Molecular Quality Assessment: an evaluation over the last 5 years

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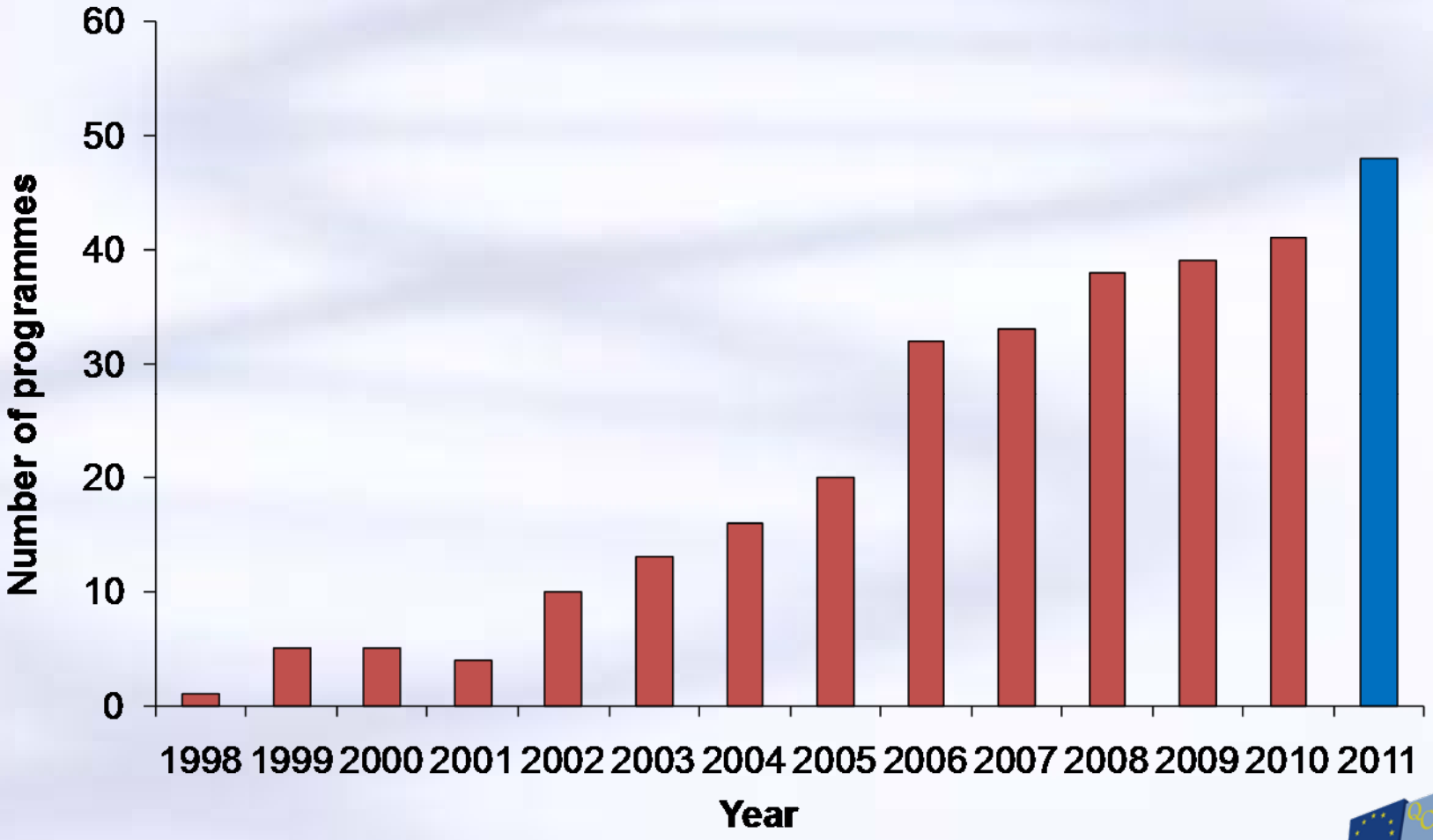
QCMD

Quality Control for Molecular Diagnostics

- Provider of EQA programmes to the molecular diagnostics community worldwide
- An independent and international organisation
- Endorsed by the major scientific societies (ESCV & ESCMID)

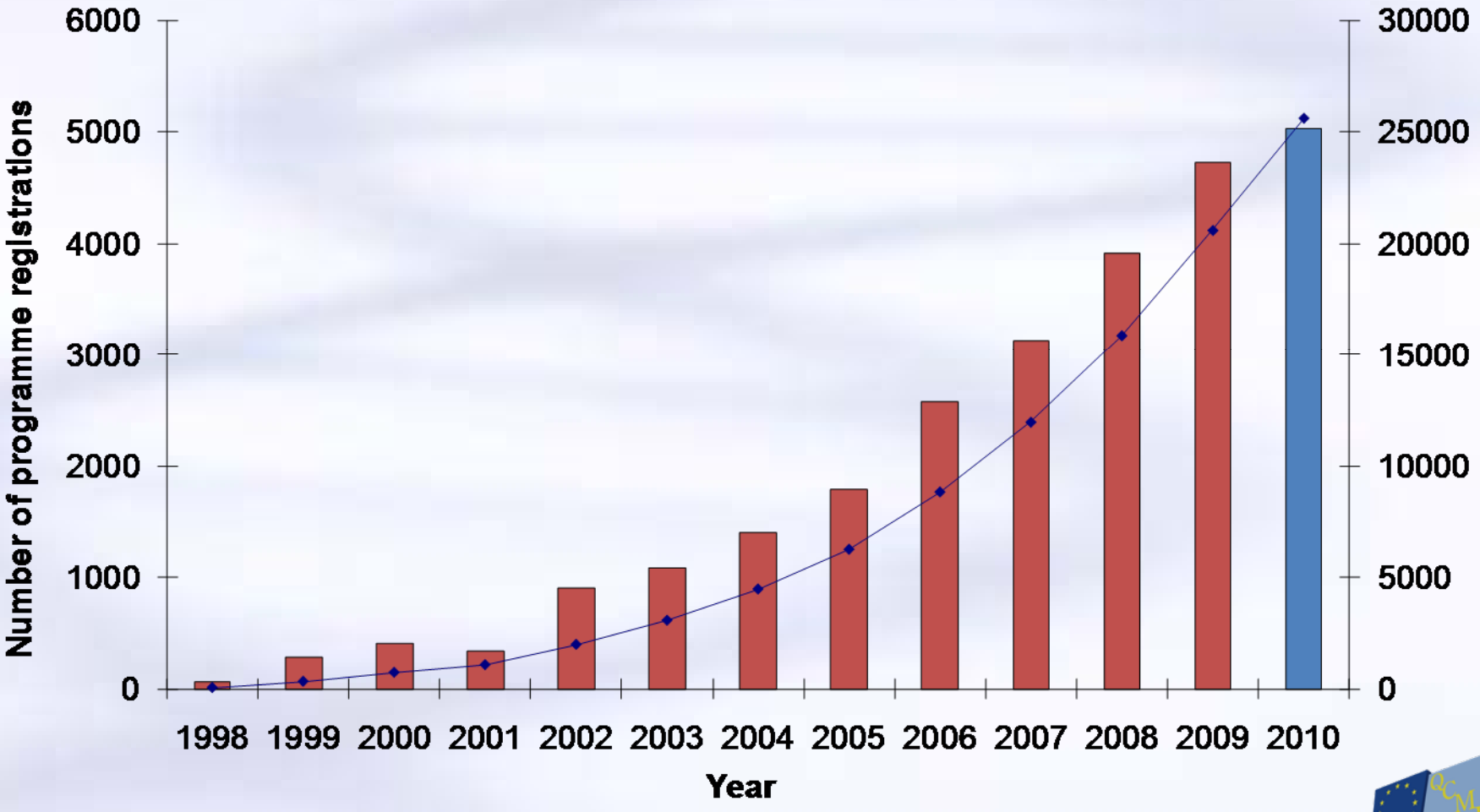
Number of programmes per year



Pilot EQA Programmes in 2011 – *so far*

- Dengue Virus
- HIV-1 Drug Resistance (Integrase)
- *Borrelia burgdorferi*
- PCP (human *Pneumocystis carinii* / *Pneumocystis jirovecii*)

Number of registrations per year



EQA data reporting overview

Provision of expertly designed EQA programmes

- Help labs to determine their performance
- Composition determined by scientific experts
- Consist of 8 - 12 samples
- Include different serotypes / genotypes at various concentrations
- Reporting time 4 - 6 weeks
- Accompanied by technical questionnaire

Panel design

- Panels design: dilution series, duplicates, negative samples, specificity samples

Sample	Sample content	Sample * matrix	Sample conc. Copies/ml	Sample status
CMV09-07	CMV (Strain AD 169)	Plasma	23,174	Frequently detected
CMV09-12	CMV (Strain AD 169)	Plasma	4,613	Frequently detected
CMV09-06	CMV (Strain AD 169)	Plasma	3,266	Frequently detected
CMV09-05	CMV (Strain AD 169)	Plasma	1,028	Frequently detected
CMV09-02	CMV (Strain AD 169)	Plasma	1,009	Frequently detected
CMV09-11	CMV (Strain AD 169)	Plasma	245	Detected
CMV09-10	CMV (Strain AD 169)	Plasma	238	Detected
CMV09-03	CMV (Strain AD 169)	Plasma	211	Detected
CMV09-09	CMV (Strain AD 169)	VTM	2,228,435	Frequently detected
CMV09-04	CMV (Strain AD 169)	VTM	252,348	Frequently detected
CMV09-01	CMV (Strain AD 169)	VTM	24,099	Frequently detected
CMV09-08	Negative Plasma	Plasma		Negative

