

**Report of a Pilot Study on Using OraQuick HIV-1/2 Rapid Test in
AIDS Counselling and Testing Service**

Special Preventive Programme

Centre for Health Protection

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In remembrance of our beloved

Ms Maria Fan

who had devoted her life to serve those most in need,
including people living with HIV/AIDS

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CONTENTS

Executive Summary.....	1
Background.....	2
Objectives.....	3
Methodology.....	3
A. Sampling and recruitment of subjects.....	3
B. The two groups.....	4
C. Evaluation.....	6
D. Ethical considerations.....	7
E. Statistical analysis.....	7
Results.....	8
A. Clients’ profile and testing outcomes.....	8
B. Client satisfaction of rapid testing.....	11
C. Counsellor acceptance.....	13
Discussion.....	17
Acknowledgments.....	22
References.....	23
Tables & Figures.....	25
Appendix I Brief Introduction for Pilot Rapid Test Study.....	34
Appendix II (a, b) Satisfaction Survey for Rapid Test.....	35
Appendix III Design and Workflow of the Study.....	39
Appendix IV Guiding Questions of the Focus Group Discussion.....	40
Appendix V Consent Form for Verbal Consent by Client.....	41

EXECUTIVE SUMMARY

A pilot study was conducted from February to May 2004 to examine the feasibility and client satisfaction of applying Oraquick HIV 1/2 rapid test at the government AIDS Counselling & Testing Service. Three hundred and twenty-two subjects successfully recruited through the AIDS Hotline (tel: 2780 2211) participated in the study. Two hundred twenty four clients were systematically sampled into the rapid test group whereas 98 were in the control group using conventional HIV antibody test (EIA and reactive ones tested by western blot) group.

Demographically, significantly more heterosexuals were in the rapid test group (92.4% vs. 84.7%, $P=0.034$). All subjects in the rapid test group did not opt out a parallel conventional HIV offered per study, with blood collected via separate venepuncture. There was full concordance of rapid tests results and the corresponding conventional tests results. Five subjects were found to be reactive on rapid testing, all of which were subsequently confirmed positive by western blot. None of the 219 subjects with non-reactive rapid test were found positive by conventional HIV antibody testing. All 222 (99.1%) rapid test clients who completed a satisfaction survey were satisfied with rapid testing. "Result available within the same day of rapid testing" was the most satisfied part, as expressed by 193 subjects (87.3%). The mean aggregate satisfaction score derived from 8 questions on specific aspects of satisfaction was 3.2 (full mark being 4); tertiary or above education ($P<0.001$) and having prior HIV test ($P<0.001$) were associated with greater satisfaction on multivariate analysis. Nurse counsellors who participated in the project were also satisfied with and confident of doing rapid test, as found in a focus group discussion. However, logistic arrangement was more complex and total time spent by nurse counsellors in telephone recruitment, pre-test and post-test counselling were significantly more for clients in the rapid test group. Furthermore, risk reduction counselling for HIV negatives may be limited by the lack of a second clinic visit in most rapid test clients.

BACKGROUND

1. Conventional HIV antibody testing comprised an enzyme immunosorbent assay (EIA) screening test, followed by confirmatory western blot for reactive sample. There is often a long time lag for result availability, stemming from blood collection at testing site to transport of specimen to laboratory for test itself and conveyance of result back to client. To hasten the turn around time for HIV serology result, the alternative rapid antibody testing comes into place.
2. Rapid test has been recommended for use in various settings to determine the HIV status of: source clients in health care exposure (Kallenborn *et al.* 2001), pregnant women who present in labour (Nogueira *et al.* 2001) and have not been tested before, patients who are unlikely to return for test results such as sexually transmitted disease (STD) patients (CDC 1998), and people in other settings for which test results affect immediate decisions. Besides its use in point-of-care settings, rapid test may also be useful to improve the access to HIV testing for vulnerable communities, especially for the hard-to-reach populations (Galvan *et al.* 2004). Hence, the use of rapid test has bearing for both clinical and public health considerations.
3. SUDS HIV-1 test is the first such test approved by the US Food and Drug Administration (FDA). It, however, must be performed by a trained laboratory technician. In November 2002, the FDA approved the OraQuick HIV-1 rapid test as a moderate complexity test, which has to be performed in a Clinical Laboratory Improvement Amendments (CLIA) approved laboratory. But in January 2003, the FDA waived the CLIA requirement, thus extending the use of the test to other potential sites. In comparison with SUDS, OraQuick has several advantages: (a) centrifugation of blood not needed, (b) single step only, and (c) internal control in place. It has over 99% of sensitivity and specificity (United States Department of Health & Human Service 2003). As with all screening tests for HIV, positive (reactive) result must be confirmed with an appropriate test

such as western blot.

4. Special Preventive Programme of the Department of Health has been operating an anonymous AIDS Hotline and voluntary counselling and testing (VCT) clinic at Yaumatei clinic since 1994. Conventional HIV antibody testing using EIA screening and confirmatory western blot approach has all along been adopted. The turn around time for result availability is about 10 days. Syphilis screening is offered in parallel to HIV test. Yet, increasingly there are clients who request a faster clarification of their HIV status. We thus set to conduct a pilot study project to examine the feasibility and applicability of OraQuick rapid test in our VCT service.

OBJECTIVES

5. The objectives of the study are:
- (a) to explore the acceptance of OraQuick rapid test;
 - (b) to evaluate clients' satisfaction of using the rapid test;
 - (c) to examine the work processes, arrangement and manpower implications of employing the test; and
 - (d) to compare the proportions of clients knowing their HIV status through conventional and rapid test.

METHODOLOGY

A. Sampling and recruitment of subjects

6. This was a comparative study on rapid test using a conventional test control group. The rapid test procedures were compared with the standard pre- and post-test procedures to evaluate HIV counselling and testing using rapid test. Clients requesting an HIV antibody test via calling the AIDS Hotline (2780 2211) during the study period of February to May 2004 were subjects for recruitment. There were two exclusion criteria: (a) client who had participated in the study, and (b) client whose blood sample for HIV antibody test will not be tested immediately – needle stick injury cases. Walk-in clients were not target subjects in this study.

