Stability of User-Friendly Blood Typing Kits Stored Under Typical Military Field Conditions

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ABSTRACT To help preserve in-theater strength within deployed military units, commercially available, rapid, user-friendly ABO-Rh blood typing kits were evaluated to determine their stability in storage conditions commonly encountered by the warfighter. Methods for environmental exposure testing were based on MIL-STD-810F. When Eldon Home Kits 2511 were exposed to various temperature/relative humidity conditions, the results were comparable to those obtained with the control group and those obtained with industry-standard methods. For the ABO-Rh Combination Blood Typing Experiment Kits, 2 of the exposure treatments rendered them unusable. In addition, a third set of exposure treatments adversely affected the kits, resulting in ~30% blood type misclassifications. Collectively, this evaluation of commercial blood typing kits revealed that diagnostic performance can vary between products, lots, and environmental storage conditions.

INTRODUCTION

On a day-to-day basis, warfighters face injuries far from the nearest medical treatment facility. Some of these injuries lead to considerable blood loss requiring blood transfusions at the site of injury. To date, hemorrhage remains a leading cause of death in military trauma patients.[1,2]

Military doctrine for blood management in the theater of operations discusses transfusion practices according to echelon level.[3] Echelon I units provide no blood product support, although second-echelon units are authorized to transfuse only universal-donor (blood group O) packed red blood cells (PRBCs).[3] Most echelon III and IV units, in addition to other types of blood products, are authorized to maintain a supply of ABO group-specific red blood cells.[4] These units also have the capability to type and crossmatch blood and determine its Rh factor. Under ideal conditions, determination of ABO blood group type and Rh factor, as well as crossmatching should be done before administering a transfusion. Determining ABO blood type and doing crossmatching to ensure that the donor's red blood cells are compatitible with the recipient's serum prevent a potentially fatal hemolytic reaction resulting from agglutination of donated red blood cells. Assuring Rh compatibility for females helps prevent chronic extravascular hemolysis or hemolytic disease of the newborn.[3] In 1995, the services were directed to provide, during contingencies, Rh negative blood to Rh negative males and females based on Rh factor as noted on their ID cards and dog tags. The services were to ensure this was done at the second echelon level of medical care where, historically, random group O positive and group O negative red blood cells had been provided.[5]

Identification (ID) cards and dog tags are issued to military personnel upon entering the service. One of the reasons is to facilitate the identification of potential donors, by identifying the warfighter's ABO blood type and Rh factor status. Despite the fact that policy dictates the use of type O blood for transfusions,[6] emergency transfusions may be necessary at a far-forward location where type O blood is unavailable. Unfortunately, research has brought into question the accuracy of ID card and tag information. Historically, an 11% prevalence of blood typing errors on these cards and tags has been reported.[7] More recently, a survey revealed that 3.7% of soldiers have a different blood type than that listed on the tag. Of these discrepancies, 2.3% involved ABO group errors, 1.1% involved Rh type errors, and 0.2% involved both ABO group and Rh type errors.[8] A comparable rate of 4.2% blood typing errors has been reported with Air Force ID cards.[6]

Screening of blood and/or donors can be difficult in the field, as the diagnostic capabilities are typically limited to laboratory settings. Within the last few years, there have been advances in diagnostic capabilities. These efforts have resulted in a number of user-friendly point-of-care commercial kits, some of which might be life-saving resources for military field units that require decentralized blood supplies and screening of mobilized blood donors. The majority of these tests, including those that have received premarket clearance [i.e., 510(k)] from the U.S. Food and Drug Administration (FDA), are rarely tested in environments that are encountered by the warfighter. Numerous reports in the literature

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indicate that environmental conditions can adversely impact the performance and shelf-life of diagnostic test reagents. For example, the accuracy of rapid blood tests was reduced after cumulative exposure to temperatures encountered in tropical malaria-endemic zones.[9,10] Consequently, a preliminary step in identifying potentially viable blood typing devices for possible use in far-forward areas should be to test and evaluate them under a wide range of temperature and humidity conditions.

The aim of this study was to test and evaluate commercially available technologies that could support point-of-care blood typing and Rh factor determination by ancillary medical personnel. To accomplish this, experiments were conducted to determine the stability of the kits under temperature and humidity conditions simulating those commonly encountered in the field.

