Journal of Associated Medical Sciences 2019; 52 (1): 42-47

JAMS
Journal of Associated Medical Sciences

Thai-Journal Citation Index Centre (TCI) & ASEAN Citation Index (ACI)

Journal of Associated Medical Sciences

Journal homepage: https://www.tci-thaijo.org/index.php/bulletinAMS/index

Accuracy performance of an oral fluid-based HIV rapid diagnostic test to scale up the opportunity for treatment and prevention in Thailand

Apisada Rasmi[1*] Jurairat Ratanalertnavee[2] Sutthisak Ngamvachiraporn[3]

[1]Bamrasnaradura Infectious Diseases Institute, Department of Disease Control, Ministry of Public Health, Nonthaburi Province, Thailand
[2]Takuapa Hospital, Phang Nga Provincial Health Office, Office of the Permanent Secretary, Ministry of Public Health, Bangkok, Thailand
[3]Rajprachasamasai Institute, Department of Disease Control, Ministry of Public Health, Samut Prakan Province, Thailand

ARTICLE INFO

Article history:
Received 28 May 2018
Accepted as revised 16 October 2018
Available online 2 November 2018

Keywords:
Oral fluid HIV test, HIV rapid test, diagnostic test evaluation

ABSTRACT

Background: Rapid HIV tests increase an opportunity to access HIV testing, especially for high risk groups. One of the interesting approaches is oral HIV self-testing. However, performance of oral HIV test has not yet been evaluated in Thailand.

Objectives: To evaluate the performance of an oral fluid HIV rapid test for detecting recent HIV infection

Materials and methods: Men who have sex with men (MSM), transgender (TG) and female sex workers (FSW) were recruited in Bangkok, Chonburi, and Phuket. All participants were screened HIV status by oral fluid (OraQuick), whole blood (Alere Determine HIV-1/2 Ab), and plasma (Elecsys HIV combiPT). Discordant results were confirmed by nucleic acid amplification test. Performance of oral fluid and whole blood HIV rapid tests were evaluated by MedCalc's Diagnostic test. MacNemar's exact test was used to compare the numbers of detected HIV-infected participants.

Results: Five hundred and twenty nine participants were enrolled to perform HIV testing, including MSM/TG (n=289, 54.63%) and FSW (n=240, 45.37%). There were 68, 69 and 71 reactive cases from oral fluid, whole blood and plasma, respectively. Concordant reactive results among three tests were found in 64 participants, whereas 11 participants showed discordant results. Four false positive and seven false negative cases with oral fluid test were exhibited. Among false negative participants, two cases were recent infection, by which one case has received antiretroviral drugs during last 60 days. Oral fluid test had 90.14% (95% CI 80.74-95.94) sensitivity, 99.13% (95% CI 97.78-99.76) specificity and 97.92% (95% CI 96.31-98.96) accuracy. This test could detect fewer infections than those of whole blood (p=0.0019) and plasma (p=0.0057).

Conclusion: This study demonstrated that oral fluid test could detect fewer HIV infections than blood-based HIV tests since recent HIV-infected MSM/FSW were undiagnosed. Thus, this test might be inappropriate for high risk and general populations who receiving antiretroviral therapy.

Introduction

HIV is one of the most frequently addressed pathogens that has been targeted in the millennium. At the end of 2016, there were approximately 36.7 million persons living with HIV (PLWH) and 3.5 million persons in South-East Asia.[1] Knowing of HIV status is the key to early access to HIV treatment and prevention services. In 2014, UNAIDS announced 90-90-90 target and goal to end AIDS by 2030.[2] The strategies of this target and goal were at least 90% of HIV-infected people knew their status, and at least 90% of those who knew their status obtained antiretroviral therapy (ART), and at least 90% of those who received ART were

