UK NEQAS

International Quality Expertise

# HIV1 RNA quantification

## History

Developmental work 1997 to 1998

Introduced 1999

Accredited to ISO 17043

## Review

Ten Years of External Quality Assessment of Human Immunodeficiency Virus Type 1 RNA Quantification

Senechal and James

J. Clin. Micro. 2012: 50 (11), 3614-3619

# Scheme format

- Lyophilised specimens
- Normal human plasma diluent
- Paired specimens prepared from a single HIV RNA positive plasma to represent sequential specimens from an individual patient
- Data analysis based on the difference in concentration between the specimens

# Results presentation and performance evaluation

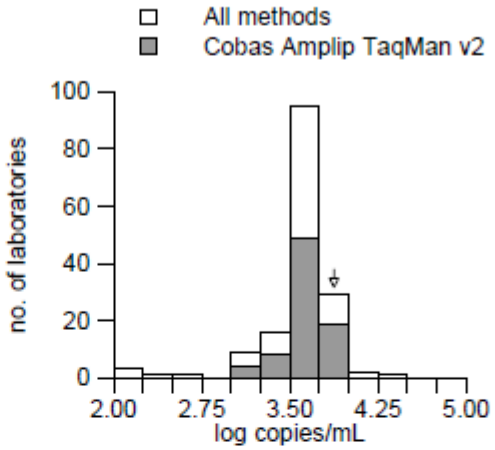
- No reference standard available when the scheme was introduced
- Absolute values
  - Consensus result
    - Promotes comparability and is an ideal objective
    - Over 12% failure to report to within 0.5 log copies of the median (2010 figures); ~7% (2014 figures)
  - Consensus by kit
    - Use of in-house assays would exclude evaluation for some participants
- Difference in viral load between paired specimens
  - Clinically relevant
  - Avoids bias due to differences in absolute values obtained with different manufacturers' kits
  - Not affected by differences in reporting units

# Report excerpt: distribution 3480, June 2014

Specimens 2061 and 2062 originated from a serial dilution from a single HIV-1 RNA plasma (subtype C) diluted 1:2.9 and 1:16 respectively in negative human plasma, yielding a theoretical difference of 0.74 log copies/mL.

**Specimen : 2061**

| | n (UK) | range | median | 5%-95% |
|---|---|---|---|---|
| All methods | 164 (54) | 2.00-7.00 | 3.64 | 3.11-3.90 |
| Abbott Real-Time | 37 (17) | 3.38-4.17 | 3.65 | 3.46-3.89 |
| Cobas Amplip TaqMan v2 | 80 (23) | 3.03-3.92 | 3.66 | 3.29-3.88 |
| Cobas HP TaqMan v2 | 10 (1) | 3.11-7.00 | 3.59 | 3.11-5.56 |
| Nuclisens Easy-Q v2 | 6 (3) | 2.00-2.62 | 2.27 | 2.05-2.59 |
| Qiagen: Artus | 8 (4) | 3.56-4.23 | 3.77 | 3.59-4.19 |
| RAS Amplisure | 1 | 3.24-3.24 | | |
| Real-Time Single target | 2 (2) | 3.83-4.40 | | |
| Roche: Cobas TaqMan | 7 (2) | 3.03-3.79 | 3.56 | 3.17-3.77 |
| Siemens: kPCR | 8 | 3.56-3.69 | 3.63 | 3.57-3.68 |
| Unspecified | 1 (1) | 3.42-3.42 | | |



