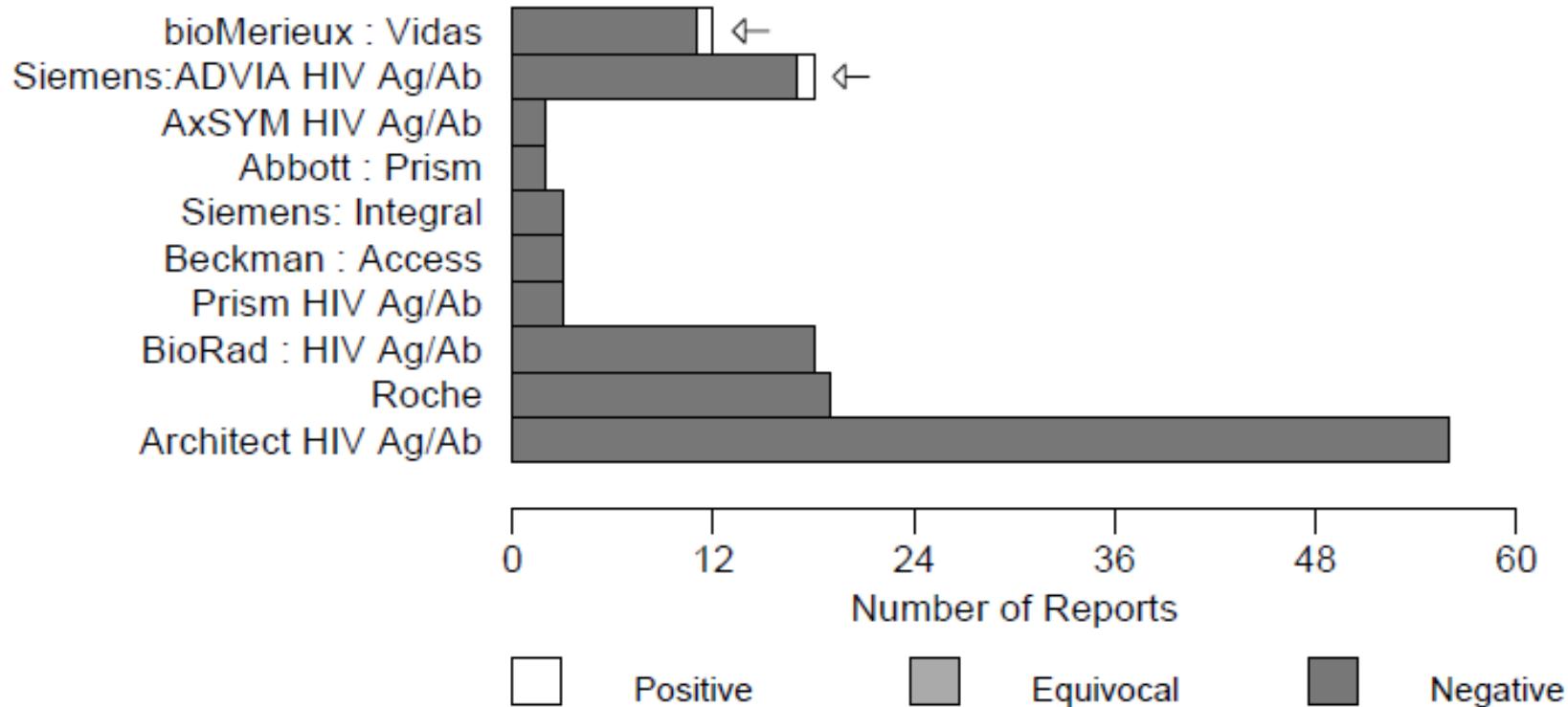
Swapping specimens

Specimen : 1537

Intended result

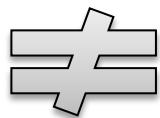
Anti-HIV negative

Your score is below 2. The reason should be investigated

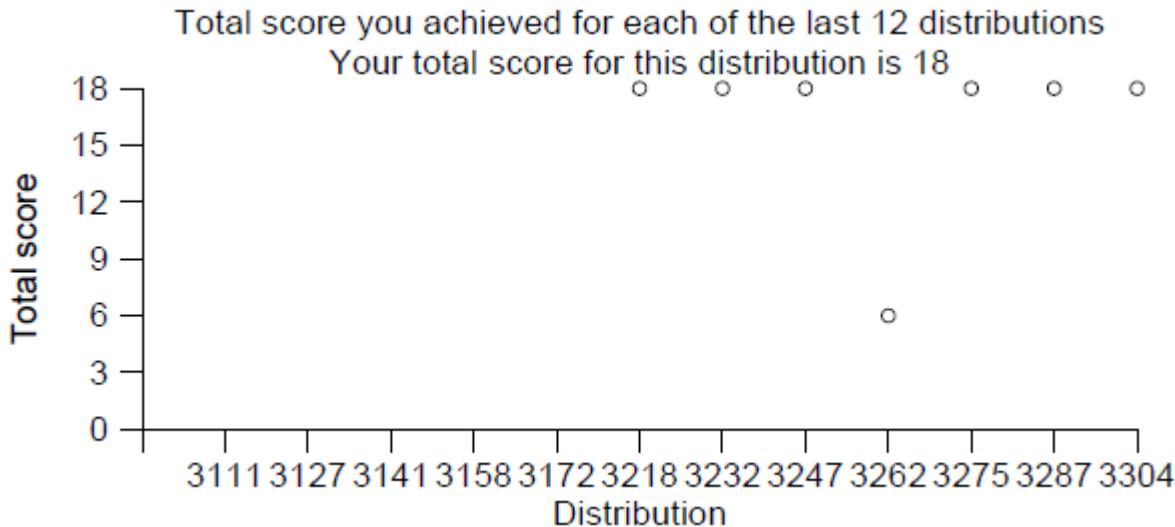


Single error – effects through time

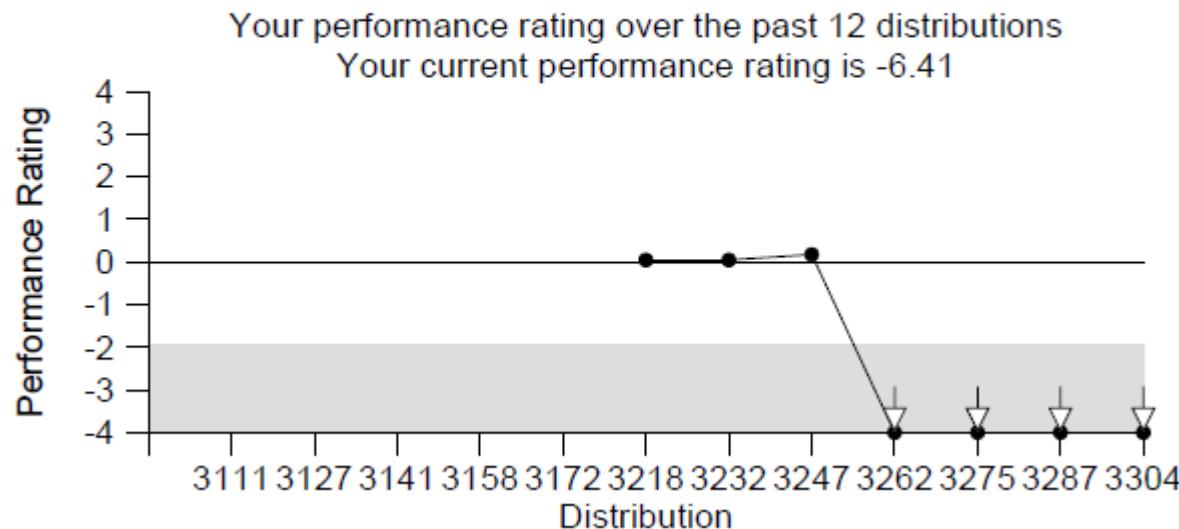
Single
error



QMS
problem



Your performance rating indicates possible poor performance

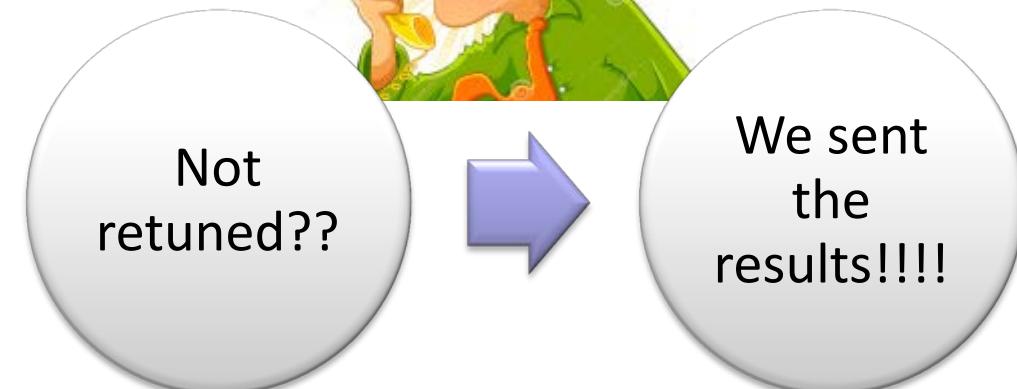


Transcriptional errors

- We have recently reviewed the results submission
- We found that 1 specimen has been transcribed incorrectly
- This resulted in a significant loss of points
- We did get the correct results for all 3 specimens
- Would it be possible to correct the score?

Intended Result	Your Report	Your Score