* **Corresponding author.**
Author's Address: Bamrasnaradura Infectious Diseases Institute, Department of Disease Control, Ministry of Public Health, Nonthaburi Province, Thailand
** **E-mail address:** : apisadar@yahoo.com
doi: 10.14456/jams.2019.8
E-ISSN: 2539-6056

viral suppressed. The initial step to reach the United Nations' 90-90-90 targets to end the HIV epidemic was 90% of people living with HIV to learn their HIV status. Therefore, HIV testing is essential for achieving "the first 90". Approximately 30% of people with HIV are unaware of their infection in world-wide.[1] The only way to determine a person's HIV status is the HIV testing. In many countries, critical gaps exist in HIV services, including prevention, testing and treatment. There is an opportunity to prevent 1.5 million infections per year by 2020 and reach the "fast-track" goals if we can improve prevention and testing services, as well as ensure high-quality, well-adhered-to treatment and care for all.[3] In Thailand, Reach-Recruit-Test-Treat-Retain (RRTTR) program has urged to scale up HIV prevention and treatment services among undiagnosed PLWH, especially for high risk groups, such as men who have sex with men (MSM), transgender (TG), sex workers, prisoners, people who inject drugs (PWID) and migrants. However, passive services and stigma are barriers to approach HIV testing. Mobile service at Drop in Center (DIC) and brothels using whole blood rapid HIV tests has been implemented at health care centers for professional use since 2014 in order to expand the access for HIV testing to non-clinical sites and provide an opportunity for faster linkage to treatment and care.[4-5] Moreover, rapid HIV tests have given the same-day results within 30-60 minutes. In 2004, rapid test using oral fluid (OraQuick Advance Rapid HIV-1/2 Antibody Test; OraSure Technologies, INC., Bethlehem, Pennsylvania, USA) was approved by US Food and Drug Administration (FDA) and it was approved for home use in 2012.[6] The widespread enlargement of home-based HIV testing in USA and new supervised self-testing initiatives in sub-Saharan Africa have occurred since 2006. Oral fluid HIV testing has constituted as one of the most favorite point-of-care test (POCT).[7,8] It is likely to satisfy patients due to the rapid result, non-invasive and pain-free specimen collection.[9-11] Nevertheless, HIV tests using oral fluid have not yet been approved for diagnostic purpose in Thailand.[12-13] The aim of this study was to compare the performance of oral fluid HIV test (OraQuick) with whole blood (Alere Determine HIV-1/2 Ab) and plasma (Elecsys HIV combiPT) in order to detect recent HIV infection.

Materials and methods

Study design and participants

During January-June 2015, this study was conducted in RRTTR program, AIDS ZERO Plan of Thailand at DIC and three mobile HIV testing services, including Bangkok, Chon Buri, and Phuket. High risk populations (MSM, TG and FSW) aged more than 15 years old were recruited, by which they had unknown or negative HIV status and no antiretroviral uptake (pre-exposure Prophylaxis (PrEP) and post-exposure prophylaxis (PEP)) within last two months to avoid false negative results by using oral fluid. Writing or verbal consent was given by all participants. They were received counseling before getting the HIV test in oral fluid, whole blood and EDTA plasma. This study was approved by Department of Disease Control, Ministry of Public Health, Thailand.

HIV testing

One rapid HIV test in oral fluid (OraQuick Advance Rapid HIV-1/-2 Antibody Test, OraSure Technologies, Bethlehem, PA, USA, 5 µL) and three whole blood HIV POCTs were used. Alere Determine HIV-1/2 (Inverness Medical Japan Co., Ltd., Japan, 50 µL) was used for screening. Any HIV-reactive whole blood specimens were confirmed by using DoubleCheckGold Ultra HIV1&2 (Organics LTD., Israel, 25 µL) and SD Bioline HIV-1/2 (Standard Diagnostics, Inc. Korea, 10 µl). All EDTA plasma specimens were also tested by 4thgen EIA (Elecsys HIV Combi PT, Electrochemiluminescence Immunoassay, Roche Diagnostics GMBH, Germany, 40 µL). Any HIV-reactive plasma specimens were tested by using Alere Determine HIV-1/2, DoubleCheckGold HIV1&2 and SD Bioline. Discordant result cases were confirmed by HIV Ag EIA (Elecsys HIV Ag, Electrochemiluminescence Immunoassay, Roche Diagnostics GMBH, Germany, 40 µL) and nucleic acid amplification test (NAAT, Cobas ampliPrep/Cobas TaqMan HIV-1 test, version 2.0, Roche Molecular Systems, Inc., USA, 1,000 µL). For the participants who had discordant HIV results among three specimens, new EDTA plasma were collected within 14 days in order to identify recent infection by using HIV Ag EIA, Determine HIV-1/2 Ag/Ab Combo (Determine Combo, Alere Inc., Japan, 50 µL) and NAAT.