7. During the study period, all eligible subjects accessing nurse counsellors at AIDS Hotline were systematically sampled in a 2:1 ratio to rapid test group and conventional test group. The target number of subjects was 200 and 100 for rapid test and conventional test group respectively. We used standard information to brief clients about the study for recruitment, both at telephone encounter and during clinic attendance (Appendix I). Clients who declined invitation to join the study would be recorded in the overall statistics of the study, and offered conventional test per usual service provision. Clients who accepted recruitment into the study would have a case-based record opened, which tracked his/her participation from appointment booking, through attendance for pre-test counselling and testing, to the post-test counselling for final result.

B. The two groups

Rapid test group

8. For subjects sampled and recruited to the rapid test group, a parallel conventional HIV antibody test would be offered to them at the telephone call. The participants can opt-out conventional testing during appointment booking at telephone or when they later attended the clinic on site. No syphilis testing was performed if rapid test was done alone without conventional HIV antibody test. Pre-test counselling was tailored to rapid testing when the client attended for

HIV screening. Blood for the rapid test was collected by finger prick using haemoglucose meter with puncher. This approach was to simulate the situation in other settings using rapid test. Blood for the conventional antibody test was collected separately by venepuncture. A self-administered client satisfaction survey (Appendix II a,b) on the rapid testing was done after blood taking.

9. All clients were explained of the arrangement for learning their conventional test results, if done. Clients with negative rapid test were to call back to confirm their conventional test results as such without returning in person for it, except under the following circumstances: (a) the 1 out of 30 subjects who were randomised to return per study design, (b) non-negative conventional test, (c) reactive syphilis test, and (d) other reasons considered necessary by nurse counsellors. Clients with reactive rapid test must return for reading their conventional test result. These clients were counselled of the preliminary positive result and had conventional test performed (if not yet done), and they were instructed to call in 10 days' time to book appointment for reading the conventional result. A helpline for support during the waiting period was given to clients. Western blot testing was performed irrespective of the EIA results for clients with reactive Oraquick. In this study, a 3-month period after blood collection is allowed for clients to learn their conventional test results before case closure. Subjects confirmed HIV positive were referred for care.

Conventional test group

10. Subjects sampled to the conventional test group would have basically the same arrangement per usual clinic practice, i.e. pre-test counselling, blood collection by venepuncture, and call for appointment to read result with post-test counselling. Similar to the rapid test group clients, a 3-month period to learn of their conventional test results is allowed and subjects confirmed HIV positive were referred for care. An overview of the flow of clients from recruitment through completion of the study in the two groups is at Appendix III.

C. Evaluation

11. Several process and outcome indicators were defined per the study objectives and its implementation: (a) study participation, (b) time implication for client and service provider, (c) test result conveyance and follow-up. The conventional test group, which is the existing service delivery mode, served as a real-time counterpart for comparison of the different parameters with rapid test group as applicable. Due to practical constraints, only nurse counsellor manpower in terms of man-hour was used to determine the resources required in the two test groups. Man-hours consumed for each client were logged and analysed at 3 time points through the study: (a) telephone recruitment, (b) pre-test counselling/testing at clinic visit, and (c) post-test counselling and support at clinic visit.

12. To assess the clients' level of satisfaction on rapid testing, all rapid test subjects were invited to participate in a self-administered questionnaire survey after they received pre-test counselling and blood taking. The questionnaire comprised multiple choice and open-ended questions and was designed to evaluate rapid testing from the point of views of clients who underwent the test. Assistance from counsellors was rendered where necessary for the survey.

13. To gather opinions from the nurse counsellors, a focus group discussion was held after completion of recruitment and HIV screening for all clients of the study. Hence, perspectives of clients as well as care providers were covered in the present study. Objectives of the focus group discussion are to: (1) identify problems experienced by the counsellors when offering the rapid tests, (2) assess acceptance of counsellors in offering rapid tests, and (3) gauge readiness of counsellors to provide training on the conduction of rapid tests. All counsellors who have conducted rapid tests in this pilot study were recruited into the focus group. The moderator and two recorders were health care professionals not directly involved in conducting the pilot study. Participants were asked to provide their number of year of nursing experience, number of year of

counselling experience and approximate number of rapid tests done. The focus group was audio recorded and notes were taken by recorders. Notes were read repeatedly to identify emergent and recurrent themes. The focus group was conducted in Cantonese. The guiding questions are at Appendix IV.

D. Ethical considerations

14. Ethical approval was received from the Ethics Committee of the Department of Health where the study was based. There were several ethical issues identified of the study. Firstly, informed consent was sought from the clients, after discussion on the rapid test, the conventional test and the study arrangement. As our AIDS Counselling & Testing Service is anonymous, the clients were asked to give oral instead of written consent. The consent form (Appendix V) was signed by counsellors on behalf of the client, before doing the rapid or conventional tests. Secondly, clients who refused to participate in the study would not be denied access to care. They were offered conventional HIV antibody testing per usual clinic practice. Thirdly, the standard of care received by the clients including test results would not be compromised through joining the study. Subjects who were randomised to the rapid test group can freely choose to have or not have a parallel conventional test. Fourthly, confidentiality of the information collected in the study was upheld. It was only used in global analysis for evaluation of the study, publication and service planning. Fifthly, no person-identifying information extra to that required for usual service provision was collected from the study subjects. Lastly, counsellors were available to answer any questions or concerns regarding our HIV testing and counselling service and the study.

E. Statistical analysis

15. Descriptive statistics was compiled for the data obtained in rapid test and conventional test group clients. Observed differences between the rapid test group and conventional test group were compared using Chi-square test or the Fisher exact test for categorical variables and Mann-Whitney tests for continuous variables. To assess the associations between clients' characteristics and overall satisfaction scores, independent sample t-test and one-way analysis of variance (ANOVA) were used. An overall aggregate satisfaction score was used to examine the clients' satisfaction level of using rapid test. It was calculated by averaging the score of eight opinion questions that ranged from 1 to 4, where 1 represented strong disagreement and 4 represented strong agreement with a statement favouring rapid test. Reverse scoring was given for statements against rapid test, i.e. 1 represented strong agreement with the statement and 4 represented strong disagreement. Multiple linear regression model with stepwise method was used to ascertain which factors were independently associated with the overall satisfaction score. Only factors that were significant in univariate analysis were entered into the regression model. Data were entered with EPI-Info version 6.04 and analyzed with SPSS for Windows, version 11.0.1. All tests of significance were two-sided and a P-value of less than 0.05 was taken as statistically significant for difference between groups.