MATERIALS AND METHODS

Specimens

Fresh whole blood was purchased from Golden West Biologicals, Inc. (Temecula, CA). The donor site associated with this company is an FDA-inspected and American Association of Blood Banks (AABB)-accredited facility. Using BD Vacutainer spray-coated K2EDTA tubes (Becton Dickenson, Franklin Lakes, NJ), approximately 5 mL of blood was collected by venipuncture. Samples were packed, maintained at a temperature of approximately 4°C, and shipped to the Naval Institute for Dental and Biomedical Research, Great Lakes, IL for analyses. Upon receipt, the specimens were stored at 4°C until tested. The only donor information that accompanied each sample was age, ethnic group, gender, and blood type. The latter was determined using industry-standard procedures set forth by the FDA, and they served as the gold standard against which the control group (i.e., laboratory conditions) was compared.

Agglutination Card Rapid Tests

For ABO and Rh blood typing, numerous rapid commercial tests were identified. For inclusion in this study, the diagnostic product needed to possess the following characteristics: (1) small, lightweight device; (2) no moving parts; (3) simple to use; (4) fast (i.e., ≤10 minutes); (5) reliable diagnostic performance; (6) results obtained visually with 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)], which is required before a medical device is marketed in the United States, was not a requirement for testing a particular device in this study, because the purpose of the research was solely to identify blood typing products whose performance was unaffected by environmental exposure testing. The Eldon Home Kit 2511 (Eldon Biologicals A/S, Gentofte, Denmark) and ABO-Rh Combination Blood Typing Experiment Kit (Lab Aids, Inc., Ronkonkoma, NY) met these selection criteria. Although these tests have somewhat different configurations, they function through the same basic principle. The ABO-Rh blood group is determined on the basis of the presence or absence of inherited antigenic substances called agglutinogens (e.g., antigen A, antigen B, and antigen D) on the surface of red blood cells. Blood typing is achieved by mixing a drop of blood with antisera directed against antigen A, antigen B, or antigen D. If the surface of red blood cells possesses the respective agglutinogens, agglutination will be observed. If no agglutination is observed, the blood is classified as type O negative.

The Eldon Home Kit 2511 comes with a test card that is precoated with anti-A, anti-B, and anti-D antibodies. To use the card, the antisera are reconstituted by adding a drop of water to each of the designated areas, followed by a drop of test blood. Using a single-use disposable applicator (EldonStick), the blood samples are mixed by gentle rotating motion to cover the entire field. The card is then tilted slowly in a rotating motion. The result is obtained by observing the thin layer of the blood-serum film for the presence or absence of agglutinating cells. To preserve the result, an adhesive plastic film is used to laminate the card. One significant advantage of this card is that it includes a control spot to detect nonspecific agglutinates (i.e., invalid result).

The second self-contained blood typing kit is the ABO-Rh Combination Blood Typing Experiment Kit. It is used by applying a drop of blood onto each of 3 distinct areas on the Combi-Slide-Guide. One drop of anti-D, anti-A, or anti-B serum is then applied beside each drop of blood. The antiserum and blood are hand-mixed using a single-use disposable spatula. After allowing the card to sit for approximately 1 minute, the Combi-Slide-Guide is tilted back and forth, so that a thin layer of the blood-serum film can be observed for agglutinated cells. To preserve the results, the Combi-Slide-Guide is air dried and then laminated with an adhesive plastic film.

Environmental Exposure

As was done in previous studies of other rapid point-of-care diagnostic tests[11] and field dental equipment,[12] 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) 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.[11]

The effect of short-term exposure of the devices to high temperature was also determined by placing the kits in the environmental chamber at 10°C. The relative humidity was then allowed to reach 95%. The temperature was raised over a 24-hour period to 50°C and the relative humidity lowered to 20%. The materials were then removed from the chamber.

The control group was stored in ambient laboratory temperatures (20 to 26°C), which adhered to the manufacturers' recommended storage conditions. The ambient relative humidity was uncontrolled; the average ranged from 27 to 58%. For each set of conditions, a new group of 442 devices (221 blood samples tested in duplicate) was used.

The testing of the devices was conducted under ambient laboratory temperature and humidity conditions as described above. Normal artificial lighting supplied by standard fluorescent bulbs was used.

Statistical Analyses

Differences in rates of positive tests between the lab condition and the various environmental test exposures, for the ABO-Rh blood types, were analyzed using the Fisher exact χ^2 method (which is necessary when cell frequencies are at or near 0) to determine whether differences existed between 2 independent proportions. This approach was also used to compare results obtained from the control group to the industry standard. For all analyses, $p \leq 0.05$ was considered to be significant.