Quality control measurements of HIV tests were done. Medical technologists who performed OraQuick were well-trained on biological principles of the test, kit storage, specimen collection, testing, interpretation and quality control by OraSure personnel staffs. Other HIV tests were assayed together with internal quality control (IQC) panels provided by Department of Medical Sciences, Ministry of Public Health. The OraQuick and Determine Combo have not yet been approved in Thailand. Therefore, method verification is needed before use. Both test kits passed our verification with in-house panels (three known HIV status volunteers) including HIV-negative antigen/antibody, HIV-positive antigen and HIV-positive antibody.

Statistical analysis

The diagnostic performance of oral fluid and whole blood HIV rapid tests were comprised of accuracy, sensitivity, specificity, false positive (FP), false negative (FN), positive predictive value (PPV), and negative predictive value (NPV) by using MedCalc's Diagnostic test evaluation calculator (free statistical calculators).[14] McNemar's exact test was used to compare the numbers of detected HIV-infected participants.[15]

Results

A total of 529 participants were recruited including 289 MSM/TGs and 240 FSWs. Results of OraQuick, Determine HIV-1/2 and Elecsys HIV Combi PT tests were shown in Figure 1A. OraQuick was found to be reactive in 68 cases. Sixty-nine HIV-reactive cases by Determine HIV-1/2 had concordantly reactive results with doubleCheckGold, SD Bioline HIV-1/2 tests and Elecsys HIV Combi PT. Two participants, who were HIV- reactive with Elecsys HIV Combi PT but non-reactive with doubleCheckGold, SD Bioline HIV-1/2

tests and Determine HIV -1/2 tests, were positive by Elecsys HIV Ag and NAAT.