RESULTS

16. A summary of the number of subjects going through the various stages of recruitment, clinic attendance, counselling and testing, and receipt of confirmatory results is at Figure 1.

A. Clients' profile & testing outcomes

Telephone recruitment

17. A total of 462 clients booked for HIV antibody testing at Yaumatei VCT clinic during the 3-and-a-half-month study period spanning from 5 February to 18 May 2004. Twenty-three clients refused to join the rapid test group, giving a response rate of 92.5%. Ten clients refused to join the conventional test group, giving a response rate of 93.5%. As a result, 429 clients were recruited into the study at telephone encounter, of which 285 (66.4%) and 144 (33.6%) were in the rapid test group and conventional test group respectively (Table 1).

18. Table 2 shows the demographic characteristics of clients who agreed to participate in the study during appointment booking. More than 80% (n = 234, 82.1% in rapid test; n = 120, 83.3% in conventional test) were male. The turn-up and eventual participation rate in rapid test group (n = 224, 78.6%) was statistically significantly higher than that of the conventional test group (n = 98, 68.1%) (P=0.017). The overall participation rate after consenting at telephone recruitment was 75% (322/429).

Demography of study clients

19. Table 3 shows the demographic characteristics of the 322 clients who attended VCT clinic and successfully participated in the study. The vast majority were male (n = 186, 83.0% in rapid test; n = 85, 86.7% in conventional test), with a mean age of 33.8±11.0 years in rapid test group and 33.4±10.2 years in conventional test group. More than half (n = 134, 60.1% in rapid test; n = 62, 63.3% in conventional test) were never married. Over 90% in both groups were Chinese. Most of the clients had received secondary education or above (n = 214, 95.9% in rapid test; n = 95, 97.0% in conventional test). While the main suspected route of exposure was heterosexual contact for both groups, its proportion of 84.7% in conventional test clients was statistically lower than the 92.4% in rapid test clients (P=0.034). Ninety-seven (43.3%) and 48 (49.0%) of rapid test and conventional test group clients had ever tested for HIV (P=0.346).

HIV test results and knowledge of serostatus

20. None of the 224 subjects in the rapid test group opted out parallel conventional HIV antibody testing. All received their rapid test results with post-test counselling on the same day of testing. As shown in Table 4, 29 (12.9%) clients of rapid test group vs. none in the conventional test group did not comply with the requirement for clinic attendance or phone call within 3 months to learn of their confirmatory HIV antibody result. In the rapid test group, 219 clients tested negative (97.8%) and 5 tested positive with the rapid test (Table 4). There was no indeterminate/non-valid rapid test result in this study. Three of the five reactive clients reported that they had been tested HIV positive by EIA test done outside Hong Kong, and they were all prepared for the positive result upon rapid testing. The other 2 rapid test clients also accepted the positive results with counselling. All these five preliminary positive clients were subsequently confirmed by EIA and Western blot testing using serum obtained by venepuncture. Two (40%) of them did not return for reading their confirmatory results within the 3-month period. These 2 clients were couple and non-Hong Kong residents. Husband was tested HIV positive before and alleged that they might not be able to return for the confirmatory result. The other 3 positive clients received post-test counselling at clinic and were referred to government HIV clinic for further care. All the non-reactive rapid tests were found negative subsequently in the parallel conventional test. There were 3 partners of HIV-infected patients in the rapid test group and they were greatly relieved when learnt of a negative rapid test result.

21. All 98 conventional test group subjects attended for HIV result and post-test counselling within 3 months of screening during the study period. One client tested positive while all the rest were negative. The positive client was referred for HIV care.

Process and outcome evaluation

22. Table 5 shows the process and outcome indicators of the study. As noted, participation rate was higher among the rapid test group clients. The time spent by counsellors as well as total time incurred in the whole process in telephone recruitment, pre-test counselling and HIV screening and post-test counselling for both HIV negative and positive clients were statistically more in the rapid test group than conventional test group. A proportion of rapid test clients but none of conventional test clients did not receive their western blot results; the rapid test results were however completely concordant with the confirmatory results in this study.

B. Client satisfaction of rapid testing

Respondent characteristics

23. Two hundred and twenty-two (99.1%) clients of the rapid test group responded to the satisfaction survey. Not all respondents answered every question: 7 (3.2%) respondents missed one question and 1 (0.5%) missed six questions. A majority of the respondents were male (83.3%). The mean age was 33.7 years, with 84.2% aged between 15 and 44 years old. Most respondents were Chinese (93.7%) and never married (60.6%). Almost all had secondary or above education (96.0%), of which half were tertiary/university or above. Sexual contact was the overwhelming risk exposure: heterosexual (92.3%) and sex between men (6.8%). Ninety-one respondents had tested for HIV antibody before (41.2%); 68 out of 86 respondents had tested 1 or 2 times (79.1%). There were no significant differences in age ($P = 0.432$) and sex ($P = 0.108$) between the 224 participated subjects and the 61 subjects who agreed to join the rapid test group at telephone recruitment but did not attend clinic.

Satisfaction level and most satisfied part

24. “Result available within the same day” was perceived as the most satisfied part of rapid testing (87.3%). This was followed by “rapid test with counselling in risk assessment” (33.9%),

“providing choices of test (rapid test with offer of parallel conventional test)” (33.5%), and “others”, including the attitude of counsellors and painlessness of rapid testing (2.7%).

25. Respondents’ satisfaction level of using rapid test according to agreement or disagreement to 8 opinion statements was summarized in Table 6. All respondents preferred receiving results in the same day and were satisfied with the rapid test. Nearly 40% of respondents found the rapid testing stressful (38.3%). Few respondents found it better to wait for a week before getting any results (5.9%). More than half of the respondents preferred taking blood from finger stuck than vein (57.5%). Nearly all respondents would recommend rapid testing to a friend (97.7%). All respondents understood the meaning of the preliminary result. Most respondents preferred having rapid test even if they have to pay a charge (79.2%). Overall, all questions had an average satisfaction score above 2.5 (range, 2.7-3.8). The mean of the aggregate satisfaction scores of respondents was 3.2 (standard deviation 0.3), indicating that our respondents were well satisfied with rapid test.