QCMD: comprehensive feedback to participants

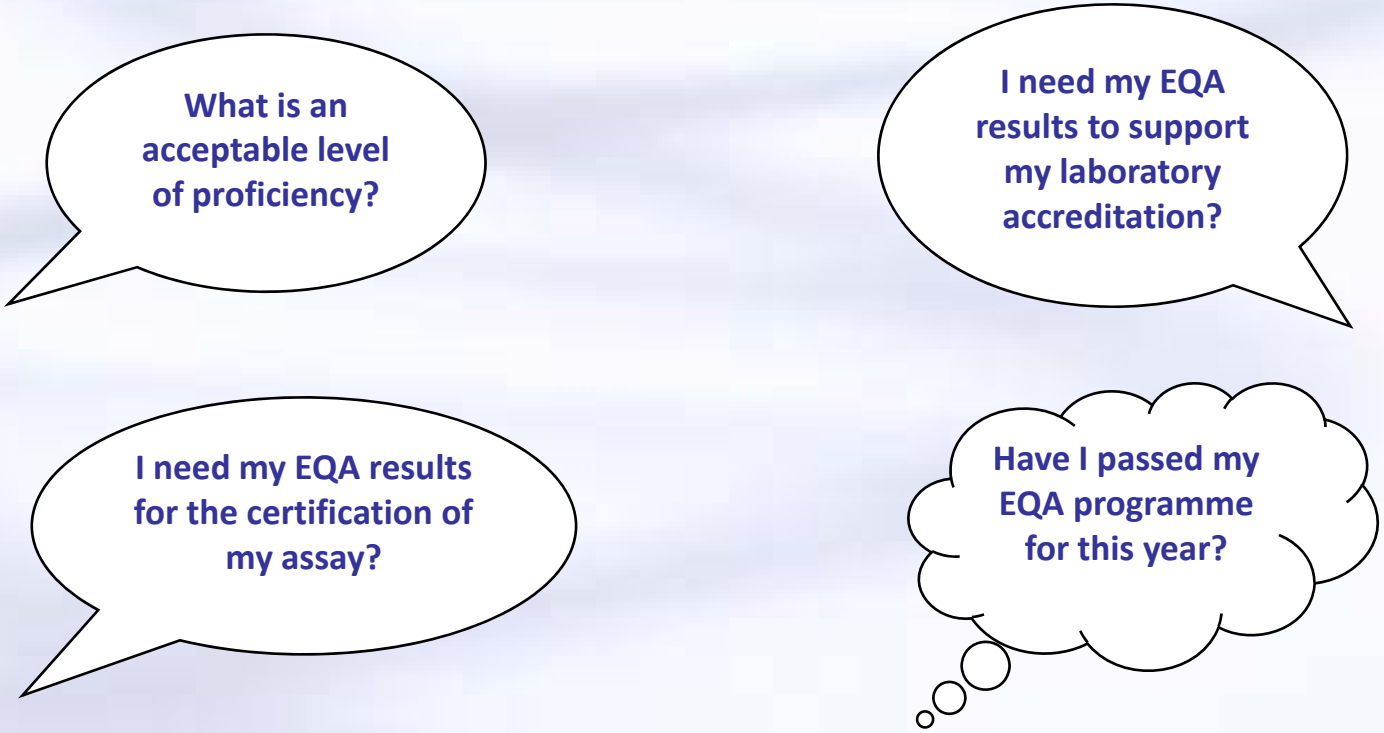
- State of the art scoring systems
- Covering qualitative and quantitative data, and genotyping / sequencing where applicable
- Detailed final reports with expert feedback
  - Including region / country specific reports
- Individualised reports for each participant
- Supported through the QCMD Neutral Office

Reporting framework

- Expected results letter – approx. 2 weeks following close of programme
  - Data analysis completed and draft final report prepared
- Final report – approx. 6 weeks following close of programme
  - Extensive internal (QCMD) and external (scientific expert) review
  - Additional data analysis where applicable
  - Review of previous trends in performance and data from the scientific literature
- Region / country specific reports and data (approx. 3 weeks after release of the final report

Core proficiency samples – why?

- Feedback from participants in the EQA programmes
  - How do laboratories determine if they have ‘passed’ the EQA?
  - Do the QCMD EQA reports provide sufficient information for accreditation / certification?

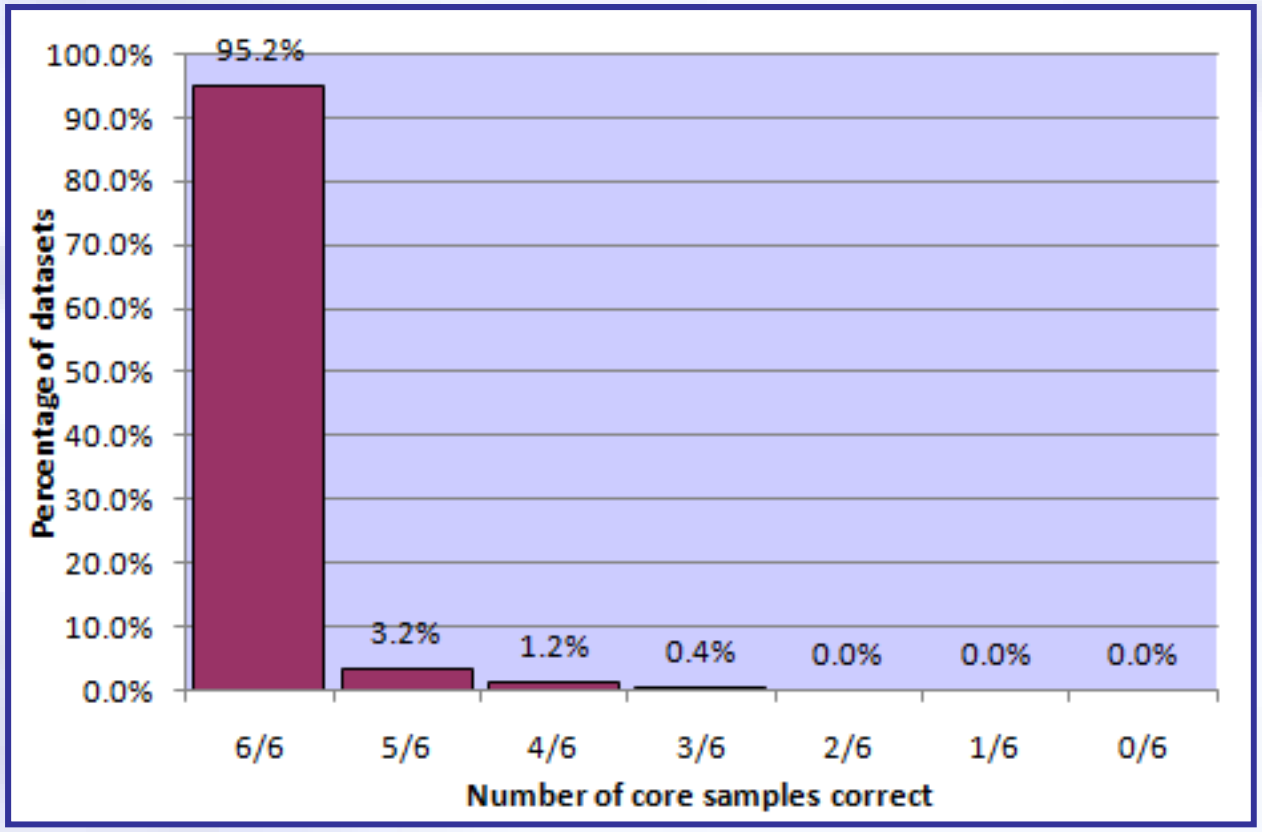


Core proficiency samples

- QCMD EQA panels contain a range of samples included to assess different aspects of assay performance
- QCMD now defines a set of core proficiency samples that participants are expected to detect
- Core proficiency samples are selected based on scientific information, clinical relevance/experience and prior QCMD EQA data
- Additional samples provide educational information to participants (assay sensitivity etc.)

Core proficiency samples – HBVDNA 2010

- Participants are expected to correctly detect all core proficiency samples



EQA participant feedback - qualitative

Sample	Sample content	Sample conc. Copies/ml	Total datasets n=247		PCR								TMA		bDNA	
					Conventional				Real time							
					Commercial n=7		In-house n=7		Commercial n=190		In-house n=37		n=4		n=2	
			n	%	n	%	n	%	n	%	n	%	n	%	n	%
HBV 10-03	HBV Type A	5,012	246	99.6	7	100.0	7	100.0	190	100.0	36	97.3	4	100.0	2	100.0
HBV 10-07	HBV Type A	505	245	99.2	7	100.0	7	100.0	189	99.5	36	97.3	4	100.0	2	100.0
HBV 10-05	HBV Type A	472	244	98.8	7	100.0	7	100.0	189	99.5	35	94.6	4	100.0	2	100.0
HBV 10-01	HBV Type A	61	188	76.1	4	57.1	3	42.9	156	82.1	21	56.8	3	75.0	1	50.0
HBV 10-08	HBV Type D	19,055	245	99.2	7	100.0	7	100.0	188	98.9	37	100.0	4	100.0	2	100.0
HBV 10-06	HBV Type D	1,950	246	99.6	7	100.0	7	100.0	189	99.5	37	100.0	4	100.0	2	100.0
HBV 10-02	HBV Type D	195	232	93.9	6	85.7	5	71.4	183	96.3	32	86.5	4	100.0	2	100.0
HBV 10-04	HBV Neg Plasma		239	96.8	7	100.0	7	100.0	182	95.8	37	100.0	4	100.0	2	100.0

- Overall qualitative results by panel sample
- Breakdown of results by technology groups
- Provides an overview of the results of the EQA round

The QCMD EQA scoring schemes

- Developed by the expert QCMD statistics team
- Piloted in 2006 with a selected cohort of QCMD EQA participants
- Introduced into EQA in 2007
- Peer-reviewed and published in ‘Accreditation and Quality Assurance’
- Covers qualitative and quantitative data

QCMD EQA scoring system – qualitative

Sample status	Participant's result		
	Negative	Not determined	Positive
Frequently detected	3	3	0
Detected	2	2	0
Infrequently detected	1	1	0
Negative	0	3	3

The scores awarded for qualitative data are based on the sample status where 0 is 'highly satisfactory' and 3 is 'highly unsatisfactory'. Colour has been included as an extra visual aid.

