Development of a UK NEQAS Scheme for HIV Point of Care Testing

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Abstract

Introduction

The use of POCTs is rising in both the laboratory and other settings such as sexual health clinics (fig. 2). HIV testing has traditionally been performed in laboratory based settings but as POCTs are developed the need for appropriate quality assurance schemes also increases. While there are EQA schemes for the laboratory setting none exist for POCTs. For POCTs to perform their intended role they need training, quality assurance and regular monitoring of performance and results. For POCTs to perform their intended role they need training, quality assurance and regular monitoring of performance and results. POCTs are more widely used now and are often used in non-laboratory settings. HIV POCTs are increasingly used at point of care in healthcare settings in order to provide quick and easy results. POCTs are increasingly used at point of care in healthcare settings in order to provide quick and easy results. They provide rapid results for both patients and healthcare providers, and allow anti-viral therapy treatment to begin earlier. Testing for HIV at the point of care may increase the number of adults willing to take a HIV test as well as increase the number of people being diagnosed early in the infection process. The POCTs were assessed using existing HIV positive serology EQA specimens. Twenty respondents participated in the pilot scheme. Twenty responded and chose to participate in the pilot scheme. Participants were identified from the results of the HIV POCT questionnaire and invited to participate in the pilot scheme. Twenty responded and chose to participate.

Aims of the project

To investigate the various kits/assays available on the market for HIV POCT.

To determine the effects of various subgroups of HIV-1 strains on the HIV POCT results.

To distribute, and report on, a pilot EQA scheme for HIV POCT.

HIV Assays

All previously characterised serology specimens were re-tested using Genescreen ULTRA HIV-1/2 Ag/Ab EIA and OraQuick kits as an assay to determine HIV group 1 or 2.

Materials & Methods

All specimens were tested in parallel at 35°C for 30 minutes and viral inactivation was fully completed by adding 10% Tween 80. None of the specimens included in the study were positive for HIV p24 antigen; it is likely that they were false positive results.

First Set of Specimens: 20 serology specimens, 16 HIV-1 and 4 HIV-2, were selected to determine performance on POCTs.

HIV-2

Specimens were chosen for the first set of serology specimens on the basis of: 1) previous characterisation and results using the INSTI HIV-1/2 Test; 2) presence of samples from countries where HIV-2 is endemic; and 3) availability of specimens.

Results

Materials & Methods

HIV Positive Specimens

All specimens were sent back to 35°C for 30 minutes and viral inactivation was fully completed by adding 10% Tween 80.

First Set of specimens: 20 serology specimens, 16 HIV-1 and 4 HIV-2, were selected to determine performance on POCTs.

All specimens had already been characterised by Genescreen HIV-1/2 Ag/Ab EIA and OraQuick kits as positive or negative for HIV-1 and HIV-2.

Second Set of Specimens: Five molecules of subtypes B, C and CRF02_AG were selected.

Results

HIV-2

Specimens were chosen for the second set of serology specimens on the basis of: 1) previous characterisation and results using the INSTI HIV-1/2 Test; 2) presence of samples from countries where HIV-2 is endemic; and 3) availability of specimens.

Second Set of Specimens: 10 serology specimens, 8 HIV-1 and 2 HIV-2, were selected to determine performance on POCTs.

A. Distribution of Pilot EQA Scheme for HIV POCT

Specimens: Four specimens, two HIV-1 and one HIV-2, treated with 1% Tween 80 were used for the first set of non-processed specimens using Genescreen HIV-1/2 Ag/Ab EIA and OraQuick Ab/Ag Combo kits.

Participation in the study: Overall twenty responses were received and 18 participants chose to test the samples using a combination of kits namely; Determine HIV-1/2 Ag/Ab Combo, Determine HIV-1/2 Ab and INSTI HIV-1/2 Ab (fig. 7). Three participants chose to test the samples using Genscreen ULTRA HIV-1/2 Ab & Ab EIA. The EIA results were used as a reference for POCT results.

B. Distribution of Pilot EQA Scheme for HIV POCT

Specimens: Four specimens, two HIV-1 and one HIV-2, were selected for 30 minutes for viral inactivation. The tests were performed by non-laboratory trained staff.

Results

Materials & Methods

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First Set of Specimens: 20 serology specimens, 16 HIV-1 and 4 HIV-2, were selected to determine performance on POCTs.

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A. Effect of Viral Inactivation by Tween 80

Four specimens, two HIV-1 and one HIV-2, treated with Tween 80 were used for the non-processed specimens using Genescreen HIV-1/2 Ag/Ab EIA and OraQuick Ab/Ag Combo kits.

No effect was observed on the reliability of the results for HIV POCTs.

Performance of specimens correctly showed reactive results for HIV-1 and HIV-2 with all POCTs. However, 7 out of 20 specimens showed weak reactive results for HIV-1 antibodies on both INSTI and OraQuick kits including 3 HIV-1 and 1 HIV-2. All specimens were correctly negative for HIV p24 antigen (fig. 4).

B. Effect of Various Subgroups of HIV-1 on POCT assay results

No difference was observed in the reactive results on the POCTs between subgroups B (22/20), C (22/22) or CRF02_AG (22/22).

Interestingly, the reactive signals observed were much stronger than the signals observed with the first set of specimens. An example of the reactive signals produced can be seen in fig. 5.

C. Overall performance

Participants reached an overall agreement of 87% with participants reporting the correct results. One participant reported on incorrect results for specimens 0217 using Determine HIV-1/2 Ab & Ag/Ab EIA and one participant reported HIV p24 antigen positive for the negative specimen 0217 using Determine HIV-1/2 Ag/Ab EIA kit (fig. 8).

Conclusions & Discussion

The investigation into the performance of the first set of serology specimens on the POCTs showed that there were no discrepancies between the previous characterisation results and the results from the POCTs.

The use of POCTs in the point of care setting offers the advantage of faster, easier and cheaper results. POCTs can be used to improve the quality of detecting and treating chronic illnesses. POCTs can be used to improve the quality of detecting and treating chronic illnesses. The results from the POCTs are then used to determine the correct treatment and management level.

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