Factors associated with satisfaction

26. From univariate analysis of the effect of respondents’ personal characteristics on overall satisfaction score, tertiary/university or above education ($P = 0.029$) and history of HIV antibody testing ($P = 0.031$) were associated with a higher score. Sex, age, marital status, ethnicity and suspected exposure were not significantly associated with the overall satisfaction score (all $P > 0.200$). In multivariate analysis, those with tertiary/university or above education ($B = 1.06$, 95% CI: 0.91-1.21, $P < 0.001$) and history of HIV antibody testing ($B = 1.04$, 95% CI: 0.88-1.20, $P < 0.001$) were still associated with higher overall satisfaction scores. About 95% of variation in the overall satisfaction scores was explained by the regression model.

Open comments

27. Forty-seven clients gave comments to the open-ended question, which were summarized in Table 7. The five most frequent comments were: satisfaction or appreciation of staff's helping attitudes and their performance (29.8%), satisfaction of the process in rapid testing (14.9%), acceptance of paying some but not high charge for rapid testing (14.9%), satisfaction of the testing arrangement (10.6%), and the hope of higher accuracy of rapid test (6.4%). Two letters on appreciation and request of rapid test were received after the satisfaction survey; the excerpts of which are at Table 8.

C. Counsellor acceptance

28. Six nurses (two nursing officers and four registered nurses) participated in the focus group interview. Their years of nursing experience ranged from 13 to 38 years (median 21 years); VCT experience ranged from 1.5 months to 11 years (median 2.25 years). Two of them were involved in the study for 6 weeks and the rest 15 weeks. They conducted a median of >30 rapid tests in this study (Table 9).

29. Nurses' comments regarding offering rapid tests in VCT clinic can be categorized into: (a) product characteristics and procurement procedure, (b) clinic management (time, venue and manpower arrangement, (c) counselling and testing process, and (d) nurses' feelings and perceived capacity to offer training.

Product characteristics and procurement procedure

30. The rapid test kits were considered satisfactory in terms of product quality, except 1) missing of desiccants in one pack of kits, 2) incomplete quality seal up in another pack, and 3) short shelf life (6 months) rendering difficulty in estimating amount of products to be procured. Nurses reckoned that the procurement procedure was tedious. Under most circumstances, procurement of drug and related products for the clinic proceeds through the government pharmacy, which at the

time of study did not have email access. The agency selling the test kit however, must be contacted through email. The clinic nurse therefore became the messenger between the agency and the government pharmacy. This added certain amount of workload to the clinic.

Clinic management

31. Each rapid test needs at least 60 minutes inclusive of pre-test counselling, testing, results turn-around, revelation of result and post-test counselling. Most required 75 minutes on average while it took 90 minutes for a positive case. As for conventional testing for which each session is of shorter duration (normally 30 minutes), the session either stops soon after completion of venepuncture or begins at revelation of results. The longer fixed timeslots necessary for conduction of rapid tests incur inflexibility in the testing schedule, and decrease the number of tests done during each fixed period.

32. The current clinic setting did not facilitate concurrent conduction of more than 2 rapid testing. This problem was partly related to the present study protocol requiring those undergoing rapid tests to undergo conventional testing. Concurrent conduction of more than 2 rapid tests in the present setting would increase possibility of handling error of test kits (mixing up of test kits and improper racking of test kits during result turnover). Nurses raised a query as to whether the testing room must be equipped with a bed (in case when the clients faint or feel dizzy). They were also concerned if the room where the test kit was placed for result turnover should be left open where the result of the test might be read by people passing by.

33. There were occasions where extra nursing staff was required to meet the VCT demand and to meet the service pledge (of offering VCT service within 7 days of booking). Yet, it was felt that the trend of VCTs was difficult to estimate and manpower arrangement was difficult. The need for extra staff may be related to longer time slot required for conduction of each rapid test.

34. All these led to increase in resource implication to conduct the rapid test study. The increase in time required for each test led to increase in manpower and necessitated changes in clinic setting. However, even when these constraints were not overcome and clients need to wait longer to have HIV screening appointment (e.g., 10 days), most clients still opt for the rapid test rather than the conventional one. It was most likely due to the one stop characteristic of rapid tests, which significantly minimizes the duration of intense anxiety during the long result turn-around time.

Counselling and testing process

35. All nurses agreed that the Oraquick test kit was very easy to use. All 5 positive cases diagnosed by rapid tests during the study period had been well prepared to accept a positive status. Nurses considered offering of counselling and revelation of results of rapid tests were not more difficult than those of the conventional test. Nonetheless, there was a limitation in opportunity to offer preventive education and counselling after the test results were disclosed when the clients had stayed in the clinic for about an hour and were eager to leave. As compared to conventional testing where clients came back to the clinic for a second time for the result, during which nurses regarded clients were more willing to disclose his concerns and offered a golden opportunity for preventive education.

36. Two other concerns were raised by nurse counsellors. First, what if the clients request to read the result directly on the test kit. A consensus on handling such request has not been in place. Some nurses admitted showing the result on the test kit, as they thought this can reassure the anxious clients of their results. Second, how to make best use of the turnover time when the clients are anxious and not ready to receive any form of education or counselling. In the present study, clients were asked to complete the satisfaction survey.

Nurses' feelings and perceived capacity to offer training

37. All nurses reported that offering rapid tests was a satisfying experience for them as compared to offering conventional tests. The whole procedure of counselling and testing by rapid test was conducted by one single counsellor who therefore could provide a comprehensive package of service to individual clients from pre-test counselling through post-test counselling. This significantly facilitated rapport building between the clients and the counsellors. Nurses felt especially gratifying for them to reveal the results to the clients they knew from pre-test counselling, and to witness their relief of anxiety and conflicts. It was because very often the test result was an important tool to relieve the anxiety of some patients whom were already assessed by the counsellors as having very low risk of contracting the virus. The counsellor who offered pre-test and post-test counselling might be different for conventional testing, and it has not been uncommon to see clients requesting the same counsellor to offer both.

38. However, nurses expressed worry regarding handling of 'indeterminate' rapid test result. They felt it was difficult to explain clearly its meaning to the clients. As it was routine to offer syphilis testing along the conventional HIV test by venepuncture, nurses felt a bit uncomfortable when it was omitted in case only rapid HIV antibody testing was carried out in the standard package of counselling and testing services. Similar to traditional testing, it was essential to have other nurses as backup to support difficult cases. There was no difference between the rapid and conventional tests in this regard.