Specimen 1734	HBsAg positive Anti-HCV negative Anti-HIV negative	HBsAg positive Anti-HCV negative Anti-HIV negative
Specimen 1735	HBsAg negative Anti-HCV positive Anti-HIV negative	HBsAg negative Anti-HCV negative Anti-HIV presumptive positive
Specimen 1736	HBsAg negative Anti-HCV negative Anti-HIV presumptive positive	HBsAg negative Anti-HCV negative Anti-HIV presumptive positive

Changes to submitted results (before closing date) - 1



From:
Sent: 13 July 2013 14:28
To: UK NEQAS Micro
Cc:
Subject: Distribution 3248
Importance: High

Hi,

~~Please investigate the attached documentation. Laboratory xxx HCV scheme distribution 3248 has been recorded as " Not returned".~~
Results entry was made and submitted on 20/06/13, see attached documentation. Request you reassessed this evidence.

Yours

Changes to submitted results (before closing date) - 2

Dear participant,

As you can see on the table below, our system didn't have your results because your last action (change result) after the first submission was not confirmed with a subsequent resubmission

Date and time	Accepted	Message
20-06-2013 21:35:10	No	(Viewed)
20-06-2013 22:23:07	Yes	(Submitted)
20-06-2013 22:23:11	Yes	Print results screen
21-06-2013 12:20:04	No	Result change : specimen 3, ((0.22 to 0.23))
Current Status :		
21-06-2013 12:20:04	No	

C

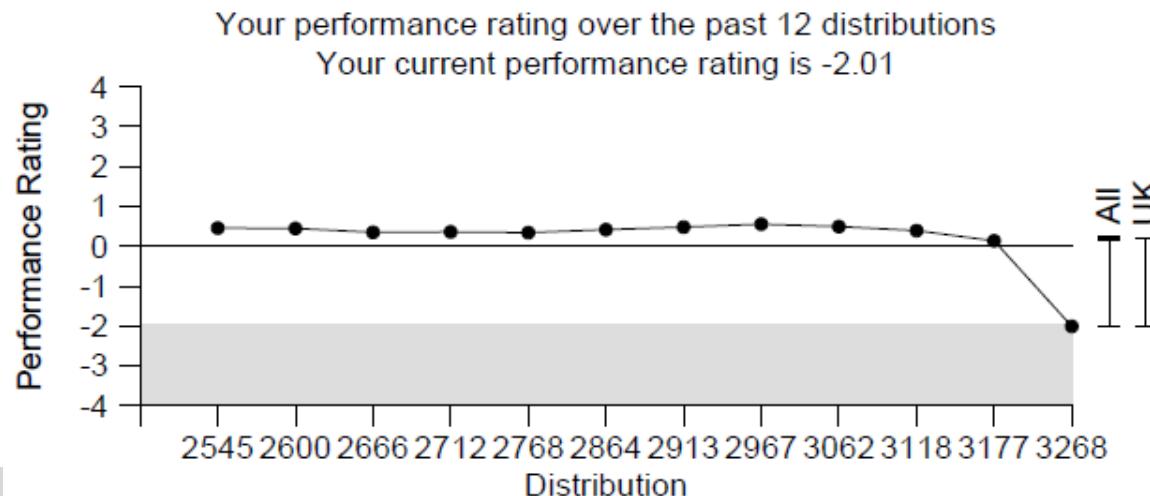
On this occasion we will exceptionally accept your results but you need to be aware that after submitting your results, if you do any change, you need to submit again. Your updated report will ready in a few days.