EQA participant feedback - qualitative

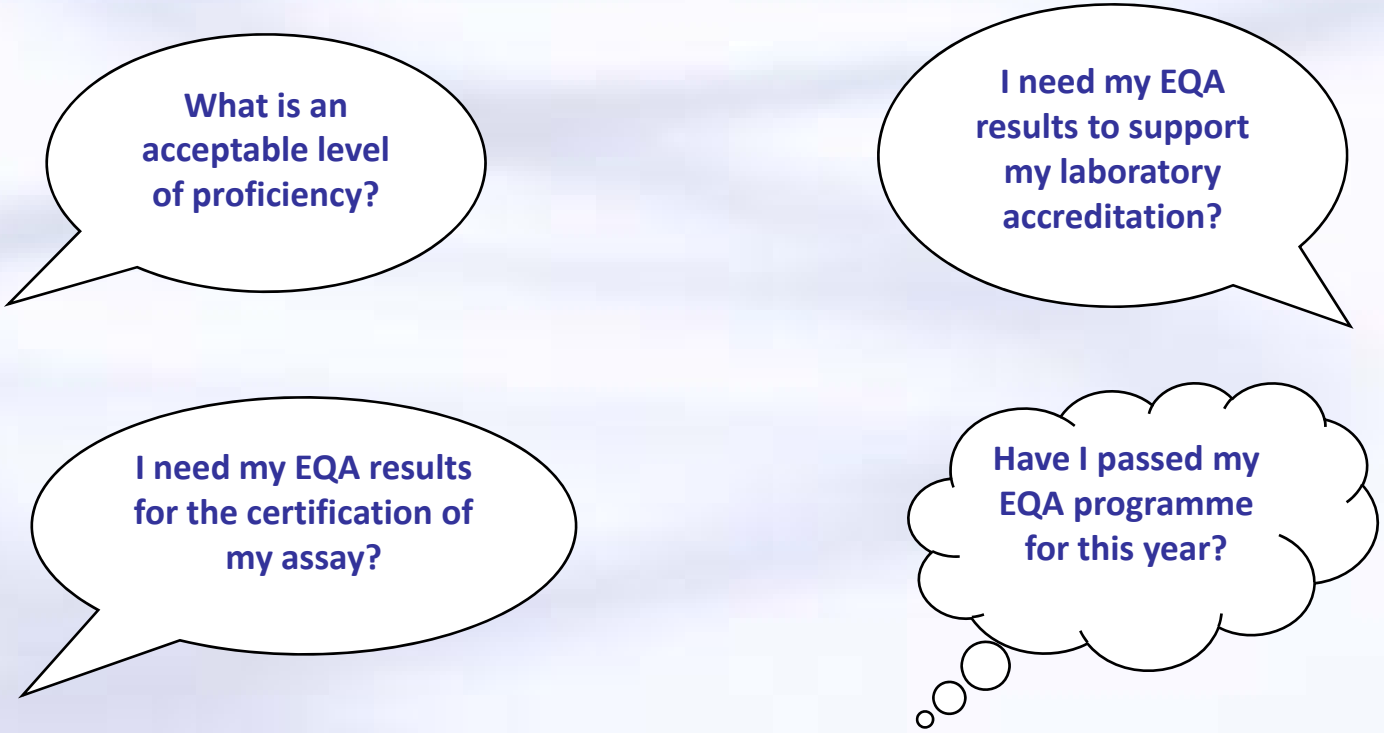
- Qualitative scoring

Sample	Sample Status	Total				PCR														TMA				bDNA			
		All technologies				Conventional								Real time															
						Commercial				In-house				Commercial				In-house											
		n=247				n=7				n=7				n=190				n=37				n=4				n=2			
		0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
HBV10-03	Frequently detected	246	0	0	1	7	0	0	0	7	0	0	0	190	0	0	0	36	0	0	1	4	0	0	0	2	0	0	0
HBV10-07	Frequently detected	245	0	0	2	7	0	0	0	7	0	0	0	189	0	0	1	36	0	0	1	4	0	0	0	2	0	0	0
HBV10-05	Frequently detected	244	0	0	3	7	0	0	0	7	0	0	0	189	0	0	1	35	0	0	2	4	0	0	0	2	0	0	0
HBV10-01	Detected	188	0	59	0	4	0	3	0	3	0	4	0	156	0	34	0	21	0	16	0	3	0	1	0	1	0	1	0
HBV10-08	Frequently detected	245	0	0	2	7	0	0	0	7	0	0	0	188	0	0	2	37	0	0	0	4	0	0	0	2	0	0	0
HBV10-06	Frequently detected	246	0	0	1	7	0	0	0	7	0	0	0	189	0	0	1	37	0	0	0	4	0	0	0	2	0	0	0
HBV10-02	Detected	232	0	15	0	6	0	1	0	5	0	2	0	183	0	7	0	32	0	5	0	4	0	0	0	2	0	0	0
HBV10-04	Negative	239	0	0	8	7	0	0	0	7	0	0	0	182	0	0	8	37	0	0	0	4	0	0	0	2	0	0	0

- Overall qualitative scores by panel sample
- Breakdown of scores by technology groups
- Provides an overview of the scoring in the EQA round

Paired samples – why?

- Improved feedback to participants
  - How do laboratories determine if they have ‘passed’ the EQA?
  - Do the QCMD EQA reports provide sufficient information for accreditation / certification?



Paired samples – why?

- Improved feedback to participants
- Quantitative assays vary in the absolute values they report

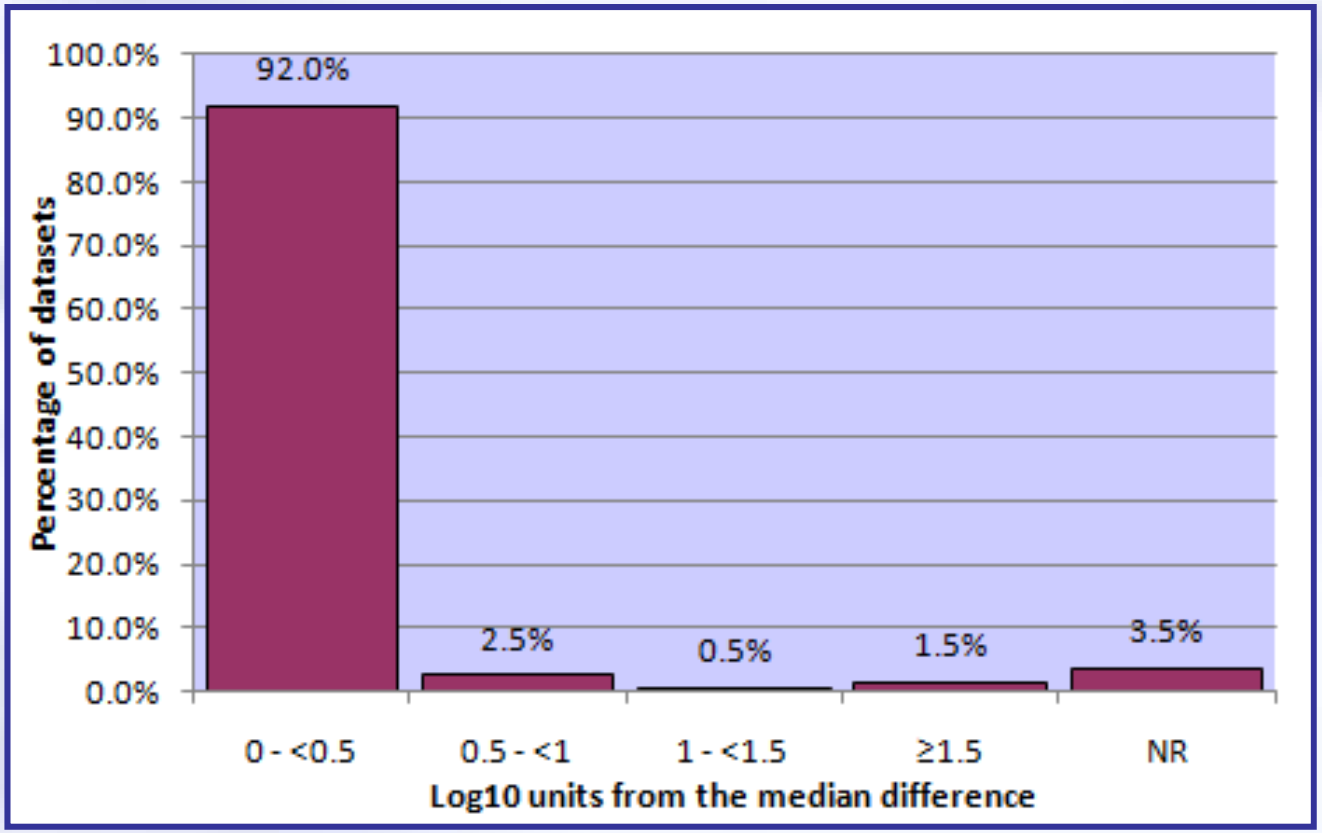
- Quantitative results influenced by the assay type used (eg real time PCR vs conventional PCR) – the EQA programmes show that

- Analysis of paired samples provides a measure of performance that is independent of technology

- General consensus is that differences of 0.5 log or more are significant from a clinical perspective

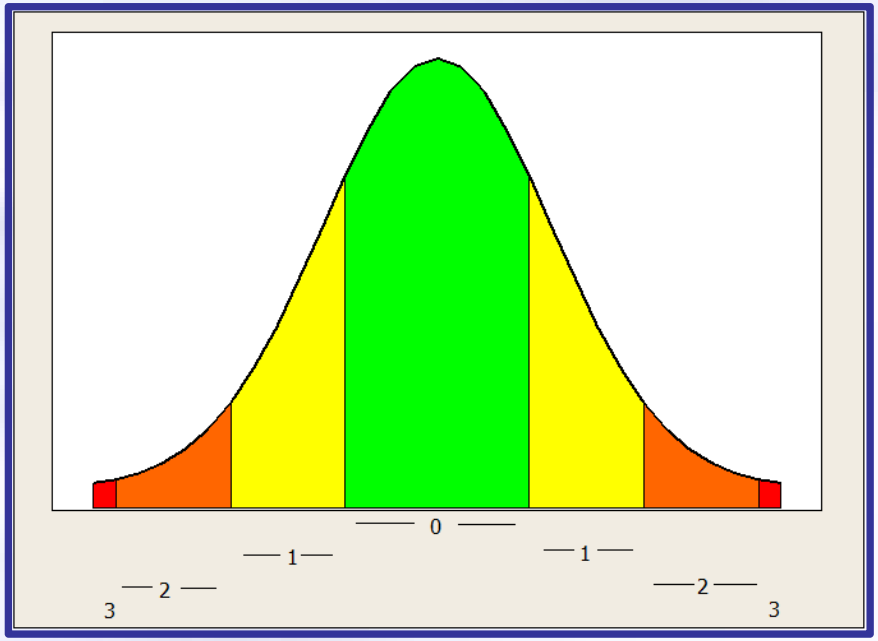
Paired samples – HBVDNA 2010

- Participants are expected to be within 0.5 log10 Copies/ml of the median in order to show acceptable proficiency



