UK NEQAS

Microbiology

An overview of NEQAS functions

Anneline Rossouw

What is EQA – what does it do? - what can it do?

- The challenge of laboratory procedures with specimens of known but undisclosed content

- EQA provides assessment of:
  - the overall standard of performance (state of the art; comparison with other participants)
  - the influence of analytical procedures (methods, reagents, instruments, calibration)
  - individual laboratory performance
  - proficiency of staff
  - the specimens distributed in the scheme

- Educational stimulus to improvement
- Provide an insight into the quality of the routine work of the laboratory
- Provide reassurance that all the components of the quality system are working
- ISO17025/15189 participation in EQA is required to document quality as a part of the accreditation process (DANAK, SWEDAC)

UK NEQAS

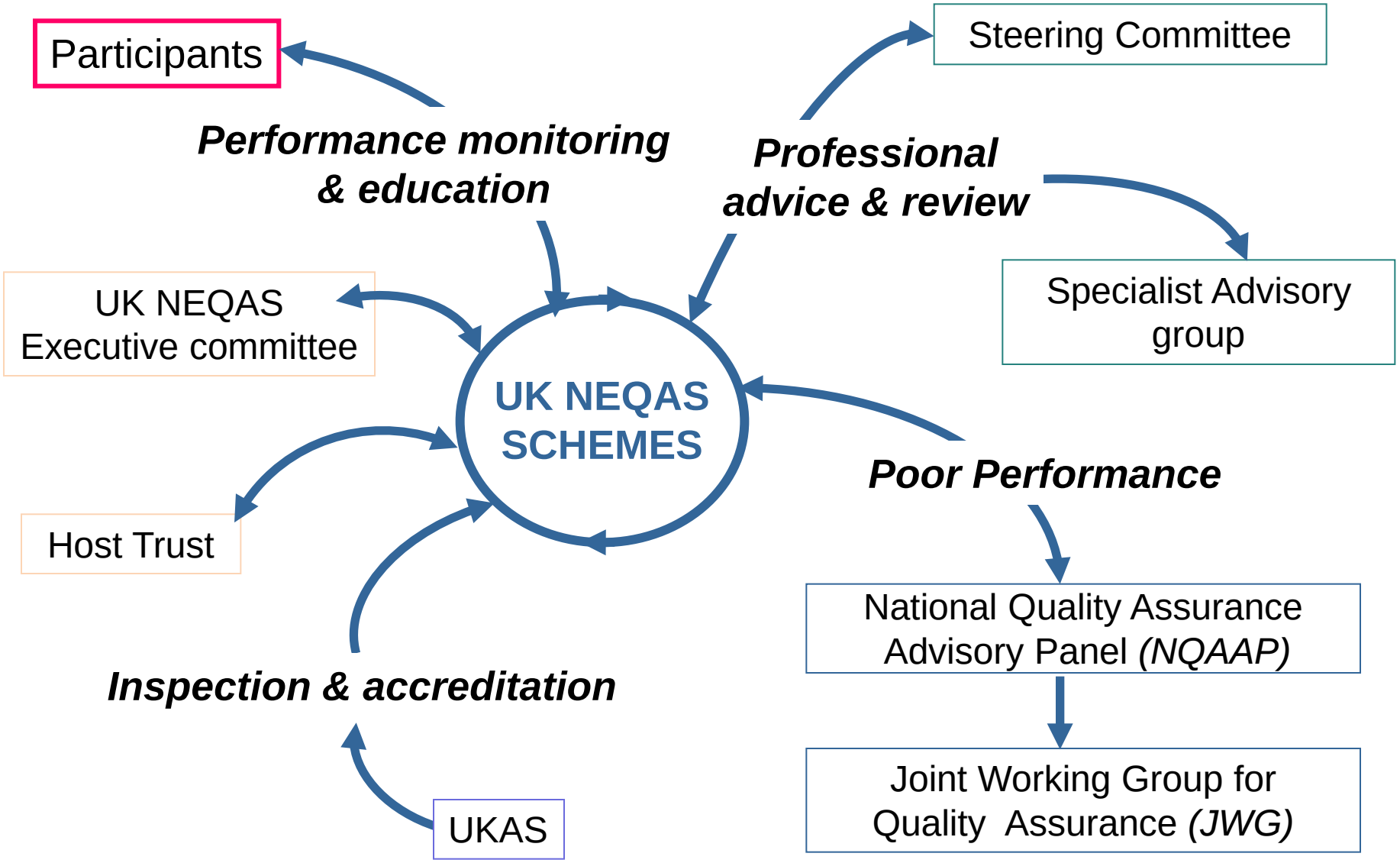
EQA and UK NEQAS

the United Kingdom National External Quality Assessment Service (UK NEQAS) provides a comprehensive world-wide service that enables laboratories to fulfil quality goals and facilitate optimal patient care

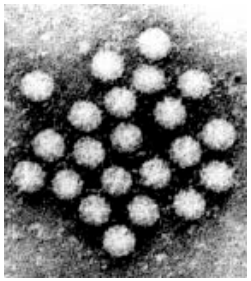
A code of practice exists to ensure that schemes work together with common values and for the benefit of participants and the patients for whom laboratory services are provided

UK NEQAS

EQA and UK NEQAS



UK NEQAS Schemes overview

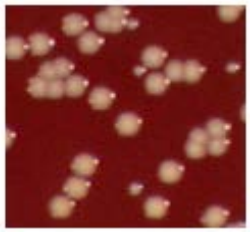


Virology
- 21 schemes

~47%

Mycology
- 2 schemes

~4%



Bacteriology
- 17 schemes

~38%

Parasitology
- 5 schemes
- 2 teaching programmes

~11%

Quantification
- Microscopic
- Molecular

Identification
- Biochemistry
- Ag (IF / agglutination…)
- Growth characteristics
- Molecular