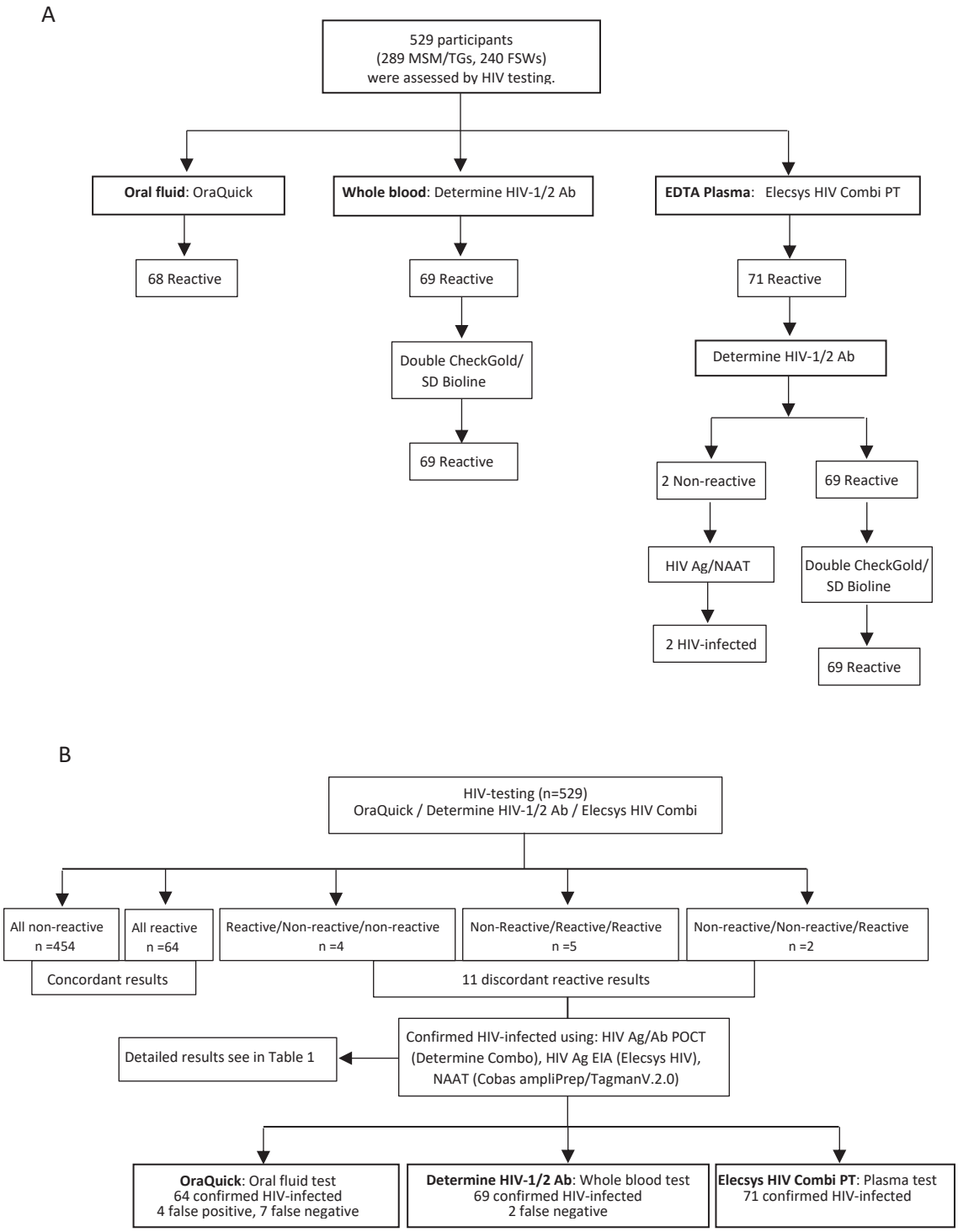

Figure 1 *The algorithm and HIV testing results in this study A) The HIV results of oral fluid, whole blood and plasma-based HIV testing. B) Eleven discordant results were identified for early HIV infection.*
OraQuick, OraQuick Rapid HIV-1/2 antibody test; 4th gen EIA, 4th generation Electrochemiluminescence Immunoassay - Elecsys HIV Combi PT; HIV Ag EIA, Electrochemiluminescence Immunoassay - Elecsys HIV Ag; HIV Ab POCT, HIV antibody point of care test, NAAT, Nucleic-acid amplification test - Cobas AmpliPrep/Tagman V.2.0; For screening test, Determine HIV-1/2 Ab; For supplementary tests, Double CheckGold and SD Bioline.

Concordant reactive results among three specimen types were found in 64 (12.10%) cases, whereas 11 (2.08%) cases had discordant results as shown in Figure 1B and Table 1. Four out of 11 cases were only reactive by OraQuick (false positive), while seven cases were non-reactive (false negative). Only five participants were concordantly reactive by Determine HIV-1/2, Elecsys HIV Combi PT and NAAT. Interestingly, two participants that were non-reactive by both OraQuick and Determine HIV -1/2, were positive by Elecsys HIV Combi PT, Elecsys HIV Ag and NAAT. Overall, 71 (13.42%) HIV-infected participants were detected. There were significantly different between OraQuick compared to 4th gen EIA, Elecsys HIV Combi PT (p=0.0057) and Alere Determine HIV -1/2 (p=0.0019) (Table 1).

Table 1. Discordant results of HIV testing among participants in this study.

No	Risk groups	Rapid HIV testing[a]						Elecsys HIV Combi PT (4th gen EIA)	HIV Ag Elecsys HIV (EIA)	HIV RNA (copies/mL)
		OraQuick[b]	Determine HIV-1/2 Ab	Double check gold	SD Bioline	Determine combo				
						Ag	Ab			
1	MSM	-	+	+	+	+	+	+	+	380,000
2	MSM/TG	-	+	+	+	+	+	+	+	474,000
3	MSM	-	+	+	+	-	+	+	+	291,000
4	MSM	-	+	+	+	-	+	+	-	49,200
5	MSM/TGc	-	+	+	+	-	+	+	-	29,800
6	MSMd	-	-	-	-	+	-	+	+	10,000,000
7	FSWe	-	-	-	-	-	-	+	+	117,800
8	MSM	+	-	-	-	-	-	-	-	ND
9	MSM/TG	+	-	-	-	-	-	-	-	ND
10	MSM/TG	+	-	-	-	-	-	-	-	ND
11	MSM	+	-	-	-	-	-	-	-	ND

Ag, antigen; Ab, antibody; EIA, enzyme Immunoassay; ND, Not done; MSM, men have sex with men; TG, transgender; FSW, female sex worker

a Oral fluid-based test: OraQuick; Whole blood-based test: Determine HIV-1/2 Ab, Double check gold, SD Bioline.

b Significant differences were found when compared to Elecsys HIV Combi PT (p=0.0057) and Determine HIV-1/2 Ab (p=0.0019).

