INTRODUCTION

Background: Rapid test kits are used throughout the world as a primary measure to protect the blood supply and provide effective 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. Therefore from September 2010 through February 2019, a total of 1604 lots were evaluated with 99.18% accuracy. More countries and kits has been added to the study since our abstract submission.

UPDATE: Data: Since October 2018 when this information was submitted, an additional 37 kits were received and evaluated. All 13 lots performed as expected. Therefore from September 2010 through February 2019, a total of 1641 lots were evaluated with 99.18% accuracy. More countries and kits has been added to the study since our abstract submission.

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 (Ag/Ab), HBsAg, HIV-1/HIV-2 p24, and syphilis (TP and RPR). 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), and performance characteristics that were one or two HIV-2 positive reactive positives, and HIV-2 Ag positive samples. In addition, test kits were evaluated with samples at 28°C under a heat lamp.

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 and 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.

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, 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.

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