The Effect of Simulated Field Storage Conditions on the Accuracy of Rapid User-Friendly Blood Pathogen Detection Kits

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ABSTRACT Being able to test for the presence of blood pathogens at forward locations could reduce morbidity and mortality in the field. Rapid, user-friendly blood typing kits for detecting Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), and Hepatitis B Virus (HBV) were evaluated to determine their accuracy after storage at various temperatures/humidities. Rates of positive tests of control groups, experimental groups, and industry standards were compared (Fisher's exact χ^2, $p \leq 0.05$). Compared to the control group, 2 of 10 HIV detection devices were adversely affected by exposure to high temperature/high humidity or high temperature/low humidity. With one exception, none of the environmentally exposed HCV or HBV detection devices exhibited significant differences compared to those stored under control conditions. For HIV, HCV, and HBV devices, there were differences compared to the industry standard. Collectively, this evaluation of pathogen detection kits revealed that diagnostic performance varies among products and storage conditions, and that the tested products cannot be considered to be approved for use to screen blood, plasma, cell, or tissue donors.

INTRODUCTION

During military operations, hemorrhage is a leading cause of death in military trauma patients.[1,2] For a successful outcome, hemorrhagic injuries must be treated in a timely fashion by properly trained health care workers who have adequate medical supplies. In some situations, injury may be so severe that blood replacement via transfusion is necessary. However, depending upon specific circumstances, at far-forward locations no blood support may be available.[3] Regardless of this limitation, emergency transfusions may be necessary. In such cases, warm fresh whole blood transfusion using "walking wounded" and/or in-facility staff personnel as donors is possible. In fact, recent conflicts have demonstrated the value of this technique.[4–6] Combat hospitals in Iraq and Afghanistan have, by necessity, used fresh whole blood for transfusion, and one recent report documents the use of more than 6,000 units of warm fresh whole blood for the treatment of life-threatening traumatic injuries with hemorrhage.[6]

One of the risks associated with the use of fresh whole blood for transfusions is transmission of infectious agents.[7] In general, the rates of transfusion-transmitted diseases such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV) have decreased in recent years.[8–10] More discriminating donation selection criteria, improved donor education, and increased sensitivity of testing techniques have contributed to this reduction.[8,9,11,12] Despite this general downward trend, at least one study suggests that continued monitoring of the blood supply and research is warranted. In a study of 66 million blood donations during the period from 1999 to 2008, HCV prevalence among first-time donors decreased by 53%. However, HIV and HCV incidence among repeat donors increased in 2007 though 2008 compared to 2005 through 2006.[13] Despite relatively low current rates, the seriousness of these diseases continues to motivate researchers to attempt to further reduce the risk.

One of the critical steps in minimizing the rates of transfusion-transmitted infections is to ensure that donated blood is tested to ensure it is free of pathogens such as HBV, HCV, and HIV. Field friendly, point-of-care products for testing blood for the presence of such pathogenic organisms are commercially available, and at least one study indicates that they can be helpful in reducing the risk of HIV, HCV, and HBV.[7]

Since the U.S. military operates in a variety of environments, the medical supplies and devices it uses must be resistant to degradation from extreme temperature and humidity conditions. The Naval Medical Research Unit San Antonio (formerly the Naval Institute for Dental and Biomedical Research, Great Lakes, IL) has exposed medical and dental supplies and equipment to different environmental conditions for various time periods and then tested their performance.[14–17] The tests indicated that environmental exposures had adverse effects on many of these products. Although previous testing has included field dental equipment and point-of-care blood typing kits, products for point-of-care blood pathogen detection have not been tested. It is important to test the temperature and humidity resistance of these products as they may eventually be used on the battlefield.

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The objective of this study was to determine the accuracy of point-of-care blood pathogen detection products after storage under temperature and humidity conditions simulating those commonly encountered in the field.

MATERIALS AND METHODS

Specimens

Blood products were purchased from Golden West Biologicals (Temecula, CA) using a donor site that is a U.S. Food and Drug Administration (FDA)-inspected and American Association of Blood Banks-accredited facility. The only donor information that accompanied each sample was sample reactivity (HIV, HCV, or HBV), gender, ethnic group, age, and anticoagulant used for specimen collection. As such, the investigation was deemed to be Institutional Review Board-exempt. Samples were frozen, packed, and shipped to the authors for analyses. Upon receipt, the specimens were stored at –20°C until tested. After thawing, the samples were used within 14 days.