c This participant had the history of antiretroviral drug uptake (Prep and PEP) for several times during last 60 days.

d This participant was acute Infection that OraQuick and Determine HIV-1/2Ab gave the non-reactive results but Determine Combo antigen was reactive. HIV RNA was >10,000,000 copies/mL and EIA HIV Ag/Ab was reactive. After two weeks, all HIV Ab tests were reactive, while oral fluid test was still non-reactive.

e OraQuick and Determine HIV-1/2 Ab had the non-reactive results. HIV RNA was 117,800 copies/mL and HIV Ag/Ab EIA test was reactive. After two weeks, all HIV Ab tests were reactive, while oral fluid test was still non-reactive.

Performance evaluation of OraQuick and Alere Determine HIV-1/2 compared with HIV status was shown in Table 2. OraQuick sensitivity (90.14%, 95% CI 80.74-95.94) was lower than Alere Determine HIV-1/2 (96.97%, 95% CI 89.48-99.63), while Alere Determine HIV-1/2 specificity (100%, 95% CI 99.21-100.00) was slightly greater than OraQuick (99.13%, 95% CI 97.78-99.76). The PPV of OraQuick (94.12%, 95% CI 85.74-97.71) was lower than Alere Determine HIV-1/2 (100.00%) although the NPV of OraQuick (98.48%, 95% CI 96.98-99.24) and Alere Determine HIV -1/2 (99.57%, 95% CI 98.34-99.89) were comparable. Accuracy of OraQuick and Alere Determine HIV-1/2 were 97.92% (95% CI 96.31-98.96) and 99.62% 95% CI 98.64-99.95), respectively. Additionally, there were 0.87% FP and 9.86% FN with OraQuick, as well as 0% FP and 3.03% FN with Alere Determine HIV-1/2.

Table 2. Performance evaluations of oral fluid rapid HIV test and whole blood HIV test compared with HIV status[a]. (n=529)

Statistical parameter	OraQuick Advance Rapid HIV-1/2[b]	Alere Determine HIV-1/2[c]
	Value (95% CI)	Value (95%CI)
Sensitivity	90.14% (80.74-95.94)	96.97% (89.48-99.63)
Specificity	99.13% (97.78-99.76)	100% (99.21-100.00)
Positive Likelihood Ratio	103.21 (38.79-274.66)	-
Negative Likelihood Ratio	0.10 (0.05-0.20)	0.03 (0.01-0.12)
Disease prevalence	13.42% (10.63-16.63)	12.48% (9.78-15.60)
Positive Predictive Value	94.12% (85.74-97.71)	100.00%
Negative Predictive Value	98.48% (96.98-99.24)	99.57% (98.34-99.89)
Accuracy	97.92% (96.31-98.96)	99.62 (98.64-99.95)
False Positive	0.87%	0%
False Negative	9.86%	3.03%

[a] HIV status: diagnosed by physical examination and risk behavior in the past. More than two-thirds of HIV Ab tests were reactive. HIV RNA was detected by NAAT and HIV Ag tests were reactive.

[b] Oral fluid-based test

[c] Whole blood-based test

Discussion

This study demonstrated that performance (sensitivity, specificity, PPV, NPV, accuracy) of oral fluid HIV test was lower than those of whole blood HIV test. In contrast, FP and FN of HIV test with oral fluid were greater than whole blood. Oral fluid test was unable to diagnose in seven HIV-infected MSM/TG/FSWs, by which early infection was found in two cases. One of them was acute infection confirmed by HIV Ag test and NAAT (HIV RNA 10,000,000 copies/ml). However, this participant was able to be detected by rapid HIV Ag/Ab test (Determine Combo). The other participant seemed to be in window period since it could not be detected by all rapid HIV tests (Table 1). The NPV of oral fluid HIV test was 98.48%, suggesting that the non-reactive result with oral fluid was more correct in high risk populations (MSM/TG/FSW) when no recent HIV infection has occurred. Moreover, the infected participants who had several antiretroviral drug uses (Prep and PEP) for last 60 days (No. 5, Table 1) showed the false non-reactive result with oral fluid test. Similarly, the previous studies have found false-negative results in participants who had ART.[16-21] Nevertheless, non-reactive results of oral fluid test in participants taking antiretroviral drugs were found to be HIV-positive afterward.[16-18] One study has explained that antiretroviral drugs might decrease glycoprotein (gp) 41 production, which used as the target antigen to detect HIV Ab in OraQuick test.[16] In fact, the quantity of HIV Ab in oral fluids was lower than whole blood and plasma, especially who had effective antiretroviral drugs.[19] A study in PWID from Thailand has indicated that oral fluid test in participants who received pre-exposure prophylaxis took longer to develop the reactive result. Blood-based HIV tests might thus be more appropriate.[20]