Many thanks.

Choosing the right option - 1

Intended Result	Your Report	Your Score
Specimen 1560 Anti-HIV negative	Anti-HIV negative	2
Specimen 1561 Anti-HIV negative	Anti-HIV negative	2
Specimen 1562 Anti-HIV1 positive	Anti-HIV1 positive	2
Specimen 1563 Anti-HIV1 positive	Anti-HIV1 positive	2
Specimen 1564 Anti-HIV2 positive	Anti-HIV1 positive	-1
Specimen 1565 Anti-HIV1 positive	Anti-HIV1 positive	2

Your performance rating indicates possible poor performance

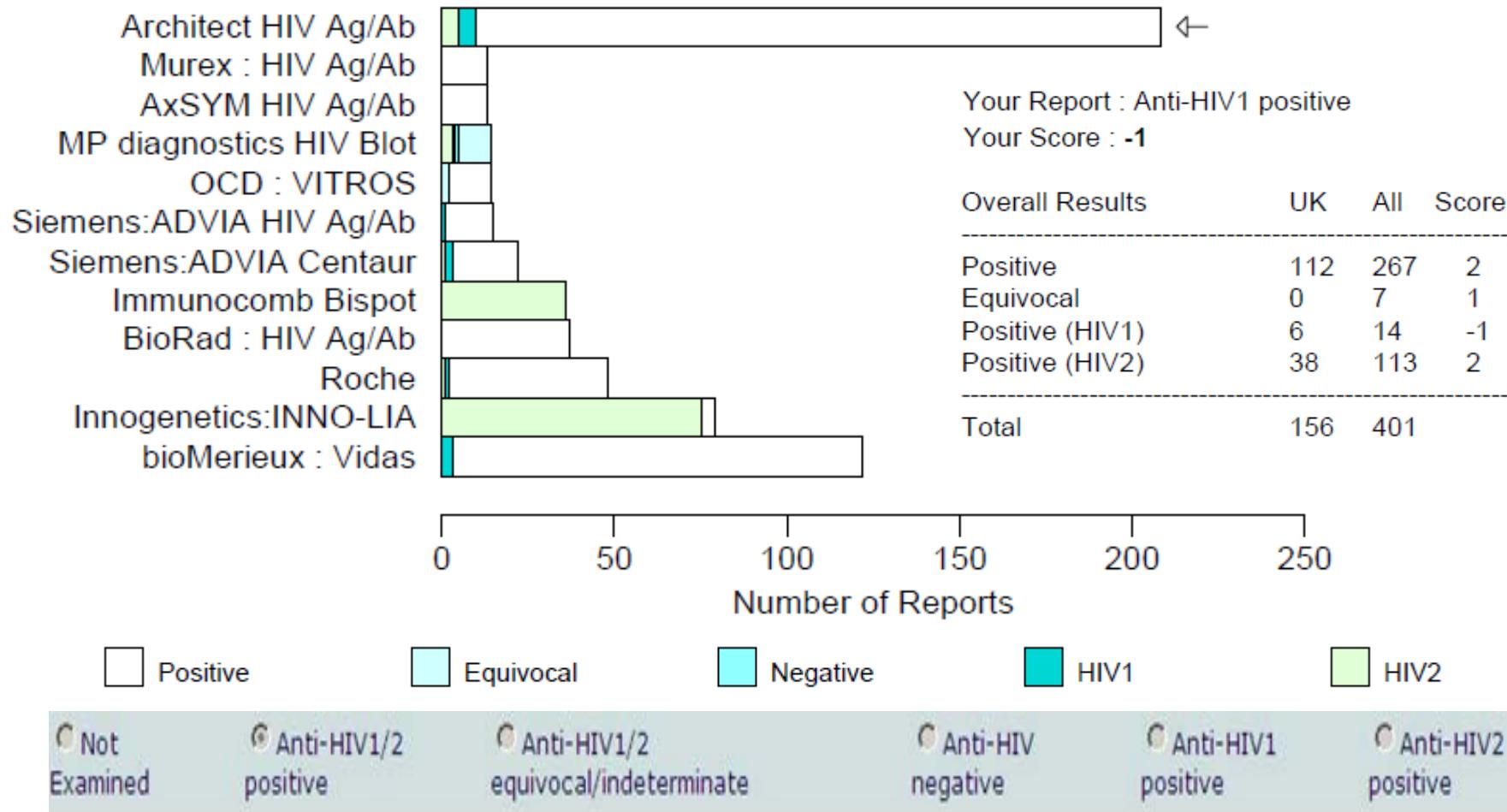


Choosing the right option - 2

Specimen : 1564

Anti-HIV2 positive

Your score is below 2. The reason should be investigated



Continuous improvement of reports - 1

From:

Sent: 09 September 2013 14:20

To: UK NEQAS Micro

Subject: Anti-HBs NEQAS report 090913.docx

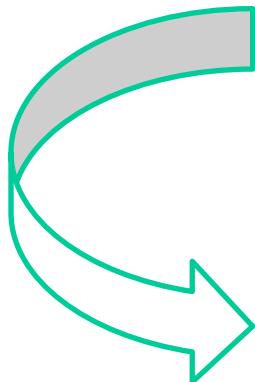


Hi,

I have just checked our NEQAS anti-HBs results and there seems to be a confusing report on the distribution 3276 with the intended results at the top of the page (alongside our results and score) not matching the results as outlined/detailed in the graphs etc below. The not scored sample number also doesn't match that indicated in the scoring table as having been not scored

	Intended Result	
Regards	Specimen 1590	Anti-HBs positive (>100 mIU/mL)
	Specimen 1591	Anti-HBs negative (<10 mIU/mL)
	Specimen 1592	Anti-HBs low level positive (10-100 mIU/mL)
	Specimen 1593	Anti-HBs low level positive (10-100 mIU/mL) Anti-HBs positive (>100 mIU/mL)
	Specimen 1594	Anti-HBs negative (<10 mIU/mL)
	Specimen 1595	Anti-HBs positive (>100 mIU/mL)

Continuous improvement of reports - 2



Specimen : 1590 Anti-HBs low level positive (10-100 mIU/mL)

	n (UK)	range	median	5%-95%
All methods	425 (167)	19-298	121	42-237

Specimen : 1590 Anti-HBs positive (>100 mIU/mL)

