

**THE FUTURE OF ORAL FLUID HIV TESTING
IN SOUTH AFRICA**

HERBERT DOUGLAS DAVIS

Assignment presented in partial fulfilment of the requirements for the degree of
Master of Philosophy (HIV/AIDS Management) at Stellenbosch University



Study leader: Prof JB du Toit

April 2005

Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my own original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

Signature:

Date:

Abstract

“Oh no, I feel uncomfortable with blood, I don’t know if I want to take the HIV test!”

This is a general attitude towards HIV/AIDS inside a voluntary testing and counselling (VCT) environment and it is enhanced by numerous superstitions and misconceptions regarding HIV/AIDS which still occur in a South African context. Yet there is an alternative, approved test for HIV/AIDS available which does not require a blood sample.

Testing for the presence of HIV/AIDS by means of an oral specimen has been used for more than 10 years, while the rapid version thereof received official endorsement in the USA in 2004. Although the oral fluid HIV testing option is utilized in SA, oral fluid tests have still to be used in an official capacity. No policy, guidelines or legislation regarding any aspect of oral fluid HIV testing currently exists in SA. As a result, this alternative HIV testing method is not well-known among the general South African public.

The aim of this research paper will be to raise - and positively influence - the profile and image of oral HIV testing as an attractive alternative to HIV testing that requires a blood specimen. The foundation for this will be laid by proving that the lack of the need for a blood specimen in oral fluid HIV testing positively influences testing for HIV.

This research project will further suggest a specific promotional strategy for oral testing with the aim of convincing more individuals to test for HIV. This strategy will be based on its distinguishing characteristic – namely the absence of blood – and entails the following: A poster campaign will be suggested to create awareness and promote these tests as a more “user friendly” version of HIV testing. At ground level the strategy will be carried out by setting up mobile HIV/AIDS testing units, specializing in oral fluid HIV testing. Moreover certain guidelines will be suggested for oral test administration.

Opsomming

“Ai toggie, ek is ongemaklik met bloed, ek weet nie of ek die Vigs-toets gaan doen nie!”

Hierdie is ’n algemene gevoel teenoor MIV/Vigs toetsing binne ’n vrywillige berading en toetsing (VCT) milieu, en word aangehelp deur die vele wanopvattinge en bygelowe rondom MIV/Vigs wat steeds in ’n Suid-Afrikaanse konteks voorkom. Tog is daar ’n alternatiewe, goedgekeurde toets vir MIV/Vigs beskikbaar wat nie ’n bloedmonster vereis nie.

Die gebruik van orale monsters om vir die aanwesigheid van MIV/Vigs te toets, is reeds meer as 10 jaar in gebruik, terwyl die gebruik van *rapid* orale monster toetse in 2004 in Amerika amptelike goedkeuring ontvang het. Hoewel hierdie orale toetse wel in Suid-Afrika gebruik word, is daar geen amptelike beleid of riglyne wat die gebruik, aanwending of verspreiding van hierdie toetse beheer of reguleer nie – met die gevolg dat hierdie toetse as ’n alternatief tot konvensionele MIV toetse grotendeels in die publieke oog onbekend is.

Die hoofdoelwit van hierdie navorsingsprojek is om die openbare beeld en profiel van orale MIV toetsing op ’n positiewe manier uit te bou. Die grondslag hiervoor sal gelê word deur te bewys dat die gebrek aan die behoefte van ’n bloedmonster in orale MIV toetsing ’n positiewe invloed op toetsing vir MIV/Vigs kan hê.

In hierdie navorsingstuk word daar dan verder ’n spesifieke strategie voorgestel om orale MIV toetsing te bevorder, met die doel om meer mense te oortuig om vir MIV te toets. Hierdie strategie word gebaseer op die onderskeidende kenmerk van orale toetse – naamlik die afwesigheid van bloed – en behels die volgende: Bewusmaking van orale MIV toetsing sal geskied deur ’n plakkaatveldtog te loods wat hierdie toetse as ’n meer “gebruikersvriendelike” alternatief tot ’n bloedtoets vir MIV sal bemark. Op grondvlak sal die strategie uitgevoer word deur gebruik te maak van mobiele eenhede wat spesialiseer in orale MIV/Vigs toetsing. Verder sal daar ook sekere riglyne voorgestel word vir die administrasie en gebruik van orale MIV toetse.

1 INTRODUCTION

In December 1994, the US Food and Drug Administration (FDA)¹ in the United States of America (USA) approved the OraSure® oral specimen collection device² as a noninvasive Human Immunodeficiency Virus (HIV) antibody test. At that stage, it was the first and only oral fluid HIV test to receive such endorsement by the FDA.

(FDA (a), 2004 & Sheon, 1996)

On March 26, 2004, the FDA accepted the OraQuick® Rapid HIV-1/2 Test² for oral fluid. Currently, this is the first and only rapid HIV test to be approved in the USA by the FDA for use with oral fluid. The FDA's approval of the rapid test for use on oral fluid was limited to detection of antibodies to HIV-Type 1 (HIV-1).

(Neergard, 2004 & Medical News Today, 2004)

Then, on June 22, 2004, the FDA announced that it had also approved the OraQuick® Rapid HIV-1/2 Test for oral fluid to use in detecting HIV-Type 2 (HIV-2) antibodies in oral samples.

(Neergard, 2004 & Medical News Today, 2004)

Oral fluid tests and the rapid version thereof adds a whole new dimension to the voluntary counselling and testing (VCT) process, as no blood specimen – as opposed to the full blood or finger-prick rapid HIV test – needs to be taken to test for HIV anymore.

The Orasure oral tests are the only FDA approved HIV oral tests in the USA. Although the FDA approved the OraSure® oral specimen collection device in 1994 and the OraQuick®

¹ The FDA is widely accepted as the benchmark for ensuring accurate and science-based information worldwide. The FDA is responsible for protecting the public health in the USA by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, as well as food supply, cosmetics, and products that emit radiation. The FDA has over 9,000 employees, located in 167 American cities. Among its staff, the FDA has chemists, microbiologists, and other scientists, as well as investigators and inspectors who visit 16,000 facilities a year as part of their oversight of the businesses that the FDA regulates.

(FDA (b), 2004)

² These oral fluid HIV tests are manufactured by OraSure Technologies, Inc., Bethlehem, Pennsylvania, USA.

Rapid HIV-1/2 Test for oral fluid in 2004 respectively, oral fluid tests still remain to be used in an official capacity in South Africa (SA) – no policy, guidelines or legislation regarding any aspect of oral fluid HIV testing currently exists in SA.

Because decisions about testing are highly personal and individual, having a choice between conventional testing and rapid testing, would allow people to select the approach that suits them and their current circumstances best and thus would enhance their autonomy.

(Elliot, 2000)

Following from the above, oral fluid HIV testing expands the individual's choice by offering a different kind of option, i.e. between the type of specimen for HIV testing. In doing so, it enhances personal autonomy even further. The individual now has a choice between a blood and a non-blood test to test for HIV.

As there are no prescribed rules or regulations governing the use, application, promotion or distribution of oral tests in SA, this alternative HIV testing method is not well-known among the general South African public. This raises the questions: Do oral fluid HIV tests have any potential to be successfully used in SA? Could it be labeled and marketed as a non-blood alternative test to test for HIV? Could it help to increase voluntary testing for HIV in SA?

It is important to note that it is not the aim of this study to argue that oral fluid testing should replace established blood specimen HIV tests like the full-blood Elisa test. These tests must always be used for confirmatory purposes.

The issue at hand is that the possible impact of oral fluid HIV tests still has to be fully realized in a South African scenario. This research paper will focus specifically on the OraQuick® Rapid HIV-1/2 Test when trying to ascertain whether oral fluid HIV testing can play a significant and constructive role in the HIV testing set-up in SA.

2 RESEARCH OBJECTIVES

The objectives of this research paper will be to:

- ✘ determine if certain qualities of oral fluid HIV testing can be utilized to help increase the acceptance of testing for HIV in the public eye and convince more people to test.
- ✘ establish whether the public opinion in SA among respondents who have been exposed to the OraQuick® Rapid HIV-1/2 Test for oral fluid are in favour of oral tests being administered by trained lay counsellors.
- ✘ ultimately lay the foundation for the wider use of oral fluid tests in an official and structured capacity in SA (this paper will focus on the OraQuick® Rapid HIV-1/2 Test for oral fluid).

3 ORAL FLUID HIV TESTS: A BRIEF GUIDE

A THE ORASURE® ORAL SPECIMEN COLLECTION DEVICE

As mentioned, the OraSure® oral specimen collection device was approved as a FDA noninvasive HIV antibody test in 1994. This test extracts antibodies from the blood vessels in the mucous membranes of the mouth and IS NOT a saliva test.

Like a blood test, OraSure® HIV-1 looks for antibodies to HIV, not the virus itself. OraSure® HIV-1 does not use saliva, but rather absorbs antibodies directly from the blood vessels in the mucous membranes. The mucous membranes have a much higher amount of antibodies than does saliva.

OraSure® HIV-1 uses a specially treated cotton fiber pad attached to a nylon stick which is placed between the lower cheek and gum and left for 2-5 minutes. The OraSure® HIV-1 collection pad draws IgG antibodies out of the tissues of the cheek and gum. This sample, called oral mucosal transudate (OMT), contains far fewer contaminants than typically found in saliva. If present, antibodies to the HIV-1 virus will be collected in this sample.

The pad is then placed in the OraSure® HIV-1 transport vial. This vial contains preservative which will keep the sample stable for up to 21 days at 2° C to 30° C. The sample is then sent

off to a qualified OraSure® HIV-1 testing laboratory for analysis using the Orasure® HIV-1 testing algorithm.

Testing of OraSure® HIV-1 oral fluid specimens is restricted to testing with the Oral Fluid Vironostika HIV-1 Microelisa System manufactured by Organon Teknika Corporation and the OraSure® HIV-1 Western Blot Kit (link to Western Blot).

(Orasure, 2004)

In the USA, the administration of this device is restricted to medical personnel who have been trained in the use of this device (Q. Pham,³ personal communication, 28 October 2004).

B THE ORAQUICK® RAPID HIV-1/2 TEST FOR ORAL FLUID

As discussed earlier, OraSure Technologies, Inc. announced that its OraQuick® Rapid HIV-1/2 Antibody Test for oral fluid had received approval from the FDA for use in detecting antibodies to both HIV-1 (March 2004) and HIV-2 (June 2004) in oral fluid.

Also in June 2004, OraSure announced that the OraQuick® Rapid HIV-1/2 Test for oral fluid had received a CLIA (Clinical Laboratory Improvements Amendments of 1988) waiver, which will allow the test to be used by more than 180,000 sites in the USA, including more health care settings, such as doctors' offices, outreach clinics, community-based organizations and some mobile labs that can offer testing in high-risk areas.

Originally, the use of the OraQuick® Rapid HIV-1/2 Test to detect antibodies to HIV in oral fluid had been limited to certified laboratories (high and moderate complexity laboratories under CLIA). However, as a result of the waiver from the requirements of CLIA, all clinical laboratories certified through CLIA (high, moderate, and waived) can now use this test.

Because the OraQuick® Rapid HIV-1/2 Test is simple and accurate, the FDA approved it as a waived test. Waived tests are determined to be easy to use and have little risk of an incorrect result. In the USA, non-clinical testing sites that plan to provide the OraQuick test

³ Quoc Pham is the regional director for OraSure Technologies, Inc. for Africa and Asia.

must either apply for their own CLIA Certificate of Waiver or establish an agreement to work under the CLIA Certificate of an existing laboratory. Any agency that has a CLIA Certificate of Waiver and is performing the OraQuick® Rapid HIV-1/2 Test, is considered a clinical laboratory.

Orasure unveiled the OraQuick® Rapid HIV-1/2 Antibody Test for oral fluid under a new name, the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test, on October 21, 2004 at the United States Conference on Acquired Immunodeficiency Syndrome or AIDS, held at the Philadelphia Marriott Hotel in Philadelphia, Pennsylvania.

Like the OraSure® HIV-1 Oral Specimen Collection Device, this test extracts antibodies from the blood vessels in the mucous membranes in the mouth and IS NOT a saliva test. Although the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test has received a CLIA waiver, it is restricted for use in the USA by trained medical persons (Q. Pham, personal communication, 28 October 2004).

To perform the test, the person being tested for HIV gently swabs completely around the outer gums, both upper and lower, one time around. The tester then takes the device and inserts it into a vial containing a developer solution. In as little as 20 minutes, the test device will indicate if HIV antibodies are present in the solution by displaying two reddish-purple lines in a small window in the device.