46 SCHEMES

Typing / subtyping
- Biochemistry
- Ag
- Molecular

Susceptibility
- phenotype
- genotype

Serology
- EIA
- Agglutination
- Line assays
- IF

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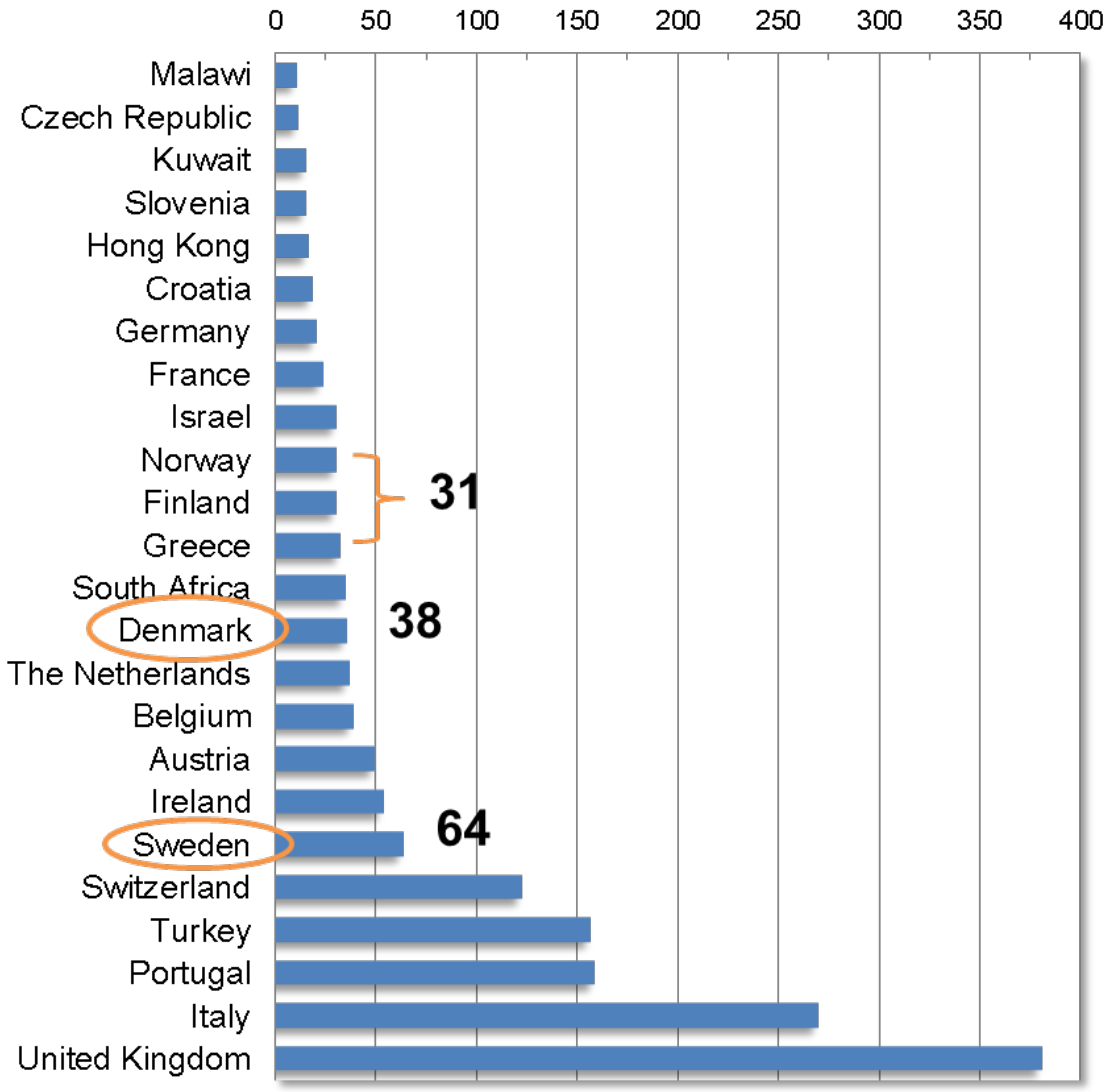
Where are our participants based?

Laboratories per country



> one < 10
Cyprus
Egypt
Iceland
India
Kenya
Lao PDR
Malta
Morocco
Romania
Saudi Arabia
Spain
Tanzania
Thailand
United Arab Emirates
United States
Vietnam
Zimbabwe

Only one
Chile
Congo
Falkland Islands
Gambia
Gibraltar
Greenland
Jamaica
Kingdom of Bahrain
Korea
Liechtenstein
Mauritius
Mongolia
Nigeria
Oman
Philippines
Poland
Qatar
Serbia
Singapore
Uganda
Zambia

UK NEQAS

UK NEQAS in numbers

Organising laboratory

Time frame

Prepare EQA Samples — **~ 531 samples/year**

- Organise, design, prepare, +/- FD, characterise, collate, approve...
- Dispense, Caps
- QC
- Set up distributions on our database and on the website
- Pre-packing
- Packing and dispatch

~195,000 vials/year

Dispatch

Analyse results — **~172 reports/year**

Prepare reports — **~4,000 queries/year**

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Virology schemes

Serology 14

- Anti-HBs detection
- Blood Borne viruses
- Dg. Serology - exanthem screen (RubM, ParvoM, ASO/ASD)
- Dg. Serology - hepatitis screen (CMV, EBV, HAV)
- Donor Screen (Blood borne viruses, HTLV, TP)
- Hepatitis B serology
- Hepatitis C serology
- HIV serology
- HIV POCT
- Immunity screen (HAV, CMV, VZV)
- Measles and Mumps IgG serology
- Rubella IgG serology
- Respiratory Rapid: RSV
- Virus identification

Dg. = Diagnostic

Molecular 7

- HBV DNA quantification
- Hepatitis C RNA detection
- HIV-1 RNA quantification
- Molecular detection of HPV
- Molecular detection of viruses in CSF
- CMV DNA quantification
- EBV DNA quantification

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Size & complexity

		Denmark		Finland		Norway		Sweden		Iceland	
Molecular virology **	**TOTAL**	**count**	**%**	**count**	**%**	**count**	**%**	**count**	**%**	**count**	**%**
HCV RNA detection	**207**	**2**	**1.0%**	**2**	**1.0%**	**1**	**0.5%**	**6**	**2.9%**		
HIV RNA quantification	**181**							**5**	**2.8%**		
HBV DNA quantification	**171**	**2**	**1.2%**					**3**	**1.8%**		
HPV DNA detection	**133**			**3**	**2.3%**	**1**	**0.8%**	**4**	**3.0%**		
Molecular detection of viruses in CSF	**126**	**5**	**4.0%**	**3**	**2.4%**	**1**	**0.8%**	**3**	**2.4%**		
CMV DNA quantification	**109**	**1**	**0.9%**	**1**	**0.9%**			**1**	**0.9%**		
EBV DNA quantification	**64**							**1**	**1.6%**		
Non-molecular virology											
Hepatitis B serology	**463**	**13**	**2.8%**	**1**	**0.2%**	**15**	**3.2%**	**16**	**3.5%**	**1**	**0.2%**
Anti-HBs detection	**458**	**12**	**2.6%**	**1**	**0.2%**	**14**	**3.1%**	**21**	**4.6%**	**1**	**0.2%**
HIV serology	**408**	**10**	**2.5%**	**3**	**0.7%**	**14**	**3.4%**	**11**	**2.7%**	**1**	**0.2%**
Hepatitis C serology	**396**	**13**	**3.3%**	**1**	**0.3%**	**14**	**3.5%**	**19**	**4.8%**	**1**	**0.3%**
Dg. Serology - hepatitis screen	**383**	**2**	**0.5%**			**14**	**3.7%**	**17**	**4.4%**		
Rubella IgG serology	**351**	**2**	**0.6%**	**1**	**0.3%**	**16**	**4.6%**	**26**	**7.4%**	**1**	**0.3%**
Immunity screen	**342**	**1**	**0.3%**	**1**	**0.3%**	**12**	**3.5%**	**16**	**4.7%**		
Dg. Serology - exanthema screen	**224**					**2**	**0.9%**	**3**	**1.3%**		
Measles & Mumps IgG serology	**190**			**1**	**0.5%**			**2**	**1.1%**		
Blood-borne viruses serology	**126**			**1**	**0.8%**	**4**	**3.2%**				
Respiratory Rapid: RSV	**104**							**1**	**1.0%**		
Virus identification	**76**			**2**	**2.6%**	**2**	**2.6%**	**1**	**1.3%**	**1**	**1.3%**
HIV POCT	**52**					**1**	**1.9%**	**2**	**3.8%**		

****New scheme** aimed at the molecular detection of **Gastrointestinal viruses** to go live **April 2015****

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Representation of Roche assays within molecular schemes