The PPV of 94.12% in these high risk populations also suggested that the oral fluid HIV test was beneficial for screening because it could provide the rapid result with non-invasive handing. However, the reactive result was needed to be confirmed by other HIV tests.[22] In this study, rapid HIV testing in whole blood using Alere Determine HIV-1/2 showed the comparable performance with Elecsys HIV Combi PT (EIA). No false reactive and two false non-reactive were observed in participants who had HIV antigen positive. Antigen reactive band was detected by whole blood HIV Ag/Ab test in one case (No. 6, Table 1). Whole blood HIV Ag/Ab test would thus be suitable for rapid screening in high risk and hard accessible groups.

According to our study, the performance of oral fluid HIV test was less accurate than blood-based tests that have also been shown in several studies.[23-26] In high HIV prevalence populations, the rapid HIV testing are appropriate for enhancing epidemic HIV control in mobile setting. If possible, whole blood rapid HIV Ag/Ab test should be the first screening test since it is able to detect both HIV antigen and antibody. In addition, it is ease of use, quick turnaround time, no requirement of cold chain and specialized equipment. However, confirmation at HIV care centers is still required for rapid HIV tests. Those who have sexual risk behavior or negative HIV test should be regularly followed up until 3 months after post-exposure. Mobile setting and decentralization of laboratory services may be useful to scale up the opportunity to detect HIV-infected population and approach them to treat with antiretroviral drugs in order to reduce transmission. Nonetheless, rapid HIV tests should be confirmatory tested by supplementary tests, e.g., HIV antigen-antibody combination assays, HIV antigen test and NAAT.[27]

Conclusion

Our findings suggested that whole blood rapid HIV tests should be used for high risk populations. If non- invasive practice is required, oral fluid tests would be one of the tools of choice but window period and ART uptake must be concerned. Furthermore, rapid HIV tests should be confirmed by other HIV tests.

Disclaimer

The content of this report is those of the authors and do not necessarily reflect the policy and views of Department of Disease Control, Ministry of Public Health, Thailand.

Acknowledgements

We thank the participants, NGO staffs (PPAT, SWING, FAR) and HIV care center. The study was supported by the Bureau of AIDS and STI (Global Fund Programs), Department of Disease Control, MOPH Thailand.

References

[1] World Health Organization (WHO). Global Health Observatory (GHO) data: HIV/AIDS. Geneva: World Health Organization; 2017.

[2] The Joint United Nations Programme on HIV/AIDS (UNAIDS). 90-90-90: an ambitious treatment target to help end the AIDS epidemic. Geneva: The Joint United Nations Programme on HIV/AIDS; 2014.

[3] World Health Organization (WHO). HIV/AIDS topical information: HIV testing services. Geneva: World Health Organization; 2017.

[4] Cherutich P, Bunnell R, Mermin J, HIV testing: current practice and future directions. Curr HIV/AIDS Rep 2013; 10(2): 134-41.

[5] Thailand National AIDS Committee. National strategic information and monitoring and evaluation plan for HIV/AIDS Thailand 2012 to 2016. Bangkok: Thailand National AIDS Committee; 2013.

[6] US Food and Drug Administration. OraQuick® In-home HIV test summary of safety and effectiveness. Silver Spring, MD: US Food and Drug Administration; 2012.

[7] CLIA database. CLIA record BP010047. Rockville, MD: US Food and Drug Administration; 2008.

[8] Wesolowski LG, MacKellar DA, Facente SN, Dowling T, Ethridge SF, Zhu JH, et al. Post-marketing surveillance of OraQuick whole blood and oral fluid rapid HIV testing. AIDS 2006; 20(12): 1661-6.

[9] Pant Pai N, Joshi R, Dogra S, Taksande B, Kalantri SP, Pai M, et al. Evaluation of diagnostic accuracy, feasibility and client preference for rapid oral-based diagnosis of HIV infection in rural India. PLoS One 2007; 2(4): e367.