QCMD EQA scoring system – quantitative

- Based on distance from the consensus (log_{10} mean)
- Two consensuses – overall and by technology type
- 0 points = up to one sd
- 1 point = one to two sd
- 2 points = two to three sd
- 3 points = three or more sd



EQA participant feedback - quantitative

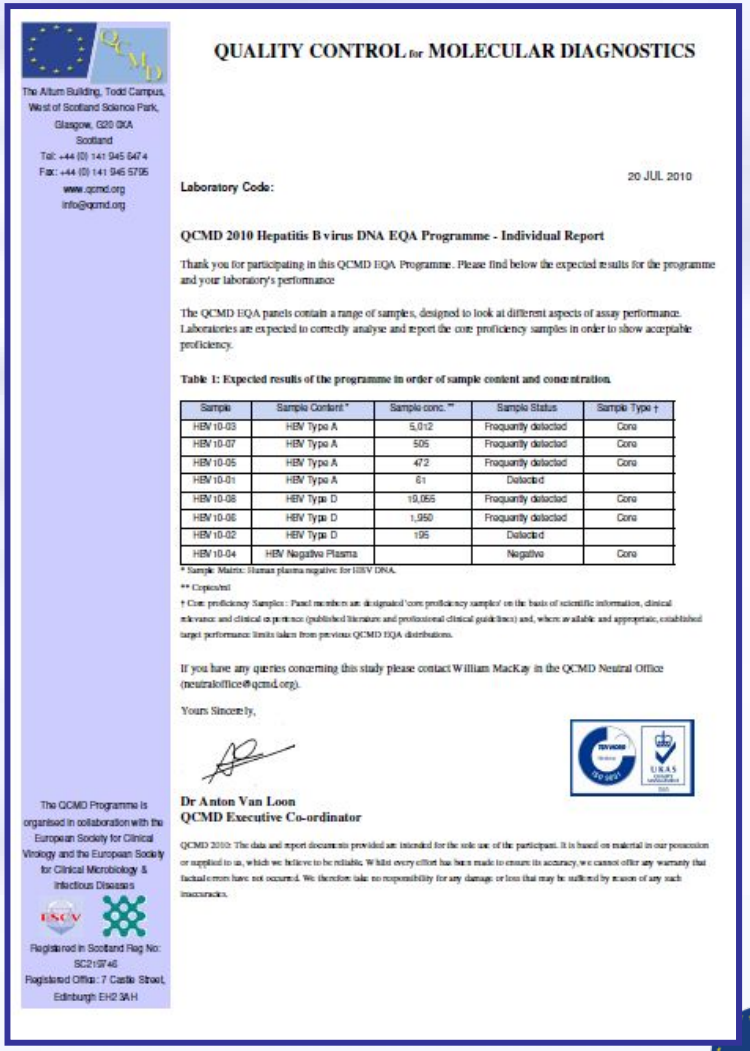
- Quantitative results and scoring

Sample	Consensus Log_{10} virus concentration		Total					PCR																bDNA				
			All technologies					Conventional									Real time											
								Commercial					In-house				Commercial					In-house						
			n=200					n=5					n=1				n=164					n=29					n=1		
	Mean	SD	0	1	2	3	LOD/NR	0	1	2	3	LOD/NR	0	1	2	3	LOD/NR	0	1	2	3	LOD/NR	0	1	2	3	LOD/NR	0	1	2	3	LOD/NR
HBV10-03	3.700	0.352	144	42	6	8	0	4	1	0	0	0	0	0	1	0	0	123	32	3	6	0	17	8	2	2	0	0	1	0	0	0
HBV10-07	2.703	0.336	138	36	14	3	9	2	0	1	0	2	0	0	0	0	1	119	28	10	2	5	17	8	3	0	1	0	0	0	1	0
HBV10-05	2.675	0.348	143	34	11	5	7	4	1	0	0	0	0	0	0	0	1	125	22	10	3	4	14	11	1	1	2	0	0	0	1	0
HBV10-01	1.784	0.568	61	15	3	3	118	2	0	0	0	3	0	0	0	0	1	48	12	3	1	100	11	3	0	1	14	0	0	0	1	0
HBV10-08	4.280	0.383	133	54	9	2	2	4	1	0	0	0	0	0	1	0	0	109	45	7	1	2	19	8	1	1	0	1	0	0	0	0
HBV10-06	3.290	0.346	140	41	10	4	5	4	0	1	0	0	0	0	0	0	1	116	34	7	3	4	20	6	2	1	0	0	1	0	0	0
HBV10-02	2.291	0.355	131	35	11	3	20	1	1	1	0	2	0	0	0	0	1	114	29	6	2	13	16	5	4	0	4	0	0	0	1	0

- Overall quantitative scores by panel sample
- Breakdown of scores by technology groups
- Provides an overview of the scoring in the EQA round

EQA – Individual report: Page 1

- Aim is to provide personalised feedback to each participant
- Panel contents
- Quantitative consensus
- Qualitative status



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QUALITY CONTROL for MOLECULAR DIAGNOSTICS

20 JUL 2010

Laboratory Code:

QCMD 2010 Hepatitis B virus DNA EQA Programme - Individual Report

Thank you for participating in this QCMD EQA Programme. Please find below the expected results for the programme and your laboratory's performance

The QCMD EQA panels contain a range of samples, designed to look at different aspects of assay performance. Laboratories are expected to correctly analyse and report the core proficiency samples in order to show acceptable proficiency.

Table 1: Expected results of the programme in order of sample content and concentration.

Sample	Sample Content *	Sample conc. **	Sample Status	Sample Type †
HBV 10-03	HBV Type A	5,012	Frequently detected	Core
HBV 10-07	HBV Type A	505	Frequently detected	Core
HBV 10-05	HBV Type A	472	Frequently detected	Core
HBV 10-01	HBV Type A	61	Detected	
HBV 10-08	HBV Type D	19,055	Frequently detected	Core
HBV 10-06	HBV Type D	1,950	Frequently detected	Core
HBV 10-02	HBV Type D	195	Detected	
HBV 10-04	HBV Negative Plasma		Negative	Core

* Sample Matrix: Human plasma negative for HBV DNA.

** Copies/ml

† Core proficiency Samples : Panel members are designated 'core proficiency samples' on the basis of scientific information, clinical relevance and clinical experience (published literature and professional clinical guidelines) and, where available and appropriate, established target performance limits taken from previous QCMD EQA distributions.

If you have any queries concerning this study please contact William MacKay in the QCMD Neutral Office (neutraloffice@qcmd.org).

Yours Sincerely,

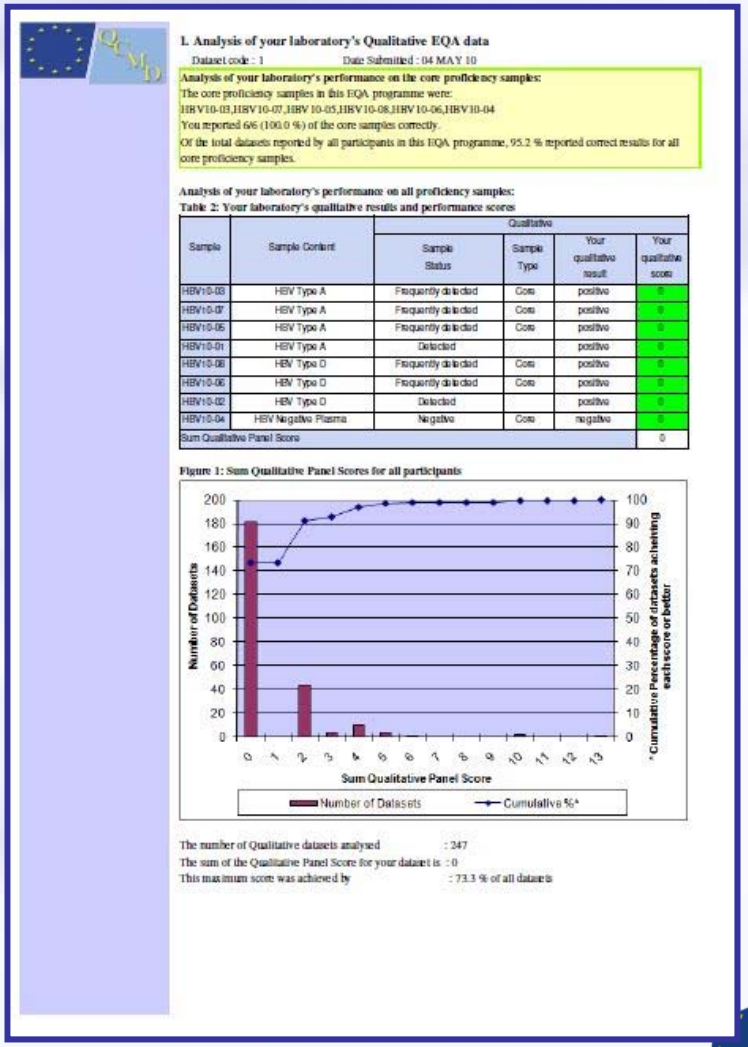
Dr Anton Van Loon
QCMD Executive Co-ordinator

The QCMD Programme is organised in collaboration with the European Society for Clinical Virology and the European Society for Clinical Microbiology & Infectious Diseases

Registered in Scotland Reg No: SC219746
Registered Office: 7 Castle Street, Edinburgh EH2 3AH

EQA – Individual report: Page 2

- Performance on the core proficiency samples
- Summary of results and performance on the whole EQA panel (core and non-core samples)
- Measure of performance on the whole EQA panel (sum qualitative panel score



1. Analysis of your laboratory's Qualitative EQA data

Dataset code : 1 Date Submitted : 04 MAY 10

Analysis of your laboratory's performance on the core proficiency samples:

The core proficiency samples in this EQA programme were:
HBV10-03,HBV10-07,HBV 10-05,HBV10-08,HBV10-06,HBV10-04
You reported 6/6 (100.0 %) of the core samples correctly.
Of the total datasets reported by all participants in this EQA programme, 95.2 % reported correct results for all core proficiency samples.