(Orasure, 2004 & Centers for Disease Control and Prevention or CDC (a), 2004)

C ORAL FLUID TESTING: A SOUTH AFRICAN PERSPECTIVE

The Human Tissue Act, Act 65 of 1983, only allows health workers to administer HIV tests that require a blood sample (Medical Research Council or MRC, 2001). This means that only certified phlebotomists are allowed to conduct blood rapid and full blood tests.

General discussions of certain HIV tests are featured in, for example, the *Presidential AIDS Advisory Report* (Department of Health (a), 2001); and papers like *HIV/AIDS Policy Guideline: Rapid HIV Testing* (Department of Health (b), 2000). In no official documents,

however, is mention made of oral fluid HIV testing or tests and no laws exist regarding the administration of oral fluid tests in SA. But this does not mean that oral fluid tests are not being used in SA.

The OraSure® oral specimen collection device was used in the first *Nelson Mandela/HSRC Study of AIDS* (Human Sciences Research Council or HSRC, 2002).

OraSure has successfully completed its clinical trial for the OraQuick® Rapid HIV-1/2 Test with the National Institute for Virology (NIV) in SA. The NIV functions as the national resource centre for viral diseases in SA, and is a public health institute within the Department of Health providing comprehensive medical virological diagnostic services. This clinical trial is a requirement for companies to participate in the public tender business in SA.

(Business Wire, 2001)

The OraQuick® Rapid HIV-1/2 Test for oral fluid is currently being used in governmental VCT sites in Kwazulu-Natal (KZN). As a result of oral fluid rapid testing resources at these sites being fully stretched, medically trained personnel (for example nurses) have had to turn to lay counsellors to help conduct oral fluid rapid HIV testing in order to meet the demand (J. Hills,⁴ personal communication, 31 August 2004).

⁴ Jackie Hills is associated with UCB Pharma – the company which is the sole distributor of the OraQuick® Rapid HIV-1/2 Test for oral fluid in SA.

4 RESEARCH PROBLEM

The aim of this research paper is to determine if individuals can be motivated to test for HIV by using the oral fluid test's distinct quality - of having no *blood barrier* to overcome - as the point of departure and consequently the selling point.

In essence, the **research problem** to be discussed and analyzed is:

Can the lack of the need for a blood specimen in oral fluid HIV testing positively influence testing for HIV?

5 WHY USE THE *BLOOD BARRIER* TO INCREASE TESTING?

- ✂ The lack of the need for a blood specimen is the major contributing factor to the noninvasive nature of the oral testing. This characteristic of oral testing can facilitate in changing the view that people might have of HIV testing as being uncomfortable as a result of having to give a blood sample, thereby positively influencing testing for HIV:**

The New York State Department of Health (NYSDOH) AIDS Institute's Anonymous HIV Counselling and Testing Program (ACT) in the USA conducted an 11-week oral fluid testing implementation and preference pilot study in June of 1997. The ACT programme provided services in both the community and state correctional services.

During the study period, all clients at these sites were offered a choice of venipuncture or oral fluid testing. At the conclusion of the pre-test session, clients participating were asked to complete a survey. This survey collected information as to the reasons clients chose a particular testing method.

Thirty-seven percent (37%) of programme clients tested in the community and who selected oral fluid testing, indicated that the most important reason for their selection was that “this method seemed easier than blood testing”, while 53% of inmates who selected oral fluid testing also cited this reason.

(Berberian *et al*, 1998)

Since 1987, HIV testing and counselling has been a cornerstone of HIV prevention efforts in the state of Michigan, USA. Testing and counselling are provided in each of the state’s local public health agencies as well as through 51 community-based and non-governmental agencies in the country.

Ongoing quality assurance and evaluation activities conducted by the Michigan Department of Community Health (MDCH) included assessment of barriers to access and appropriate use of prevention strategies. One of the barriers to the use of counselling and testing services that was identified was related to the method of specimen collection, i.e. the taking of a blood specimen. This included client difficulty with blood-draw and in instances where client venous was compromised it proved inappropriate.

The strategy used to address this barrier, was the use of oral fluid for HIV testing. Beginning in March 1997, the MDCH made oral fluid collection devices available to all community-based organizations. Oral fluid based testing had been integrated with ongoing out reach and health education activities. The goal in mind: To overcome the barrier to the method of specimen collection and increase access to and appropriate utilization of counselling and testing services in at-risk populations.

A year after statewide implementation of oral fluid testing, it was concluded that the MDCH had been largely successful in achieving the abovementioned goal.

(Randall, 1998)

According to Vargo (2004), the OraSure® oral specimen collection device along with social network recruitment, were used to help increase testing for HIV in a minority community in Springfield, Massachusetts, USA.

Over an 11-month period, the number of test takers at the intervention site increased by 71.7%. At a comparison site, testing remained stable. The use of a social network recruitment strategy in combination with the noninvasive OraSure® oral specimen collection device showed promise in increasing testing and in targeting populations.

ⓧ People not testing for HIV are scared of the needles involved. The absence of the “fear factor” of blood and needles in oral testing can be used to persuade those who are scared of blood and needles to test for HIV:

The American state of Maryland sought to increase access and utilization of HIV testing and counseling services (CTS) with an oral fluid test demonstration project in 1997-98. A number of clients who agreed to oral testing indicated that they would not have been tested if the oral option was unavailable.

Participants in the oral fluid testing demonstration project completed a client survey assessing responses to the test (n = 1432). Of these clients, 21.1% agreed or strongly agreed that they would not have been tested if the oral option had not been available (i.e. blood-test avoiders).

(Bauserman *et al*, 1999)

Also in the state of Maryland, the OraSure® Demonstration Project introduced oral HIV testing for incarcerated persons at 32 counselling and testing sites between September 1997 and April 1998. Persons in the local detention and juvenile justice facilities chose oral and blood testing and reported reactions to the oral test.

Reactions to the oral testing were most favourable. Importantly, 18% of men and 16% of women indicated that they had put off or refused testing in the past owing to

the fear of needles, and 22% of men and 15% of women said that they would not have been tested without the oral option.

(Bauserman *et al*, 2001)

Research was launched to provide an overview of the use of Orasure® testing devices for HIV testing via a mobile unit as an innovative strategy for delivery to expand treatment in a resource limited community in Miami, Florida, USA.

From the time period of May 2001 to May 2002, 1,198 individuals were tested. It was found that Orasure® testing devices, due to the lack of use of blood in the testing environment of the mobile unit, is a viable approach and an innovative mechanism for HIV testing. The mobile unit, combined with the testing approach, eliminated the need to draw blood and reduced the fear level of patients.

(Rose *et al*, 2003)

Burger (2003) reported that an international oil company in SA decided to offer employees in the company the opportunity to get to know their own HIV status through a *Know Your Status* campaign launched in the beginning of 2003. A total of 776 people came forward for testing – 47% of the total number of permanent staff members and contractors. Because of the low testing percentage, an audit was done to determine the reasons for the low testing uptake.

From the audit, it was determined that one of the issues that prevented some people from testing, was the exclusive full-blood test using needles. Forty percent (40%) of respondents who did not test, indicated that the use of needles made them decide not to test. Some respondents who did test, indicated a preference for an alternative HIV test to a full-blood test using needles, for example a rapid or an oral HIV test (17%).

✘ Oral fluid HIV tests are safe to use and administer. Oral fluid testing removes possible safety concerns of HIV tests involving a blood specimen that could put off some individuals from testing or result in needle stick injuries:

Health care workers (HCWs) face a much lower risk of exposure to infectious diseases from oral fluid than from blood. Specimens can be readily collected from any individual, without risk of transmission.

(CDC (a), 2004)

Following from the discussion of Randall (1998) earlier in this paper, the MDCH assessed that one of the barriers to the use of counselling and testing services that was identified was related to the method of specimen collection, i.e. the taking of a blood specimen. Another dimension of the blood taking procedure that caused complications was the safety of the provider that was often jeopardized by following this procedure, i.e. through needle stick injuries. As mentioned, the MDCH had been mainly successful in eradicating this problem by implementing the use of oral fluid testing.

According to Rele *et al* (2002), HCWs are at a risk of occupational acquisition of HIV infection, primarily due to accidental exposure to infected blood and body fluids. At the public hospital in question, over a period of one year (June 2000 - 2001) a total number of 38 self reported incidences of needle stick injuries and other exposures to patient's blood and body fluids were reported by HCWs.

A greater incidence of occupational exposure was seen in surgery residents as compared to medicine residents. It was concluded that needle stick injuries present the single greatest risk to medical personnel and the importance of increased awareness and training in universal safety precautions, for prevention of nosocomial infection.

✘ Oral fluid HIV tests are accurate and reliable. The fact that this test is precise and dependable without having to give a blood sample can be influential in convincing individuals to test for HIV:

Tests conducted using the OraSure® HIV-1 Oral Specimen Collection Device, indicated that HIV-1 antibody testing of oral fluid is highly accurate. In the entire study population of 3570 subjects, the result obtained was incorrect for only one individual. In 3569 (>99.9%) of 3570 subjects, either the correct result was obtained with the initial oral fluid sample or appropriate follow-up testing would be triggered.

By following the Orasure® HIV-1 testing algorithm, 3558 of 3570 subjects received the correct HIV-1 antibody result from a single oral fluid sample. In 11 of the 12 remaining subjects, the Western blot was indeterminate; for these 11, the algorithm would lead to appropriate follow-up testing.

(Gallo *et al*, 1997)

Data from clinical trials submitted by OraSure Technologies, Inc. and reviewed by the FDA, showed that in limited clinical studies the OraQuick® Rapid HIV-1/2 Antibody Test provided a highly accurate HIV test result, correctly identifying at least 99.3% of specimens from HIV-infected persons and at least 99.8% of specimens from uninfected persons.

(CDC (a), 2004)

The launch of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test followed the successful completion of a previously announced assessment conducted by OraSure Technologies, Inc. regarding a subset of data from an isolated clinical trial of the new oral fluid test. As part of the assessment, OraSure Technologies, Inc. executed a study that reflected the use of the test in the field, in which over 12,000 test readings were reviewed.

The results from that study, in addition to data analyzed from several independent studies involving over 7,000 oral fluid samples, clearly indicate that the test is operating within its specifications.

(Orasure, 2004)

In KZN, SA, there is a large rural and urban population that constantly requires access to various formats of HIV testing. York *et al* (2002) reports that an investigation was launched in 2002 using four commercial assays, either oral, urine, whole blood or serum as diagnostic sample for the diagnosis of HIV.

One of the objectives was to assess the performance of the OraQuick® Rapid HIV-1/2 Test for oral fluid. An oral sample was collected from each of 500 pre-counselled consenting antenatal attendees at King Edward the VIIIth hospital. The oral test was performed at the clinic. The results were as follows:

- Sensitivity⁵: 98.6%
- Specificity⁶: 98.6%

The rapid results compared favourably with the more costly and technologically demanding full blood tests. Oral fluid was also comparably sensitive and specific as diagnostic sample. The oral assay formats performed well on the local population strain which is essentially infected with HIV clade C.

⁵ The ability of the oral fluid test to detect HIV positive results.

⁶ The ability of the oral fluid test to detect HIV negative results.

ⓧ If non-medically trained individuals are allowed to administer the oral testing process in an officially sanctioned capacity - based on the premise that no specialist blood taking procedure is involved in this relatively easy process - the number of administrators conducting testing will increase. This could positively influence the testing infrastructure for HIV (especially in remote, resource limited areas):

In research conducted using the OraSure® HIV-1 Oral Specimen Collection Device, undertaken through community-based AIDS outreach programmes in certain American states, both medical and nonmedical personnel were trained in the use of the oral specimen collection device and in HIV education, prevention, and partner notification.

Locations for the collection of specimens included such diverse settings as street corners, halfway houses, correctional facilities, gay bathhouses, shopping malls, supermarkets, and schools and universities. Collection was performed both individually and in groups.

Over a period of three months, 2934 specimens were collected from economically and ethnically diverse study populations. It was found that oral HIV testing may be performed in any setting by minimally trained medical and non medical personnel. The potential to administer it in any setting appears to overcome certain logistical barriers to HIV testing, greatly expanding the reach of traditional counselling and testing programmes.

(Judson *et al*, 1996)

In a study on how to address the logistical complexity for HIV surveillance in difficult-to-access areas, Respass *et al* (2001) concluded that oral fluids could be collected in a variety of field settings, including non-clinical settings. It was also found that oral fluid collection may be more acceptable to hard-to-reach populations than specimen collection requiring venipuncture or finger stick.