[10] Pai NP, Barick R, Tulsky JP, Shivkumar PV, Cohan D, Kalantri S, et al. Impact of round-the-clock , rapid oral fluid HIV testing of women in labor in rural India. PLoS Med 2008; 5(5): e92.

[11] Hutchinson AB, Branson BM, Kim A, Farmham PG. A meta-analysis of the effectiveness of alternative HIV counseling and testing methods to increase knowledge of HIV status. AIDS 2006; 20(12): 1597-604.

[12] Thailand Food and Drug Administration. Medical device control in Thailand. Nonthaburi: Thailand Food and Drug Administration; 1990.

[13] Department of Medical Sciences, Thailand Ministry of Public Health. Diagnostic HIV tests available in Thailand. Nonthaburi: Department of Medical Sciences; 2014.

[14] MedCalc. Diagnostic test evaluation calculator [Internet]. Ostend: MedCalc Software bvba; 2015 [cited 2015 Jul 31]. Available from: https://www.medcalc.org/calc/diagnostic_test.php.

[15] Lowry R. Vassarstats: statistical computation - McNemar's Test [Internet]. [Place unknown]: Vassarstats; 2015 [cited 2015 Jul 31]. Available from: http://vassarstats.net/propcorr.html.

[16] O'Connell RJ, Merritt TM, Malia JA, VanCott TC, Dolan MJ, Zahwa H, et al. Performance of the OraQuick rapid antibody test of diagnosis of human immunodeficiency virus type 1 infection in patients with various levels of exposure to highly active antiretroviral therapy. J Clin Microbiol 2003; 41(5): 2153-5.

[17] Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R, et al. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-based prospective study. PLoS Med 2015; 12(9): e1001873.

[18] Mavedzenge SN, Sibanda E, Mavengere Y, Hatzold K, Mugurungi O, Ncube G, et al. Supervised HIV self-testing to inform implementation and scale up of self-testing in Zimbabwe. J Int AIDS Soc 2015; 18 (Suppl 4): 96.

[19] Stekler JD, O'Neal JD, Lane A, Swanson F, Maenza J, Stevens CE, et al. Relative accuracy of serum, whole blood and oral fluid HIV tests among Seattle men who have sex with men. J Clin Virol 2013; 58(Suppl 1): e19-22.

[20] Suntharasamai P, Martin M, Choopanya K, Vanichseni S, Sangkum U, Tararut P, et al. Assessment of oral fluid HIV test performance in an HIV pre-exposure prophylaxis trial in Bangkok, Thailand. PLoS One 2015; 10(12): e0145859.

[21] McNeil Jr DG. Rapid H.I.V. home test wins federal approval. The New York Times 2012 Jul 3: A1.

[22] Facente SN, Dowling T, Vittinghoff E, Sykes DL, Colfax GN. False positive rate of rapid oral fluid HIV tests increases as kits near expiration date. PLoS One 2009; 4(12): e8217.

[23] Delaney KP, Branson BM, Uniyal A, Phillips S, Candal D, Owen SM, et al. Evaluation of the performance characteristics of 6 rapid HIV antibody tests. Clin Infect Dis 2011; 52(2): 257-63.

[24] Pant Pai N, Balram B, Shivkuma S, Martinez-Cajas JL, Claessens C, Lambert G, et al. Head-to-head comparison of accuracy of a rapid point-of-care HIV test with oral versus whole-blood specimens; a systematic review and meta-analysis. Lancet Infect Dis 2012; 12(5): 373-80.

[25] Pavie J, Ruchline A, Loze B, Niedbalski L, Delaugerre C, Laforgerie E, et al. Sensitivity of five rapid HIV tests on oral fluid or finger-stick whole blood: a real-time comparison in a healthcare setting. PLoS One 2010; 5(7): e11581.

[26] Centers for Disease Control and Prevention (CDC). False-positive oral fluid rapid HIV tests–New York City, 2005-2008. MMWR Morb Mortal Wkly Rep 2008; 57: 660-5.

[27] Stekler JD, Swenson PD, Coombs RW, Dragavon J, Thomus KK, Brenan CA, et al. HIV testing in a high-incidence population: is antibody testing alone good enough?. Clin Infect Dis 2009; 49(3): 444-53.