Molecular virology	Marker	2010, %	2012, %	2014, %	2014, n
HCV RNA detection	HCV RNA	62.6%	64.1%	63.0%	111
HIV RNA quantification	HIV RNA	57.8%	60.2%	60.8%	101
HBV DNA quantification	HBV DNA	73.0%	52.7%	50.0%	76
HPV DNA detection	HPV DNA	18.4%	36.7%	38.0%	54
Viruses in CSF	HSV DNA	no record	6.7%	5.5%	6
Viruses in CSF	VZV DNA	no record	4.8%	2.9%	3
Viruses in CSF	EV RNA	no record	2.5%	2.1%	2
CMV DNA quantification	CMV DNA	10.8%	12.0%	15.4%	14
EBV DNA quantification	EBV DNA	1.7%	1.8%	no record	no record
Molecular non-virology					
C. trachomatis & *N. gonorrhoeae*	Ct DNA	30.3%	28.8%	24.7%	75
C. trachomatis & *N. gonorrhoeae*	Ng DNA	n/a	20.5%	24.7%	59
Mycobacteria	Mycobacteria	15.3%	14.0%	7.6%	10
MRSA screening	MRSA DNA	3.8%	6.0%	5.7%	5

Design criteria for EQA specimens

- Clinically relevant
- Homogeneous specimens
- No matrix effect
- Stable specimens
- Adequately characterised
- Measurement and assessment of performance is possible

Design criteria for EQA specimens

- Organisers and staff identify possible new schemes after informal discussion with interested parties (ppts, VSAG...)
- Feedback from potential participants (questionnaires/surveys)
- Advice from the Steering Committee and Panel on the relevance and approval for pre-pilot studies.

  → gain insight into the clinical relevance

  → the routine approach to testing

  → possible problems

Scheme development: pilot to scheme introduction

- Pilot for 1-2 years to confirm design criteria and to optimise data analysis and its presentation
- Results are presented to the Panel and Steering Committee and based on approval the process of introducing the scheme starts
- Present a suggested scoring scheme to the Panel for approval
- Cost the scheme and notify charges with invitations to participate
- Finalise the developmental SOP and other associated document updates/changes/additions
- **Apply for scheme accreditation**

Source material and preparation of specimens

The main matrix is plasma/serum

National Blood Service

Purchased plasma positive for a marker e.g. anti-HCV, anti-HIV, HBV DNA…

Purchased plasma negative for anti-HCV, anti-HIV and HBsAg:

- *screened and characterised for common markers (CMV IgG, VZV IgG…)*
- used as diluent for other markers (eg CMV DNA)

Other commercial sources

Acute disease state plasma such as Rubella IgM, Acute EBV markers and PB19 IgM

VZV IgG / Rubella IgG negative plasma

Depending on the scheme type:

Used as plasma (e.g. HIV RNA) or serum (e.g. Serology schemes)

Liquid (e.g. Anti-HBs) or freeze-dried (e.g. HBV DNA) specimens

Source material and preparation of specimens

Other specimen formats

Simulated clinical specimens

- Freeze-dried specimens simulating: endocervical swabs, CSF...

  where freeze-drying matrix spiked with clinical isolate culture e.g. viruses in CSF
- Liquid/semi-liquid specimens simulating: urines, respiratory samples, swabs...

  VTM+/-gelatin matrix spiked with clinical isolate culture e.g. virus identification scheme

  Simulated urine spiked with clinical isolate e.g. molecular detection of Ct and/or Ng

Cervical specimens / HPV DNA

Liquid based cytology fluid clinical samples, either pooled or diluted

Specimens provided and characterised by the SHPVRL based at the Royal Infirmary of Edinburgh

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How do we establish our values & what instruments are used used?

Instruments & Assays

- Pre-distribution testing: specimens are tested with a panel of different assays.
- Assays: most popular manual and automated assays that reflects our participants practice (regularly reviewed)
- Reference/gold standard assay by a reference laboratory, where applicable

Intended results

- The values / intended results are established from the results obtained during pre-distribution testing.
- If pre-distribution testing shows discrepancies (‘not designated’) a decision is made on whether the specimen should be scored.

How do we establish our values

Qualitative / serology schemes

Majority of the virology serology schemes e.g. anti-HIV, anti-HAV, Rubella IgM…

Intended positive or negative

Semi-quantitative anti-HBs, Rubella IgG

Intended / < or > cut-off international unit

Rubella IgG < or ≥ 10IU/mL

Anti-HBs <10 or 10-100 or >100mIU/mL

Scoring is based on qualitative results

Quantitative / molecular schemes

Vral load of HCV, HIV-1, HBV, EBV & CMV

Pre-distribution results are only an indication for the intended result

Intended result = A consensus of the participants results

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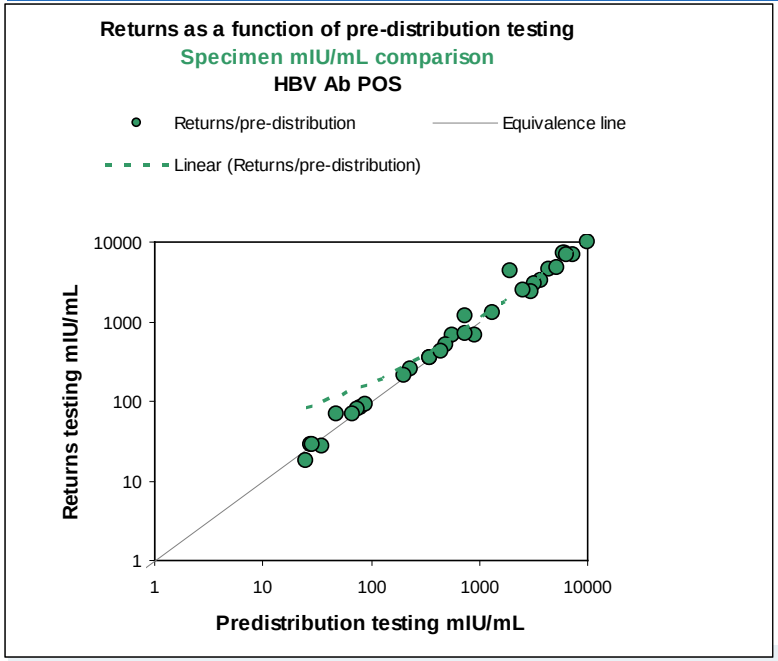
How do we confirm specimen stability?



theoretical difference of 1.00 log cp/mL

					Specimen 2224		Specimen 2225		
Laboratory	**Date tested**	**Batch [Expiry date]**	**Extraction assay/platform**	**Amplification assay/platform**	**copies/mL**	**log**	**copies/mL**	**log**	**log difference**
Bulk result	06/06/2014	S08204 (6/2015)	Roche COBAS Ampliprep	COBAS Ampliprep / COBAS TaqMan HIV-1 v2.0	2110	3.32	230	2.36	0.96
Return lab 9	20/10/2014	T01352 (11/2015)	Roche COBAS Ampliprep	COBAS Ampliprep / COBAS TaqMan HIV-1 v2.0	1935	3.29	147	2.17	1.12
Return lab 16	20/10/2014	T01352 (11/2015)	Roche COBAS Ampliprep	COBAS Ampliprep / COBAS TaqMan HIV-1 v2.0	2714	3.43	204	2.31	1.12
Return lab 36	20/10/2014	T01352 (11/2015)	Roche COBAS Ampliprep	COBAS Ampliprep / COBAS TaqMan HIV-1 v2.0	2000	3.30	190	2.28	1.02
						median 3.31		2.29	**1.07**
						0.5 log range (min) 2.81		1.79	
						0.5 log range (max) 3.81		2.79	
								0.3 log range	**0.77 – 1.37**

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EQA and Quality Assurance

- How to get the most out of EQA?

