Accuracy of Re-Reading HIV Rapid Tests and the Effect of Prolonged High Temperature

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Background

Accurate rapid diagnostic test results are critical to HIV testing, care and prevention services[4].

However, suboptimal storage of rapid test kits (RTDs) at ambient temperatures above manufacturer recommendation is common in sub Saharan Africa.

Retesting while on antiretroviral therapy (ART) is known to affect accuracy of OraQuick [1, 2,5].

Re-reading of used test kits can provide valuable programmatic quality-assurance, and "late" reading is also commonly reported following HIV self-testing[3].

Aims

We evaluated the effects of prolonged (incubated RTDs for 28 days at 37 °C) exposure to high temperatures on

1. Initial accuracy
2. Reproducibility of late reads

Methods

A cross-sectional diagnostic evaluation was conducted between 14th January and 6th March 2013 in Blantyre, Malawi.

Assuming 98% (95% CI:94-99%) concordance with "gold standard" results, 188 HIV +ve and 188 HIV –ve participants were required to achieve precision of +/- 2%.

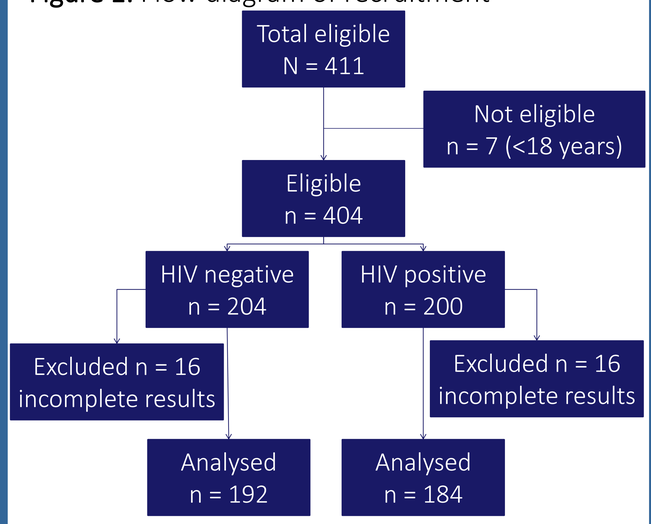
Sequential consenting adults (18+) attending routine HIV testing services were systematically recruited following routine HIV testing at a primary clinic.

Parallel re-testing used 6 RTDs: 2 kits for each of 1 oral and 2 types of blood-based RDT devices (OraQuick, Determine and Unigold, respectively). One of the 2 of each type of RDT had been pre-incubated for 28 days at 37 °C (intact packages) or stored under optimal conditions (6 tests in total).

Kits were read by a study nurse on site, and then again by a lab technician on the same day, with OraQuick kits then read monthly for 12 months without reference to previous results.

Optimally stored Uni-Gold/Determine/SD Bioline were used to provide the "gold standard" for each client.

Figure 1: Flow diagram of recruitment



Results

Table 1: Baseline characteristics of study participants

Characteristic	N	%
Total participants	376	100
Male*	198	53
Median (inter quartile range) age (years)	31	25-40
Never tested before*	121	33
Self-reported HIV positive	53	15
HIV positive on gold standard**	184	49

*Missing values: sex 7 (1.9%); past test 15 (4.0%); gold standard 2 (0.53%)

**HIV prevalence reflects sampling strategy.

Table 2: Initial accuracy, sensitivity and specificity for rapid HIV diagnostic tests stored for 28 days in high temperature (37 °C) and optimal temperature

Type of rapid test kit	TP/FN	Sensitivity (95% CI)	TN/FP	Specificity (95% CI)
Normal temperature OraQuick	177/3	98.3 (95.2-99.7)	186/1	99.5 (97.1-100)
High temperature OraQuick	178/5	97.3 (93.7-97.3)	190/0	100 (98.1-100)
Normal temperature Determine	182/2	98.9 (96.1-99.9)	189/1	99.5 (97.1-100)
High temperature Determine	182/2	98.9 (96.1-100)	189/1	99.5 (97.1-100)
Normal temperature Uni-Gold	183/1	99.5 (97.0-100)	192/0	100 (98.1-100)
High temperature Uni-Gold	182/2	98.9 (96.1-100)	189/0	100 (97.1-100)

CI: confidence interval; TP: true positive; FN: false negative; TN: true negative; FP: false positive

Over 12 months of re-reading used OraQuick kits; 1 (0.3%) in both optimal-stored and high temperature groups changed from negative to positive (different clients). In both cases participants were known to be on ART.

Conclusions

This study showed that:-

- Rapid diagnostic HIV test kits stored at prolonged high temperature did not appreciably affect diagnostic performance, although this is not recommended
- Repeated reading of OraQuick kits up to 12 months after testing appears to be highly reproducible, although not recommended by the manufacturer
- Clients seeking retesting while while already known to be HIV positive and in some cases on ART maybe an increasing common cause of inaccuracy in HTC clinics

Key references

1 Press Release (2012) Approval Letter, OraQuick. U.S. FDA; 2 Jaspard M, et al. (2014) PLoS One 9: e101148; 3 Choko AT, et al. (2011) PLoS Med 8: e1001102; 4 Pai NP, et al. (2012) Lancet *Infect Dis 2012; 12: 373-380; 5* Kumwenda M, et al. (2014) AIDS Care and Behaviour

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