	n (UK)	range	median	5%-95%
All methods	425 (167)	19-298	121	42-237

CC13-1907 | RE: Anti-HBs NEQAS report 090913.docx; Our Ref: CC13-1907

Sent: Mon 09/09/2013 16:30

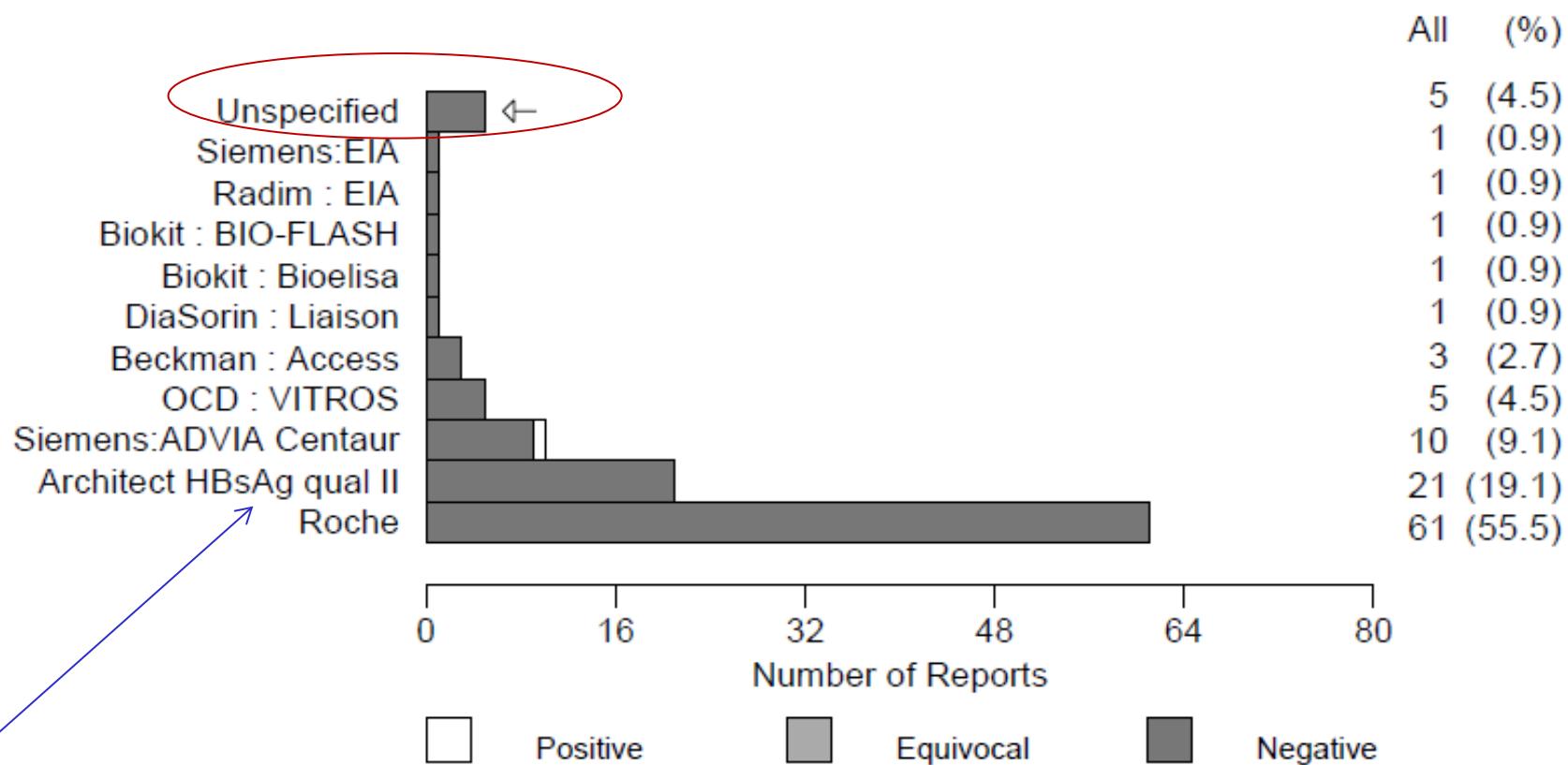
Hi

We really appreciate your careful look to spot these inaccurate aspects. We are working on the amended report that should be ready today or tomorrow morning.
Thanks once again.

Kind regards

Continuous improvement of reports - 3

Specimen : 1735 Intended result
HBsAg negative



Recommendations 1 – No special treatment

There are several ways in which EQA specimens may be treated differently to clinical specimens

- Handled by more senior grades of staff
- Subjected to a greater range of diagnostic procedures than normal
- Tested on more than one instrument/method (unless that is how they test patient specimens)
- Repeated analysis of specimens: unless patient specimens are similarly tested (duplicates, ...)
- Results may receive special scrutiny
- Results subject to inter-laboratory discussion



Recommendations 2 – Attention to detail



Read carefully instructions! Dispatch sheet and Web first page. Storage, reconstitution, changes, ...



Report the right assay (method details box): let us know of any changes



Select the **right option** from options available on the menus. Complete overall report.



Any **changes** made need a **re-submission**



Records of all EQA testing and reporting should be maintained over a period of time



Recommendations 3 – Submit results on time

The system **does not accept** results submitted after the submission deadline



The **closing date is clearly stated** on the information sheet (use alarms/reminders).