- Treat EQA specimens in the same way as routine specimens

  → EQA results give an insight into routine results

  → If EQA specimens are given special treatment, EQA results may be correct but nothing will be learnt about the quality of the routine service

- On receipt of the individual report → review the results with all staff (include successes and failures)

- If there was a problem:

  'How many other participants failed with the specimen?'

  'Are there any relevant comments?'

  Keep records of your reviews and the reasons for any decisions made

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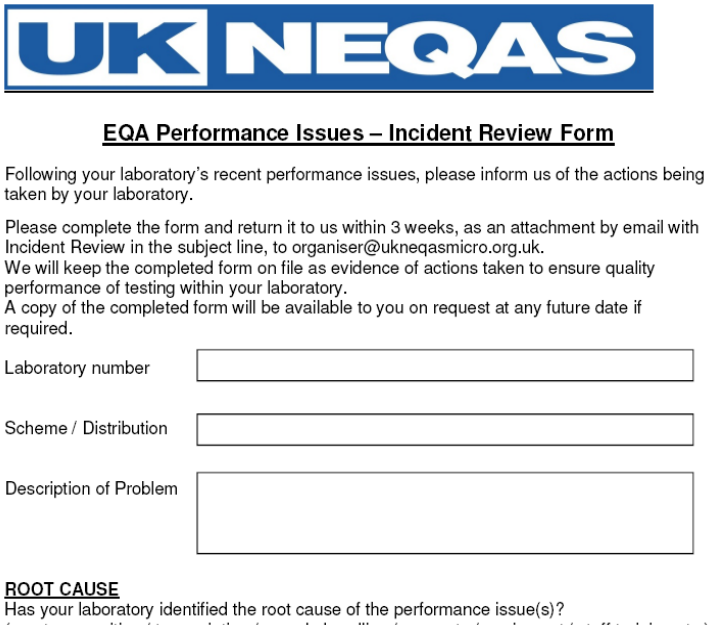
How to deal with EQA failures

Most failures with EQA specimens are as a result of inadequacies in other components of the quality systen



UK NEQAS

EQA Performance Issues – Incident Review Form

Following your laboratory's recent performance issues, please inform us of the actions being taken by your laboratory.

Please complete the form and return it to us within 3 weeks, as an attachment by email with Incident Review in the subject line, to organiser@ukneqasmicro.org.uk.
We will keep the completed form on file as evidence of actions taken to ensure quality performance of testing within your laboratory.
A copy of the completed form will be available to you on request at any future date if required.

Laboratory number

Scheme / Distribution

Description of Problem

ROOT CAUSE
Has your laboratory identified the root cause of the performance issue(s)?

Appropriate reactions:

- Introduce or refine IQC procedures
- Train or retrain staff
- Introduce or refine stock control
- Alter or formalise work up procedures
- Revise standard operating procedures
- …

Cautionary points:

Single EQA specimens may not be representative of the material routinely examined in a laboratory

→*before changes are made confirm the problem is general in nature*

→*requires further investigation with clinical samples*

UK NEQAS

Report – performance tracking

Intended Result		Your Report	Your Score
Specimen 0207	HSV-1 DNA positive	HSV-1 DNA positive	2
Specimen 0208	Enterovirus RNA positive	No virus detected	-1
Specimen 0209	Enterovirus RNA positive	No virus detected	-1
Specimen 0210	VZV DNA positive	VZV DNA positive	2
Specimen 0211	HSV-2 DNA positive	HSV-2 DNA positive	2
Specimen 0212	No virus detected	No virus detected	2

Cumulative score information

Total number of specimens sent to you for **UK NEQAS for Viruses in CSF (molecular)** over the last 2 distributions is 12 **/ 1-year distributions**
For these distributions specimen numbers 9915 9916 9917 9918 9919 9920 0207 0208 0209 0210 0211 0212 have been analysed and scored.

Number of reports analysed 12
Number of specimens reported as not examined (not scored) 1
Number of specimens received too late for analysis (not scored) 0
Number of specimens for which no report was received (scored as 0) 0
Your cumulative score for these specimens was 16 out of a possible total of 22

Cumulative score is less than mean score

The mean score calculated from the reports returned by **ALL** laboratories was 19.37 (with a standard error of 2.86)
Your performance rating for **UK NEQAS for Viruses in CSF (molecular)** i.e. the number of standard errors by which your cumulative score lies above or below the mean) for **ALL** laboratories is -1.18.

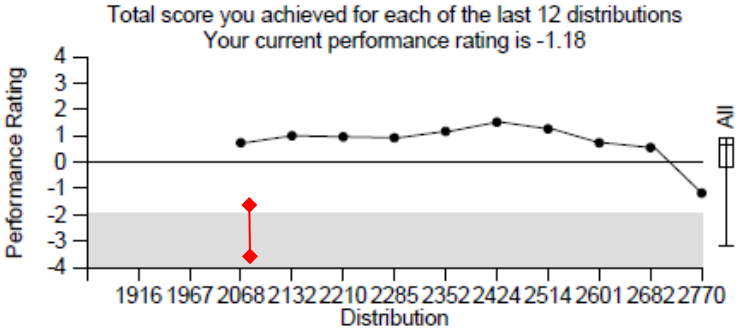
Performance Rating – a form of ranking

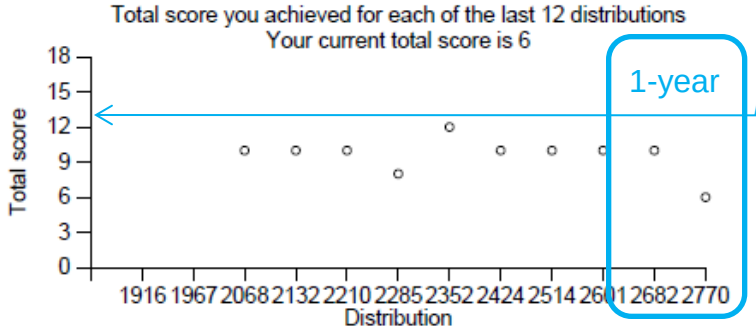
Compares other labs examining the same specimens

(country specific if over 10 labs)

A performance rating of more than 1.96 standard errors below the mean indicates possible poor performance.

Please note your performance rating may alter if other participants' results are amended.





What is the process from NEQAS side if an assay fails?

…where an assay gave discrepant results in comparison to other assays results and for a significant number of participants.