RESULTS

Laboratory Conditions

No significant differences were found between results seen for the Eldon Home Kit 2511 kits stored under laboratory conditions (i.e., control group) and those of the industry standard (Table I). Four hundred thirty-nine of the 442 Eldon Home Kit 2511 tests maintained within the manufacturer's recommended storage conditions generated the same results obtained with the industry standard. All 3 misclassifications resulted from Rh type errors. Similarly, no significant differences were found between results seen for the ABO-Rh Combination Blood Typing Experiment Kits stored under laboratory conditions and those of the industry standard. Under the same storage conditions, however, the ABO-Rh Combination Blood Typing Experiment Kit yielded a discrepancy in 4 of the 442 tests. This difference resulted from 2 blood samples that were tested in duplicate; both errors were attributed to Rh factor.

Thermal Shock

Thermal shock exposure did not significantly affect the results seen with the exposed Eldon Home Kit 2511 kits compared to those of the control group (Table I). Nonetheless, duplicate testing of one sample yielded an Rh type error. This blood sample gave similar results in Eldon Home Kit 2511 kits that were exposed to high temperature/high relative humidity, high temperature/low relative humidity, and laboratory conditions.

Exposing the ABO-Rh Combination Blood Typing Experiment Kits to thermal shock significantly ($p < 0.002$) reduced their capability to correctly identify A+, A–, AB+, AB–, and B+ blood types compared to the control group (Table I). No significant effect from thermal shock on kits used to test the B–, O+, or O– blood types was found. Approximately 70% of the ABO-Rh Combination Blood Typing Experiment Kits yielded results that were consistent with those seen with the control group. Of the discrepancies noted, 4.5% and 98.5% of the results involved Rh type error and ABO group errors, respectively. Nearly 3% consisted of both ABO and Rh type errors. The latter can largely be attributed to the failure of the anti-A reagent (i.e., no agglutination).

High Temperature/High Relative Humidity

No significant differences were seen for the results obtained with the Eldon Home Kit 2511 kits exposed to high temperature/high relative humidity conditions compared to the control groups (Table I). However, this comparison demonstrated a

TABLE I. Environmental Stability Testing of Commercial Rapid Point-Of-Care Whole Blood Card Tests for ABO and Rh Blood Typing (Positive Reactions/Number of Devices Tested)

Environmental Treatment	Blood Type							
	A+	A–	AB+	AB–	B+	B–	O+	O–
Thermal Shock								
Eldon Home Kit 2511	58/60	60/60	60/60	26/26	60/60	56/56	60/60	60/60
ABO-Rh Combination Blood Typing Experiment Kit	22/60[a]	41/60[a]	22/60[a]	18/26[a]	40/60[a]	52/56	57/60	58/60
High Temperature/High Humidity								
Eldon Home Kit 2511	58/60	60/60	60/60	25/26	60/60	56/56	60/60	60/60
ABO-Rh Combination Blood Typing Experiment Kit	—[b]	—[b]	—[b]	—[b]	—[b]	—[b]	—[b]	—[b]
High Temperature/Low Humidity								
Eldon Home Kit 2511	58/60	60/60	60/60	26/26	60/60	56/56	60/60	60/60
ABO-Rh Combination Blood Typing Experiment Kit	—[b]	—[b]	—[b]	—[b]	—[b]	—[b]	—[b]	—[b]
Low Temperature/Low Humidity								
Eldon Home Kit 2511	60/60	60/60	60/60	25/25	60/60	56/56	60/60	60/60
ABO-Rh Combination Blood Typing Experiment Kit	58/60	60/60	59/60	26/26	60/60	56/56	60/60	60/60
Short-Term High Temperature								
Eldon Home Kit 2511	20/20	22/22	20/20	18/18	20/20	20/20	20/20	20/20
ABO-Rh Combination Blood Typing Experiment Kit	20/20	22/22	20/20	18/18	20/20	20/20	20/20	20/20
Laboratory Conditions								
Eldon Home Kit 2511	58/60	60/60	60/60	26/26	59/60	56/56	60/60	60/60
ABO-Rh Combination Blood Typing Experiment Kit	58/60	60/60	60/60	26/26	60/60	56/56	58/60	60/60

[a] $p < 0.002$ when compared to ABO-Rh Combination Blood Typing Experiment kits stored under laboratory conditions. [b] Kits became unusable because reagent(s) solidified.

misclassification of an AB negative blood sample that exhibited no agglutination with the presence of anti-A or anti-B antiserum in one of two duplicates.