Analysis of your laboratory's performance on all proficiency samples:

Table 2: Your laboratory's qualitative results and performance scores

Sample	Sample Content	Qualitative			
		Sample Status	Sample Type	Your qualitative result	Your qualitative score
HBV10-03	HBV Type A	Frequently detected	Core	positive	0
HBV10-07	HBV Type A	Frequently detected	Core	positive	0
HBV10-05	HBV Type A	Frequently detected	Core	positive	0
HBV10-01	HBV Type A	Detected		positive	0
HBV10-08	HBV Type D	Frequently detected	Core	positive	0
HBV10-06	HBV Type D	Frequently detected	Core	positive	0
HBV10-02	HBV Type D	Detected		positive	0
HBV10-04	HBV Negative Plasma	Negative	Core	negative	0
Sum Qualitative Panel Score					0

Figure 1: Sum Qualitative Panel Scores for all participants

The number of Qualitative datasets analysed : 247
The sum of the Qualitative Panel Score for your dataset is : 0
This maximum score was achieved by : 73.3 % of all datasets

EQA – Individual report: Page 2

- Performance on the core proficiency samples

Analysis of your laboratory's performance on the core proficiency samples:

The core proficiency samples in this EQA programme were:

HBV10-03,HBV10-07,HBV10-05,HBV10-08,HBV10-06,HBV10-04

You reported 6/6 (100.0 %) of the core samples correctly.

Of the total datasets reported by all participants in this EQA programme, 95.2 % reported correct results for all core proficiency samples.

Analysis of your laboratory's performance on all proficiency samples:

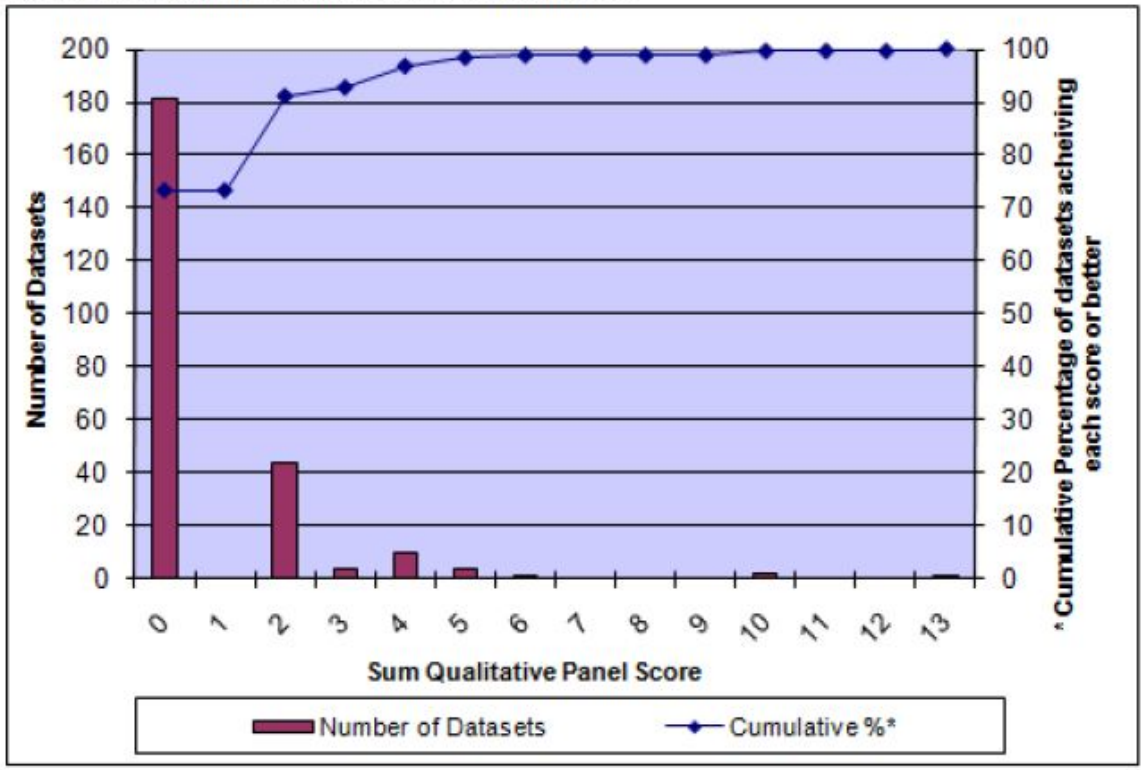
Table 2: Your laboratory's qualitative results and performance scores

Sample	Sample Content	Qualitative			
		Sample Status	Sample Type	Your qualitative result	Your qualitative score
HBV10-03	HBV Type A	Frequently detected	Core	positive	0
HBV10-07	HBV Type A	Frequently detected	Core	positive	0
HBV10-05	HBV Type A	Frequently detected	Core	positive	0
HBV10-01	HBV Type A	Detected		positive	0
HBV10-08	HBV Type D	Frequently detected	Core	positive	0
HBV10-06	HBV Type D	Frequently detected	Core	positive	0
HBV10-02	HBV Type D	Detected		positive	0
HBV10-04	HBV Negative Plasma	Negative	Core	negative	0
Sum Qualitative Panel Score					0

EQA – Individual report: Page 2

- Performance on the whole EQA panel

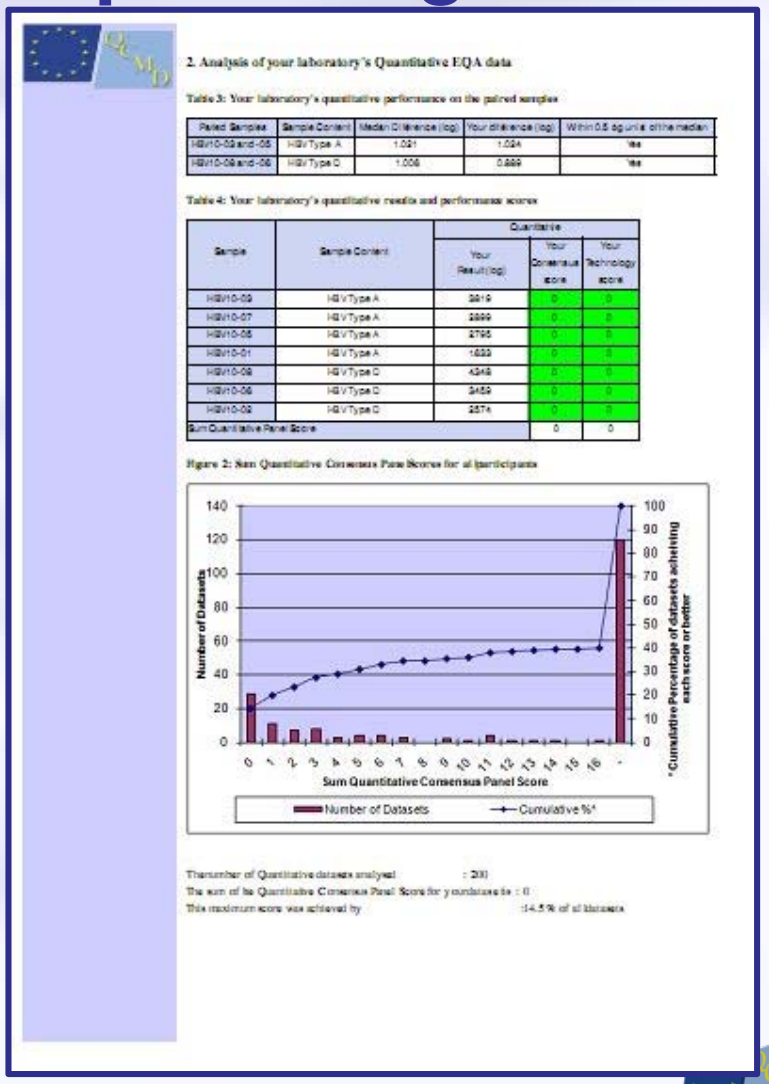
Figure 1: Sum Qualitative Panel Scores for all participants



The number of Qualitative datasets analysed : 247
The sum of the Qualitative Panel Score for your dataset is : 0
This maximum score was achieved by : 73.3 % of all datasets

EQA – Individual report: Page 3

- Individual quantitative performance score
- Quantitative performance within laboratory peer group



2. Analysis of your laboratory's Quantitative EQA data

Table 3: Your laboratory's quantitative performance on the paired samples

Paired Samples	Sample Content	Median Difference (log)	Your difference (log)	Within 0.5 log unit of the median
HIV10-03and-05	HIV Type A	1.021	1.024	Yes
HIV10-09and-06	HIV Type D	1.006	0.889	Yes

Table 4: Your laboratory's quantitative results and performance scores

Sample	Sample Content	Quantitative		
		Your Result (log)	Your Consensus score	Your Technology score
HIV10-03	HIV Type A	3819	0	0
HIV10-07	HIV Type A	3899	0	0
HIV10-05	HIV Type A	2795	0	0
HIV10-01	HIV Type A	1033	0	0
HIV10-09	HIV Type D	4348	0	0
HIV10-06	HIV Type D	3459	0	0
HIV10-02	HIV Type D	2574	0	0
Sum Quantitative Panel Score			0	0

Figure 2: Sum Quantitative Consensus Panel Scores for all participants

The number of Quantitative datasets analysed : 20
The sum of the Quantitative Consensus Panel Score for your datasets is : 0
This maximum score was achieved by :14.5 % of all laboratories

EQA – Individual report: Page 3

- Performance on the paired samples and whole panel

Table 3: Your laboratory's quantitative performance on the paired samples

Paired Samples	Sample Content	Median Difference (log)	Your difference (log)	Within 0.5 log units of the median
HBV10-03 and -05	HBV Type A	1.021	1.024	Yes
HBV10-08 and -06	HBV Type D	1.006	0.889	Yes