- Report to the manufacturer listing anonymously for each result:
  - Qualitative result
  - Batch number
  - Cut-off
  - Read out (OD/RLU/index/copies)
  - Average-SD-
  - Average-SD for 2 or 3 other assays

- Manufacturer: investigations on the specimen and on any changes in the assay (feed back from participants)
- Possible implications for clinical sample analysis: contact the MHRA e.g. batch issue

MHRA: Medical & Healthcare products Regulatory Agency

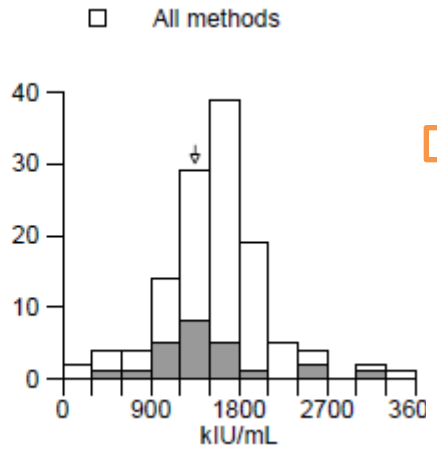
- UK NEQAS & Manufacturer to establish the cause and whether this affects only EQA specimen or may affect clinical sample analysis as well

UK NEQAS

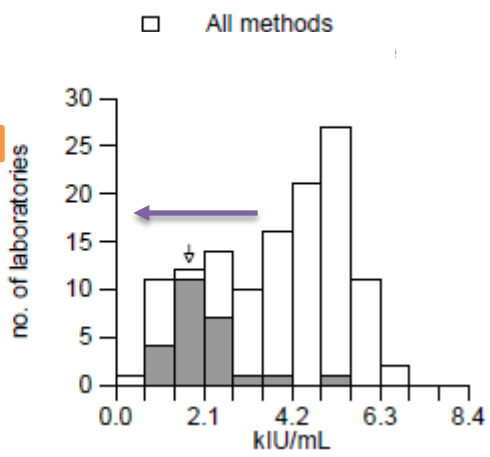
HBV DNA quantification / December 2011

Pair specimens
Genotype A

n (UK)	range	median	5%-95%
129 (25)	2.14-4.80	3.20	2.83-3.52
24 (8)	2.70-3.49	3.15	2.94-3.42
63 (8)	3.00-3.43	3.21	3.06-3.33
1	4.80-4.80		
1	3.30-3.30		
1	2.78-2.78		
10 (1)	2.14-3.85	3.14	2.18-3.66
9 (7)	2.65-4.12	3.31	2.79-3.97
11	2.93-3.53	3.24	3.00-3.40
2	3.09-4.00		
5	3.11-3.35	3.31	3.15-3.35
2 (1)	2.81-3.11		

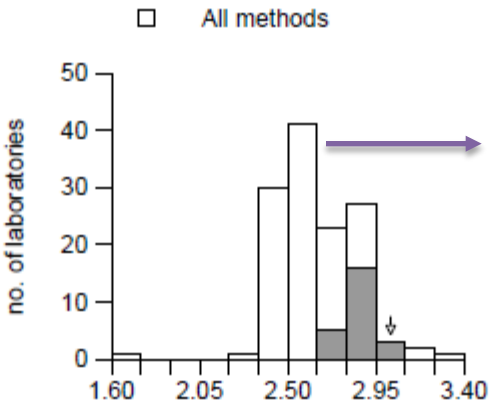


n (UK)	range	median	5%-95%
130 (25)	-0.67-1.92	0.63	0.12-0.81
25 (8)	-0.00-0.74	0.30	0.12-0.54
63 (8)	0.45-0.82	0.70	0.56-0.76
1	1.92-1.92		
1	0.03-0.03		
1	-0.03--0.03		
10 (1)	-0.67-1.11	0.45	-0.43-0.90
9 (7)	0.12-1.39	0.46	0.13-1.25
11	0.43-0.81	0.64	0.48-0.81
2	0.38-1.62		
5	0.44-0.60	0.50	0.45-0.60
2 (1)	0.06-0.20		



Intended result 2.29 to 2.89 log kIU/mL

n (UK)	range	median	5%-95%
129 (25)	1.74-3.27	2.59	2.42-2.94
24 (8)	2.70-3.09	2.86	2.74-2.96
63 (8)	2.30-2.71	2.52	2.37-2.67
1	2.89-2.89		
1	3.27-3.27		
1	2.81-2.81		
10 (1)	1.74-2.83	2.76	2.18-2.83
9 (7)	2.51-3.16	2.78	2.54-3.14
11	2.44-2.80	2.53	2.44-2.70
2	2.37-2.71		
5	2.61-2.87	2.75	2.63-2.86
2 (1)	2.75-2.92		



Your result :
Difference in conc. of 2.96 log kIU/mL

Your score : 1

Overall results	UK	All	Score
Median			
+/- 0.3 log	20	115	2
+/- >0.3 to 0.5 log	4	10	1
+/- >0.5 to 0.75 log	1	3	0
+/- >0.75 log	0	1	-1
Partial result	0	1	1

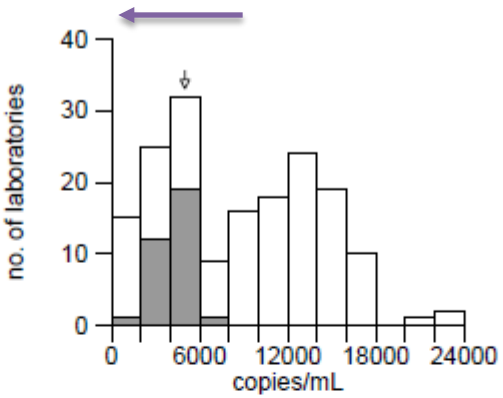
9/10
same assay

UK NEQAS

HIV-1 RNA quantification / January 2012

Theoretical difference of 0.47 log cp/mL (final median difference by all 0.46 log cp/mL)

n (UK)	range	median	5%-95%
181 (54)	0.60-4.42	3.94	3.11-4.24
35 (17)	3.08-3.83	3.62	3.46-3.73
3	3.46-3.97	3.56	3.47-3.93
91 (26)	0.60-4.42	4.10	3.65-4.24
10 (3)	3.30-4.04	3.50	3.31-3.91
5 (2)	3.61-4.40	3.89	3.64-4.33
5 (3)	3.59-4.35	3.95	3.62-4.27
5	2.81-3.99	3.51	2.85-3.97
8 (1)	3.19-4.24	3.98	3.37-4.21
1	3.09-3.09		
7	3.49-3.79	3.68	3.50-3.77
5 (1)	3.04-3.26	3.10	3.04-3.23
2 (1)	3.67-4.37		

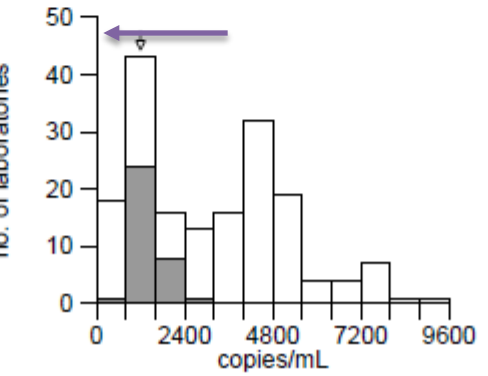


Your result :
4090 copies/mL (3.61 log copies/mL)

Method median concentration :
4153 copies/mL (3.62 log copies/mL)

Median concentration :
8705 copies/mL (3.94 log copies/mL)

n (UK)	range	median	5%-95%
182 (54)	0.60-4.21	3.47	2.65-3.86
36 (17)	2.68-3.50	3.14	2.93-3.30
3	2.86-3.80	2.99	2.87-3.71
92 (26)	0.60-3.96	3.63	3.07-3.87
10 (3)	2.47-3.43	3.02	2.64-3.38
5 (2)	3.14-3.90	3.48	3.16-3.85
5 (3)	3.08-4.21	3.55	3.13-4.11
5	2.91-3.42	2.97	2.91-3.41
8 (1)	2.64-3.85	3.51	2.83-3.81
1	2.20-2.20		
7	2.25-3.28	3.16	2.48-3.28
5 (1)	2.51-2.79	2.63	2.53-2.77
2 (1)	3.26-3.87		