HIV, HCV, and HBV status was determined using industry-standard procedures set forth by the FDA. These results served as the gold standard against which the control group (i.e., manufacturer's recommended storage conditions) was compared.

Rapid Tests

A number of rapid, commercially available blood pathogen detection devices were identified. However, to be included in this study, the tests needed to possess the following characteristics: (1) small, lightweight; (2) no moving parts; (3) easy to use; (4) < 20-minute test time; (5) reliable diagnostic performance; (6) results obtained visually with the unaided eye; and (7) independent of the need for electricity and extraneous laboratory equipment or supplies. Having received premarket clearance from the FDA [i.e., 510(k)] was not a requirement.

The devices which met the selection criteria and included in the study were: (1) OraQuick ADVANCE Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, PA); (2) CareStart HIV-1-2-O (Access Bio, Monmouth Junction, NJ); (3) CareStart HIV 1/2 2 lines (Access Bio, Monmouth Junction, NJ); (4) CareStart HIV 1/2 3 lines (Access Bio, Monmouth Junction, NJ); (5) Core Combo HIV-HBsAg-HCV (Core Diagnostics, Birmingham, United Kingdom); (6) ImmunoFlow HIV 1- HIV 2 (Core Diagnostics, Birmingham, United Kingdom); (7) Core HIV 1&2 (Core Diagnostics, Birmingham, United Kingdom); (8) BioSign HIV-1/HIV-2 WB (Princeton BioMeditech, Princeton, NJ); (9) Clearview HIV ½, STAT-PAK (Inverness Medical Professional Diagnostics, Louisville); (10) Uni-Gold Recombigen HIV (Trinity Biotech, Berkley Heights, NJ); (11) Multiplo Rapid HBV/HIV/HCV Antibody Test (MedMira Laboratories, Nova Scotia, Canada); (12) ASSURE HBsAg Rapid Test (MP Biomedicals Asia Pacific, Singapore); (13) Core HBsAg (Core Diagnostics, Birmingham, United Kingdom); (14) INSTANT-VIEW HBsAg ONE-STEP Serum Test (Alpha Scientific Designs, Poway, CA); (15) Core HCV-WB (Core Diagnostics, Birmingham, United Kingdom); (16) INSTANT-VIEW HCV Serum Test (Alpha Scientific Designs, Poway, CA); and (17) CareStart HCV 3.0 (Access Bio, Monmouth Junction, NJ). Other rapid point-of-care devices for the detection of HIV, HBV, and HCV meeting the selection criteria were commercially available, but were not obtainable through our government purchasing system. Consequently, they were excluded from this study.

With the exception of the Multiplo Rapid HBV/HIV/HCV Antibody Test, these devices are based on a lateral flow immunoassay platform. These assays are semiquantitative colorimetric tests that are well-established in the public sector (i.e., pregnancy, drugs of abuse, etc.). The lateral flow device assesses the humoral response to the etiological agent and its associated antigens. The device is commonly composed of a nitrocellulose membrane with a conjugate pad at one lateral end coupled with an absorbent pad at the other end. A sample application pad in turn flanks the conjugate pad. This combination is backed by a support and cut into test strips to fit a plastic housing with a sample application well positioned above the sample pad and a square detection window positioned above the detection strip. During use, the blood product is applied to the sample pad. Capillary action draws the fluid through the conjugate pad, which is impregnated with gold-labeled protein A or an equivalent reagent, and across a nitrocellulose membrane that has a test and control stripe. If pathogen-specific antibodies are present in the sample they will bind to the test stripe, which contains an antigen. Nonspecific antibodies bind at the control stripe. Any excess sample is taken up by the absorbent pad. After the specified time, the assay is assessed visually with the unaided eye. For all tests, any staining visible at the test line was deemed to be a positive reaction.

The Multiplo Rapid HBV/HIV/HCV Antibody Test is based on a vertical flow platform. The device for conducting vertical flow assays consists of a square plastic frame that holds a solid-phase substrate, capable of binding the target (i.e., pathogen-specific antibodies) while permitting drainage of other materials or fluids. Vertical flow assays have the target antigen immobilized on the solid-phase substrate. The test is conducted by spotting the patient's specimen on the solid-phase substrate, contacting the sample with a gold-labeled protein (or an equivalent reagent), and washing the sample with a buffer. Immediately thereafter, the assay is assessed visually with the unaided eye.

