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UKAS PROFICIENCY TESTING 4301

Weqas

HIV POCT EQA Scheme Guide

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Contents

1. Scheme Details and Repertoire

1.1 List of Analytes and Frequency of Distribution

Frequency: Bi-Monthly Number of samples: 3

Analytes	Approx. Range Covered
P24 Antigen	Positive / Negative
HIV-1 Antibody	Positive / Negative
HIV-2 Antibody	Positive / Negative

1.2 Source Material and Serum Integrity

For the HIV POCT EQA the base material is sterile human serum, filtered to 0.2 µm with Gentamicin added to maintain sterility. The base material is human serum tested at donor levels and found negative for HIV Antibody, Hepatitis B Surface Antigen and Hepatitis C Antibody. A source of Recombinant HIV-p24 Ag and HIV1 and HIV2 Ab is added to the serum.

The serum is dispensed aseptically into 0.5 mL aliquots and stored at -70°C until dispatched. The samples are dispatched by first class mail as frozen samples packaged in containers conforming to Post Office guidelines

The samples are suitable for assay on 4th generation kits / devices.

1.3 Sample Stability

Please refer to separate WEQAS HIV Stability Document.
WEQAS advise that the samples are assayed immediately on receipt, or stored at 4^{o}C and assayed within 4 days of the "send out" date.

2. Instructions for use

Frequency
Three samples will be distributed on a bimonthly basis, along with a results return sheet.
The return sheet gives details of your assigned laboratory code, section name, distribution code and the date for return of results.

Material
The samples are prepared from human serum and do not include stabilisers or preservatives. Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical/patient specimens. The samples are for ***in vitro*** diagnostic use only.

Procedure for Sample Testing
Please analyse on the day of receipt. If you are unable to assay the HIV samples on that day, please refrigerate the samples and **assay within 4 days of the 'send-out date'.**

1. On the day of assay, allow the sample to reach room temperature.

2. Gently invert the sample a couple of times, ensuring adequate mixing.

3. Carefully remove the lid.

4. Please assay the samples as if they were patient samples, but DO NOT use the chase buffer; this is for whole blood samples only. Follow the test procedure in the manufacturers' instructions provided with the kit.

5. Safely dispose of any excess sample in accordance with local waste policy guidelines.

6. Results should be entered on the input sheet provided. Once the results have been entered copy the sheet and return by the "return-by" date stated. Participants can either return results by first class mail or FAX.

3. Statistical Analysis

Qualitative results are submitted for all analytes.

3.1 Interpretation of the Scoring System.

The spiked values for each analyte are used to determine the correct interpretative comments. The correct interpretation is provided on the report. Your results are compared with the correct interpretation.
The scores broadly reflect clinical importance. A correct result (in agreement with interpretive comment) is given a score of 0. A score of 3 is assigned for a gross misclassification of the result.

Generally, a negative result for a positive sample is given a score of 2
a negative result for a strong positive sample is given a score of 3
any positive result for a negative sample is given a score of 3.

The sensitivities of the methods, the intended purpose of the kits, whether "rule in" or "rule out" are also taken into account in the scoring.

These Scores are treated in the same way as SDI scores for Performance Surveillance in our quantitative schemes. **Please refer to WEQAS POCT Participants Manual for full explanation.** The report shows individual sample scores, plus an average score across the 3 samples. Where a true negative (non spiked) sample has been distributed, and a negative result has been returned, this individual score is not included in the average.

3.2 Interpretation of Individual Score

Score	Interpretation
0	good
2	Warning needs further investigation
3	unacceptable

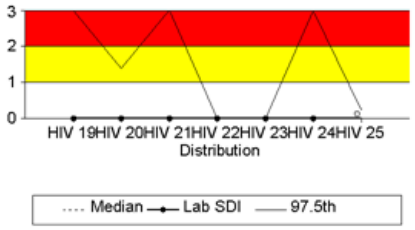
3.3 Typical Report

An example of a typical participant's report is given below. Each report includes the scoring criteria (see section 3.1 for interpretation), a summary of the qualitative results, the broad method used (manufacturer), and method specific performance.