Your result :
1593 copies/mL (3.20 log copies/mL)

Method median concentration :
1367 copies/mL (3.14 log copies/mL)

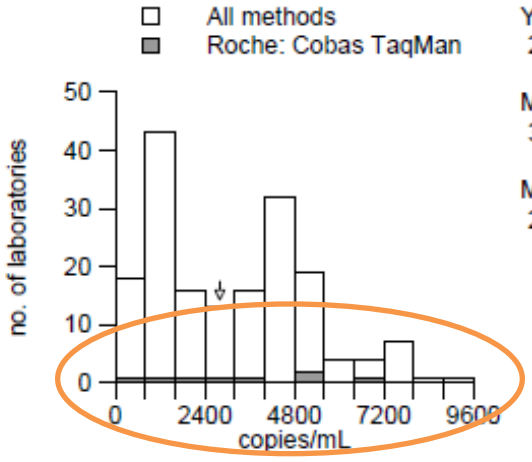
Median concentration :
2950 copies/mL (3.47 log copies/mL)

UK NEQAS

HIV-1 RNA quantification / January 2012

Specimen : 0713

	n (ZA)	range	median	5%-95%
All methods	182 (9)	0.60-4.21	3.47	2.65-3.86
	36 (2)	2.68-3.50	3.14	2.93-3.30
	3 (1)	2.86-3.80	2.99	2.87-3.71
◀	92 (3)	0.60-3.96	3.63	3.07-3.87
	10 (1)	2.47-3.43	3.02	2.64-3.38
	5	3.14-3.90	3.48	3.16-3.85
	5	3.08-4.21	3.55	3.13-4.11
	5	2.91-3.42	2.97	2.91-3.41
	8 (2)	2.64-3.85	3.51	2.83-3.81
	1	2.20-2.20		
	7	2.25-3.28	3.16	2.48-3.28
	5	2.51-2.79	2.63	2.53-2.77
	2	3.26-3.87		



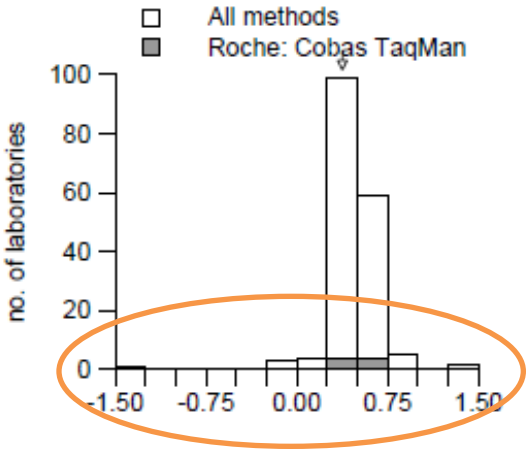
Your result :
2820 copies/mL (3.45 log copies/mL)

Method median concentration :
3240 copies/mL (3.51 log copies/mL)

Median concentration :
2950 copies/mL (3.47 log copies/mL)

Intended result 0.16 to 0.76 log cp/mL

	n (ZA)	range	median	5%-95%
	173 (7)	-1.32-1.50	0.46	0.25-0.63
	33 (2)	0.04-0.60	0.47	0.35-0.57
	4 (1)	-1.32-1.50	0.59	-1.03-1.36
◀	90 (2)	0.00-0.83	0.46	0.28-0.59
	8	0.25-0.86	0.44	0.28-0.83
	4	0.35-0.51	0.44	0.36-0.50
	5	0.13-0.51	0.41	0.16-0.50
	5	-0.10-0.61	0.45	-0.07-0.60
	8 (2)	0.39-0.55	0.46	0.40-0.54
	1	0.89-0.89		
	7	0.43-1.29	0.48	0.43-1.09
	5	0.26-0.75	0.42	0.29-0.70
	2	0.41-0.49		



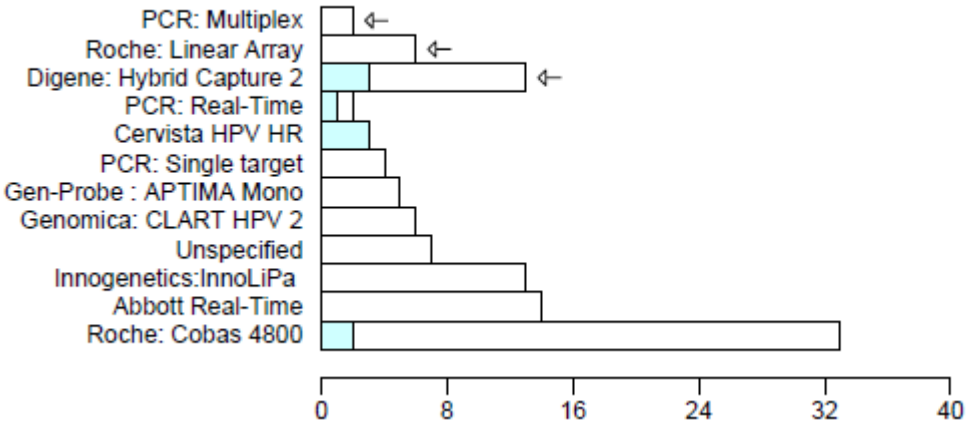
UK NEQAS

Molecular detection of HPV scheme / September 2012

• single sample + for HR genotypes

Scoring: **detecting presence / absence of high risk genotypes**
feedback on genotype collated but genotyping is not scored