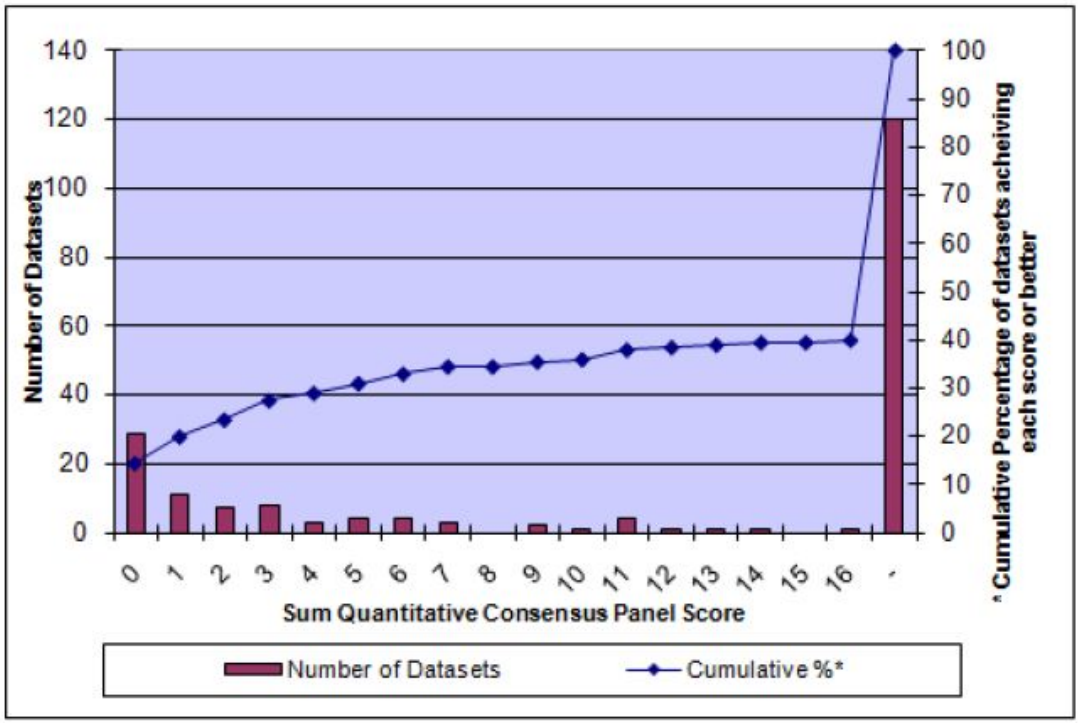
Table 4: Your laboratory's quantitative results and performance scores

Sample	Sample Content	Quantitative		
		Your Result (log)	Your Consensus score	Your Technology score
HBV10-03	HBV Type A	3.819	0	0
HBV10-07	HBV Type A	2.899	0	0
HBV10-05	HBV Type A	2.795	0	0
HBV10-01	HBV Type A	1.633	0	0
HBV10-08	HBV Type D	4.348	0	0
HBV10-06	HBV Type D	3.459	0	0
HBV10-02	HBV Type D	2.574	0	0
Sum Quantitative Panel Score			0	0

EQA – Individual report: Page 3

- Performance on the whole EQA panel

Figure 2: Sum Quantitative Consensus Panel Scores for all participants



The number of Quantitative datasets analysed : 200
The sum of the Quantitative Consensus Panel Score for your dataset is : 0
This maximum score was achieved by : 14.5 % of all datasets

Group reporting

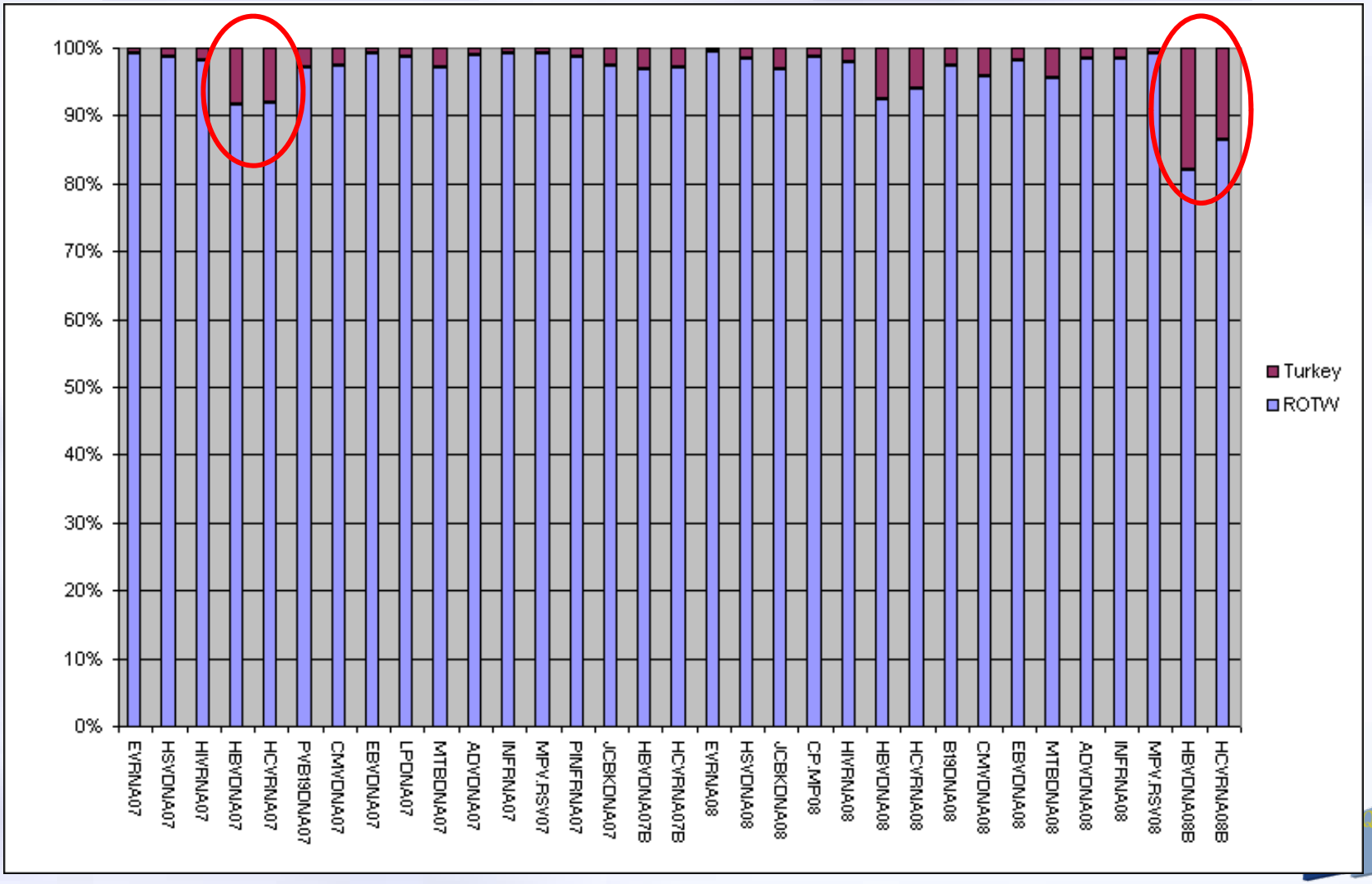
- Final report tailored to the group
- Same layout as the full EQA report
- Can be directly compared with overall final report
- Provides targeted information to support local QA activities

