Assessment of internationally-available rapid test kits for their suitability to meet manufacturers' claims

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ABSTRACT

Background: Rapid test kits are used throughout the world as a primary measure to protect the blood supply and provide diagnosis to save lives. The US government purchases large numbers of HIV, syphilis and HBsAg tests from a variety of manufacturers at considerable expense, and expects them to perform adequately.

Methods: From September 2010 through October 2018, a total of 1,567 lots of rapid test kits from 20 manufacturers, and representing 16 different tests from 27 countries, were received for evaluation at the IHV. The performance of each test kit was assessed for performance characteristics using panels of sera (n=30 or 160) that included positives (n=20-80), and negatives (n=20-80).

Results: Of the 1,567 rapid test kit lots, 99.2% successfully passed the evaluation with perfect performance. Of the 13 lots from four manufacturers that did not pass, 4 were found to produce high background that interfered with reading, 2 performed inadequately with high-temperature testing, 5 gave more than one false-positive result, and 2 gave more than one false-negative result. In one case, the failure resulted in cessation of bulk purchase of test kits by the US Government and removal from WHO's e-catalogue. In another case, a report resulted in a visit to the country to assess the laboratory's activities that were subsequently found to be unsuitable.

Conclusion: In our evaluation of a large number and variety of rapid test kit lots from 20 manufacturers from 27 countries, nearly all performed as expected and met the manufacturers' claims.

Updated Data: Since October 2018 when this information was submitted, an additional 37 kits were received and evaluated. All kit lots performed as expected. Therefore from September 2010 through February 2019, a total of 1604 kits were evaluated with 99.18% accuracy. More countries and kits has been added to the study since our abstract submission.

INTRODUCTION

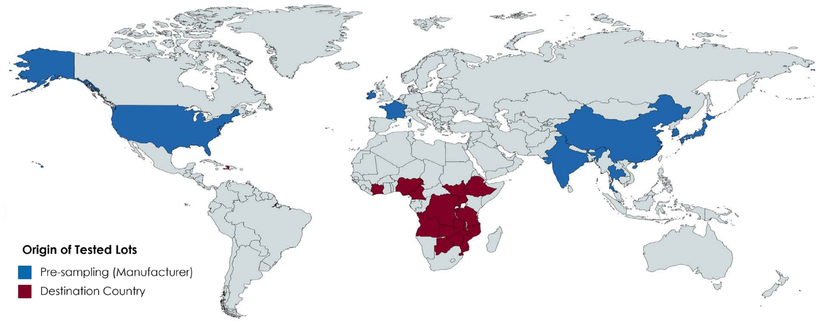
HIV rapid tests are used throughout the world as a primary means to protect the blood supply, for epidemiologic purposes, and to diagnose infection. These tests are robust and offer a number of advantages over other tests, including fast results, high temperature storage (up to 30°C), ease of performance in a variety of testing venues, and are essential in facilities that cannot support stable electricity. For many years, the US Government (USG) has provided HIV rapid tests to a number of countries to assist with addressing the HIV pandemic. For ensuring the quality of these test kits, the USG has instituted a quality assessment effort to ensure that these test kits meet manufacturers' claims. The consequences of using test kits that are not accurate include misdiagnosis that results in further infections, falsely informing persons that they are infected, and the loss of millions of dollars in contracts. This report is a summary of efforts from rapid test kit evaluations during the period September 2010 through October 2018.

OBJECTIVE

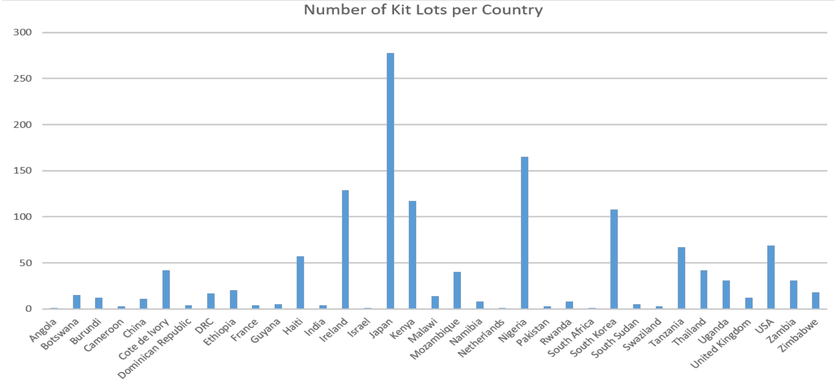
To assess a large number and variety of rapid test kits, purchased for many countries to determine if they meet the claims of the manufacturers.