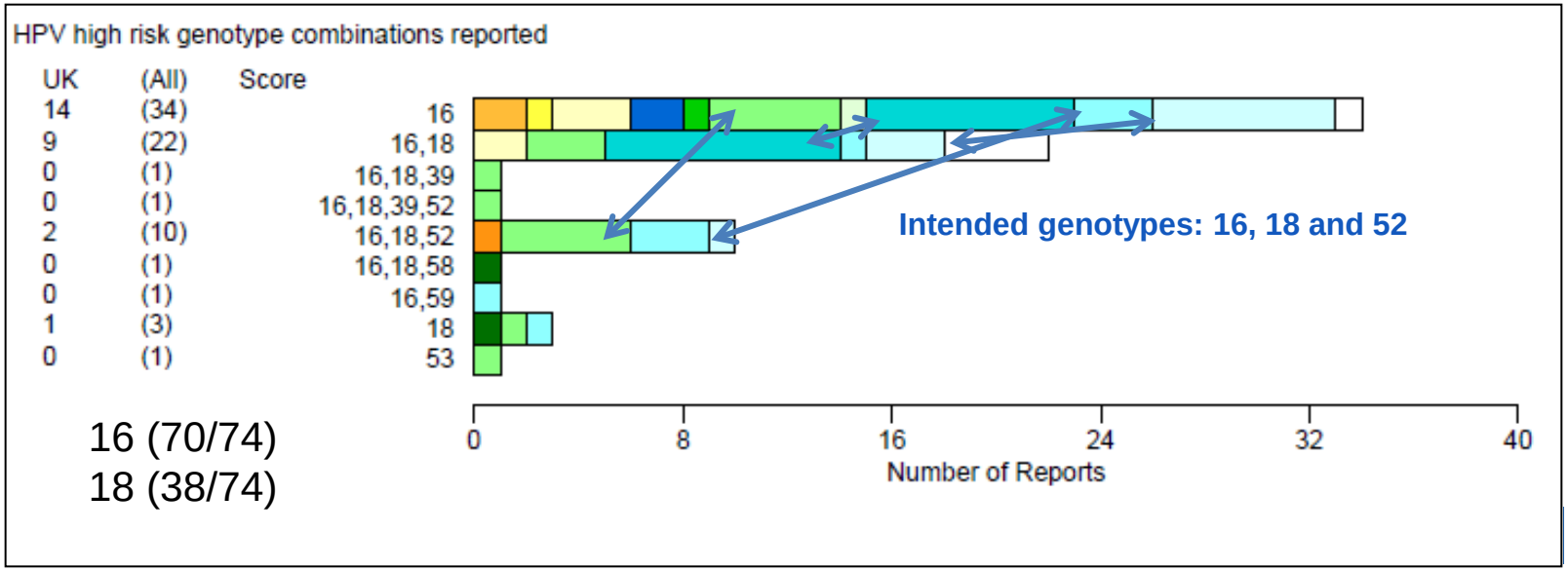
specimen 1122



	UK	(%)	All	(%)
PCR: Multiplex	2	(4.0)	2	(1.7)
Roche: Linear Array	1	(2.0)	6	(5.2)
Digene: Hybrid Capture 2	6	(12.0)	13	(11.2)
PCR: Real-Time	0	(0.0)	2	(1.7)
Cervista HPV HR	3	(6.0)	3	(2.6)
PCR: Single target	1	(2.0)	4	(3.4)
Gen-Probe : APTIMA Mono	5	(10.0)	5	(4.3)
Genomica: CLART HPV 2	0	(0.0)	6	(5.2)
Unspecified	3	(6.0)	7	(6.0)
Innogenetics:InnoLiPa	0	(0.0)	13	(11.2)
Abbott Real-Time	6	(12.0)	14	(12.1)
Roche: Cobas 4800	23	(46.0)	33	(28.4)

Intended HR report: detected

Overall Results	UK	All
Detected	41	96
Not detected	2	4
% correct	95.3%	**96%**



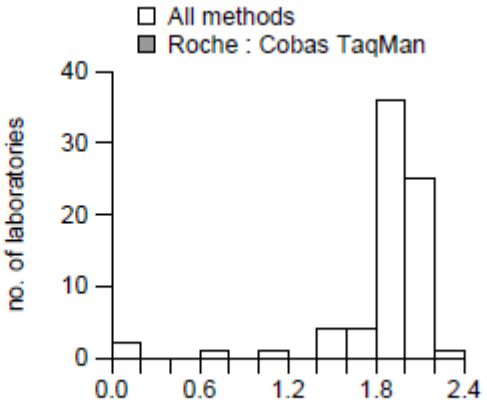
CMV DNA quantification / September 2014

- Source: clinical strain isolated from human embryonic fibroblasts from neonate's urine
- Produced specimen pair with theoretical level of 5.70 and 3.70 log cp/mL
- Yielding a theoretical difference of 2.00 log cp/mL

94.6% (70/74) within +/- 0.50 log cp/mL

DIFFERENCE between specimen 2194 and 2195

	n (UK)	range	av.median	5%-95%
All methods	74 (26)	0.01-2.34	1.89	1.34-2.15
Abbott Real-Time	5 (1)	1.89-2.08	1.91	1.89-2.06
Altona: RealStar	2	1.92-2.13		
Argene	7 (2)	0.01-2.34	1.77	0.06-2.28
ELITech: ELITe MGB	7	1.78-2.18	2.05	1.83-2.16
Focus: Simplexa	1 (1)	2.02-2.02		
FTD	3 (2)	1.08-1.85	1.48	1.12-1.81
Nanogen AD: R-T Alert	9	1.80-2.13	2.00	1.87-2.12
PCR: Multiplex	1 (1)	1.80-1.80		
Qiagen: Artus	17 (7)	1.60-2.16	1.99	1.76-2.13
Real-Time Multiplex	5 (4)	1.90-2.14	1.94	1.90-2.11
Real-Time Single target	16 (8)	1.50-2.20	1.98	1.50-2.15
Unspecified	1	2.00-2.00		



Your result :
Difference in conc. of log copies/mL

Your score : 0

Overall results	UK	All	Score
Median			
+/- 0.5 log	25	70	2
+/- >0.5 to 0.75 log	0	0	1
+/- >0.75 to 1.0 log	1	1	0
+/- >1.0 log	0	3	-1
One incorrect	3		0
Two incorrect	4		-2

CMV DNA quantification scheme / September 2014

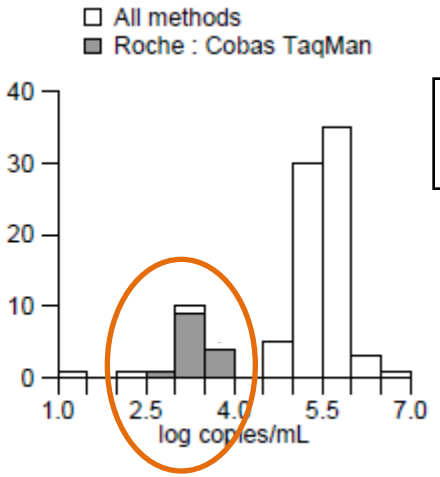
14 Roche users		specimen number	
	batch	2194	2195
A	T01571	2.85	<2.17
B	S12086	3.15	<2.17
C	T01355	3.20	<2.17
D	*not reported*	3.26	<2.17
E	T01355	3.27	<2.17
F	S08215	3.32	<2.17
G	*not reported*	3.47	<2.17
H	S1794400000	3.48	<2.17
I	T01571	3.49	<2.17
J	T01355	3.50	<2.17
K	T01571	3.51	<2.17
L	*not reported*	3.55	<2.17
M	T01571	3.64	<2.17
N	T0135500000	3.80	<2.17

Other one incorrect		specimen number	
	kit	2194	2195
O	Real-Time Multiplex	1.04	<2.70
P	GeneProof: Real-Time	2.31	<5.00
Q	Altona: RealStar	5.25	<2.40

Two incorrect		
	kit	count
	Real-Time Single target	n=3
	Real-Time Multiplex	n=1

- Produced specimen pair with theoretical level of **5.70** and 3.70 log cp/mL

specimen 2194	n (UK)	range	median	5%-95%
All methods	91 (29)	1.04-6.59	5.40	3.18-5.97
Abbott Real-Time	5 (1)	5.14-5.54	5.20	5.15-5.51
Altona: RealStar	3	5.15-5.81	5.25	5.16-5.76
Argene	7 (2)	3.14-5.88	5.42	3.66-5.81
ELITech: ELITe MGB	7	5.40-5.91	5.86	5.44-5.90
FTD	3 (2)	5.04-5.66	5.27	5.06-5.62
GeneProof: Real-Time	1	2.31-2.31		
Nanogen AD: R-T Alert	9	5.44-5.83	5.66	5.44-5.81
Qiagen: Artus	17 (7)	4.76-5.77	5.33	4.92-5.72
Real-Time Multiplex	6 (5)	1.04-6.59	5.75	2.13-6.56
Real-Time Single target	16 (8)	5.10-6.12	5.72	5.11-6.11
Roche : Cobas TaqMan	14 (2)	2.85-3.80	3.47	3.04-3.70
Unspecified	1	5.00-5.00		



Method median 3.47 cp/mL
Under quantified by ~ 2 Log_{10}

- Median achieved for specimen 2195 = 3.60 log cp/mL

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CMV DNA quantification scheme / September 2014