39. All nurses expressed confidence in offering rapid tests in the VCT clinic setting. They also felt confident if they were asked to train other people to offer rapid tests. The issues that concern themselves were crisis management, counselling skills, and the context where the tests are going to be offered. They also pointed out that the management and referral of any rapid test positive case would be of paramount importance, given that it is a screening test. The technique required to use the test kit was minimal and would not be a concern for them.

DISCUSSION

40. Rapid test is especially valuable in settings where rapid HIV results are important. For example, a reactive rapid test result in a pregnant woman who present late in labour can be useful to maximise intrapartum and neonatal antiviral prophylaxis for mother-to-child transmission in such clinical situation, while waiting for the final result. In a VCT service, the use of rapid HIV testing also offers several potential advantages to the clients. Firstly, most uninfected clients, which are the bulk of the population, can have counselling and testing completed in one single visit and do not have to attend the clinic again. Secondly, anxiety of waiting for over a week for the result is obviated. Satisfaction of the clients with the process can be improved because they receive their results sooner. Thirdly, clients can receive counselling that is relevant to their HIV infection status on the same day of first visit.

41. Demographic characteristics of subjects in this study are similar to those of the usual clients of AIDS Counselling & Testing Service. A majority of them are Chinese, male, heterosexuals or men who have sex with men. The demographic profile also accords with the HIV-infected population in Hong Kong. Response rate and eventual participation rate of the subjects in this study is considered satisfactory. Rapid test clients had a significantly higher clinic turn up rate for HIV screening. In this study, the below 70% clinic attendance rate in conventional test group was lower than historical attendance of about 80%. However, the full turn up for post-test counselling in conventional test group clients was higher than the 90% service figures.

42. Because of the concern for false negative rapid test result, a parallel conventional HIV antibody test was offered to all rapid test clients on an opt-out approach. This approach proves to be acceptable to clients as none of the rapid test clients opted out the parallel testing. This is despite a separate blood collection through venepuncture besides the finger prick for Oraquick test.

Some clients actually expressed more confidence towards rapid testing with a parallel conventional test.

43. A satisfaction survey using a standard questionnaire was designed to evaluate the clients' satisfaction of using rapid test. Results of the clients' satisfaction survey were very encouraging. Consistent with other studies (Kassler *et al.* 1997; Liu *et al.* 2003), clients preferred to have result available within same day, and our survey showed that same day result was the most satisfaction part in rapid testing. Most clients preferred collection of blood by finger stuck than vein and preferred having rapid test even if a charge is needed. Although some clients found the rapid testing stressful, the overall satisfaction of using rapid test was still high. Client satisfaction is certainly one factor but not all to be considered for the introduction or not of a new service.

44. The use of rapid test kits required minimal technique and even counsellors with little VCT experience found it simple to use in the present study, which may be related to the robustness of the kit. The requirement for counsellors was perceived not too different from those when offering conventional testing. In this study, the high level of specificity (100%) and sensitivity (100%) of the test kits also increased the confidence of the counsellors when conducting rapid tests. As revealed in the focus group discussion, problem areas identified from offering rapid tests mainly arose from its logistic arrangement and resource implication, rather than the process of rapid test per se. Besides client satisfaction, good acceptance on the side of care providers also supports the use of rapid test in HIV VCT setting. Nevertheless, if used in point-of-care setting such as testing of delivering woman or source of needle-stick injury, the immediate result for aiding care decision may paradoxically pose more stress to the service provider. Backup with a parallel conventional test should, however, ease the stress, as further action can be taken when the confirmatory result is available.

45. In the present study, all rapid test clients received their initial HIV antibody results and

tailored counselling. All understood their rapid test results and preferred the procedures. More than 97% of those tested were uninfected. As a consequence, a majority of the clients have their counselling and testing completed in one visit and do not have to attend the clinic again for result clarification. Such single visit would undoubtedly be more convenient for the client than the usual scene of attending the clinic again for antibody result and post-test counselling. For HIV-infected clients who have to attend the clinic for confirmatory result, delivering preliminary positive results might encourage behavioural change (Weinhardt *et al.* 1999).

46. However, the fact that clients request and accept rapid HIV testing does not necessarily mean that they are prepared for their results. It is important that counsellors attend to clients' readiness and explore the extent to which clients are prepared to receive results, particularly for preliminary positive ones. Indeed, in contrast to conventional test, one challenge of rapid test is preparing clients for an "instant" result, which may be positive. That the preliminary positive result may turn out to be true positive or false positive further adds to the complexity. Potential stress on the clients is reflected by that over 30% found the rapid test stressful in the satisfaction survey. Nevertheless, all clients with reactive rapid tests in the present study had been taken care of smoothly by the trained nurse counsellors.

47. It is indisputable to say that the use of rapid tests improved the counsellors' and clients' satisfaction; trade off were increased resource implication including manpower and need to modify clinic management, limitation in opportunity to offer preventive counselling and potential of positive or negative not knowing their confirmatory results. Rapid HIV test alone without blood taking for other investigations also has the disadvantage of not screening for other sexually transmitted infections. Manpower consumption was significantly higher for both HIV positive and negative subjects through longitudinal time logging. This is because more time was spent on explaining rapid test procedure and the meaning of results. Besides, an extra of 20 minutes was required for the rapid test result turn-around time. Due to these logistic requirements, time slots for

VCT using rapid test have to be changed and lengthened. In selected clients, it is possible that intensity of risk reduction counselling is less with single rather than two post-test counselling occasions. We are especially interested and concerned if the use of rapid test will result in more or less clients knowing their final HIV result. In this study, turn up rate in conventional test group clients was unexpectedly high – 100%. As a result, the proportion of both HIV negative and positive clients learning their confirmatory results were lower in the rapid test groups, as some of them did not follow the requirements of calling or re-attending the clinic within 3 months of testing per study protocol. However, as all rapid test results concurred with the western blot results in the present study, practically all of the clients in either group had learnt their HIV status.