Exposure of the ABO-Rh Combination Blood Typing Experiment Kit to high temperature/high relative humidity rendered the kits unusable—specifically, the anti-B and the anti-Rh blood grouping sera became solidified in all kits (32 tests per kit). Of the 4 lots exposed to high temperature/high relative humidity conditions, the anti-A reagent became solidified in all kits within a single lot. To determine whether evaporation of the antisera was a contributing factor, we compared the weight of the reagents. The mean weights of antisera vials exposed to high temperature/high relative humidity conditions and laboratory conditions were comparable (7.17 ± 0.082 grams and 7.20 ± 0.101 grams, respectively).

High Temperature/Low Relative Humidity

High temperature/low relative humidity environmental exposure did not significantly affect the performance of the Eldon Home Kit 2511 (Table I). As observed with the control group, a single A+ sample tested in duplicate yielded a blood typing error.

As described for the high temperature/high relative humidity group, exposure of the ABO-Rh Combination Blood Typing Experiment Kit to high temperature and low relative humidity rendered the kits unusable because all the antisera solidified. Similar to high temperature/high relative humidity exposure, evaporation associated with the high temperature/low relative humidity exposure was minimal.

Low Temperature/Low Relative Humidity

The performance of the Eldon Home Kit 2511 and ABO-Rh Combination Blood Typing Experiment Kit was not significantly affected by exposure to low temperature/low relative humidity environmental conditions (Table I). For the latter, duplicate testing of an AB+ sample resulted in a single ABO type error. This was in addition to misclassification of the abovementioned A+ sample.

Short-Term High Temperature

Short-term high temperature conditions did not adversely affect the performance of either the Eldon Home Kit 2511 or the ABO-Rh Combination Blood Typing Experiment Kit (Table I).

DISCUSSION

The Armed Services Blood Program operates at approximately 150 locations worldwide. These include over 80 blood banks and donor centers (Inspector General, Department of Defense Arlington, VA, 2002). Notwithstanding, battlefield injuries often occur far from the nearest medical treatment facility. Some of these injuries lead to considerable blood loss requiring blood transfusions. In many cases, banked blood is not readily available at the site of injury; however, potential blood donors are typically closer in proximity. Hence, field-friendly screening tests to determine ABO and Rh compatibility of mobilized donors at the point-of-care could be a life-saving resource.

Whenever a blood transfusion is necessary, it is critically important to guard against transfusion errors. Having field-friendly blood typing tests would not eliminate all types of transfusion error but would hopefully lessen their occurrence. The most serious result of error is fatal hemolytic reaction, which occurs at rates of from 1 in 600,000 to 1 in 800,000.[13–15] While these can occur for a variety of reasons,[16] one of the most common is administration of correctly typed blood to the wrong patient.[17] It is safe to assume that the chance of this type of error increases in busy, mass-casualty situations such as those that can occur on the battlefield. While the availability of user-friendly blood typing kits would not prevent this error, it would lessen the occurrence of others. Advances in diagnostic capabilities have resulted in an array of user-friendly commercial kits. For ABO and Rh blood typing, 14 rapid commercial tests were identified. Two of the 14 tests utilize synthetic blood and are commercialized for educational purposes. Eleven of the blood tests require equipment and supplies (e.g., centrifuge, micropipettes, saline solution) that may not be readily available in a field setting. Given this, only the Eldon Home Kit 2511 and ABO-Rh Combination Blood Typing Experiment Kit met our selection criteria. The Eldon Home Kit 2511 is manufactured by Eldon Biologicals A/S and distributed in the U.S. by 4 companies. It is important to note that these types of kits only identify the patient's ABO blood type and Rh factor status; they do not crossmatch the donor's and recipient's blood. Crossmatching is an additional step that would need to be done to ensure blood compatibility before transfusion. In crossmatching, the recipient's serum is mixed with the donor's red blood cells to check for agglutination resulting from plasma antibody incompatibility.

