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Expansion of HIV screening to non-clinical venues is aided by the use of dried blood spots for Western blot confirmation

Timothy J. Sullivan[a], Mara San Antonio-Gaddy[b], April Richardson-Moore[b], Linda M. Styer[a,c], Deborah Bigelow-Saulsbery[b], Monica M. Parker[a,*]

[a] Bloodborne Viruses Laboratory, Wadsworth Center, New York State Department of Health, Albany, NY 12201, United States
[b] Bureau of HIV and STD Field Services, AIDS Institute, New York State Department of Health, Albany, NY 12201, United States
[c] Department of Biomedical Sciences, School of Public Health, University at Albany, Albany, NY 12201, United States

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ABSTRACT

Background: HIV rapid testing programs in New York State (NYS) are required to collect a specimen for confirmation of a preliminary positive result; however, some venues have limited capacity to collect venous blood, and confirmation using oral fluid is restricted by cost and availability.
Objective: To evaluate the feasibility of using dried blood spots (DBS) at non-clinical HIV rapid testing sites for Western blot testing.
Study design: The New York State Department of Health facilitated registration of 48 non-clinical HIV test sites and provided training on DBS procedures. Following a reactive rapid test, DBS were collected by fingerstick onto filter paper cards, dried and mailed to the NYS public health laboratory for Western blot testing.
Results: From October 2010 to December 2012, 280 DBS specimens were submitted for confirmation. Four (1.4%) were unsatisfactory for testing and 276 (98.6%) DBS were tested. Of these, 235 (85.1%) were positive, 37 (13.4%) were negative and 4 (1.4%) were indeterminate. During this period, the laboratory also received 1033 venous blood specimens for rapid test confirmation, and 35 (3.4%) were unsatisfactory. Of the 998 tested by Western blot, 784 (78.6%) were positive, 197 (19.7%) were negative and 17 (1.7%) were indeterminate.
Discussion: Compared to venous blood, the percentage of rapid test referral specimens with a positive Western blot was significantly greater for DBS specimens and the frequency of unsatisfactory specimens did not differ significantly. These results indicate that DBS are a suitable alternative to venous blood for confirmation of HIV rapid tests conducted at non-clinical sites.

1. Background

Identifying HIV-infected persons and linking them to medical care and prevention services is a national priority as referenced in the United States National HIV/AIDS Strategy [1]. HIV testing provides a critical pathway to prevention and treatment services that can prolong lives and help stop the spread of HIV. For almost a decade, rapid HIV tests have played an important role in HIV prevention programs by increasing the number of individuals tested and aware of their status [2]. As part of a comprehensive HIV/AIDS prevention plan, the New York State Department of Health (NYSDOH) AIDS Institute has established a network of community-based health and human services providers that offer HIV rapid testing outside of clinical settings as a public health prevention strategy. These community-based organizations target non-traditional venues to facilitate access to HIV screening for individuals who may not seek testing in clinical settings. To ensure high quality testing is carried out in these settings, staff from the Wadsworth Center Laboratory and the AIDS Institute HIV testing program collaborated to implement, monitor and guide community-based HIV rapid testing strategies in NYS.

HIV rapid testing programs in New York State (NYS) are governed by public health laws [3,4]. Under NYS clinical laboratory regulations, providers that conduct waived tests are required to register as limited service laboratories with the NYSDOH Clinical Laboratory Evaluation Program and meet Clinical Laboratory Improvement Amendments quality standard requirements [5]. In 2010, an amendment to the HIV testing law included several key provisions to facilitate HIV testing and promote HIV-positive persons entering into care [3]. Prior to 2010, non-clinical providers

* Corresponding author at: Wadsworth Center, New York State Department of Health, 120 New Scotland Avenue, Albany, NY 12208, United States. Tel.: +1 518 402 4563; fax: +1 518 473 0008.
E-mail address: mmp09@health.state.ny.us (M.M. Parker).

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could either refer HIV preliminary positive clients to clinical sites for confirmatory testing and follow-up care or they could collect an oral fluid specimen for Western Blot (WB) confirmation by a reference lab and then refer HIV-infected individuals to medical care. However, the 2010 NYS HIV testing law stipulates that sites conducting HIV rapid testing are required to collect a specimen for laboratory confirmation upon receipt of a preliminary positive result [3]. Many non-clinical providers lack access to skilled phlebotomists and therefore are not able to collect blood specimens by venipuncture to confirm a reactive rapid test. The availability of oral fluid testing has become a less practical alternative for rapid test confirmation. No laboratories in NYS currently accept and process oral fluid specimens for HIV-1 Western blot testing. Additionally, the cost of oral fluid specimen collection products, mailers and the charge for processing of oral fluid at an out-of-state commercial reference laboratory has increased significantly, further limiting the options for grant-funded HIV testing programs to comply with NYS's public health laws.