48. There are several limitations of this study. Firstly, while the present study aims to examine the feasibility and applicability of using rapid testing in a VCT setting, its design did not allow evaluation of if rapid test can promote the use of VCT service. This would of course be interesting and relevant if more intended clients of VCT service are attracted to use it through the availability of rapid testing. Secondly, the study was not powered to look at the correlation between Oraquick and conventional test results. Previous studies had shown a high sensitivity and specificity of Oraquick in overseas populations. Even though the specificity, sensitivity and predictive values of rapid test were all found to be excellent in the present study, reproducibility of such test results in future, particularly when used on a bigger scale, is unclear. The absence of non-valid rapid test result had facilitated smooth operation of the study. Thirdly, generalisability of the experience of clients and service providers to other HIV testing settings is also questionable. Each individual setting and client population has its unique features and needs. Tailored specific evaluation of rapid test use might be required for each setting. Also, it has to be acknowledged that different testing environments can affect the rapid test performance and the good results in this study may or may not be reproducible. Conceivably, more difficulties would be encountered when rapid test is employed in outreach settings for the hard-to-reach marginalised populations, including the arrangement for confirmatory test, post-test counselling and referral of positive client for follow up

care. Fourthly, we only studied manpower but not other monetary and non-monetary costs of rapid test vs. conventional test. Fifthly, the present study was not meant to identify who are the “best” clients for rapid test. Nevertheless, some lights were shed on this issue through the conduct of this study.

49. From this pilot study, staff working at VCT service gained experience in using rapid test kit. A protocol for implementation of rapid testing at VCT clinic was developed and field-tested. Capacity was built on effectively developing and implementing targeted strategies for the in-need clients. The experience and capacity would be useful for supporting other AIDS workers who choose rapid HIV tests for clinical and public health purposes in future. Findings from the study support that VCT service is an appropriate setting for using rapid test but optimal and effective use of such tool remains a big challenge. Application of rapid testing in point-of-care settings to clarify HIV status for decision making is well established. In our VCT setting, we would not encounter pregnant women in labour with unknown HIV status for which rapid test is extremely helpful. Testing source clients in occupational exposure may rarely be encountered by us. One possible application is the scenario of partner counselling and referral. Partners of known infected patients often suffer from big stress due to the excess risk of being infected. There were three clients whose partners were HIV positive in this study; they expressed great relief when they knew their rapid test results were negative. The big satisfaction towards rapid test may possibly attract more clients to undergo test; hence improving access of HIV testing. Clients who are most satisfied with rapid test may be targeted for that. In this study, these are clients with higher education level and with prior HIV antibody testing. On the other hand, attracting more people to undergo HIV testing would be most valuable for the vulnerable community groups; more so if they belong to hard-to-reach populations. Finally, it should not be forgotten that rapid test was first advocated overseas to increase the proportion of tested clients knowing their HIV status. This is certainly more meaningful for positive patients whose knowledge will have implications on clinical care of

the client as well public health control of HIV spread. Needless to say, obtaining consent from a client for HIV testing is a must irrespective of using conventional or rapid test method.

50. In summary, rapid testing means much more than just a finger-prick. Appropriate counselling was reckoned as equally crucial when offering a comprehensive HIV VCT service. In fact, it was the quality of counselling and the comprehensive service package from counselling, testing, care and referral that were perceived by the counsellors as the key assets of YMT VCT clinic. Such quality should be upheld regardless of providing conventional testing, rapid testing or both. The excellent test performance, high client satisfaction and good counsellor acceptance coupled with increased resource implication support the introduction of rapid test in selected VCT clients. Prime consideration is whether there is added impact with the test. Impact on learning of HIV status in positive / at risk clients, prompt referral for care of positive patients, immediate relief of stressed clients at increased risk of infection, improving access to testing and knowledge of HIV status in vulnerable communities are principles to be considered for introducing the test.

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TABLES & FIGURES

	<u>Rapid test group</u>	<u>Conventional test group</u>
Recruitment at telephone booking		
Invited	308	154
	↓	↓
Accepted	285	144
	↓	↓
Attended clinic and participated in the study	224	98
	↓	↓
Completed satisfaction survey (rapid test clients)	222	
	↓	↓
Received confirmatory result by visit or phone call (eligible rapid test clients)	195	98

Figure 1. An overview of the number of clients in rapid test and conventional test groups going through different stages of the study.

Table 1. Recruitment during telephone booking for HIV antibody test

	Rapid test group (n = 308) No. (%)	Conventional test group (n = 154) No. (%)	P-Value
Recruitment			
Agreed	285 (92.5)	144 (93.5)	0.702
Refused	23 (7.5)	10 (6.5)	

Table 2. Gender, age and participation rate of the telephone recruited clients (n=429)

	Rapid test group (n = 285) No. (%)	Conventional test group (n = 144) No. (%)	P-Value
Sex			
Male	234 (82.1)	120 (83.3)	0.752
Female	51 (17.9)	24 (16.7)	
Age (years)			
Mean, standard deviation	33.3 , 11.0	32.6 , 10.0	0.741
Median	31	30.5	
Range	15 - 73	15 - 69	
Attended clinic and joined the study			
Yes	224 (78.6)	98 (68.1)	0.017*
No	61 (21.4)	46 (31.9)	

*P<0.05

Table 3. Demography of subjects who attended clinic and participated in the study (n=322)

	Rapid test group (n = 224) No. (%)	Conventional test group (n = 98) No. (%)	P-Value
Sex			
Male	186 (83.0)	85 (86.7)	0.403
Female	38 (17.0)	13 (13.3)	
Age (years)			
Mean, standard deviation	33.8 , 11.0	33.4 , 10.2	0.875
Median	31	32	
Range	16 - 73	17 - 69	
Marital Status			
Married	82 (36.8)	34 (34.7)	0.784
Divorced/Separated/Widowed	7 (3.1)	2 (2.0)	
Never Married	134 (60.1)	62 (63.3)	
Ethnicity			
Chinese	210 (93.8)	93 (94.9)	0.688
Non-Chinese	14 (6.3)	5 (5.1)	
Education Level			
No schooling or Primary	9 (4.0)	3 (3.1)	0.902
Secondary	106 (47.5)	48 (49.0)	
Tertiary/university or above	108 (48.4)	47 (48.0)	
Suspected exposure			
Heterosexual contact	206 (92.4)	83 (84.7)	0.034*
Non-Heterosexual contact	17 (7.6)	15 (15.3)	
Ever tested for HIV			
Yes	97 (43.3)	48 (49.0)	0.346
No	127 (56.7)	50 (51.0)	

*P<0.05

Table 4. Knowledge of conventional HIV antibody test results and referral for HIV care (n=322)