All the devices were used according to the manufacturers' instructions, after the environmental exposure. With one exception, the test devices were manufactured for use with serum and plasma. As such, serum and plasma (collected with ethylenediamenetetraacetic acid or heparin) samples were included in this study. The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test is not intended for use with serum. Given this, statistical analyses were conducted with the exclusion of serum sample results for this device.

Environmental Exposure

As was done in previous studies of other rapid point-of-care diagnostic tests[16] and field dental equipment,[14] the methods for environmental exposure testing were based on MIL-STD-810F. The devices were placed in an environmental chamber (model WP-216-THCM1-3-3, Thermotron Industries, Holland, MI or model EWPH205-CCA, Espec North America, Hudsonville, MI) and exposed to conditions of thermal shock, high temperature/high relative humidity, high temperature/low relative humidity, and low temperature/low relative humidity as described previously.[16] The control group was stored at ambient laboratory temperatures (20–26°C), which adhered to the manufacturers' recommended storage conditions. For each set of environmental conditions, a new group of devices (blood samples tested in duplicate) was used. After exposing the devices to the abovementioned environmental conditions, the devices were tested within an A2 biosafety cabinet under ambient laboratory temperature and humidity conditions.

Statistical Analyses

Differences in rates of positive tests between the control groups and the various environmental test exposure groups were analyzed using the Fisher exact χ^2 method (which is necessary when cell frequencies are at or near 0) to determine if differences existed between two independent proportions. This approach was also used to determine if significant differences existed between the control groups and the industry-standard groups. For all analyses, $p \leq 0.05$ was considered to be significant.

RESULTS

HIV Devices

When compared to the control group, exposure to high temperature/high relative humidity negatively affected ($p < 0.05$) the results observed with 2 of the 10 HIV detection kits (Table I). The discrepant results were observed with the ImmunoFlow HIV 1–HIV 2 kits and CareStart HIV-1-2-O tested with nonreactive HIV samples. For the latter, less than 30% of the devices tested yielded a true negative result. When the performance of all 10 products exposed to high temperature/high relative humidity is compared to the industry standard, significant differences ($p < 0.05$) are seen in 9 of 10 and 2 of 10 of them tested with HIV-reactive samples and HIV-nonreactive samples, respectively.

With two exceptions, no significant differences were seen between the results obtained with the HIV detection kits exposed to high temperature/low relative humidity conditions and those from the control group (Table I). Exposing the CareStart HIV-1-2-O test and the Core Combo HIV-HBsAg-HCV to high temperature/low humidity significantly ($p < 0.05$) reduced their capability to correctly identify nonreactive HIV samples. When compared to the industry standard, the performance was markedly lower ($p <$; 0.05) in 9 of 10 and 2 of 10 products tested with HIV-reactive samples and HIV-nonreactive samples, respectively.

There were no significant differences between any of the HIV detection products tested under low temperature/low relative humidity conditions and those stored under laboratory conditions. Eight of 10 products tested with HIV-reactive samples yielded significantly different results than those obtained with industry standard procedures. The two that did not differ significantly were the Multiplo Rapid HBV/HIV/HCV Antibody Test and the CareStart HIV-1-2-O test. Although the sensitivity for the CareStart HIV-1-2-O test was acceptable, the specificity of this product was unfavorable, as the number of true negatives detected was less ($p \leq 0.05$) than that determined using the industry standard.

Compared to those of the control group, thermal shock exposure did not significantly affect the results seen with the exposed HIV detection devices tested with HIV-reactive or HIV-nonreactive samples. Of the 10 products tested with HIV-reactive samples, 9 differed ($p \leq 0.05$) from the industry standard. The CareStart HIV-1-2-O test only had true positive results with HIV-reactive samples (i.e., 100% sensitivity); notwithstanding, the samples nonreactive for HIV yielded a significant number ($p \leq 0.05$) of false results.

As indicated above, results for the control were significantly different from those for a number of the devices exposed to high temperature/high relative humidity and high temperature/low relative humidity. Besides the effect of temperature, we observed that 9 of 10 unexposed (control) products tested with HIV-reactive samples were significantly different from the industry standard (Table I). Only 1 of the 10 products tested with nonreactive HIV samples differed from the industry standard.