In research done in Minneapolis, Minnesota, USA, HIV prevention counsellors received additional training to do OraQuick® Rapid HIV-1/2 Test for oral fluid testing using oral fluid. They went to community-based organizations such as chemical dependency programmes, homeless shelters, etc. The team did onsite pre-test counselling, testing, and post-test counselling (including clients with reactive tests).

The study showed that rapid HIV testing enabled a high percentage of clients to learn test results. HIV prevention counsellors from non-medical backgrounds were able to achieve proficiency in OraQuick® testing.

(Keenan *et al*, 2004)

6 RESEARCH METHODOLOGY

A RESEARCH DESIGN

An attitude survey⁷ was done among the 350 employees at the Santam Head Office in Bellville, South Africa, during October/November 2004 to determine if the lack of the need for a blood specimen in oral fluid HIV testing could play a role in promoting voluntary HIV testing.

Employees from Santam were chosen as population for this survey because they had been exposed to the workings of the OraQuick® Rapid HIV-1/2 Test for oral fluid during a HIV/AIDS intervention launched in September 2004. Here they gained first hand knowledge of this oral fluid test - by learning about it during compulsory HIV/AIDS awareness training and pre-test counselling sessions. They also had the opportunity to voluntarily test for HIV by using the OraQuick® Rapid HIV-1/2 Test for oral fluid. Administration of the tests was conducted by lay counsellors.

The survey method is a widely used descriptive research technique. According to Christensen (2001), a survey can be defined as a field study in which an interview technique

⁷ See *Addendum A* for the survey questions. The results and discussion of the survey follow later in this paper.

is used to gather data on a given state of affairs in a representative sample of the population. Kerlinger (1992) states that surveys are appropriate for gathering data regarding opinions and attitudes on the one hand, and behaviour on the other. According to Shiffman and Kanuk (1994) the survey is an accepted method of measuring both attitudes and behaviours.

The descriptive research technique provides a description or a picture of a particular situation, and tries to describe the relationship that exists between variables. In this case scenario, neither random assignment nor experimental manipulation of the variables are possible, therefore an descriptive research approach, and more specifically an ex post facto research design, will be used in this study. This is because the variables are not under the experimenter's control and are not subject to direct manipulation but must be chosen after the fact.

(Christensen, 2001)

The weaknesses and limitations of the particular design were taken into consideration during the interpretation of the results. These include low response frequency and incomplete response information (Kerlinger, 1992). Other possible disadvantages of a survey include sampling error, time required, and constraints in the length of the survey.

(Christensen, 2001 & Theron, 2001)

B SAMPLING

Because the survey is optional to complete, each employee in the sample of size $n= 350$ had the same probability of being part of the survey. All responses were gathered over a two week period.

C DATA COLLECTION

Respondents were notified via the Santam intranet of the survey. The survey questionnaire was distributed by the secretaries of Santam's various departments. Employees of the various departments were randomly asked to complete it.

At the beginning of the survey, respondents were assured that the survey was voluntary, anonymous and confidential. If they chose to proceed, they were asked to indicate their gender and specific age group.

The first survey question tried to ascertain how respondents perceived the use of the OraQuick® Rapid HIV-1/2 Test during the recent intervention.⁸ In doing this, they were assigned to one of three groups:

- ✘ Those who perceived the use of the OraQuick® Rapid HIV-1/2 Test to have been a success
- ✘ Those who perceived the use of the OraQuick® Rapid HIV-1/2 Test as being unsuccessful
- ✘ Those who were undecided about the issue

For Question 2, the following issue was under discussion: If you had to make a choice, would you prefer to test for HIV by giving a blood specimen, an oral specimen or doesn't it matter which specimen you have to give?⁹

In doing so, respondents were assigned to one of three groups:

- ✘ Those who prefer to test for HIV by giving a blood specimen
- ✘ Those who prefer to test for HIV by giving an oral specimen
- ✘ Those who feel indifferent toward the issue

Christensen (2001) defines open-ended questions as questions that enable respondents to answer in any way they please; and closed-ended questions as questions that require respondents to choose from a limited number of predetermined responses. These type of questions were not applicable for and could not be used to test attitudes regarding the stated

⁸ Refer to Question 1 in the survey.

⁹ Refer to Question 2 in the survey.

research problem. Therefore, the rest of the survey was made up of questions¹⁰ in the form of attitude statements and completed via the survey by using a Likert scale format.

The reasons for this were that the survey could only be done after the whole testing intervention at Santam was completed, as well as the fact that Santam employees tested for HIV using a barcode system as identification, which guaranteed anonymity and confidentiality. If the survey questions were asked using open-ended or closed-ended questions, it would have meant that employees who tested had to first be identified in order to complete the questionnaire. This was impossible to do, as testing was done anonymously and such actions would have jeopardized confidentiality in any case.

As a result, not all employees that completed the survey, tested. In the chosen population however, there was a 95% testing take-up. Taking into account the high testing take-up, as well as the fact that all Santam employees learned about oral tests during compulsory HIV/AIDS awareness training and pre-test counselling sessions before the testing intervention, the following deductions are made:

- ✘ the majority of respondents who completed the survey did test, and
- ✘ the small percentage who did not test but completed the survey, were taught about the workings of the oral test during training sessions.

Therefore, the assumption is made that all respondents were able to form a learned opinion of these tests, irrespective of whether they tested or not. Santam employee' response and opinion were thus considered as pivotal to providing an answer to the stated research problem.

For Questions 3 – 8, a Likert scale was used. This scale measures the extent to which a person agrees or disagrees with a question (Kirakowski, 2004). The Likert technique presents a set of attitude statements. Subjects were asked to express agreement or disagreement on a five-point scale.

¹⁰ Refer to Questions 3 - 8 in the survey.

Each degree of agreement is given a numerical value from one to five. Consequently, a total numerical value can be calculated from all the responses. Each respondent was asked to rate each question in the survey (i.e. item on the Likert scale). These items were rated on a 1-to-5 Agree - Disagree response scale where:

- ✂ 1 = strongly agree
- ✂ 2 = agree
- ✂ 3 = neither agree nor disagree
- ✂ 4 = disagree
- ✂ 5 = strongly disagree

For the questions under discussion, respondents were asked to indicate the extent of their agreement or disagreement with a particular statement:

- ✂ Questions 3 – 5 dealt with psychological barriers to HIV testing.
- ✂ Questions 6 – 7 dealt with the scientific relevance of HIV testing.
- ✂ Question 8 dealt with logistical aspects of HIV testing.

For the interpretation of the Likert scale results for Questions 3 - 8, the answers of the three groups mentioned in Question 2 of the survey will be used, i.e.

- ✂ those who prefer to test for HIV by giving a blood specimen (Group 1);
- ✂ those who prefer to test for HIV by giving an oral specimen (Group 2); and
- ✂ those who feel indifferent towards the issue (Group 3).

The answers for Questions 3 – 8 in the survey will be examined and analyzed by:

- ✂ comparing the mean responses of the three groups for each of the questions respectively;
- ✂ using analysis of variance (ANOVA) to determine significant differences in the mean responses of the three groups at a 5% significance level ($p < 0.05$); and
- ✂ discussing the relevance of these differences/lack of these differences.

7 RESULTS

A total of 145 responses were gathered during the two week period. Of these, 142 were fully completed. The discussion of the demographics and results of the survey questions¹¹ are summarized as follows:

7.1 SURVEY DEMOGRAPHIC BACKGROUND

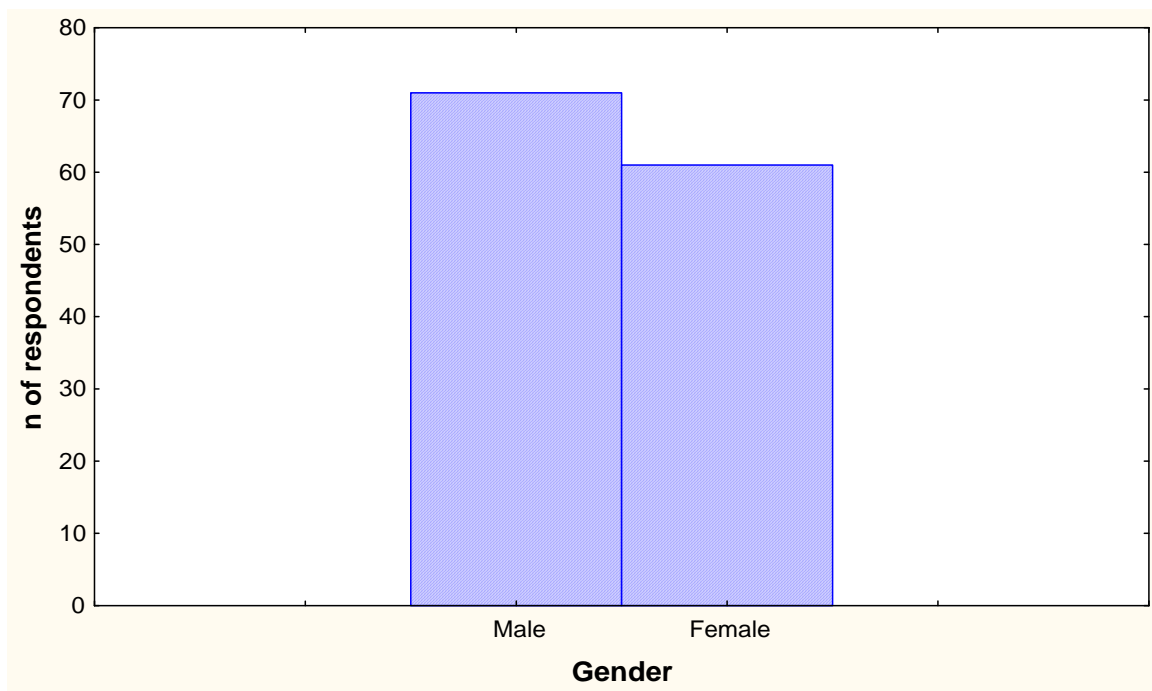


FIGURE 7.1

Figure describing the gender distribution of the employees who completed the attitude survey.

- ✘ In the survey, 50% of respondents were male and 43% were female. Seven percent (7%) of the respondents did not indicate their gender.

¹¹ See *Addendum A* for the survey questions.

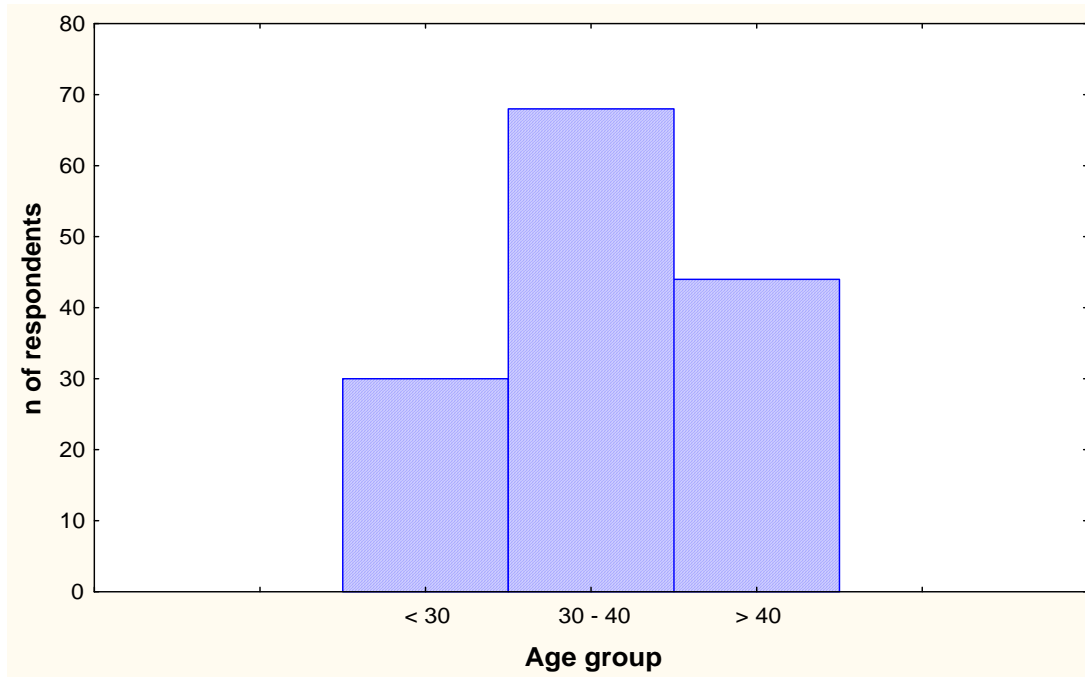


FIGURE 7.2

Figure describing the age group distribution of the employees who completed the attitude survey.