	Rapid test group (n = 224) No. (%)	Conventional test group (n = 98) No. (%)	P-Value
HIV conventional test result			
Negative	219 (97.8)	97 (99.0)	0.671
Positive	5 (2.2)	1 (1.0)	
Attended for conventional test result			
Yes, by clinic attendance	15 (6.7)	98 (100.0)	-
Yes, by phone call for eligible cases	180 (80.4)	-	
No, within 3 months	29 (12.9)	0 (0.0)	
HIV antibody positive	2		
HIV antibody negative	27		
Referral made for the client (HIV positive)			
Yes	3 (60.0)	1 (100.0)	1.000
No	2 (40.0)	0 (0.0)	

Table 5. Process and outcome evaluation of the pilot HIV rapid test study

Indicator	Rapid test group	Conventional test group	P-value	Definition
<i>Study participation</i>				
Recruitment rate	92.5%	93.5%	0.702	Denominator = no. systematically sampled to the test group Numerator = no. agreed
Participatory rate	78.6%	68.1%	0.017	Denominator = no. agreed to join the test group of the study Numerator = no. attended clinic and participated
Opt-out rate of parallel conventional test in rapid test group	0%	-	-	Denominator = no. participated in the rapid test group Numerator = no. having rapid test only
<i>Time implication for client and service provider</i>				
Total time spent (minutes) by counsellors in recruitment, pre-test counselling & HIV screening and post-test counselling for HIV negative subjects (mean, median)	72.4, 71.0	46.1, 43.0	<0.001	Only subjects who completed all required steps are included. (Excluded time spent in telephone support)
Total time spent (minutes) by counsellors in recruitment, pre-test counselling & HIV screening and post-test counselling for HIV positive subjects (mean, median)	147.0, 135.0	135.0, 135.0	<0.001	Only subjects who completed all required steps are included. (Excluded time spent in telephone support)
Proportion requiring one clinic visit to learn all test results in the rapid test group (Include both HIV negative and positive cases)	92.3%	-	-	Denominator = no. of subjects who completed all required steps Numerator = no. of subjects who required one clinic visit to learn all test results
<i>Result conveyance and follow-up</i>				
Proportion of reactive rapid test subjects having concomitant conventional test	100%	-	-	Denominator = no. of subjects with reactive rapid test Numerator = no. who had a concomitant conventional test
Proportion of HIV negative subjects who know and are counselled of their final test result	87.7	100%	0.001	Denominator = no. of HIV confirmed negative (take conventional test result if done) subjects Numerator = no. who had completed all required steps per study protocol
Proportion of HIV positive subjects who know and are counselled of their final test result	60.0%	100%	1.000	Denominator = no. of confirmed HIV positive subjects Numerator = no. who had completed all required steps per study protocol
Proportion of HIV positive subjects referred for care	60.0%	100%	1.000	Denominator = no. of confirmed HIV positive subjects Numerator = no. who were referred for care

Table 6. Satisfaction level with rapid testing

	No. (%) of respondents (n = 222)				Score	
	SA	A	D	SD	Mean	StD
I prefer receiving my results the same day	175 (78.8)	47 (21.2)	0 (0.0)	0 (0.0)	3.8	0.4
*I found the rapid testing stressful	25 (11.3)	60 (27.0)	103 (46.4)	34 (15.3)	2.7	0.9
*It would have been better to wait a week before getting any result	2 (0.9)	11 (5.0)	111 (50.2)	97 (43.9)	3.4	0.6
I would rather have my finger stuck than have blood drawn from my vein	40 (18.1)	87 (39.4)	83 (37.6)	11 (5.0)	2.7	0.8
I would recommend rapid testing to a friend	81 (36.7)	135 (61.1)	5 (2.3)	0 (0.0)	3.3	0.5
I understand the result of my rapid test	87 (39.4)	134 (60.6)	0 (0.0)	0 (0.0)	3.4	0.5
I am satisfied with the rapid test	102 (46.2)	119 (53.8)	0 (0.0)	0 (0.0)	3.5	0.5
I prefer having rapid test even if I have to pay a charge	35 (15.8)	140 (63.3)	34 (15.4)	12 (5.4)	2.9	0.7

Notes: SA = Strongly agree, A = Agree, D = Disagree, SD = Strongly Disagree and StD = standard deviation

For positive scoring, SA=4, A=3, D=2, SD=1. * denotes reverse scoring, i.e. SA=1, A=2, D=3, SD=4.

Table 7. Rapid test clients' open comments

	Respondents (n = 47)
	No. (%)
Satisfaction/appreciation of staff's helping attitudes and their performance	14 (29.8)
Satisfaction of the process in rapid testing e.g. quick, painless and result available within minutes	7 (14.9)
Acceptance of paying some but not high charge for rapid testing	7 (14.9)
Satisfaction of the testing arrangement in our service e.g. booking and testing with counselling and risk assessment	5 (10.6)
Hope of higher accuracy of rapid test as stressful during waiting period for conventional test result	3 (6.4)
Satisfaction of contacting only one counsellor throughout the rapid testing	2 (4.3)
Stress during waiting period for rapid test result	2 (4.3)
Acceptance of conventional test with rapid test	2 (4.3)
Provision of rapid test for tested person in future	2 (4.3)
Increase of education on AIDS and rapid testing	2 (4.3)
Longer VCT service hours	2 (4.3)
Computerization of VCT system	1 (2.1)
Strength of psychological counselling	1 (2.1)
Increase the provision of information on rapid test for the tested person	1 (2.1)
Hope of negative result in rapid test	1 (2.1)
Suggest risk assessment during waiting period for rapid test result	1 (2.1)
All read conventional test result by clinic attendance	1 (2.1)
Anxious about recent sexual contact	1 (2.1)

Note: Respondents can give more than 1 comment

Table 8. Excerpts of letters from two rapid test clients after the study ended

Letter (1)

I have had my rapid test done on 13/5 at Yau Ma Tei. I would like to give some of my opinion to the test and process. The rapid test itself took 20 minutes to have the result ready on spot. It is great news for those suspect one self have been infected by the virus.

.....

Anyway I do appreciate of the availability of the rapid test so I don't have to wait for another 10 days to read the result (less 10 days of fear). In my opinion, it is good to have the test on spot as people need to take up lot of courage to perform the test and this courage might "goes out" after taking the test, therefore some might not go back to read the result. That will distort the preventive meaning of the test as some infected person doesn't go back for result that makes the situation even worse.