METHODS

From September 2010 through October 2018, a total of 1,567 lots of rapid test kits were received for evaluation at the Institute of Human Virology (IHV). Some test kits were shipped directly from user countries, while other test kits that were targeted to be sent to countries were shipped directly by the manufacturer (pre-sampling) for evaluation. Test kits included those for HIV (Ab/Ag), HBsAg, HCV, Cryptococcus, hCG, Chagas, and syphilis (TP and RPR). Each test kit lot was assessed for performance characteristics using panels of sera (n=30 or 160) that included positives (n=20-80), and negatives (n=20-80); also included were one or two HIV-2 positive, weak reacting positives, and HIV p24 Ag positive samples. In addition, test kits were evaluated with several samples at 28C under a heat lamp.



Kits Evaluated	
Cambridge Biotech HIV-1 Western Blot Kit	One Step HCG urine Pregnancy test
Clearview Complete HIV-1/2 test kits	OraQuick HIV Self-test
CrAg LATERAL FLOW ASSAY	RPR Kit
Determine HIV COMBO SET	Rapid Test for HIV
Determine HIV-1/2 Set	SD BioLine HIV 1/2 3.0
FIRST RESPONSE HIV1-2.2 CARD TEST	SD BioLine Syphilis 3.0
hCG TEST KITS 50 TESTS	SD HBsAg WB (multi)
HIV 1/2 STAT PAK Dipstick	SURECHECK HIV 1/2
HIV 1/2 TRI-LINE HIV RAPID TEST DEVICE	Sure-Vue Urine hCG Strips
HIV-1/2 STAT PAK	TPHA test kit (for Treponea pallidum detection)
IMMUTREP RPR	Uni-Gold HIV
Instant Chek-HIV1+2	Vikia HIV-1/2
Latex-Cryptococcus antigen test	Wampole Impact RPR Card Test
Murex anti-HCV (Version 4.0)	Murex HBsAg Version 3
Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	



RESULTS

During the 8 year period, a total of 1,567 lots of rapid test kits from 20 manufacturers and representing 16 different rapid tests from 27 countries (see graphs), were received for evaluation at the IHV. Of the rapid test kit lots evaluated, nearly 99.2% successfully passed the evaluation with perfect performance for sensitivity, specificity, precision, and high temperature testing. Of the 13 lots from four manufacturers that did not pass, 4 were found to produce high background that interfered with reading, 2 performed inadequately with high-temperature testing, 5 gave more than one false-positive result and 2 gave more than one false-negative result. In one case, the failure resulted in cessation of bulk purchase of test kits by the US Government and removal from WHO's e-catalogue. The HIV Ag/Ab Combo tests performed as expected. The figures indicate the number and names of the test kits.

DISCUSSION

Nearly all rapid test kit lots performed as claimed by the manufacturer. For the 13 lots that did not meet expectations, there were discussions with the manufacturers, review of some manufacturers' laboratory procedures/records, and sequestration/ replacement of test kits. In one case, the manufacturer verified that a lot had performed less accurately than usual in their in-house evaluation; this resulted in a review of their test kit components for better optimization. In another case, poor performance of the test lot resulted in the removal from WHO's e-catalogue purchase list; a subsequent inspection of manufacturer's facility indicated poor lot release record keeping. In another case, a country reported poor performance while the test passed our evaluation, resulting in a visit to the country to assess laboratory practices that were subsequently found to be unsuitable. Although most users expect test kit lots to perform as expected, it was found that this is not always the case. This test kit assessment program is not a large-scale assessment, but a "snap-shot" of the performance of the test kit lots. It has met its objective of determining if test kits appear to be suitable for use as claimed by the manufacturers, particularly in resource-limited countries.

CONCLUSIONS

In our evaluation of a large number and variety of rapid test kit lots, nearly all performed as expected and met the manufacturers' claims. However, because some test kit lots were found not to perform acceptably, quality assessment programs to determine the suitability of test kit lots are important and monitoring test kit performance should continue.

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