- ✂ In terms of age groups, 21.13% of employees were younger than 30 years; 47.89% were between 30 and 40 years and 30.99% were older than 40 years.

7.2 DISCUSSION OF SURVEY QUESTIONS 1 & 2

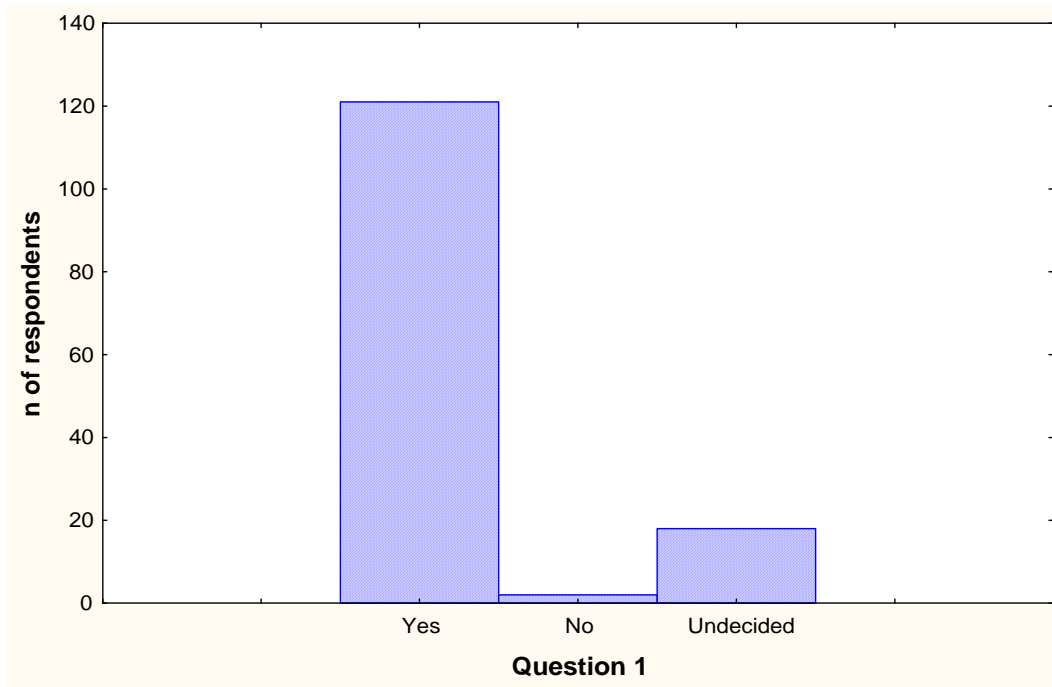


FIGURE 7.3

Figure describing the perceived success rate of the use of the OraQuick® Rapid HIV-1/2 Test in the VCT process.

- ✂ From Figure 7.3 it can be seen that the use of the OraQuick® Rapid HIV-1/2 Test was perceived as a big success. More than 85% of respondents thought that the use of oral tests in the VCT process was a successful venture.

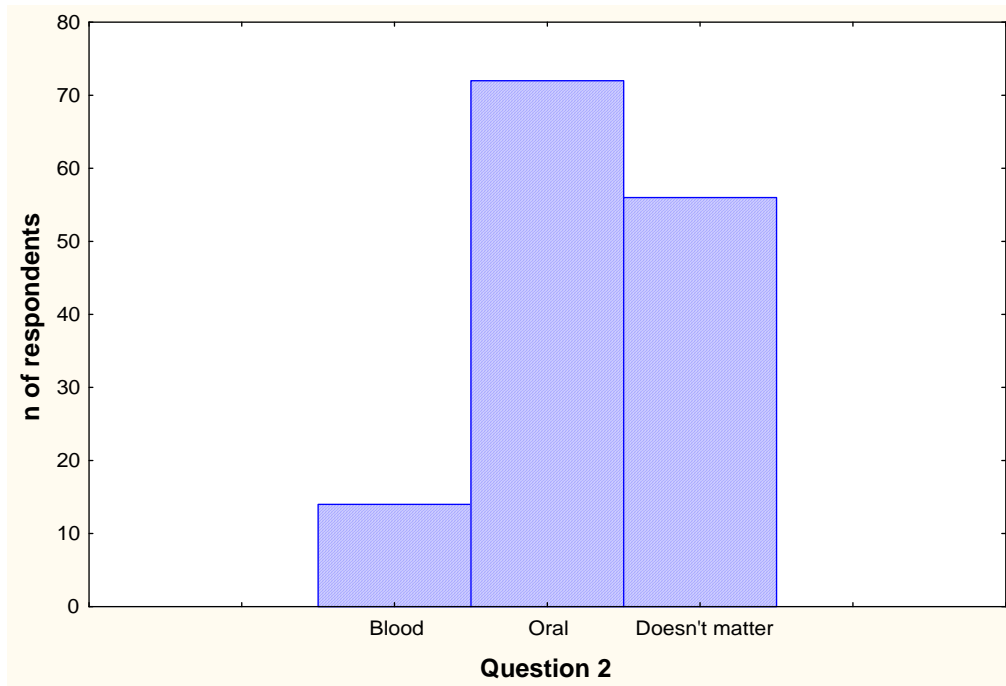


FIGURE 7.4

Figure describing employee preference for a specific HIV test.

- ✘ More than 50% of respondents indicated that they would prefer oral fluid tests when testing for HIV. Less than 10% of employees preferred a blood test to test for HIV. Almost 40% of respondents indicated that they felt indifferent towards the issue.

7.3 DISCUSSION OF THE LIKERT SCALE SURVEY QUESTIONS 3 - 8

As discussed earlier, the answers of the three groups mentioned in Question 2 of the survey (Figure 7.4 above), i.e. respondents who

- ✘ prefer to test for HIV by giving a blood specimen (Group 1);
- ✘ prefer to test for HIV by giving an oral specimen (Group 2); and
- ✘ feel indifferent towards the issue (Group 3)

were compared with results of Questions 3 – 8 in the survey.

7.3.1 DISCUSSION OF THE LIKERT SCALE SURVEY - QUESTION 3

TABLE 7.1

Table giving an overview of the descriptive statistics for the three groups with respect to survey Question 3.

Cell No.	Question 2	Question 3 Mean	Question 3 Std.Err.	N
1	Group 1	2.21	0.15	14
2	Group 2	1.46	0.07	72
3	Group 3	1.75	0.08	56

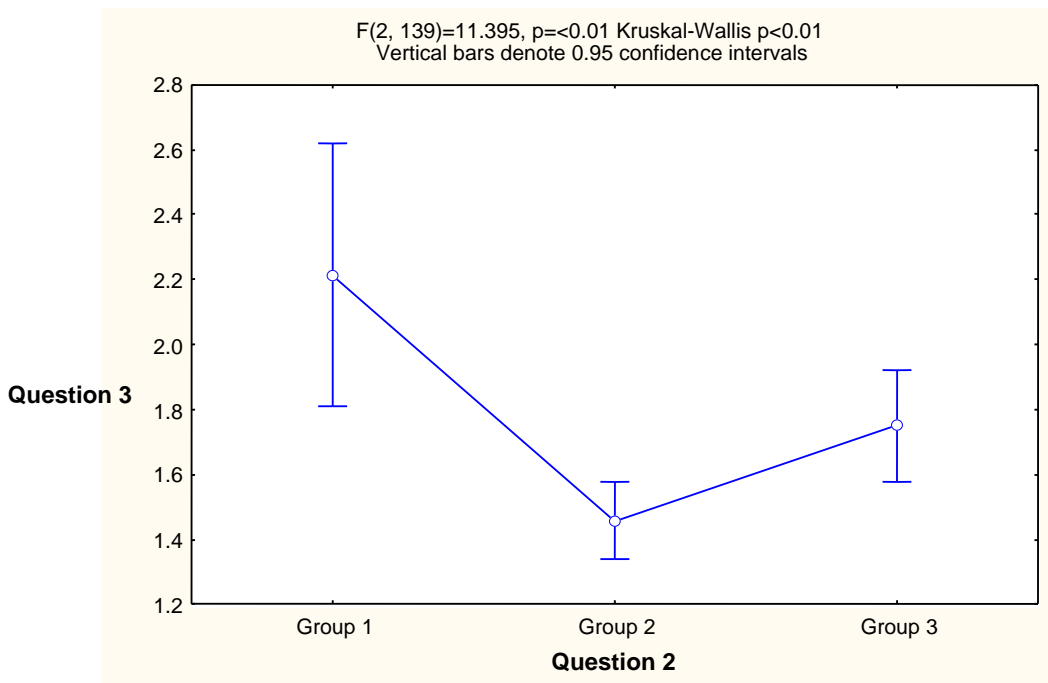


FIGURE 7.5

Graph showing the average response for Question 3 per group.

- ✘ Ascertaining from Table 7.1 and Figure 7.5, all the groups either agreed or strongly agreed that the noninvasive nature of oral fluid testing could serve as motivation for more individuals to test for HIV. Group 1 had the highest average, with Group 2 the lowest (i.e. agreeing most strongly).

TABLE 7.2

Table showing the post hoc comparisons for the three groups with respect to survey Question 3.

Bonferroni test; variable Question 3				
Cell No.	Question 2	{1}	{2}	{3}
		2.2143	1.4583	1.7500
1	Group 1		$p < 0.01$	0.02
2	Group 2	$p < 0.01$		0.02
3	Group 3	0.02	0.02	

✂ From Table 7.2 it can be seen that there was a statistically significant difference ($p < 0.05$) between the averages of all three groups regarding Question 3. It is important to note that all three groups, to some extent, agreed on the issue in question.

7.3.2 DISCUSSION OF THE LIKERT SCALE SURVEY - QUESTION 4

TABLE 7.3

Table giving an overview of the descriptive statistics for the three groups with respect to survey Question 4.

Cell No.	Question 2	Question 4 Mean	Question 4 Std.Err.	N
1	Group 1	2.29	0.17	14
2	Group 2	1.43	0.08	72
3	Group 3	1.66	0.09	56

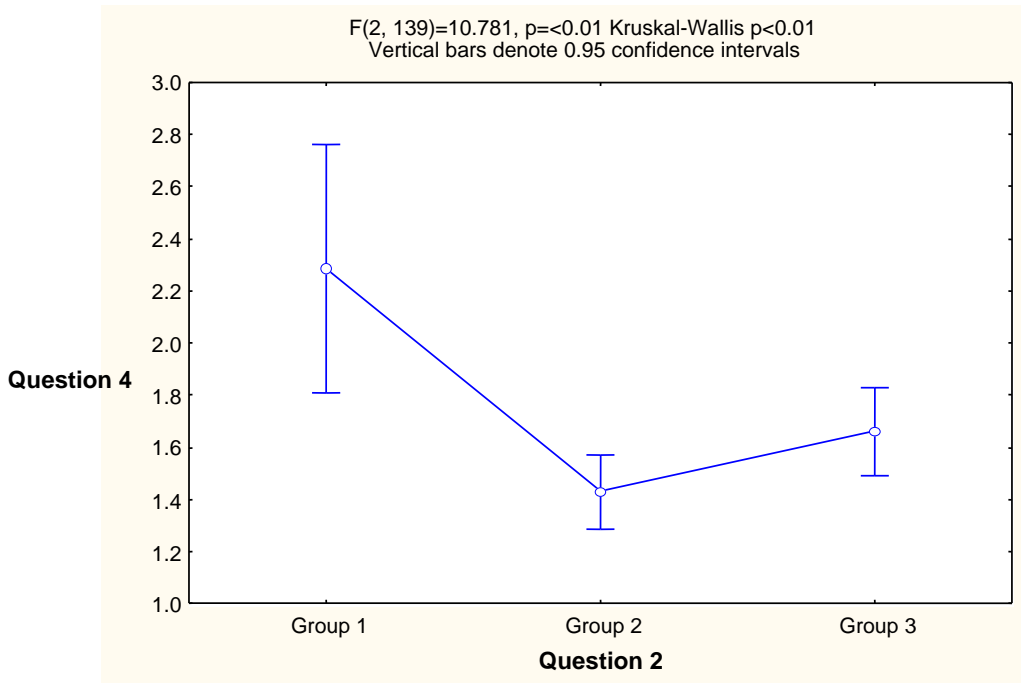


FIGURE 7.6

Graph showing the average response for Question 4 per group.

✂ From Table 7.3 and Figure 7.6, on average, all the groups either agreed or strongly agreed that the lack of fear of needles and blood in oral fluid HIV testing could be instrumental in motivating more individuals to take the test. Group 1 again had the highest average with Group 2 the lowest.

TABLE 7.4

Table showing the post hoc comparisons for the three groups with respect to survey Question 4.