Manager's Summary Report

Distribution Date: 7/07/14. Final. Report Issued: 25/07/14

This Distribution	
Overall Lab SDI:	0.00
Median All Laboratory:	0.00
97.5th centile:	0.25



All SDI Ranges	
< 1	Good
1 - 2	Acceptable
> 2	Poor

Section SDI scores for this distribution

Section	HIV
Overall	0.00
p24 Ag	0.00
HIV Ab	0.00

SDI Code	Meaning
N/A	Not enrolled for this analyte
?	Analyte enrolled but no results returned
N/S	This analyte not scored
NNR	Non-numerical results
**	SDI score greater than 2

Please note: Method and Instrument Summary reports are available to download via the 'Lab Stats' or 'Section Stats' menu.

If you don't currently have interactive access , please contact WEQAS for a registration form on 02920 314750.

Comments:

Distribution HIV 25 - p24 Antigen

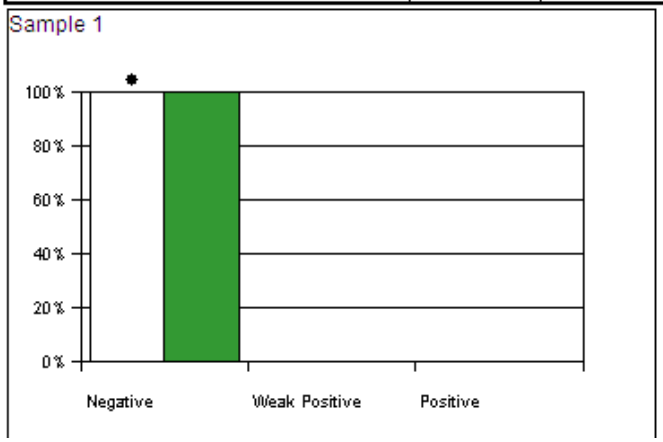
p24 Antigen	Sample No 1	Sample No 2	Sample No 3
Spiked Value	Non-spiked	Spiked with p24 Antigen	Spiked with p24 Antigen
Interpretation	Negative	Positive	Positive

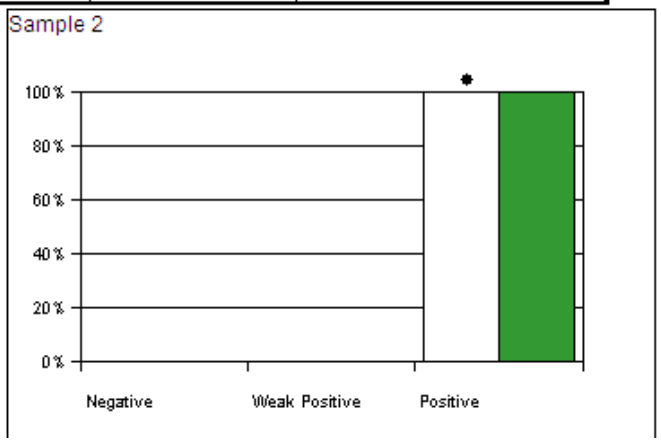
Distribution HIV 25 - HIV Antibody

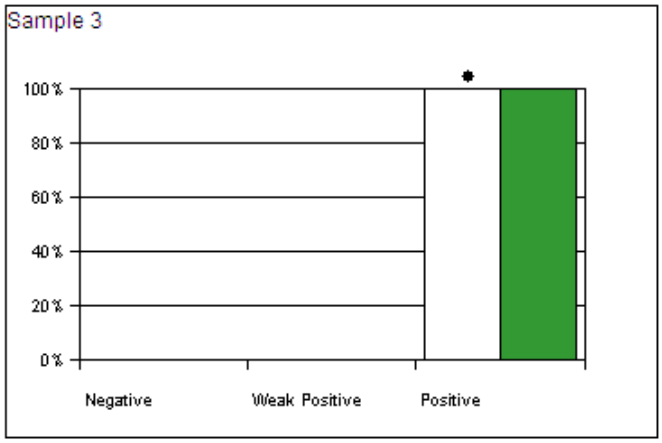
HIV Antibody	Sample No 1	Sample No 2	Sample No 3
Spiked Value	Spiked with HIV-1 Ab	Spiked with HIV-1 Ab	Non-spiked
Interpretation	Positive	Positive	Negative