.....

In conclusion, I do appreciate the availability of the rapid test and the high quality standard of personnel in counselling.

Thanks

Letter (2)

I would like to express my views on your free and anonymous HIV Testing.

.....

My experiences with the staff at Yau Ma Tei clinic were very pleasant and your recent research project with the rapid test showed that Hong Kong is a modern place. The rapid test cut the long waiting time and complicated procedures. However, as I was undertaking a test recently I was shocked that the Department of Health stopped the HIV rapid test research project and went back to the old traditional test which requires the tester to come to the clinic twice and which again takes longer than 10 days.

.....

Table 9. Experience of nurse counsellors who participated in the study

	Nurse 1	Nurse 2	Nurse 3	Nurse 4	Nurse 5	Nurse 6
Year of nursing experience (year)	20	22	38	13	15	26
Year of VCT experience (year)	2.5	<1	7	1.5 months	2	11
Period of participating in doing rapid test (week)	6	15	15	6	15	15
Approximate number of rapid tests conducted	30	60	35	10	60	5

Brief Introduction for Pilot Rapid Test Study

We have been offering free, anonymous, confidential HIV antibody screening by enzyme immunosorbent assay (EIA) test and Western blot for confirmation since 1994. The EIA (conventional test) is the standard screening test used to detect the presence of antibodies to HIV. It takes about 10 days for the result after blood taking. Clients are advised to call up for appointment booking for conventional result reading.

We are now undergoing a study offering clients with Rapid Test for HIV antibody screening parallel with conventional EIA test. Some clients may need to come back to see the result or confirm the conventional test result by phone. The rapid test takes around an hour and the advantage of this test is that clients can read their result on the same day of the test. The sensitivity and specificity of the test is over 99%. If the result turns up to be positive, it is only treated as a preliminary result. We will do another test to confirm your status.

Official Use:
Case No. : _____

Satisfaction Survey for Rapid Test

Date : ___/___/___(dd/mm/yyyy)

Study Code : Q_____

(1) Have you ever have HIV antibody testing before?

1. Yes, please specify times _____
2. Never

(2) What test did you had this visit?

1. rapid test
2. rapid test with conventional screening test

(3) What do you find most satisfied with? (choose 1 or more)

1. result available within the same day of rapid testing
2. providing choices of test (rapid test with offer of parallel conventional test)
3. rapid test with counselling in risk assessment
4. Others, please specify _____

(4) Do you agree with the followings?

A. "I prefer receiving my result the same day"

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

B. "I found the rapid testing stressful"

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

C. "It would have been better to wait a week before getting any results"

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

D. "I would rather have my finger stuck than have blood drawn from my vein."

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

E. "I would recommend rapid testing to a friend."

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

F. "I understand the result of my rapid test."

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

G. "I am satisfied with the rapid test."

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

H. "I prefer having rapid test even if I have to pay a charge."

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree

(5) Other comments, please specify

THANK YOU

Case No.: _____

快速測試問卷調查

Date: ____/____/____(dd/mm/yyyy)

Study Code: Q_____

1. 你過去曾否接受愛滋病病毒抗體測試？
 - 1) 有，請列明次數 _____
 - 2) 無

2. 你已採用以下那種測試？
 - 1) 快速測試
 - 2) 快速測試及傳統測試

3. 請選出你最滿意的部份？（可選擇一個或以上）
 - 1) 快速測試可於即日內知道結果
 - 2) 可選擇測試方式（傳統及快速測試）
 - 3) 快速測試並提供風險評估
 - 4) 其他，請列明 _____

4. 你是否同意以下的說法：
 - A ‘我希望在測試當日知道結果’
 1. 非常同意
 2. 同意
 3. 不同意
 4. 非常不同意

 - B ‘採用快速測試令我非常緊張’
 1. 非常同意
 2. 同意
 3. 不同意
 4. 非常不同意

 - C ‘我寧願多等一週才知道測試結果’
 1. 非常同意
 2. 同意
 3. 不同意
 4. 非常不同意

D ‘我寧願從指尖採血也不願通過靜脈抽血’

1. 非常同意
2. 同意
3. 不同意
4. 非常不同意

E ‘我會推薦朋友用快速測試方法’

1. 非常同意
2. 同意
3. 不同意
4. 非常不同意

F ‘我明白快速測試的結果’

1. 非常同意
2. 同意
3. 不同意
4. 非常不同意

G ‘我滿意快速測試方法’

1. 非常同意
2. 同意
3. 不同意
4. 非常不同意

H ‘假若快速測試需要收費，我也願意接受’

1. 非常同意
2. 同意
3. 不同意
4. 非常不同意

5. 其他意見

謝謝

Design and Workflow of the Study



*data collection points for evaluation

Guiding Questions of the Focus Group Discussion

1. How would you comment about using rapid test in VCT clinics (In terms of work process, arrangement, manpower implications etc)? What are the problems encountered when offering rapid tests, as compared to conventional tests? How did you handle and how to prevent the same problem from recurring?

2. How's your feeling about using rapid test in VCT clinics? How comfortable/ confident about doing this?

3. How would you feel if you are now asked to train others to use rapid test?

4. Do you have any other comment about the use of rapid test?

自願性參與口頭承諾書

本人_____（參與號碼）同意參與‘愛滋病病毒抗體快速測試試驗計劃’目的是檢視快速測試在自願性愛滋病病毒抗體測試及輔導診所的可行性。本人明白受驗者將會被分為不同組別以接受靜脈抽血或快速測試以作比較。本人亦明白若被編入快速測試組別，亦將同時接受靜脈抽血測試。無論本人同意參與是項試驗計劃與否，本人只須提供需要的個人資料，同時亦被確保能獲得同等的對待。本人明白在參與是項試驗計劃中可隨時退出。

Consent form for verbal consent by client

I _____ (study code) agree to participate in the study ‘Pilot testing of OraQuick HIV-1/2 rapid test in Voluntary Counselling and Testing Clinic’, which examines the feasibility and subjects are sampled into either conventional testing group or rapid test group for comparison. I understand that I am offered a parallel conventional test if I am in the rapid test group. I understand that I will not be denied of access to care if I refuse to participate in the study. I do not need to give personal particulars for joining the study, other than that required for the usual service provision. I understand that I can withdraw from the study any time during my participation.

Explained by: _____
(Block Letters): _____