		Bonferroni test; variable Question 4		
Cell No.	Question 2	{1}	{2}	{3}
1	Group 1	2.2857	1.4306	1.6607
2	Group 2	$p < 0.01$		0.14
3	Group 3	$p < 0.01$	0.14	

✂ From Table 7.4 it is observed that there was no statistically significant difference ($p=0.14$) between the averages of Group 2 and Group 3. There was a highly significant statistical difference between Group 1 on the one hand and Group 2 and Group 3 respectively on the other hand ($p<0.01$). What is relevant, is that all three groups agreed on the issue under discussion.

7.3.3 DISCUSSION OF THE LIKERT SCALE SURVEY - QUESTION 5

TABLE 7.5

Table giving an overview of the descriptive statistics for the three groups with respect to survey Question 5.

Cell No.	Question 2	Question 5 Mean	Question 5 Std.Err.	N
1	Group 1	2.50	0.18	14
2	Group 2	1.53	0.08	72
3	Group 3	1.84	0.09	56

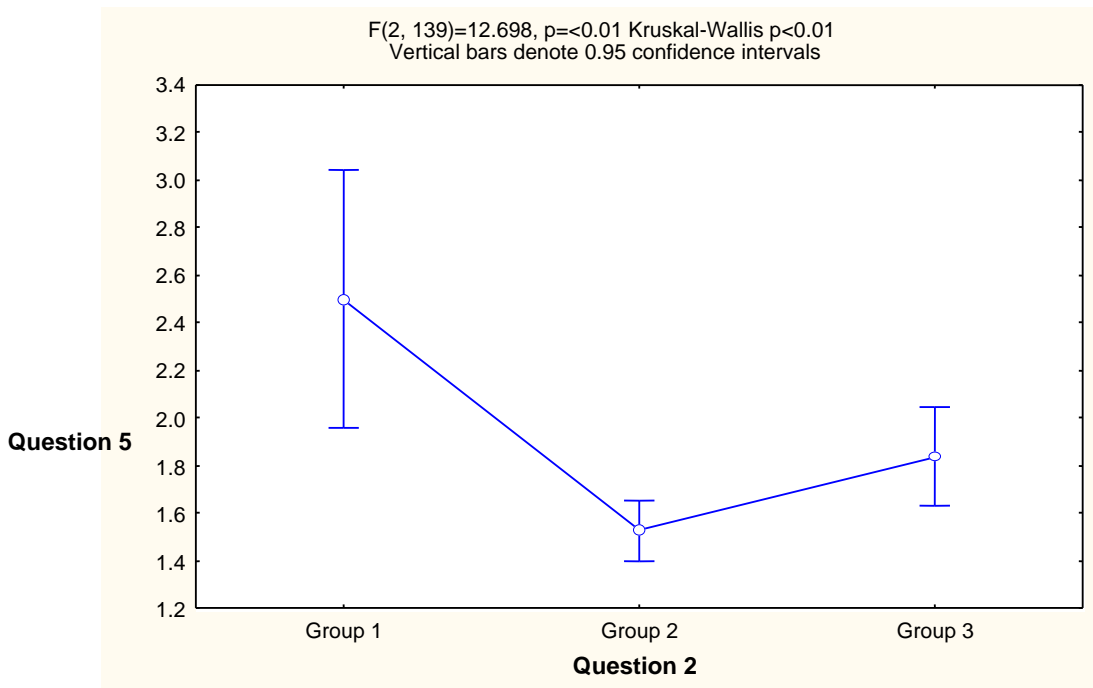


FIGURE 7.7

Graph showing the average response for Question 5 per group.

- ⚡ Deducing from the mean answers to Question 5, the three groups agreed or strongly agreed that the absence of a transmission risk through oral testing could be a motivating factor to test for HIV. Again, the trend of Group 2 having the highest average and Group 1 the lowest is noted.

TABLE 7.6

Table showing the post hoc comparisons for the three groups with respect to survey Question 5.

Cell No.	Bonferroni test; variable Question 5			
	Question 2	{1}	{2}	{3}
		2.5000	1.5278	1.8393
1	Group 1		$p < 0.01$	$p < 0.01$
2	Group 2	$p < 0.01$		0.03
3	Group 3	$p < 0.01$	0.03	

✂ There was a statistically significant difference ($p < 0.05$) between the average answers of all the groups regarding Question 5. It is imperative to bear in mind that all three groups displaying a statistically significant difference in terms of answering this question still agreed – but to different degrees - that safety issues could play a part in motivation for HIV testing.

7.3.4 DISCUSSION OF THE LIKERT SCALE SURVEY - QUESTION 6

TABLE 7.7

Table giving an overview of the descriptive statistics for the three groups with respect to survey Question 6.

Cell No.	Question 2	Question 6 Mean	Question 6 Std.Err.	N
1	Group 1	3.07	0.21	14
2	Group 2	1.79	0.09	72
3	Group 3	2.13	0.11	56

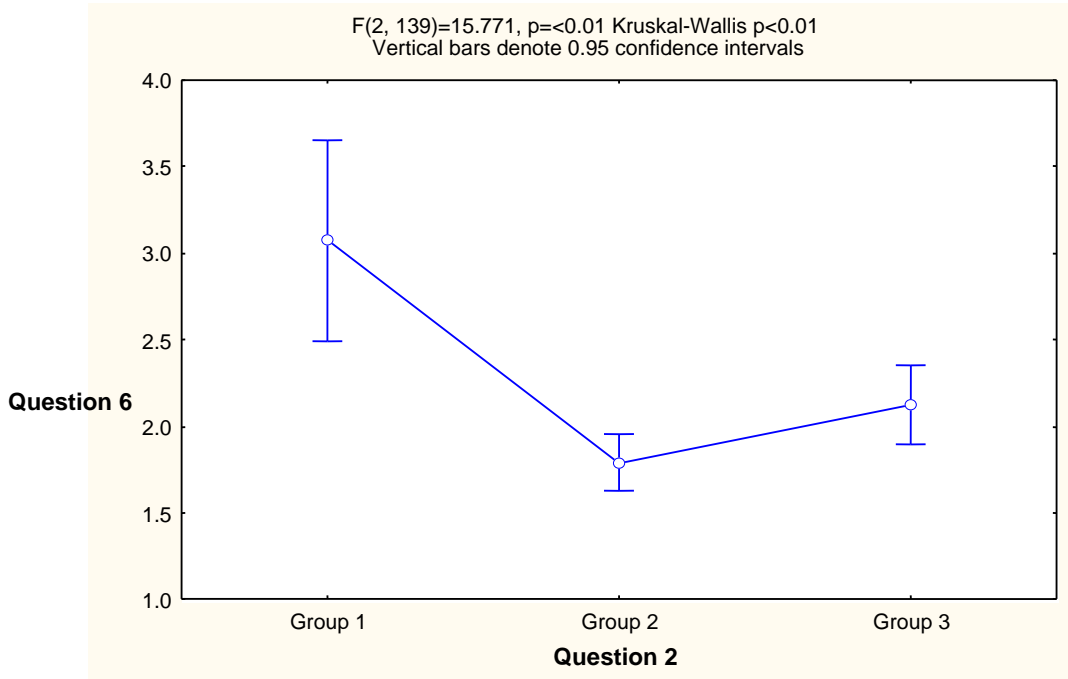


FIGURE 7.8

Graph showing the average response for Question 6 per group.

⚠ Table 7.7 and Figure 7.8 suggest that all three groups had a different viewpoint pertaining to whether the proven accuracy levels of oral tests to test for HIV without the need for a blood sample could play a part in motivation to test for HIV. On average, respondents in Group 1 felt indifferent towards the issue; Group 2 respondents tended to strongly agree that the proven accuracy levels of oral tests to test for HIV without the need for a blood sample could influence motivation to test; while Group 3 respondents generally agreed it could play a part.

As observed with previous questions, the trend of Group 1 having the highest average and Group 2 the lowest (i.e. agreeing most strongly) is again prominent.

TABLE 7.8

Table showing the post hoc comparisons for the three groups with respect to survey Question 6.

Bonferroni test; variable Question 6				
Cell No.	Question 2	{1}	{2}	{3}
1	Group 1	3.0714	1.7917	2.1250
2	Group 2	p < 0.01	p < 0.01	0.06
3	Group 3	p < 0.01	0.06	

✂ From Table 7.8 it can be seen that, like Question 4, there was a highly statistically significant difference ($p < 0.01$) between the answers of Group 1 on the one hand and Group 2 and Group 3 respectively on the other hand. There was no statistical difference ($p = 0.06$) between Group 2 and Group 3.

Deduced from these research results, individuals in the population who prefer blood HIV tests, are of the opinion that the promotion of the accuracy level of oral tests to test for HIV will not play an important part in convincing individuals to test.

7.3.5 DISCUSSION OF THE LIKERT SCALE SURVEY - QUESTION 7

TABLE 7.9

Table giving an overview of the descriptive statistics for the three groups with respect to survey Question 7.

Cell No.	Question 2	Question 7 Mean	Question 7 Std.Err.	N
1	Group 1	2.86	0.22	14
2	Group 2	1.79	0.10	72
3	Group 3	2.13	0.11	56

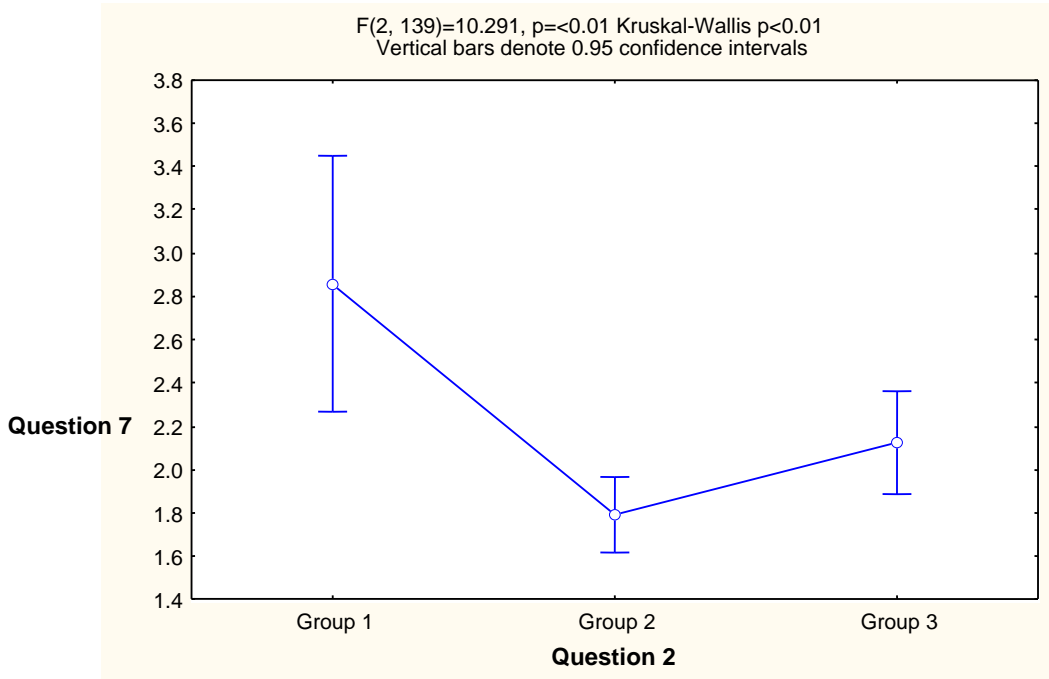


FIGURE 7.9

Graph showing the average response for Question 7 per group.

✂ The average scores in Table 7.9 and Figure 7.9 suggest that respondents from Group 2 and Group 3 agreed or strongly agreed that the proven reliability of oral fluid HIV tests to test for HIV without the need for a blood sample could play a part in motivation to test. Group 1 respondents tended to be more indifferent toward the issue. As in the case with the averages for Question 3, Question 4, Question 5 and Question 6, Group 2 has the highest average and Group 1 the lowest.

TABLE 7.10

Table showing the post hoc comparisons for the three groups with respect to survey Question 7.

Cell No.	Bonferroni test; variable Question 7			
	Question 2	{1}	{2}	{3}
		2.8571	1.7917	2.1250
1	Group 1		$p < 0.01$	0.01
2	Group 2	$p < 0.01$		0.08
3	Group 3	0.01	0.08	

✂ Like the results for Question 4 and Question 6, the same tendency can be seen in Table 7.10 for Question 7. There was a highly statistical significant difference ($p < 0.01$) between the answers of Group 1 in the one corner and Group 2 and Group 3 respectively

in the other corner. Like the trend in Question 6, Group 1 and Group 2 did not show a statistical difference ($p=0.08$) in their responses.