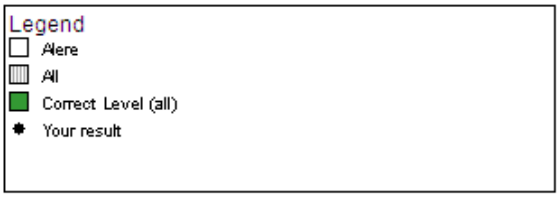
Individual Section Report Example

Lab Code	Section	Method	Instrument	Sample Number			Sample Score			Average Score
				1	2	3	1	2	3	(Average)
ABE	HIV	Alere	Determine	Negative	Positive	Positive	0	0	0	0.00
Interpretation				Negative	Positive	Positive				
Spiked Value				Non-spiked	Spiked with p24 Ag	Spiked with p24 Ag				









Number of Responses	Sample 1		Sample 2		Sample 3	
	Method	Overall	Method	Overall	Method	Overall
Negative	40	40	-	-	-	-
Weak Positive	-	-	-	-	-	-
Positive	-	-	40	40	40	40
TOTAL	40	40	40	40	40	40

Individual Sample Score Interpretation

Score	Interpretation
0	Good
1	Acceptable
2	Warning
> 2	Unacceptable

Overall summary page – available with every distribution.

Qualitative Report

Distribution HIV 29

p24 Ag Results

Lab Code	Method	Instrument	Sample Number			Sample Score			Average Score
			1	2	3	1	2	3	
ABE	Alere	Determine							
ACN	Alere	Determine	Positive	Negative	Negative	0	0	0	0
ACS	Alere	Determine	Positive	Negative	Negative	0	0	0	0
ACT	Alere	Determine							
ACU	Alere	Determine	Positive	Negative	Negative	0	0	0	0
ACX	Alere	Determine							
AGF	Alere	Determine							
AGF	Alere	Determine	Positive	Negative	Negative	0	0	0	0
AGF	Alere	Determine	Positive	Negative		0	0		0
AGF	Alere	Determine	Positive	Negative	Negative	0	0	0	0
CL	Alere	Determine							
CL	Alere	Determine	Positive	Negative	Negative	0	0	0	0
DJ	Alere	Determine	Positive	Negative	Negative	0	0	0	0
DJ	Alere	Determine	Positive	Negative	Negative	0	0	0	0
HP	Alere	Determine	Positive	Negative	Negative	0	0	0	0
HP	Alere	Determine	Positive	Negative	Negative	0	0	0	0
HP	Alere	Determine							
HP	Alere	Determine	Positive	Negative	Negative	0	0	0	0
HP	Alere	Determine	Positive	Negative	Negative	0	0	0	0
HP	Alere	Determine							
KL	Alere	Determine	Positive	Negative	Positive	0	0	3	1.5
KL	Alere	Determine	Positive	Negative	Negative	0	0	0	0
KT	Alere	Determine	Positive	Negative	Negative	0	0	0	0
ME	Alere	Determine	Positive	Negative	Negative	0	0	0	0
ME	Alere	Determine	Positive	Negative	Negative	0	0	0	0
MQ	Alere	Determine	Positive	Negative	Negative	0	0	0	0
NC	Alere	Determine	Positive	Negative	Negative	0	0	0	0
NC	Alere	Determine	Positive	Negative	Negative	0	0	0	0
NC	Alere	Determine	Positive	Negative	Negative	0	0	0	0
RJ	Alere	Determine	Positive	Negative	Negative	0	0	0	0
RJ	Alere	Determine	Positive	Negative	Negative	0	0	0	0
RJ	Alere	Determine	Positive	Negative	Negative	0	0	0	0
TU	Alere	Determine	Positive	Negative	Negative	0	0	0	0
TW	Alere	Determine	Positive	Negative	Negative	0	0	0	0
TW	Alere	Determine	Positive	Negative	Negative	0	0	0	0
YS	Alere	Determine	Positive	Negative	Negative	0	0	0	0

Interpretation	Positive	Negative	Negative
Spiked Value	Spiked with p24 antigen	Non spiked	Non spiked