- Clinical strain was fully sequenced
- Pre-distribution QC results:
  - ✓ 3 reference labs confirmed results close to theoretical values (Qiagen artus n=2, in house n=1)
  - ✘ 2 reference labs could not detect CMV DNA (both in house)
- Alignment with primers & probes used in in house glycoproteinB* assay revealed **7** mismatches

Assay (number of users)	target gene	coding for	specimen 2194	specimen 2195	specimens difference
theoretical vial load	-	-	5.70	3.70	2.00
ELITech: ELITe MGB (n=7)	UL122-123	majorIE	5.86	3.76	2.05
Focus: Simplexa (n=1)	UL83	pp65	5.20	3.19	2.02
Altona: RealStar (n=3)	*not specified*	-	5.25	3.46	2.02
Nanogen AD: R-T Alert (n=9)	UL123	IE-2	5.66	3.67	2.00
Unspecified (n=1)	*not specified*	-	5.00	3.00	2.00
Qiagen: Artus (n=17)	UL122	IE-1	5.33	3.39	1.99
Other In-house-assays (n=22)	*not specified*	-	5.74	3.81	1.96
Abbott Real-Time (n=5)	UL34, UL80.5	DNA bindingP, pAP	5.20	3.29	1.81
Argene (n=7)	UL83	pp65	5.42	3.49	1.77
FTD (n=3)	US7, US8	cytoplasmic gp	5.27	3.81	1.48
GeneProof: Real-Time (n=1)	UL123	IE-2	2.31	not detected	not applicable
Roche : Cobas TaqMan (n=14)	UL54	DNA pol	3.47	<2.17	not applicable
'In-house gpB' (n=5)	UL55	gpB	not detected	not detected	not applicable

- UL54 gene = 3729 bases
- Clinical strain vs. AD169 - 50 base differences (1.3%)
- loci prone to mutations e.g. UL128 confirmed strain was unaltered by culture step
- Similar mutation patterns have been identified **

Overall: RT PCR assays which target the gpB gene may NOT detect all CMV clinical strains***
? potential detection impact on RCTaq

* Transplantation. 2001 Jun 15; 71(11):1609-15
** Virology Journal. 2009 Nov 26; 6:210
*** Journal of Clinical Microbiology. 2011 Aug; 49(8):3033-5

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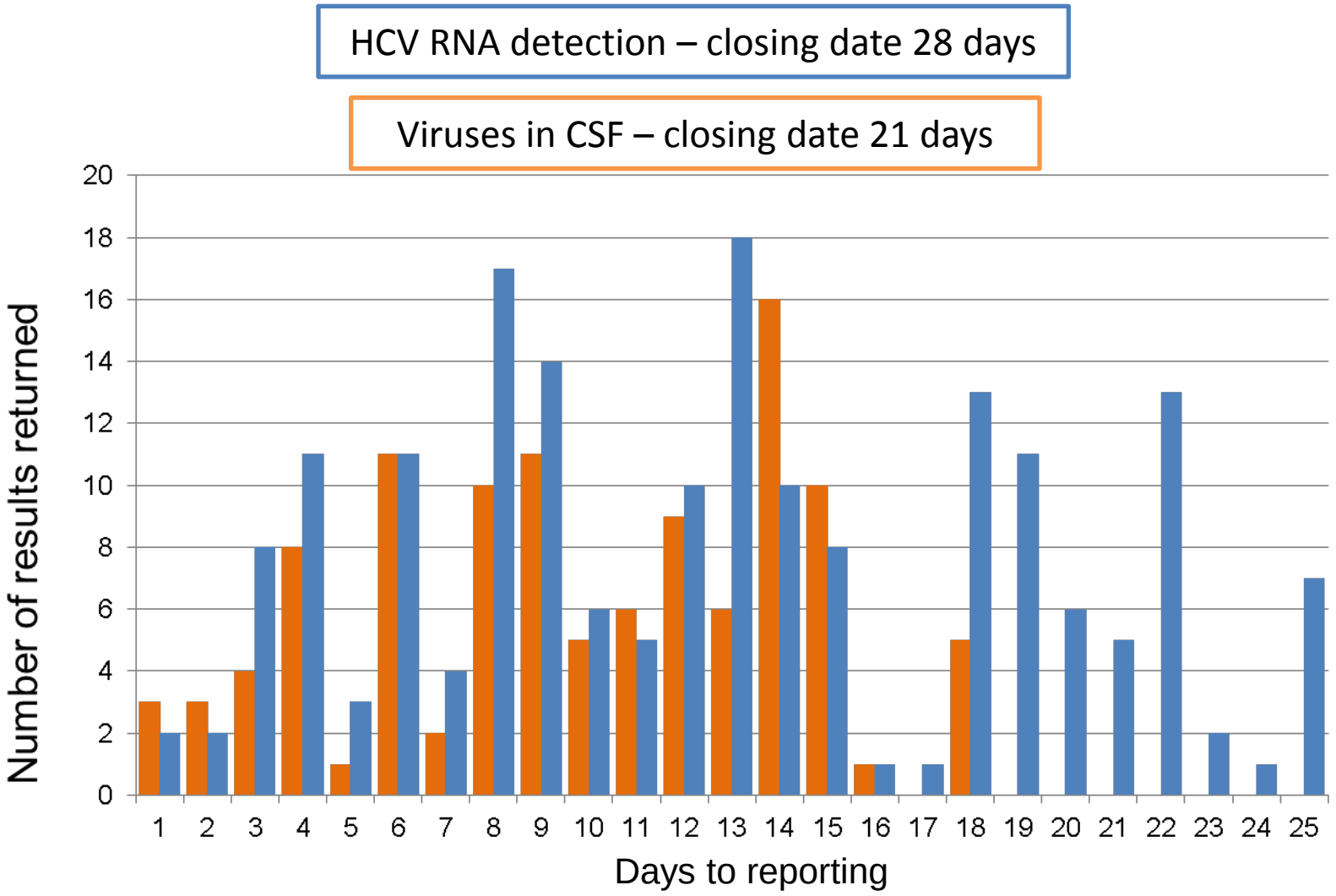
Other additional data collated
Time to submission of results



Example: a distribution of each scheme dispatched in 2013

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Summary

- EQA can provide information on:
  - the overall standard of performance
  - the influence of analytical procedures
  - individual laboratory performance
  - performance of staff

- Requirement on the EQA providers to review schemes to ensure they remain fit for purpose
  - On going update of schemes

UK NEQAS

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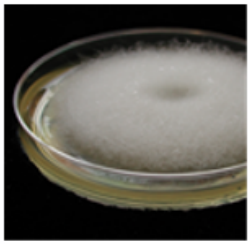
EQA provision with UK NEQAS



The United Kingdom National External Quality Assessment Service for Microbiology offers a number of features and benefits: Professionally led and educational service. The service is organised by professional microbiologists...

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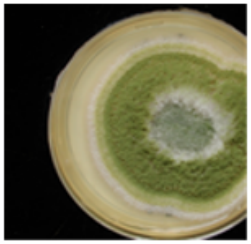
Introduction to schemes



UK NEQAS for Microbiology provides external quality assessment for clinical laboratories that carry out examinations in; General bacteriology, Virology, Serological testing, Blood donor testing (blood borne viruses and syphilis) and Parasitology...

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UK NEQAS

Microbiology Division Scientific Meeting

5th December 2014

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Gastrointestinal Infections – Going Through the Motions!

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