Judging from these findings, individuals in the population who prefer blood HIV tests, are of the opinion that the promotion of the reliability of oral fluid HIV tests to test for HIV would not play an important part in convincing individuals to test.

7.3.6 DISCUSSION OF THE LIKERT SCALE SURVEY - QUESTION 8

TABLE 7.11

Table giving an overview of the descriptive statistics for the three groups with respect to survey Question 8.

Cell No.	Question 2	Question 8 Mean	Question 8 Std.Err.	N
1	Group 1	2.43	0.21	14
2	Group 2	1.81	0.09	72
3	Group 3	2.11	0.11	56

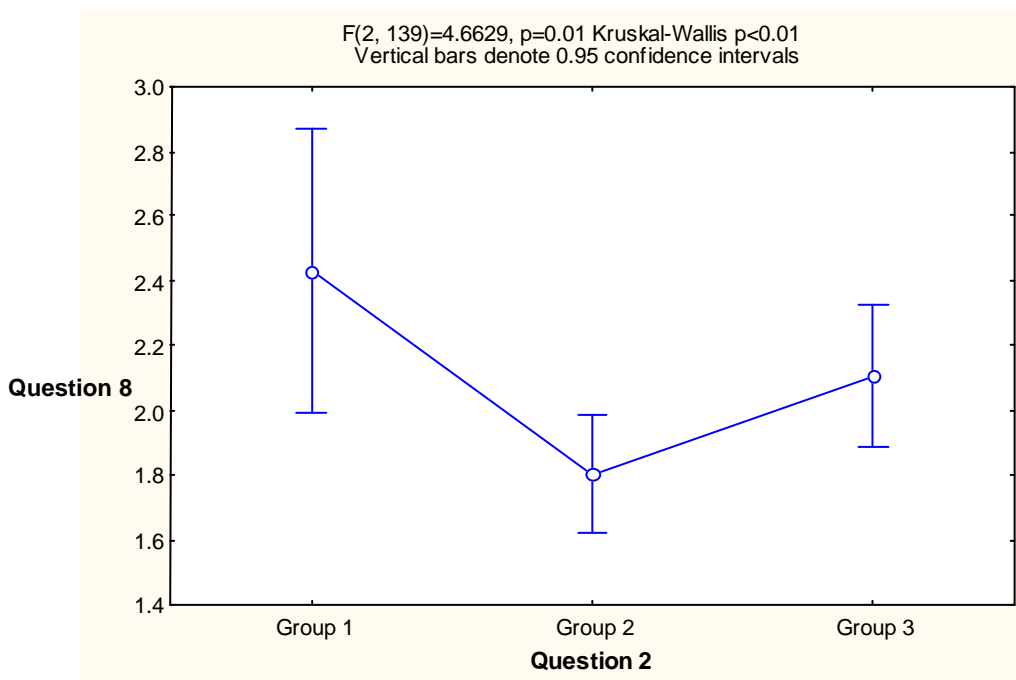


FIGURE 7.10

Graph showing the average response for Question 8 per group.

✂ The mean answers to Question 8 indicate that all three groups either agreed or strongly

agreed that trained lay counsellors should be allowed to administer oral rapid testing. The same trend as previously discussed pertaining to Group 1 and Group 2, continues.

TABLE 7.12

Table showing the post hoc comparisons for the three groups with respect to survey Question 8.

Cell No.	Bonferroni test; variable Question 8			
	Question 2	{1}	{2}	{3}
		2.4286	1.8056	2.1071
1	Group 1		0.02	0.54
2	Group 2	0.02		0.11
3	Group 3	0.54	0.11	

✂ Table 7.12 suggests that there was a statistically significant difference ($p=0.02$) between the answers of Group 1 and Group 2. No statistically significant difference was found between the answers of Group 1 and 3 ($p=0.54$) and Group 2 and 3 ($p=0.11$) respectively. It is important to note that to a certain level, all three groups agreed on the issue in question.

7.4 RESULTS SUMMARY OF LIKERT SCALE SURVEY QUESTIONS

In summary, two trends have been identified:

- ✂ In all the questions, when comparing the average responses of the three groups, Group 2 had the highest average, Group 1 the lowest and Group 3 fell somewhere in between.
- ✂ In Question 4, Question 6 and Question 7, there was a statistically significant difference ($p<0.05$) between the averages of Group 1 on the one hand and Group 2 Group 3 on the other hand, with no significant difference detected between the mean responses for Group 2 and Group 3.

8 **RECOMMENDATIONS**

The results of this research paper indicate that there are a strong preference for oral fluid testing and that a campaign highlighting the various advantages that oral fluid testing offers above conventional HIV testing because no blood specimen is required, could boost testing averages. Therefore, the following recommendation is made:

⌘ Devise a strategy to promote the use of the OraQuick® Rapid HIV-1/2 Test for oral fluid.

A poster campaign¹² is suggested as strategy to promote the use of the Oraquick® Rapid HIV-1/2 Test for oral fluid. Posters with pictures and slogans could be used as visual stimulation to endorse oral fluid tests as a more user-friendly version of and an attractive alternative to conventional HIV testing. The poster campaign will aim to:

- positively influence the public perception of HIV oral tests and testing;
- educate and inform the general public on the advantages of the oral fluid rapid test;
- persuade those who have any kind of aversion towards a blood HIV test to test for HIV by using oral fluid tests; and
- eradicate any misconceptions that anyone might have about using oral fluid to test for HIV.

The findings in this report also suggest that public opinion of those who have been tested by lay counsellors are in favour of trained lay counsellors being allowed to administer oral rapid tests. Hence, the following is suggested:

⌘ Submit and pass legislation that recognizes lay counsellors to administrate oral fluid testing in an official sanctioned capacity.

¹² See *Addendum C* for a proposed poster campaign to promote oral fluid rapid HIV testing.

Although it is not the intention of this study to promote the administration of blood rapid HIV tests by lay counsellors, research by Delaney *et al* (2002) to determine whether persons with no laboratory experience could successfully perform blood rapid HIV tests at sites in Los Angeles, Phoenix, New York, Chicago, Atlanta, Miami and New Orleans in the USA, concluded that untrained, inexperienced persons:

- obtained a correct result in 827 (96.6%) of 856 OraQuick® Rapid HIV-1/2 Tests after reading only the written instructions provided by the manufacturer; and
- who performed the OraQuick® Rapid HIV-1/2 Test obtained proficiency scores considerably higher than the 80% required by CLIA of trained laboratory workers.

The oral fluid version of the OraQuick® Rapid HIV-1/2 Test is even more simple to perform than the blood rapid version, serving as further evidence that non-medically trained individuals should be allowed to administer the oral testing process in an official sanctioned capacity.

This action will empower more individuals (i.e. lay counsellors) to administer HIV testing, as apposed to only medically trained personnel performing these tests. Such legislation should only be passed on the condition that structures are in place to create a training standard for performing oral fluid rapid tests that would be compulsory for lay counsellors to successfully complete before administering these tests.

In the Department of Health's document, *HIV/AIDS Policy Guideline: Rapid HIV Testing*, mention is made that rapid tests are not necessarily easy to perform or interpret. Adequate training and experience is necessary before health care workers use these tests. Quality control procedures should be instituted to ensure that test kits are stored and conducted in a proper manner. Strict stock control should also be instituted to ensure that test kits are properly accounted for.

The document goes on to say that the HIV/AIDS and STD Directorate recommend that a quality assurance (QA)¹³ process be implemented to evaluate and monitor test kit performance, as well as to ensure that suitably trained personnel are monitored in the correct use of these kits and that these kits are approved.

(Department of Health (b), 2000).

Currently no QA process is in place for the use of the OraQuick® Rapid HIV-1/2 Test for oral fluid. Although oral tests are relatively easy to carry out, it is essential to have structures in place to make sure that all parties involved receive proper training in the workings of these tests. This would guarantee the accountable distribution, application and management of oral tests, thereby creating a standard of excellence that has to be adhered to when facilitating any aspect of oral fluid testing.

If lay counsellors are permitted to administer these tests, it makes it even more essential to institute such regulations enforcing quality control for oral testing administrators and VCT sites. Consequently, the following recommendation is made:

✂ Develop QA guidelines for the use of the OraQuick® Rapid HIV-1/2 Test for oral fluid.

This research project proposes QA guidelines¹⁴ for testing using the OraQuick® Rapid HIV-1/2 Test for oral fluid. These guidelines outline the basic processes and procedures that should be in place before a site offers oral fluid rapid HIV testing. It describes steps that could be taken to identify and prevent errors in the testing process.

¹³ QA refers to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. It is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible for all persons being tested. QA activities should be in place during the entire testing process; this means from the time a person asks to be tested until the test result is provided (CDC (b)).

¹⁴ See *Addendum B* for the Proposed Quality Assurance (QA) Guidelines for Oral Fluid Rapid 1/2 HIV Testing document. It is based on the *Quality Assurance Guidelines for Testing using the OraQuick® Rapid HIV-1 Antibody Test* from the Centres for Disease Control and Prevention (CDC (b)).

QA guidelines should preferably be initiated, developed and implemented in collaboration with the Department of Health. This is an essential step to help lay the foundation for creating a benchmark of quality so as to ensure the responsible use and administration of these tests.

Implementing oral fluid testing on a countrywide scale to increase HIV testing is, at present, not a viable venture. The cost of the OraQuick® Rapid HIV-1/2 Test for oral fluid cannot currently compare to that of finger-prick rapid HIV tests, which are much cheaper to use (D. Ritson,¹⁵ personal communication, 16 November 2004).

The OraSure® HIV-1 Oral Specimen Collection Device is also expensive, and this was one of the main reasons for not using this test again in the second *Nelson Mandela/HSRC Study of AIDS* that was launched on November 8, 2004. It was decided to rather use dry blood spot-tests for the second study (M. Colvin,¹⁶ personal communication, 12 November 2004).

Furthermore, the regular availability of the OraQuick® Rapid HIV-1/2 Test has proven to be problematic, for example for institutions like the MRC (D. Makhubela,¹⁷ personal communication, 12 November 2004). Therefore, it could be difficult to deploy these tests at a national level.

Yet, this research project has shown that the lack of the need for a blood specimen in oral fluid testing can positively influence testing for HIV, and does have a role to play in SA. Hence, the following more affordable and feasible way is suggested to promote HIV oral fluid testing:

⚡ Set up mobile HIV/AIDS testing units promoting HIV testing using oral fluid.

¹⁵ Diane Ritson is MD of PeopleManagement, a HIV/AIDS consultancy based in Cape Town, SA.

¹⁶ Dr Mark Colvin is the senior research associate for CADRE, affiliated with the MRC & HSRC in SA.

¹⁷ Dennis Makhubela is associated with the MRC HIV Prevention Unit in Durban, SA.

The following plan of action is suggested:

- Negotiate the buy-in from relevant role players (for example the Department of Health, OraSure Technologies, Inc. and private concerns) to generate the necessary resources and manpower for the project.
- Depending on the financial backing obtained for the venture, decide on the number of mobile units to organize.
- Make a decision on how many lay counsellors to select for managing these mobile testing units.
- Select the lay counsellors for the undertaking.
- Set up and organize workshops for the training of the lay counsellors on how to manage the mobile testing units.
- Decide on training themes for the workshops, for example, how to administrate oral testing and how to set up a platform for quality control.¹⁸
- Decide on target areas and plan a mobile clinic road show accordingly (high risk, resource limited communities could, for example, be targeted).
- Make the mobile units visually striking, prominent and eye-catching by covering them with pictures and slogans¹⁹ promoting oral fluid HIV testing in terms of the advantages it offers as result of the lack of the need for a blood specimen.
- Customize the mobile units for oral fluid HIV testing, making it as convenient as possible, without jeopardizing confidentiality.
- Include a counselling room in these units for pre- and post-test counselling sessions.
- Develop a resource list for the specific intervention areas that will serve as an information brochure for people on what to do after testing and receiving their results. This document must advise individuals where and how to consult and obtain information about HIV/AIDS care and support systems in their specific community (for example where to go for a confirmatory test, the closest hospitals, clinics, etc.).

¹⁸ See *Addendum B* for the proposed QA guidelines.

¹⁹ See *Addendum C* for the proposed poster campaign.

- Plan an official launch and involve the media, all relevant stakeholders and the public.