Once the intended results are uploaded is **impossible to accept** (ISO and UKAS recommendations)

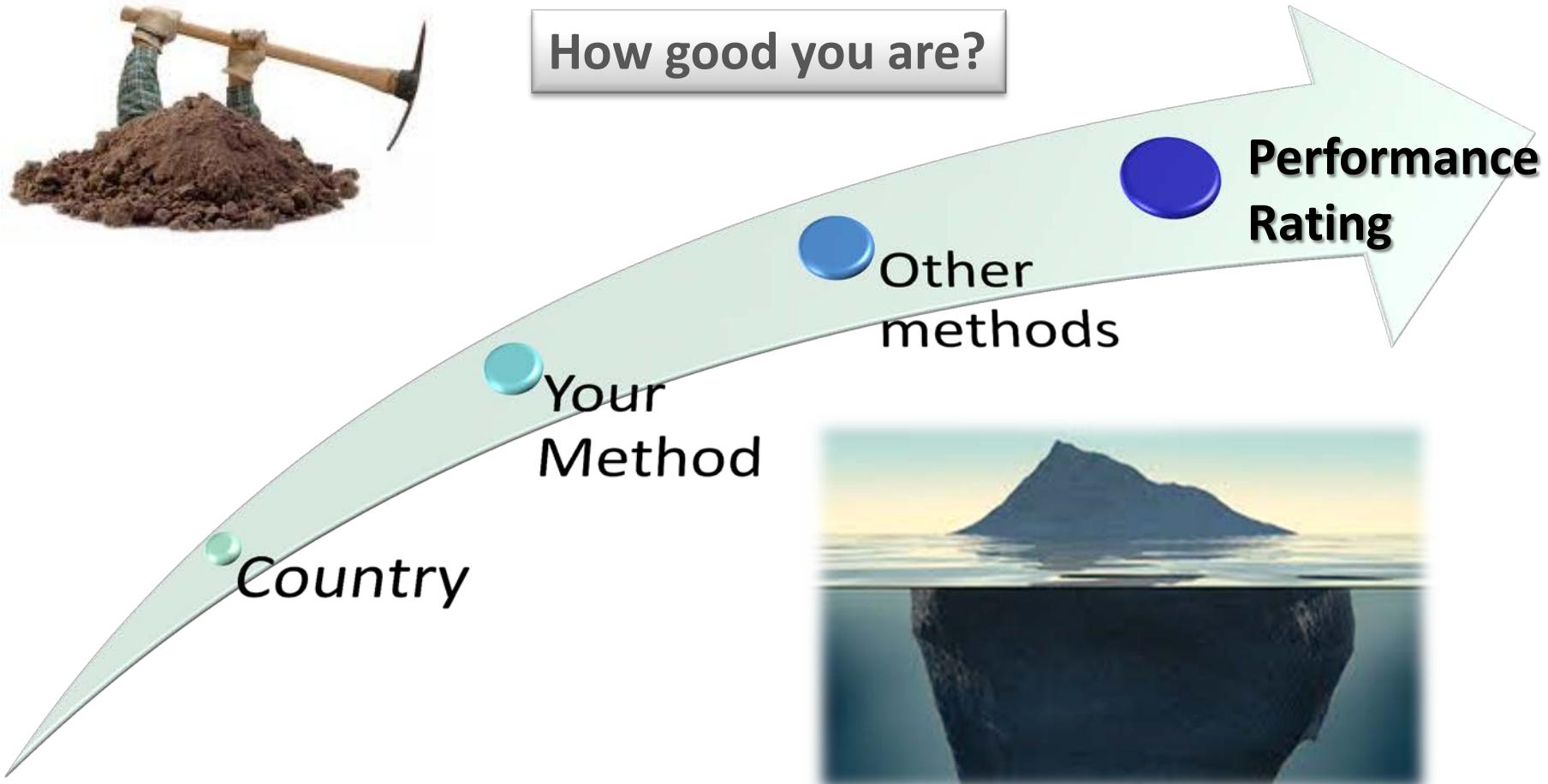
You don't receive extra points!

We encourage early submission!

Recommendations 4 – Read the report



How good you are?



EQA FAILURE

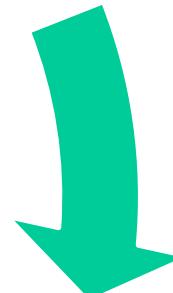
• INVESTIGATE!

Final KEY MESSAGES about EQA

Is a system for objectively **checking the laboratory's performance**

Uses valuable resources! The

laboratory should make the best use possible of its participation



Is one of **the critical elements** of a laboratory **quality management system**

Should not be punitive. Should be viewed as **educational** and used as a **tool** to help direct **improvement** efforts



Many thanks!



Contact

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