EQA performance overview for Turkish participants 2007- 2010

Turkish vs ROTW participation 2007-2008

2007: 0.7 – 8.4%

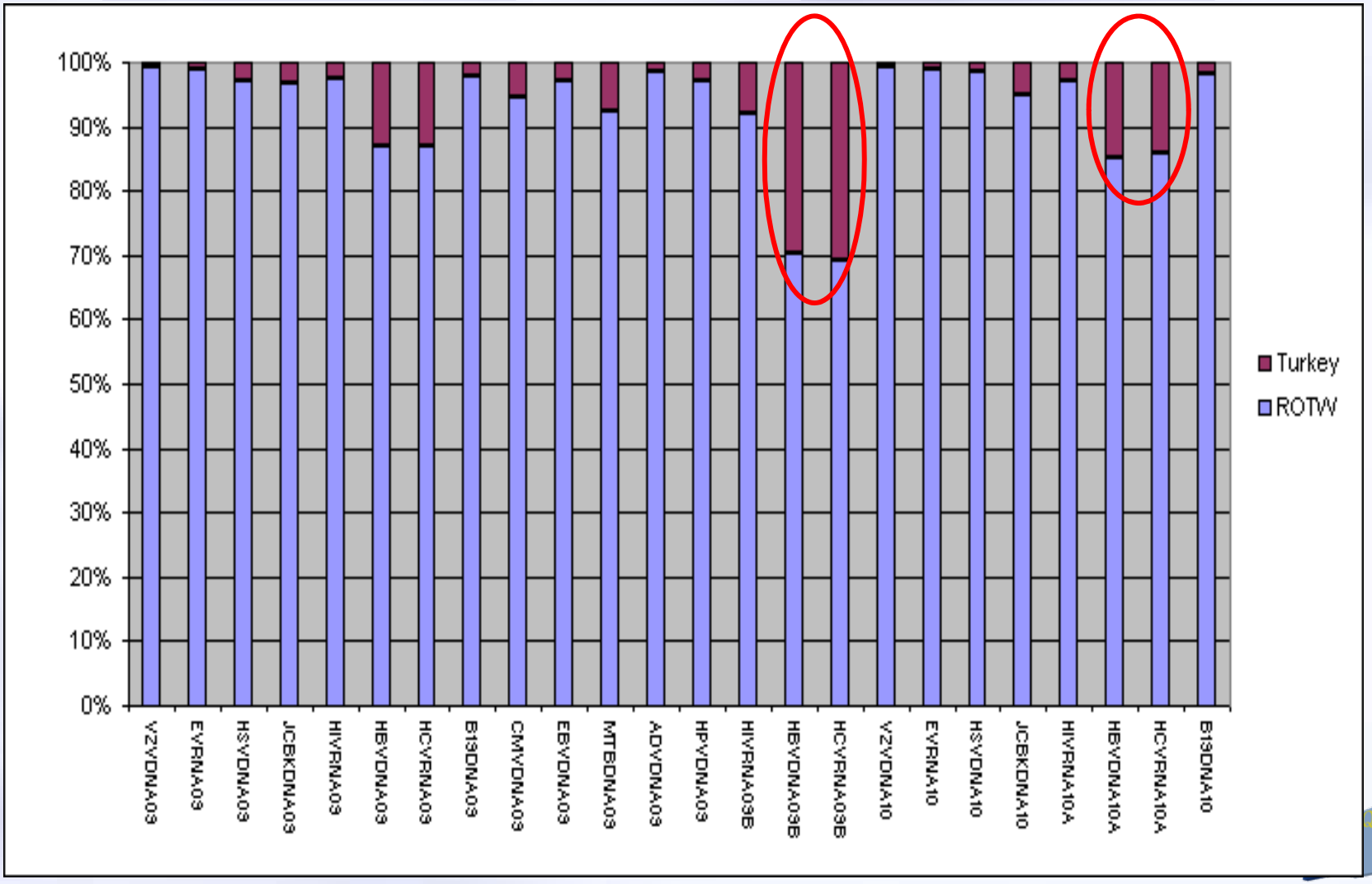
2008: 0.5 – 17.9%



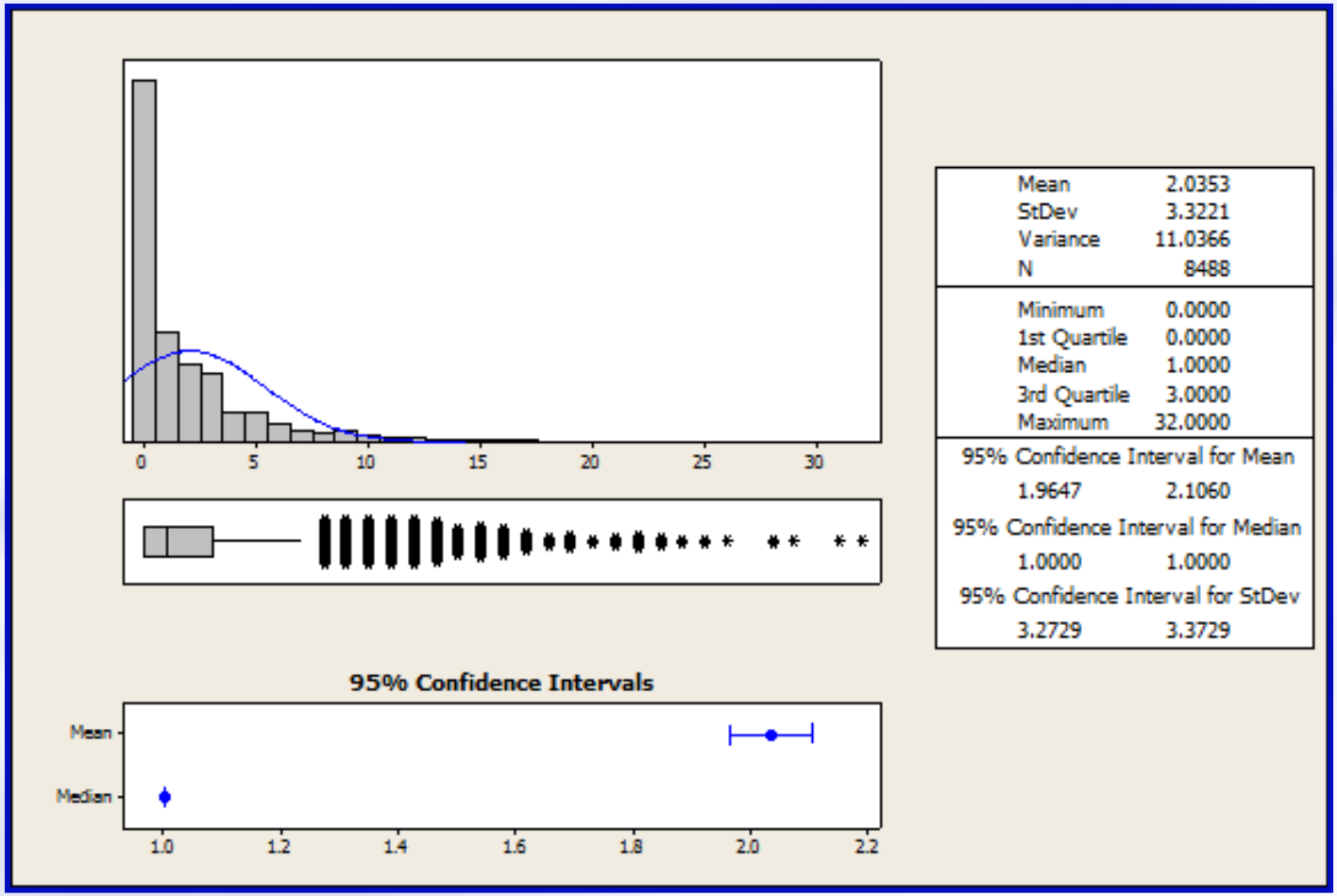
Turkish vs ROTW participation 2009-2010

2009: 0.6 – 30.9%

2010: 0.6 – 14.7%



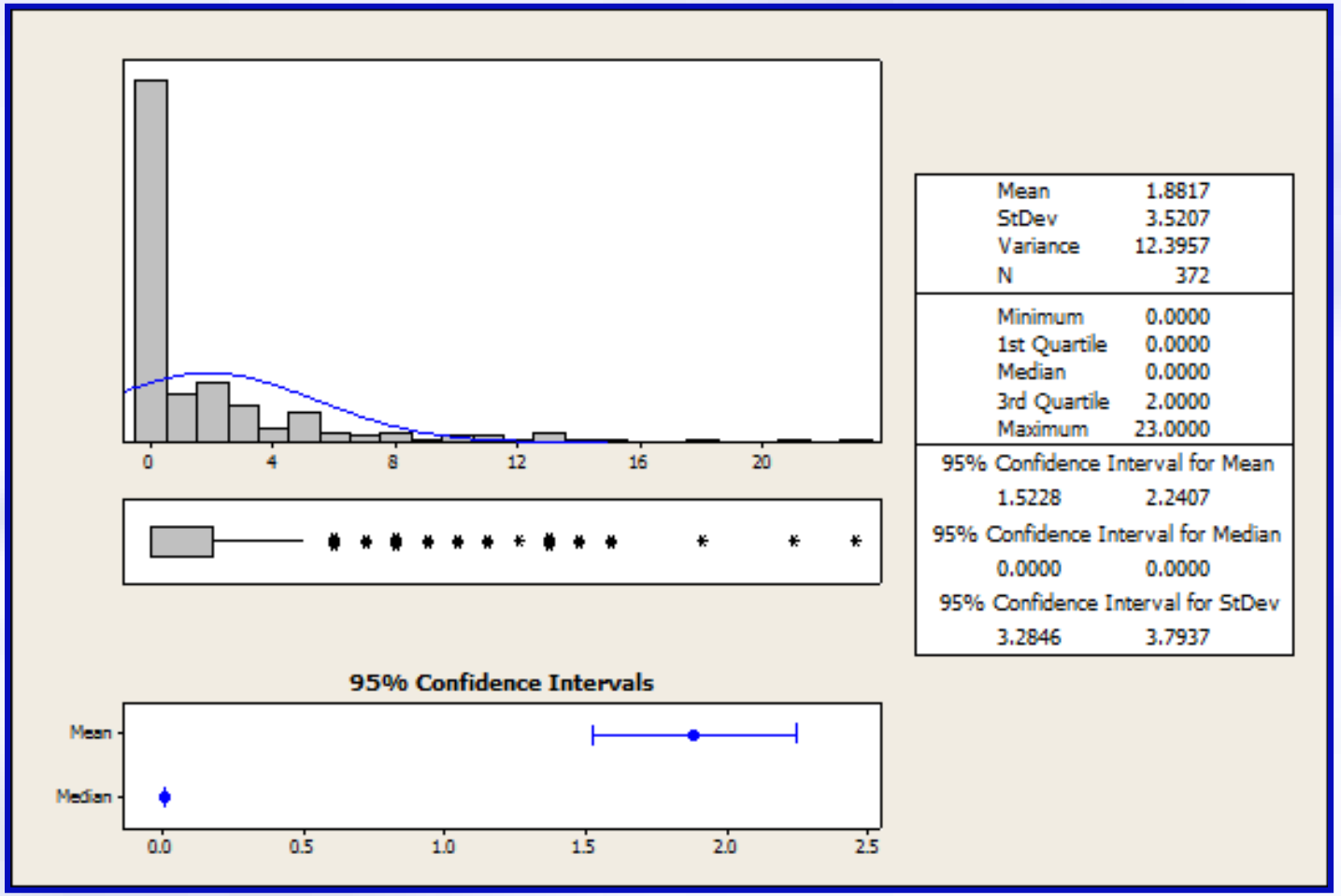
Summary of ROTW performance



Mean	2.0353
StDev	3.3221
Variance	11.0366
N	8488
Minimum	0.0000
1st Quartile	0.0000
Median	1.0000
3rd Quartile	3.0000
Maximum	32.0000
95% Confidence Interval for Mean	
1.9647	2.1060
95% Confidence Interval for Median	
1.0000	1.0000
95% Confidence Interval for StDev	
3.2729	3.3729