9 **CONCLUSION**

In summary, the findings and proposed recommendations of this research project stipulates that:

- ✂ The lack of the need for a blood specimen in oral fluid testing offers a fresh, new and innovative way to persuade at-risk individuals to get tested for HIV.
- ✂ The profile, image and public awareness of oral fluid testing in SA need to be improved.
- ✂ QA guidelines should be developed and put in place for oral fluid HIV testing in South Africa.
- ✂ Trained lay counsellors should conduct oral fluid HIV testing and counselling in an official sanctioned capacity by means of a mobile unit road show. It is believed that such actions will help to take the load off already stretched medical services and create additional resources to, for example, more readily access remote urban and rural areas of SA to conduct HIV testing.

The abovementioned actions should lay the platform for successfully promoting and boosting HIV testing in general, while at the same time creating additional opportunities to get tested. These actions would have a trickle-down effect on the number of individuals knowing – and owning – their HIV status.

A lot of excitement vis-à-vis oral fluid HIV testing currently exists in the USA:

- ✂ The White House announced its continued support for efforts to promote prevention while encouraging research to combat HIV/AIDS in 2004. These efforts include encouraging testing: approximately 40,000 Americans become infected with this disease each year. The White House endorsed the FDA's action to facilitate in this

effort by approving the quicker and less invasive OraQuick® Rapid HIV-1/2 Test for oral fluid.

(White House, 2004)

On June 23, 2004, American President George W. Bush visited Philadelphia in Pennsylvania to discuss the need for providing treatment to Americans living with HIV/AIDS, and to highlight the work of faith-based and community organizations as they seek to treat and care for Americans living with HIV/AIDS. In his speech, Bush said:

Testing (for HIV) now is easier than ever. My administration is encouraging health care providers to test for HIV routinely, to save lives, that's why we're doing that. For the sake of their health and for the sake of the health of others, I urge all Americans at risk to get the test. By getting the test, you'll be making a significant contribution to making sure that we arrest the spread of HIV/AIDS.

(White House, 2004)

✘ On December 1, 2004, OraSure Technologies, Inc. opened the NASDAQ Stock Market in recognition of World AIDS Day. OraSure President and CEO, Douglas A. Michels, presided over the NASDAQ Market Open ceremony in New York City, USA. In his speech, Michels said:

"In order to help control HIV/AIDS and provide treatment to those in need, it is critical that individuals who may be infected learn their HIV status. We believe the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test is the most versatile and comprehensive rapid HIV test available and are committed to making the test available to the widest possible range of customers in the United States and abroad."

In recognition of World AIDS Day 2004, major cities across the USA are launching rapid oral fluid HIV testing initiatives with OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test in conjunction with World AIDS Day activities.

The manufacturers of the FDA approved oral tests, OraSure Technologies, Inc. have indicated that they are considering ways to readdress their test pricing structure to make it more affordable in SA (Q. Pham, personal communication, 28 October 2004). Therefore, the future promotion of oral HIV testing on a larger scale in this country (similar to what is currently the case in the USA as discussed above), is not improbable.

In the long run, the minimal training required to administer oral tests and the lack of the need for specialized facilities (for example laboratories) and additional testing devices (for example blood lancets for finger-prick HIV/AIDS tests) associated with these tests, could also contribute to bringing down the costs involved.

In an era where the emphasis is on expediency in all aspects of our lives, the use of oral fluid brings the HIV testing process – through its effortlessness and simplicity - in line with this modern day expectation. This aspect, therefore, makes it so much more important to never forget that the testing at issue here is testing for HIV/AIDS - a disease that continues to have a social and cultural impact far beyond the number of people infected.

&*&*&*&*&*&*&*&*&*&*&*&*&*&*&*&*&

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ADDENDUM A

Oral HIV and Aids Test Questionnaire

This questionnaire is to get your thoughts on the Oraquick oral fluid rapid HIV tests used in the recent HIV and Aids campaign.

This is for a joint research project between PeopleManagement (the company who facilitated the HIV and Aids training and testing intervention) and the University of Stellenbosch.

Please complete it, even if you did not test. It is completely voluntary, anonymous and confidential. Thank you very much for your co-operation.

Please indicate your:			
GENDER	Male	Female	
AGE	<30	30 - 40	>40

Place a tick in the appropriate column:			
1. Did you perceive the use of oral tests to test for HIV as a success?	Yes	No	Undecided
2. If you had to make the following choice: Would you prefer to test for HIV by giving a ...	Blood specimen	Oral specimen	Blood or Oral specimen. It doesn't really matter.

Please indicate the extent of your agreement or disagreement with the statements below. Do this by placing a tick in the appropriate column.	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
3. Because of the noninvasive nature of oral testing, more individuals will be willing to test for HIV.					
4. Because there is no fear of needles and blood involved in oral testing, more individuals will be willing to test for HIV.					
5. Because there is no safety risk of HIV transmission through blood in oral testing, more individuals will be willing to test for HIV.					
6. Because oral fluid tests are just as accurate in correctly determining your HIV status without taking blood, more individuals will be willing to test for HIV.					
7. Because oral fluid tests are just as reliable in consistently giving the same HIV test result without taking blood, more individuals will be willing to test for HIV.					
8. Because no specialist blood taking procedure is involved in oral testing, non-medical personnel, trained in performing the oral HIV test, can be allowed to conduct the testing process.					

ADDENDUM B

Proposed Quality Assurance (QA) Guidelines for Testing using the OraQuick® Rapid HIV-1/2 Test for Oral Fluid

Introduction

Summary of Basic Elements of a QA Programme for the OraQuick® Rapid HIV-1/2 Test for Oral Fluid

Even though the OraQuick® Rapid HIV-1/2 Test for oral fluid is simple to use, things can go wrong. To help find and prevent problems, the basic elements of a quality assurance (QA) programme should be in place before offering testing. These basic elements are the corner stones of a QA programme and are listed below. More detail on these five elements is provided in this document.

1. Organization of the QA programme
 2. Testing personnel
 3. Process control
 - a. Before testing
 - b. During testing
 - c. After testing
 4. Documents and records
 5. Troubleshooting
-

Organization of the QA programme

Establishing a QA programme

Someone must oversee the programme and ensure that the necessary staff and supplies are available. Each organization must:

- ✘ identify the person(s) responsible for managing the QA programme (this could be a senior staff member, outside consultant or a network of individuals who oversee different aspects of the QA programme);
- ✘ write procedures (step-by-step instructions) and make them available to all staff involved in testing;
- ✘ verify the testing process;
- ✘ ensure staff know how to perform processes and procedures (see the section on personnel who conduct testing); and
- ✘ create mechanisms for communication so that those who need to know are informed about QA issues, as well as all staff, when appropriate.

Verifying the testing process

Before offering the test to clients or patients, each site should make sure (verify) that the testing process works as planned. This verification should be completed before testing is offered. Verification includes ensuring that staff have been trained and are able (competent) to perform their assigned tasks, the test kits work as expected and the logistics for providing confirmatory testing (if a person tests positive, he or she still has to have a test to confirm the finding) are in place.

Providing written procedures

It is strongly recommended that step-by-step, written instructions be made available to all staff performing testing. This will help to ensure that they know how to perform specific tasks and testing success is not left to chance. Testing personnel must follow instructions provided by the manufacturer. Additional procedures, as listed below, should be provided along with the manufacturer's instructions. Text from the current OraQuick package insert may be used for some of the items denoted by an asterisk (*) in the list below. Written instructions should describe how to:

- ✂ train new employees;
 - ✂ assess their ability to do the testing and document training;
 - ✂ provide information to persons being tested before testing;*
 - ✂ maintain sufficient supplies;
 - ✂ check that tests and control kits have not yet expired;
 - ✂ follow the manufacturer's instructions for storage;
 - ✂ check performance of new test kit lots (a test kit lot is defined as the boxes of test devices that contain either 25 or 100 tests that have the same lot number labeled on the outside of the boxes) and shipments;
 - ✂ perform quality control testing and take action if controls don't work;
 - ✂ collect the OraQuick specimen; *
 - ✂ perform steps in the test procedure; *
 - ✂ report results;
 - ✂ refer persons being tested for confirmatory testing where necessary;
 - ✂ record test and quality control results;
 - ✂ conduct external quality assessment;
 - ✂ review records and store and destroy them when they are outdated; and
 - ✂ take corrective action when things go wrong.
-

Testing Personnel

Overview

Having qualified, trained staff to perform and supervise OraQuick testing and the various activities in the QA programme is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element include:

- ✘ Qualifications
- ✘ Training
- ✘ Competency assessment (i.e. how well they are doing their job)

Personnel qualifications

It is recommended that certain qualities be considered when selecting personnel to perform the OraQuick® Rapid HIV-1/2 Test for oral fluid. The following list of qualities resulted from practical considerations and expert opinion:

- ✘ *Sincerity and commitment* – A dedication to performing testing according to defined procedures.
 - ✘ *Literacy* – The ability to read instructions and record results is critical.
 - ✘ *Organizational skills* – The need for this quality will depend on the number and complexity of tasks an individual performs in the testing process. If test volume is high and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be critical.
 - ✘ *Decision-making skills* – Testing personnel should be able to interpret results and be able to recognize and handle problems that might crop up.
 - ✘ *Communication skills* – If the person performing the test also is the one who shares results or other information with the person being tested, being able to communicate clearly is important.
-

Components of training

Training is crucial to ensuring quality testing. Staff should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each staff member. The key components to include in a training programme are:

- ✘ how to perform the test, including procedures performed before, during and after testing;
- ✘ how testing is integrated into the overall counselling and testing programme; and
- ✘ the importance of QA and the elements of the site's QA programme.

Training method

Training method should optimally include the following activities:

- ✘ Read the instructions for performing the test.
- ✘ Watch someone perform the test or view a video of someone performing the test.
- ✘ Practice performing the test with positive and negative control materials.
- ✘ Review the procedures and forms on how to document testing.
- ✘ Update counselling skills, focussing on updating counselling skills specifically relevant to single-session counselling used in conjunction with rapid HIV testing.

Competency assessment

Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test should be demonstrated and documented. A supervisor or trainer should perform the assessment, using a combination of methods to determine competency.

Examples of these methods are presented below.

Assessing performance of tasks done before testing

To assess the task performance before testing, staff should be observed as they:

- ✘ run the external controls and record results; and
- ✘ set up the testing area, label the device and prepare control & test results sheets.

Assessing performance of tasks done during testing

To assess staff's ability to perform the test and interpret results:

- ✘ Observe the staff member performing the oral test.
- ✘ Observe how the test is performed on a client/patient. If such observation interferes with actual client-provider interactions, observe test performance on a volunteer.
- ✘ Appraise the individual's ability to interpret results. This might include utilizing previously used test devices or pictures of devices that show non-reactive, weakly reactive, reactive and invalid results.

Assessing performance of tasks done after testing

To assess task performance after testing:

- ✘ Review test records and quality control results documentation.
 - ✘ Observe oral reporting of results to a test subject (if trainee's responsibility).
 - ✘ Observe the handling of procedures for confirmatory testing referral.
 - ✘ Verify that confidentiality is maintained.
-

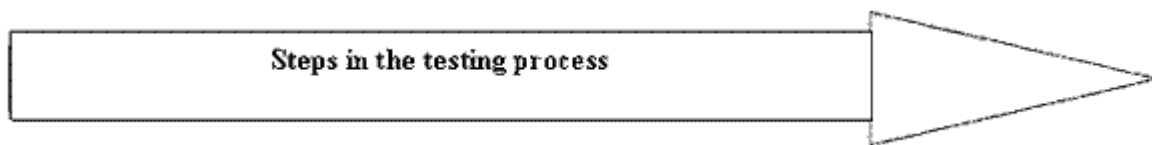
Process Control

What is process control?

Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

Steps in the testing process

Steps in the testing process follow the path of workflow beginning with tasks before testing, followed by those conducted during and after testing. This path of workflow and the associated steps are shown in the table below. Detailed descriptions about each of the steps listed in this table are provided in the remainder of this document.



Before testing	During testing	After testing
<ul style="list-style-type: none"> ⌘ Check storage temperatures ⌘ Check inventory and test kit lots, as needed ⌘ Receive request for testing ⌘ Provide HIV/AIDS information to the test subject ⌘ Set up test area, label test device ⌘ Perform external quality control according to the manufacturer's and the site's instructions 	<ul style="list-style-type: none"> ⌘ Perform the test ⌘ Interpret test results 	<ul style="list-style-type: none"> ⌘ Report results to client ⌘ Document results ⌘ Participate in external quality assessment (periodically)

Before Testing

Overview

As shown in the table above, there are a number of steps that must be followed before testing the oral fluid sample for HIV. These activities are in place to ensure that the conditions in which the tests are stored and performed are suitable, the test area and the test subject are prepared, and the test is working appropriately.