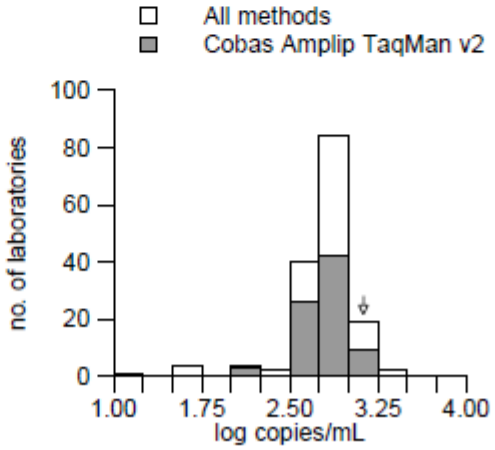

Your result :
3.88 log copies/mL

Method median concentration :
3.66 log copies/mL

Median concentration :
3.64 log copies/mL

**Specimen : 2062**

| | n (UK) | range | median | 5%-95% |
|---|---|---|---|---|
| All methods | 161 (53) | 1.00-3.73 | 2.81 | 2.25-3.08 |
| Abbott Real-Time | 37 (17) | 2.64-3.38 | 2.90 | 2.72-3.12 |
| Cobas Amplip TaqMan v2 | 80 (23) | 2.15-3.12 | 2.79 | 2.59-3.07 |
| Cobas HP TaqMan v2 | 10 (1) | 1.00-3.01 | 2.72 | 1.63-2.99 |
| Nuclisens Easy-Q v2 | 4 (2) | 1.54-1.71 | 1.63 | 1.56-1.70 |
| Qiagen: Artus | 8 (4) | 2.73-3.73 | 2.98 | 2.75-3.52 |
| Real-Time Single target | 2 (2) | 2.78-3.30 | | |
| Roche: Cobas TaqMan | 7 (2) | 2.15-3.05 | 2.74 | 2.29-3.01 |
| Siemens: kPCR | 8 | 2.61-2.89 | 2.85 | 2.63-2.88 |
| Unspecified | 1 (1) | 2.67-2.67 | | |




Your result :
3.07 log copies/mL

Method median concentration :
2.79 log copies/mL

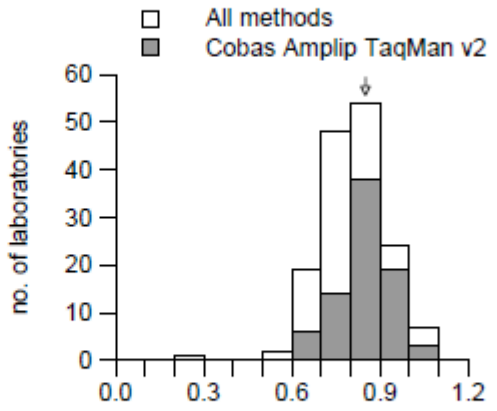
Median concentration :
2.81 log copies/mL

# Report excerpt: distribution 3480, June 2014

**Intended result** : 0.48 to 1.08 log copies/mL
(average median of the reported differences in concentration between specimen 2061 and 2062 +/- 0.3 log copies/mL, with an uncertainty of 0.043)

Difference in concentration between specimen 2061 and 2062 expressed in log copies/mL :

| | n (UK) | range | av.median | 5%-95% |
|---|---|---|---|---|
| All methods | 156 (51) | 0.29-6.00 | 0.78 | 0.65-1.00 |
| Abbott Real-Time | 36 (16) | 0.57-0.99 | 0.73 | 0.66-0.85 |
| Cobas Amplip TaqMan v2 | 80 (23) | 0.63-1.02 | 0.85 | 0.68-0.97 |
| Cobas HP TaqMan v2 | 10 (1) | 0.57-6.00 | 0.74 | 0.62-3.71 |
| Nuclisens Easy-Q v2 | 4 (2) | 0.29-0.98 | 0.67 | 0.35-0.93 |
| Qiagen: Artus | 7 (4) | 0.64-1.00 | 0.85 | 0.66-0.98 |
| Real-Time Single target | 2 (2) | 1.05-1.10 | | |
| Roche: Cobas TaqMan | 7 (2) | 0.74-0.91 | 0.82 | 0.76-0.90 |
| Siemens: kPCR | 8 | 0.75-1.04 | 0.80 | 0.75-0.98 |
| Unspecified | 1 (1) | 0.75-0.75 | | |




Your result :
Difference in conc. of 0.81 log copies/mL

Your score : 2

| Overall results | UK | All | Score |
|---|---|---|---|
| Median | | | |
| +/- 0.3 log | 50 | 153 | 2 |
| +/- >0.3 to 0.5 log | 1 | 2 | 1 |
| +/- >0.5 to 0.75 log | 0 | 0 | 0 |
| +/- >0.75 log | 0 | 1 | -1 |
| One incorrect | 1 | 2 | 0 |
| Two incorrect | 0 | 1 | -2 |
| Total | 52 | 159 | |
| %Correct | 96.2 | 96.2 | |

A total of 179 sets of specimens were distributed for testing with 163 participants responding within the specified period: four participants did not examine the specimens. Valid results for both specimens were reported by 156 participants with 153/156 (98%) reporting results within 0.30 log copies/mL of the average of the median difference in concentration.

Of the outlying results: two participants reported a result within 0.3 to 0.5 log copies/mL (Method: Nuclisens Easy-Q v2, Real-Time Single target) and one participant reported a result over 0.75 log copies/mL (Method: Cobas High Pure TaqMan v2). Two participants reported a false negative result for specimen 2062 (Method: Unspecified and Nuclisens Easy-Q v2), this is categorised as 'One incorrect'. One participant reported a false negative result for both specimens (Method: Sacace Real-TM).

# Contact details

Dr Vivienne James

**UK NEQAS for Microbiology**

PO Box 63003

London NW9 1GH

Tel: + 44 (0)20 8905 9890

Fax: + 44 (0)20 8205 1488

Email: organiser@ukneqasmicro.org.uk

Website: www.ukneqasmicro.org.uk