The HIV detection devices included in this study had a control to confirm that the test had operated correctly. According to the manufacturers' instructions, the test is deemed invalid or faulty if the control line/spot is not visible. The occurrence of faulty tests did not appear to be associated with any particular storage treatment. Most devices had a low rate of faulty results (i.e., a range 0–7%). The exception to this was the Multiplo Rapid HBV/HIV/HCV Antibody Test, which had a range of 23 to 38% faulty outcomes (data not shown).

The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test is unique from the other HIV detection devices in that serum should not be used as a specimen. An adequate assessment of the sensitivity of the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test could not be made inasmuch as the majority of our HIV-reactive specimens were sera. Notwithstanding, our experiment suggested that environmental storage conditions did not have a negative impact on the 30 HIV nonreactive samples (data not shown).

HCV Devices

There was no statistically significant evidence that thermal shock, high temperature/low relative humidity conditions, or

TABLE I. Environmental Stability Testing of Commercial Rapid Point-of-Care HIV Tests (Number of Positive Reactions/Number of Devices Tested)

Environmental Treatment	HIV Status	
	Reactive	Nonreactive
BioSign HIV-1/HIV-2 WB		
Thermal Shock	13/24*	30/30
High Temperature/Low Relative Humidity	12/24*	29/29
High Temperature/High Relative Humidity	13/24*	30/30
Low Temperature/Low Relative Humidity	13/24*	30/30
Laboratory Conditions	13/21*	29/29
Clearview HIV ½, STAT-PAK		
Thermal Shock	12/24*	30/30
High Temperature/Low Relative Humidity	12/24*	29/29
High Temperature/High Relative Humidity	12/24*	29/29
Low Temperature/Low Relative Humidity	12/24*	30/30
Laboratory Conditions	12/24*	30/30
Uni-Gold Recombigen HIV		
Thermal Shock	11/23*	30/30
High Temperature/Low Relative Humidity	12/24*	30/30
High Temperature/High Relative Humidity	12/24*	30/30
Low Temperature/Low Relative Humidity	12/24*	30/30
Laboratory Conditions	12/24*	30/30
Multiplo Rapid HBV/HIV/HCV Antibody Test		
Thermal Shock	9/18*	18/18
High Temperature/Low Relative Humidity	10/15*	21/21
High Temperature/High Relative Humidity	8/13*	22/22
Low Temperature/Low Relative Humidity	8/12	22/22
Laboratory Conditions	9/17*	24/24
CareStart HIV-1-2-O		
Thermal Shock	24/24	13/30*
High Temperature/Low Relative Humidity	23/24	6/30*,**
High Temperature/High Relative Humidity	24/24	8/30*,**
Low Temperature/Low Relative Humidity	22/24	16/30*
Laboratory Conditions	23/24	20/30*
CareStart HIV 1/2 3 lines		
Thermal Shock	14/24*	30/30
High Temperature/Low Relative Humidity	14/24*	28/30
High Temperature/High Relative Humidity	13/23*	30/30
Low Temperature/Low Relative Humidity	14/24*	30/30
Laboratory Conditions	19/24*	28/30
CareStart HIV 1/2 2 lines		
Thermal Shock	14/24*	28/30
High Temperature/Low Relative Humidity	14/24*	30/30
High Temperature/High Relative Humidity	15/24*	30/30
Low Temperature/Low Relative Humidity	15/24*	27/30
Laboratory Conditions	16/24*	30/30
Core Combo HIV-HBsAg-HCV		
Thermal Shock	6/23*	26/28
High Temperature/Low Relative Humidity	10/21*	22/30*,**
High Temperature/High Relative Humidity	8/24*	29/29
Low Temperature/Low Relative Humidity	6/23*	27/28
Laboratory Conditions	7/22*	30/30
ImmunoFlow HIV 1–HIV 2		
Thermal Shock	12/24*	28/30
High Temperature/Low Relative Humidity	12/24*	29/30
High Temperature/High Relative Humidity	14/24*	23/30*,**
Low Temperature/Low Relative Humidity	11/21*	24/24
Laboratory Conditions	10/18*	30/30
Core HIV 1&2		
Thermal Shock	9/24*	29/29
High Temperature/Low Relative Humidity	8/24*	29/30
High Temperature/High Relative Humidity	15/24*	26/29
Low Temperature/Low Relative Humidity	12/24*	26/26
Laboratory Conditions	9/24*	29/30