Sum of qualitative panel scores for QCMD EQA programmes – 2007 to 2010

Summary of Turkish performance

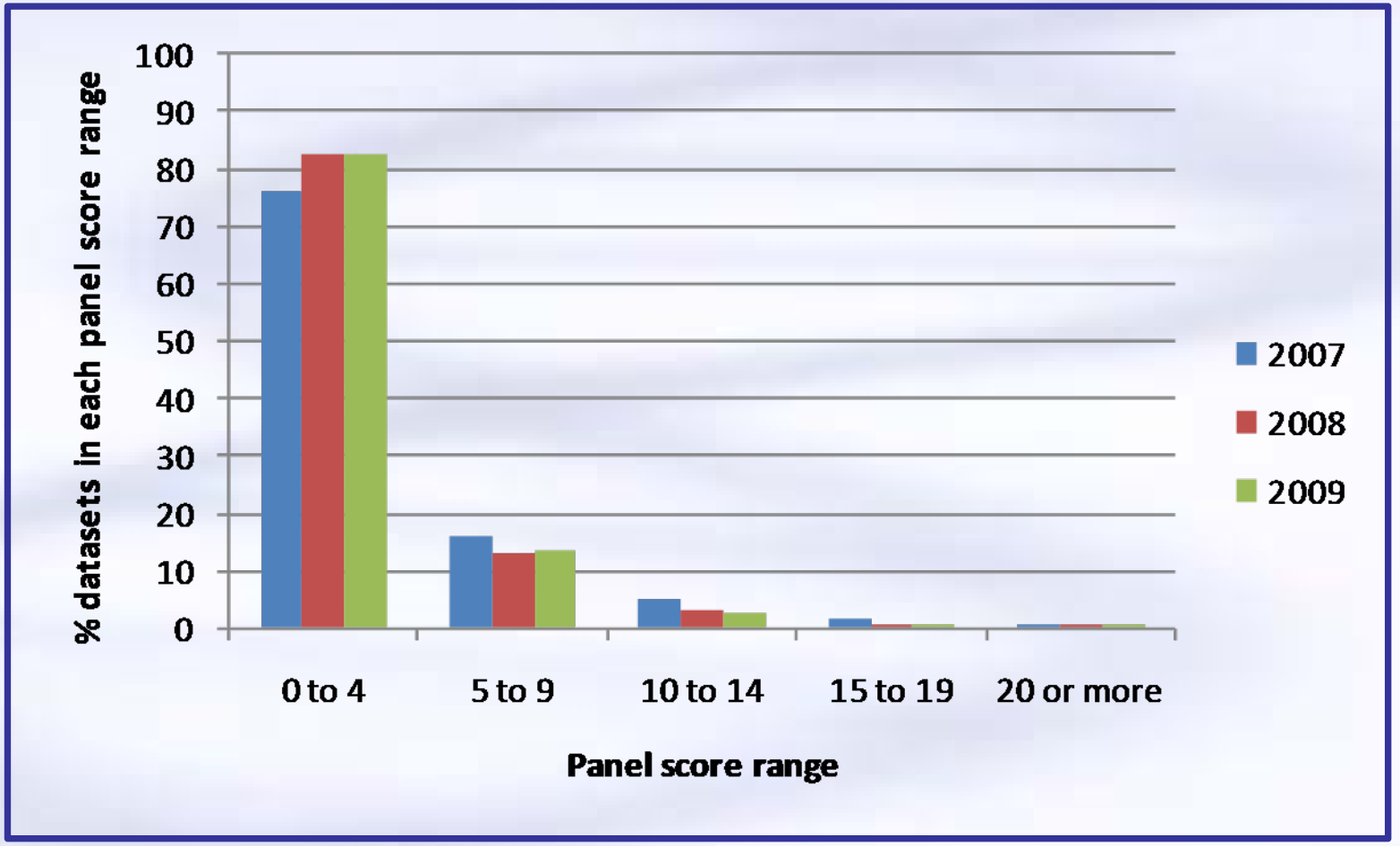


Mean	1.8817
StDev	3.5207
Variance	12.3957
N	372
Minimum	0.0000
1st Quartile	0.0000
Median	0.0000
3rd Quartile	2.0000
Maximum	23.0000

95% Confidence Interval for Mean	
1.5228	2.2407
95% Confidence Interval for Median	
0.0000	0.0000
95% Confidence Interval for StDev	
3.2846	3.7937

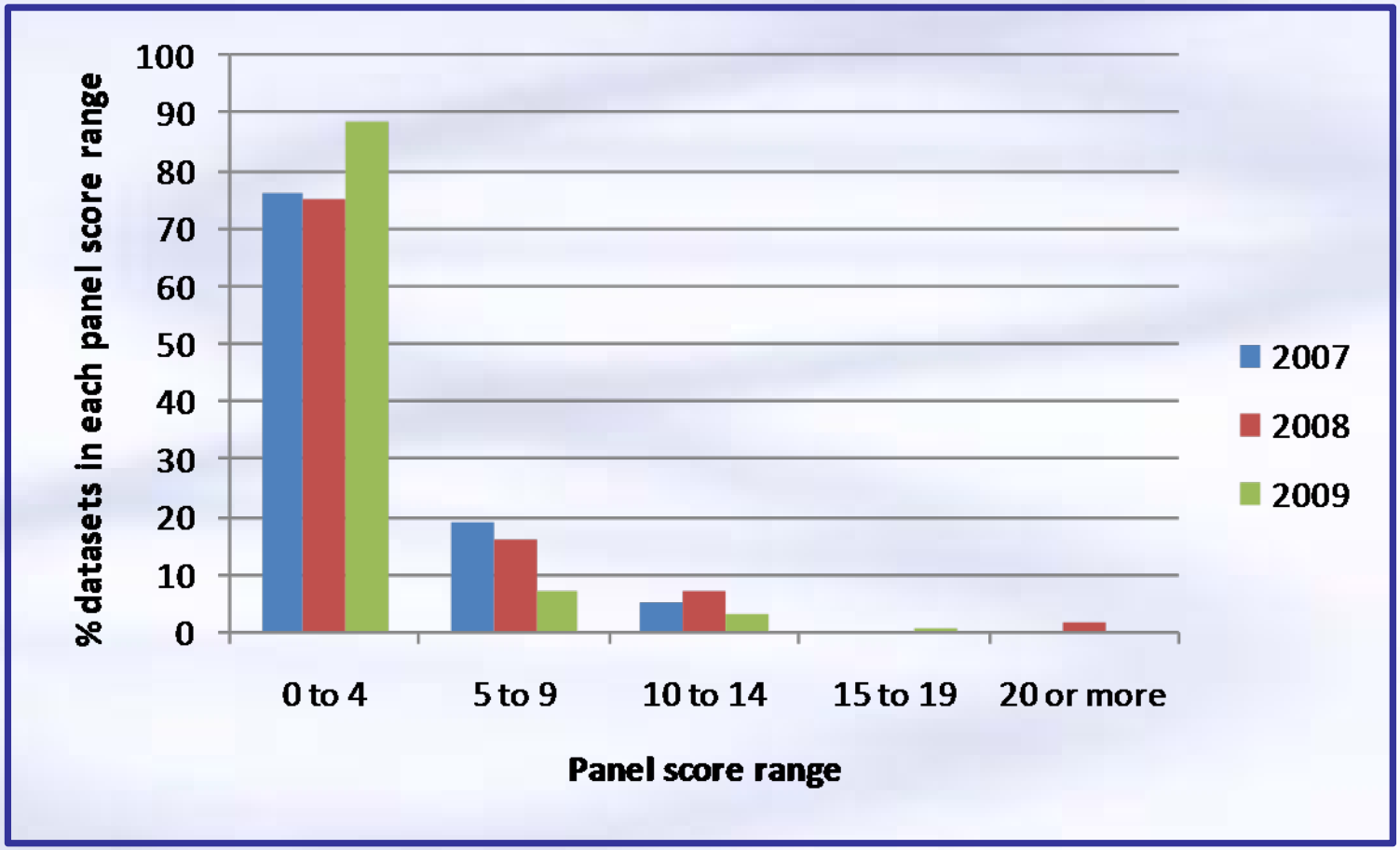
Sum of qualitative panel scores for QCMD EQA programmes – 2007 to 2010

Summary of ROTW performance



Sum of qualitative panel scores for QCMD EQA programmes – 2007 to 2009

Summary of Turkish performance



Sum of qualitative panel scores for QCMD EQA programmes – 2007 to 2009

Performance Turkish Laboratories 2007-2010: 1 – 16

	1	2	3	4	5	6	7	8
# Datasets	8	4	3	24	27	1	28	9
Total Score	7	2	2	52	108	0	58	80
Score/dataset	**0.9**	**0.5**	**0.7**	**2.2**	**4.0**	**0.0**	**2.1**	**8.9**
# score '0'	5	3	2	14	8	1	14	0
% score '0'	62.5	75.0	66.7	58.3	29.6	100.0	50.0	0.0
WD/NR	3	0	0	1	3	0	2	1

	9	10	11	12	13	14	15	16
# Datasets	22	3	9	2	6	3	2	32
Total Score	21	0	11	3	5	36	5	29
Score/dataset	**1.0**	**0.0**	**1.2**	**1.5**	**0.8**	**12.0**	**2.5**	**0.9**
# score '0'	10	3	4	1	5	0	1	25
% score '0'	45.5	100.0	44.4	50.0	83.3	0.0	50.0	78.1
WD/NR	0	1	0	0	0	1	0	1

Total: 58 labs

Performance Turkish Laboratories 2007-2010: 17 – 32

	17	18	19	20	21	22	23	24
# Datasets	10	2	9	15	9	4	10	22
Total Score	30	0	2	1	0	11	5	86
Score/dataset	**3.0**	**0.0**	**0.2**	**0.1**	**0.0**	**2.8**	**0.5**	**3.9**
# score '0'	3	2	7	14	9	3	8	3
% score '0'	30.0	100.0	77.8	93.3	100.0	75.0	80.0	13.6
WD/NR	0	0	1	0	1	0	0	0

	25	26	27	28	29	30	31	32
# Datasets	4	8	4	9	6	4	4	2
Total Score	1	27	2	14	3	6	23	11
Score/dataset	**0.3**	**3.4**	**0.5**	**1.6**	**0.5**	**1.5**	**5.8**	**5.5**
# score '0'	3	3	3	6	4	1	1	0
% score '0'	75.0	37.5	75.0	66.7	66.7	25.0	25.0	0.0
WD/NR	0	0	0	0	0	0	0	0

Performance Turkish Laboratories 2007-2010: 33 – 48

	33	34	35	36	37	38	39	40
# Datasets	1	4	2	2	1	2	3	2
Total Score	0	2	0	0	0	0	3	0
Score/dataset	**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**	**1.0**	**0.0**
# score '0'	1	3	2	2	1	2	2	2
% score '0'	100.0	75.0	100.0	100.0	100.0	100.0	66.7	100.0
WD/NR	0	0	0	0	0	0	1	0

	41	42	43	44	45	46	47	48
# Datasets	2	4	4	4	2	5	2	7
Total Score	0	0	4	0	2	17	4	8
Score/dataset	**0.0**	**0.0**	**1.0**	**0.0**	**1.0**	**3.4**	**2.0**	**1.1**
# score '0'	2	4	3	4	1	3	0	5
% score '0'	100.0	100.0	75.0	100.0	50.0	60.0	0.0	71.4
WD/NR	0	0	0	0	0	0	0	0

Performance Turkish Laboratories 2007-2010: 49 – 58

	49	50	51	52	53	54
# Datasets	4	2	2	2	2	2
Total Score	9	0	2	0	0	0
Score/dataset	**2.3**	**0.0**	**1.0**	**0.0**	**0.0**	**0.0**
# score '0'	1	2	1	2	2	2
% score '0'	25.0	100.0	50.0	100.0	100.0	100.0
WD/NR	0	0	0	0	0	0

	55	56	57	58
# Datasets	2	2	2	2
Total Score	0	13	0	0
Score/dataset	**0.0**	**6.5**	**0.0**	**0.0**
# score '0'	2	1	2	2
% score '0'	100.0	50.0	100.0	100.0
WD/NR	0	0	0	0

Conclusions 1

- QCMD continues to develop its EQA reports in line with participants' requirements
  - to help participants analyse their performance
  - to assist in accreditation activities
  - to help improve the performance of diagnostic tests

Conclusions 2

- Turkish participants performed well in the QCMD EQA programmes when compared to the performance of participants internationally

- The range of sum qualitative panel scores was comparable to the rest of the world

Conclusions 3

- The Turkish group and QCMD now have an established history of collaboration

- The Turkish group and QCMD share similar aims - to improve on the diagnosis of infectious diseases and ultimately improve patient outcome

Molecular Quality Assessment: an evaluation over the last 5 years

http://www.qcmd.org

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