Temperature control

Test kits must be stored in an environment within the temperature ranges specified by the manufacturer. Store test kits at 2° to 30° C. Perform tests at 15° to 27°C. If the test must be performed at a temperature below 15°C or above 27°C, run external controls that have been stored within the proper temperature range to find out if the test can be performed at another temperature.

Checking inventory and test kits

Procedures should be in place to ensure that an adequate supply of unexpired test kits, controls, and supplies is available. Test kits and controls have a defined shelf life. Use the oldest first. Never use test or control kits beyond their expiration dates. It is helpful to use a log sheet to document when test and control kits are received, their lot numbers and expiration dates. As described in the package insert and in the section on quality control below, run the positive and negative controls with new lots and new shipments of test kits before using them for testing (i.e. to verify that they work as expected).

Setting up the testing area and labeling the test device

Before testing, the testing area should be prepared according to the specific site procedure, which should include directions for setting up the workspace listed in the test kit instructions, as well as instructions for how to label testing devices and complete report forms, including the method for identifying each person to be tested to ensure specimens are not mixed up during the testing process. Labeling is especially important when more than one test is being performed at the same time. Label components of the test with the name or identifying number of the person being tested before collecting the specimen. These components include the developer solution vial, test device, and documents for recording results. Using pre-printed labels improves the efficiency of performing this task.

Note: *Do not place a label over the two holes on the back of the test device as this can cause an invalid result.*

Providing information to test subjects

It is important to explain how the test works to each person being tested prior to performing the test. This can also be done in the pre-test counselling session.

Quality control

There are two types of quality control (QC) for the the OraQuick® Rapid HIV-1/2 Test for oral fluid. These are described in the table below.

Type of quality control	Description of activity
Internal Controls	A control is built in to each testing device to verify that the specimen was adequate and the solution flowed through the device as intended.
External Controls	Known reactive and non-reactive specimens (controls) are available from the manufacturer to sites purchasing this test. They are used to evaluate the accuracy of the test in detecting antibody to HIV and to check if the person conducting the test performs it correctly.

External quality control

To verify that the test device is accurately detecting HIV-1 antibodies, external controls must be tested from time to time. The test kit manufacturer provides external controls and can be ordered separately from the test kit. How often controls are run to verify the accuracy of the test will depend on the number of tests carried out by the site, how often new test kit shipments or lot numbers are received by a site, and how often staff who conduct the testing change.

The manufacturer has set guidelines for the running of external controls. The test kit instructions specifies running controls under the circumstances below. Run controls:

- ✘ prior to a new operator performing testing on patients;
- ✘ whenever two consecutive invalid test results are obtained on a person being tested;
- ✘ when opening a new test kit lot or a new shipment of test kits is received (even if it is the same kit lot number in current use);
- ✘ if the temperature of the test storage area falls outside of 2°-30° C;
- ✘ if the temperature of the testing area falls outside of 15°-27° C; and
- ✘ at periodic intervals as dictated by the user facility.

Frequency of running external controls on the basis of test volume

When external controls provide incorrect results, none of the tests that were run since the last time control results were correct can be considered valid. This means that everyone who was tested since the last time controls ran correctly will need to be called back and retested, which is not practically possible. Sites testing large numbers of persons, and especially those that offer anonymous testing, should plan to run controls more often than facilities that conduct fewer tests. Facilities that test 25 or more subjects a day should run controls every day. Low volume sites, such as those testing fewer than 25 subjects per month, should run external controls every two to four weeks at a minimum.

During Testing

Overview

This phase of the testing process involves running the test and interpreting the results. Activities during testing include collecting the specimen, performing the test and interpreting the internal control and client/patient test results.

Collecting, performing and interpreting test results

Follow the written procedure for oral specimen collecting, performing and interpreting the results. Results can be one of the following:

- ⓧ *Nonreactive* (negative)
 - ⓧ *Reactive* (preliminary positive)
 - ⓧ *Invalid* (the test result is inconclusive and cannot be interpreted; see below for information on handling invalid results)
-

Evaluating internal control results

Each test device includes a built-in (internal) control. When an appropriate line develops at the center of the “C” location on the device, the patient’s specimen has been correctly loaded and has traveled through the test strip, indicating a valid test. Additional information is provided in the test kit package insert. These controls are included in every device, and control results are evaluated with every test. If the internal control does not produce the expected result, the test result for the patient is not valid, cannot be reported, and the test must be repeated. If a second invalid result occurs, external controls should be evaluated as described below before repeating the test a third time.

After Testing

Overview

Quality assurance extends to those activities completed following the performance of the test.

Each site should have established procedures for:

- ⓧ reporting and recording results;
 - ⓧ referral procedure for test subjects for confirmatory testing; and
 - ⓧ conducting external quality assessment.
-

Giving Results

This entail how results are provided to the person being tested and how results are documented in the test result logs. This may differ from site to site.

Referral for Confirmatory Testing

Whenever the test result is reactive (preliminary positive), a confirmatory test must be performed using a blood HIV test to confirm that the person being tested is infected with HIV. Therefore, each site must have established procedures for referral of persons having to go for confirmatory testing.

Follow up Testing for Negative and Indeterminate Confirmatory Results

Some test results may be negative or indeterminate. If the confirmatory test result is negative, specimen mix-up needs to be ruled out versus a false positive result. It is recommended that the confirmatory test be repeated.

Managing confirmatory results

OraQuick testing sites that refer specimens for confirmatory testing should have established procedures describing how to:

- ✘ match the client's/patient's confirmatory test results with their results to find potential discrepancies and to ensure that testing was performed according to protocol;
 - ✘ report the test result to the person being tested; and
 - ✘ obtain any additional specimens needed to resolve potential specimen mix-up and for retesting, as needed.
-

Handling result discrepancies

Procedures should describe how to handle result discrepancies when the test result was reactive and the confirmatory test negative or indeterminate. If the laboratory providing confirmatory testing performed by one confirmatory test only and reported a non-reactive or negative result, the testing site should contact the confirmatory testing laboratory and request a different confirmatory test. If the original specimen is not available, a new specimen will need to be collected from the person in question to be used for confirmatory testing.

External assessment

External assessment can look at how testing is being performed and whether it is being performed reliably. Some external assessment mechanisms include:

- ✘ comparing the reactive results with the confirmatory test results;
 - ✘ arranging for someone outside the organization to observe testing; and
 - ✘ participating in a proficiency testing or external evaluation programme.
-

Documents and Records

Overview

Sites using the OraQuick® Rapid HIV-1/2 Test for oral fluid should have policies and procedures describing what QA records are required and how and when they are reviewed, stored and destroyed. Having a supervisor review records periodically is recommended. QA records include the following:

- ✘ Training documentation
- ✘ External control result logs
- ✘ Test result logs

Training documentation

Training documents should keep record of how the trainee performs each objective or procedural step, as applicable. This should include:

- ✘ reading the test procedure;
 - ✘ determining if requirements for acceptable testing environment are met;
 - ✘ practicing the test with external controls;
 - ✘ giving person getting tested the “Subject Information” brochure;
 - ✘ labeling test device components and appropriate paperwork;
 - ✘ inserting the test device, keeping time & reading the result;
 - ✘ recording results on report forms and log sheets;
 - ✘ recording internal and external quality control (QC) results in QC log;
 - ✘ evaluating new OraQuick test kit lots;
 - ✘ numbering and recording results in QC log;
 - ✘ reporting test results to the person being tested; and
 - ✘ explaining what to do if QC results show a problem.
-

External control result logs

External control records should include the:

- ✘ date and time of control testing;
- ✘ lot number and expiration of the test kit;
- ✘ lot number and expiration date of the controls; and
- ✘ control results, and corrective action taken if control results are unacceptable.

Control records should be kept in the order in which they were completed so they can be easily compared with the test records. This will help find answers if there are questions about testing performed within a specific time frame.

Test result logs

Test result records should include the date and time of testing, an identifier for the person being tested, a test kit lot number and expiration date, test result, action taken if the result was invalid and the identification of the person who performed the test, whether confirmatory testing was requested and the confirmatory test results when they are available.

Troubleshooting

Overview

Each site should have a method to detect and resolve problems that occur at any point in the testing process, especially those that may affect the accuracy of test results. Significant problems should be immediately reported to the appropriate supervisory personnel.

Procedures

Procedures should be available to all testing personnel for the following:

- ⌘ When to discontinue testing, e.g., when the external control results are unacceptable as described in the package insert.
 - ⌘ How to take corrective action, or an action taken in response to a problem.
 - ⌘ How to document problems and actions taken.
 - ⌘ How to verify the corrective actions taken addressed the problem.
-

ADDENDUM C

NO BLOOD NEEDED TO TEST FOR HIV!

NEW!!!



**QUICK – EASY – COMFORTABLE – CONVENIENT
ACCURATE – RELIABLE - APPROVED**

GET TESTED FOR HIV - TODAY!

HOW DOES IT WORK?

- * A TEST ADMINISTRATOR GIVES YOU A TOOTHBRUSH LIKE DEVICE TO SWAB ACROSS YOUR GUMS
- * THIS DEVICE COLLECTS DNA SAMPLES FROM YOUR GUM CELLS
- * THE TOOTHBRUSH DEVICE IS PUT INTO A SPECIAL SOLUTION
- * YOUR HIV RESULT IS KNOWN IN 20 MINUTES

WANT TO **KNOW** YOUR **HIV STATUS**?

THOUGHT YOU HAD TO GIVE
A **BLOOD** SAMPLE?

RIGHT??
WRONG!!



TEST BY GIVING AN ORAL SAMPLE!

QUICK – EASY – COMFORTABLE – CONVENIENT
ACCURATE – RELIABLE - APPROVED

GET TESTED FOR HIV - TODAY!

NEW!



HOW DOES IT WORK?

- * A TEST ADMINISTRATOR GIVES YOU A TOOTHBRUSH LIKE DEVICE TO SWAB ACROSS YOUR GUMS
- * THIS DEVICE COLLECTS DNA SAMPLES FROM YOUR GUM CELLS
- * THE TOOTHBRUSH DEVICE IS PUT INTO A SPECIAL SOLUTION
- * YOUR HIV RESULT IS KNOWN IN 20 MINS

WANT TO **KNOW** YOUR **HIV STATUS**?



BUT...



SCARED OF BLOOD OR NEEDLES??

THE SOLUTION?

TEST BY GIVING AN ORAL SAMPLE!

QUICK – EASY – COMFORTABLE – CONVENIENT
NO BLOOD! NO FEAR! NO PROBLEM!

GET TESTED FOR HIV - TODAY!

NEW!!



HOW DOES IT WORK?

- * A TEST ADMINISTRATOR GIVES YOU A TOOTHBRUSH LIKE DEVICE TO SWAB ACROSS YOUR GUMS
- * THIS DEVICE COLLECTS DNA SAMPLES FROM YOUR GUM CELLS
- * THE TOOTHBRUSH DEVICE IS PUT INTO A SPECIAL SOLUTION
- * YOUR HIV RESULT IS KNOWN IN 20 MINS

WANT TO **KNOW** YOUR **HIV STATUS**?

BUT...



UNCOMFORTABLE WITH BLOOD?

THE SOLUTION?

TEST BY GIVING AN ORAL SAMPLE!

QUICK – EASY – SIMPLE – CONVENIENT
NO BLOOD! NO FEAR! NO PROBLEM!
GET TESTED FOR HIV - TODAY!

NEW!!



HOW DOES IT WORK?

- * A TEST ADMINISTRATOR GIVES YOU A TOOTHBRUSH LIKE DEVICE TO SWAB ACROSS YOUR GUMS
- * THIS DEVICE COLLECTS DNA SAMPLES FROM YOUR GUM CELLS
- * THE TOOTHBRUSH DEVICE IS PUT INTO A SPECIAL SOLUTION
- * YOUR HIV RESULT IS KNOWN IN 20 MINS

WANT TO **KNOW** YOUR **HIV STATUS**?

BUT...



DON'T FEEL SAFE WITH BLOOD?

THE SOLUTION?

TEST BY GIVING AN ORAL SAMPLE!

QUICK – EASY – COMFORTABLE – CONVENIENT

NO BLOOD! NO FEAR! NO PROBLEM!

GET TESTED FOR HIV - TODAY!

NEW!!



HOW DOES IT WORK?

- * A TEST ADMINISTRATOR GIVES YOU A TOOTHBRUSH LIKE DEVICE TO SWAB ACROSS YOUR GUMS
- * THIS DEVICE COLLECTS DNA SAMPLES FROM YOUR GUM CELLS
- * THE TOOTHBRUSH DEVICE IS PUT INTO A SPECIAL SOLUTION
- * YOUR HIV RESULT IS KNOWN IN 20 MINS