*Significantly different when compared to blood bank test results ($p \leq 0.05$)
**Significantly different when compared to device stored under laboratory conditions ($p \leq 0.05$).

low temperature/low relative humidity conditions degraded the performance of the HCV pathogen detection devices tested (Table II). However, high temperature/high relative humidity conditions significantly ($p < 0.02$) reduced the performance of the CareStart HCV 3.0. For example, only 2 of 30 devices tested with HCV-reactive samples had a true positive reaction. All results, regardless of product type or environmental exposure, obtained using HCV-reactive samples were significantly lower than those obtained with the industry standard.

HBV Devices

There was no statistical evidence that any of the environmental exposure conditions degraded the performance of the HBV pathogen detection devices tested (Table III). All results, regardless of product type or environmental exposure, obtained using HBV-reactive samples were significantly different from those obtained with the industry standard.

TABLE II. Environmental Stability Testing of Commercial Rapid Point-of-Care Hepatitis C Tests (Number of Positive Reactions/Number of Devices Tested)

Environmental Treatment	HCV Status	
	Reactive	Nonreactive
Thermal Shock		
Core HCV-WB	15/29*	30/30
CareStart HCV 3.0	10/30*	30/30
INSTANT-VIEW HCV Serum Test	21/30*	30/30
High Temperature/High Humidity		
Core HCV-WB	15/30*	28/30
CareStart HCV 3.0	2/30*,**	30/30
INSTANT-VIEW HCV Serum Test	18/28*	30/30
High Temperature/Low Humidity		
Core HCV-WB	19/30*	29/30
CareStart HCV 3.0	5/30*	30/30
INSTANT-VIEW HCV Serum Test	20/29*	30/30
Low Temperature/Low Humidity		
Core HCV-WB	18/30*	30/30
CareStart HCV 3.0	11/30*	30/30
INSTANT-VIEW HCV Serum Test	20/29*	30/30
Laboratory Conditions		
Core HCV-WB	17/30*	30/30
CareStart HCV 3.0	10/30*	30/30
INSTANT-VIEW HCV Serum Test	21/29*	30/30

*Significantly different when compared to blood bank test results ($p \leq 0.05$).
**Significantly different when compared to *CareStart* HCV 3.0 stored under laboratory conditions ($p = 0.02$).

TABLE III. Environmental Stability Testing of Commercial Rapid Point-of-Care Hepatitis B Tests (Number of Positive Reactions/Number of Devices Tested)

Environmental Treatment	HBV Status	
	Reactive	Nonreactive
Thermal Shock		
Core HBsAg	14/28*	25/28
ASSURE HBsAg Rapid Test	12/28*	25/25
INSTANT-VIEW HBsAg ONE-STEP	14/21*	26/26
High Temperature/High Humidity		
Core HBsAg	20/28*	27/28
ASSURE HBsAg Rapid Test	11/26*	28/28
INSTANT-VIEW HBsAg ONE-STEP	13/22*	26/26
High Temperature/Low Humidity		
Core HBsAg	16/28*	26/28
ASSURE HBsAg Rapid Test	12/28*	25/26
INSTANT-VIEW HBsAg ONE-STEP	11/21*	25/25
Low Temperature/Low Humidity		
Core HBsAg	15/28*	28/28
ASSURE HBsAg Rapid Test	15/27*	28/28
INSTANT-VIEW HBsAg ONE-STEP	14/20*	24/24
Laboratory Conditions		
Core HBsAg	16/28*	26/28
ASSURE HBsAg Rapid Test	14/28*	27/27
INSTANT-VIEW HBsAg ONE-STEP	12/20*	25/25

*Significantly different when compared to blood bank test results ($p \leq 0.05$).

DISCUSSION

The development and commercialization of diagnostic tests are moving toward simple, noninvasive assays using point-of-care technologies.[18] Some of these devices have been designed as immunochromatographic lateral flow tests to detect a target analyte (i.e., an antibody directed against infectious disease pathogens). Like other diagnostic assays, the biological components of the lateral flow test are likely to be susceptible to environmental conditions. Most manufacturers recommend that their products are stored at 20 to 25°C, and expiration dates assume these conditions are met. Temperatures above this level are commonly encountered under field conditions.[19] The aim of this study was to determine the accuracy of point-of-care HIV, HCV, and HBV rapid tests after storage under temperature and humidity conditions simulating those commonly encountered in the field.