FDA clearance was not considered a prerequisite for including a product in this study, because the purpose of the research was solely to determine whether this type of medical device could withstand environmental exposure, and not to assess its appropriateness for clinical use. These products will receive additional research and scrutiny in the future to ensure efficacy. Only Craig Medical Distribution, Inc. (Vista, CA) and Eldon Biologicals A/S have obtained FDA clearance for marketing [i.e., 510(k)] the Eldon Home Kit 2511. Interestingly, the product, while cleared by the FDA, bears a stamp stating it is "not for use for screening purposes before transfusion." It is clear, however, from the manufacturer's web site and the fact that it has received a 510(k) indicating clearance from the FDA, that it is intended for clinical use. This method of labeling and marketing confuses the issue as to whether it is intended for clinical use. This confusion does not exist for the ABO-Rh Combination Blood Typing Experiment Kit; it is solely geared toward educational settings and is not intended for clinical or diagnostic use. As noted earlier, FDA clearance

was not mandatory for a kit to be included in the study because the research was only to determine whether the methodology and technology used by such blood typing kits is resistant to environmental challenge.

A search of the literature yielded no published scientific studies evaluating the accuracy of either of the 2 blood typing products tested in the current study. However, 2 studies of the Eldon product performed by the manufacturer were found. In a study involving 4 European blood centers, Eldon Biologicals A/S evaluated the reliability of blood typing using EldonCards by comparing results obtained blindly using the cards with results obtained using conventional blood typing techniques.[18] Two versions of the cards were tested, one of which was the card version tested in the current study. Of the 2,990 cards that were used, 2,988 gave ABO type results in agreement with the results produced at the blood centers (an agreement rate of >99.9%). In another study, the manufacturer tested the suitability of the product when used by 63 nonprofessionals (i.e., laypersons). The authors concluded that nonprofessionals were capable of accurately using the product and interpreting its results.[19]

None of the environmental exposures exerted a statistically significant negative effect on the performance of the Eldon Home Kit 2511. Nonetheless, a low number of misclassifications occurred. While these failures did not lead to a statistically significant outcome, it is important to consider the potential clinical significance of blood type misclassifications. An acute hemolytic reaction can occur if an incompatible blood type is administered to a patient. The severity and timing of an acute immune-mediated hemolytic reaction depend on the types of antibody involved, the temperature at which they bind to the antigen, and how efficiently they fix complement. Hemolysis can be extravascular or intravascular. With the latter, there is systemic activation of hemostasis and production of systemic hypotension, shock, and renal failure.

It is also important to note that the potential clinical importance of the errors seen during our testing depends upon the specific error and on whom it occurs (i.e., recipient versus donor). For example, an error in type O typing has much different implications when made in typing the donor versus the recipient. Also, errors that result in typing the recipient of the transfusion incorrectly as a type AB have a much different clinical impact than errors that misidentify the donor as type AB. It is important, therefore, that health care providers who use point-of-care blood typing in a forward setting understand these types of differences that can occur when typing the donor and the recipient. This is particularly true because the potential danger of adverse reactions can be exacerbated under field conditions where the diagnosis of transfusion error can be difficult.

Among the samples tested, 1 or 2 appeared to have a weak anti-D response. Standards for blood banks and transfusion services by the AABB require that if the initial test with anti-D reagent is negative, the blood is tested using a method that is designed to test weak antigen D. When either test is positive, the blood sample is deemed to be Rh positive.[20] Limitations present in a field setting may not allow confirmatory testing.

High temperature/high relative humidity and high temperature/low relative humidity rendered the ABO-Rh Combination Blood Typing Experiment Kits unusable, as some of the reagents solidified. A failure of potentially greater significance occurred with the ABO-Rh Combination Blood Typing Experiment Kits that were exposed to thermal shock. With this exposure, it was not outwardly evident that the kits had been adversely affected. Further, the adverse effect of thermal shock varied between lots. The failures were primarily associated with a particular lot (i.e., batch manufacturing) and not with individual tests or kits. For clinical applications, use of quality control samples would be prudent to ensure the efficacy of the kits.

Although this study using different temperatures and humidities is a strong indicator of the effect the environment can have on rapid blood typing tests, it may not reflect test performance in the field after prolonged storage. There is a need to evaluate the effect of the environment on long-term (i.e., >6 months) storage of these types of kits. Studies that evaluate the effect of the environment (i.e., temperature and humidity) on actual use of commercial tests would also yield useful data as would research assessing the effect of direct sunlight. Research of this kind would help make inexpensive screening tools available to troops serving on the battlefield in even the most remote areas of the world. The availability of effective tests would greatly enhance Force Health Protection by improving the safety of blood used for transfusion in deployed military personnel. Further testing and premarket clearance by the FDA (if not already received) are required before a recommendation for use of such products in a clinical setting can be made.

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