There were no conspicuous effects on the physical appearance of the test devices exposed to high temperatures. Notwithstanding, exposure to high temperature/high relative humidity negatively affected the performance of the CareStart HIV-1-2-O, ImmunoFlow HIV 1–HIV 2, and CareStart HCV 3.0 test kits. Similar observations have been made with *Plasmodium* lactate dehydrogenase-based malaria rapid diagnostic tests that had been exposed to ≥ 35°C.[20,21] As was observed by Chiodini et al,[20] we noted that the control and test line of these three HIV kits appeared to have different sensitivities to heat. These findings can have considerable clinical importance. If the test line fails, but the control line does not, the potential exists for transmission of blood-borne pathogens during transfusion of blood components. Alternatively, use of pathogen-free blood may be forfeited because of false-positive results.

Humidity in the air has also been reported to adversely affect the performance of rapid diagnostic tests as evidenced by failed control lines[22] or a decrease in diagnostic sensitivity.[23] Our experiment indicated that relative humidity may differentially affect the performance of some of the HIV test kits. At high temperatures, high relative humidity appears to have affected the Core Combo HIV-HBsAg-HCV and ImmunoFlow HIV 1–HIV 2 differently than low relative humidity. The packaging of the devices used in our experiment appears to be different from that of devices described in the literature, as devices used in our study were individually wrapped in a seemingly moisture-resistant pouch containing a desiccant. Further, the sample running buffer is provided in a plastic screw-topped container. Although the exposure durations used in this study were relatively limited (96 hours), it is possible that temperature and relative humidity mechanically or chemically compromised the integrity of the packaging. We believe that further experimentation may be warranted to investigate these devices and, in particular, the degree of resistance to environmental exposure provided by their packaging.

An unexpected outcome of this study was the frequency of discrepant results between the control group and the industry standard. With the exception of one device, the performance of all kits stored under control conditions, tested with HIV-, HBV-, or HCV-reactive samples, was significantly different ($p < 0.05$) from the industry standard. The failure to obtain a positive test result was usually associated with the same sample. For instance, four samples (tested in duplicate) resulted in false-negative results for ≥ 90% of the commercial devices tested. A possible explanation for these results is the threshold level of detection. Although the lateral flow assay has the advantage of being a rapid, user-friendly, point-of-care test, it appears that its sensitivity is not comparable to laboratory-based assays used by an American Association of Blood Banks-accredited facility. Although this may be true for devices evaluated in this study, it is not true for all lateral flow tests. For example, a rapid lateral flow assay for the detection of bovine antibody to *Anaplasma marginale* demonstrated that the sensitivity value was greater than that observed with a nested polymerase chain reaction or competitive enzyme immunoassay.[24]

It should be noted that even if a device yielded a result comparable to that of the industry standard (when used to test a reactive sample), this did not ensure that it would produce a similar result for a nonreactive sample. A good example of this was the CareStart HIV-1-2-O device. When using HIV-reactive samples, the CareStart HIV-1-2-O device did not differ significantly from the industry standard (i.e., it exhibited good diagnostic sensitivity). Notwithstanding, testing of the same device with nonreactive HIV samples yielded results that had significantly ($p < 0.05$) decreased specificity.

Most of the devices evaluated in this study were suitable for use with serum or plasma. For the latter, compatibility

with the anticoagulants was confirmed. As indicated, the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test is unique in that it is not intended for use with serum; nonetheless, oral fluid is a suitable specimen. Consequently, this device was not tested with an adequate number of samples to assess the effects of storage temperature and relative humidity. As false-positive rates of the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test have been reported to increase as kits near expiration,[25] there may be strong merit in evaluating the performance of this device in various environmental storage conditions using oral fluid as the test matrix.

Based on the results of this study, it is clear that the diagnostic performance of the tested blood pathogen detection kits varied among products and storage conditions. Although such simple and field-friendly tests would have obvious advantages in deployment environments, this study found that the tested products cannot be considered to be approved for use to screen blood, plasma, cell, or tissue donors/recipients.

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