The suitability of dried blood spot (DBS) specimens for HIV antibody testing, including Western blot testing, has been established [6–8]. However, with the exception of newborn screening programs, DBS are not widely used for HIV diagnostic testing in the United States. In NYS, DBS evolved as a potential solution for HIV antibody confirmation because of participation in a CDC-funded HIV surveillance project -[9,10], in which the feasibility of collecting DBS for additional testing following a preliminary positive rapid test was evaluated. When NYS was challenged to develop a solution to the lack of options for specimen collection in community-based agencies, DBS was realized as an alternative for WB confirmation based on the previous experience.

DBS specimens are simple to collect by fingerstick, require minimal equipment, no refrigeration, and, when dried, can be sent to a testing laboratory in a standard mailing envelope by regular mail [11]. In addition, an HIV-1 Western blot test with approval by the Food and Drug Administration (FDA) for use with DBS specimens is readily available in both public health and commercial laboratories.

2. Objective

This project evaluated the feasibility of using DBS specimens collected at non-clinical HIV rapid testing sites in NYS for laboratory confirmation of preliminary positive rapid HIV test results by Western blot testing.

3. Study design

The NYSDOH funds non-clinical HIV testing agencies and identified testing sites that would benefit from using DBS for Western blot confirmation of reactive rapid tests. Staff that oversees the implementation of rapid HIV testing programs partnered with Wadsworth Center laboratory staff to develop a protocol for HIV-1 Western blot confirmation using DBS. All participating testing agencies were registered as limited service laboratories with the NYSDOH. Procedures and training materials were developed for the collection of whole blood by fingerstick, drying, packaging and mailing of specimen cards. NYSDOH staff conducted training sessions that included a didactic presentation, with collection procedure demonstration, followed by a skills development/practice session and observation by the trainers to assess participant competency in specimen collection. All trained agencies were provided with DBS collection supplies including collection cards and test requisitions for submission to the Wadsworth Center laboratory. Lastly, all trained agencies were enrolled through the NYSDOH AIDS Institute as DBS submitters for the purpose of monitoring and tracking specimen submissions as well as program outcomes.

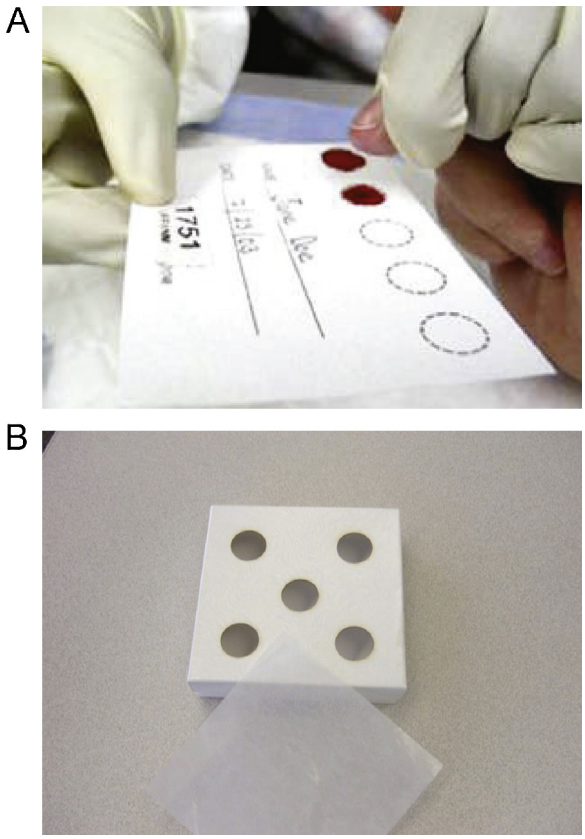

Fig. 1. (A) DBS collection. Blood from a fingerstick is collected onto pre-printed circles of filter paper cards. Cards are labeled with client's name and the collection date. (B) Transport box. Ventilation holes allow the blood spots to continue drying while being transported. After spots dry, a sheet of glassine paper is used to protect the DBS during mailing.

Following a reactive rapid test, DBS were collected by fingerstick onto filter paper cards (Whatman 903, GE Healthcare Life Sciences, Piscataway, NJ), and dried for at least four hours at ambient temperature (Fig. 1a) [11,12]. Ideally all five spots on the card are filled, but a minimum of one full spot is acceptable for testing. Since rapid testing services are carried out in mobile, nontraditional settings (parks, bars, cars), 4 in ×4 in transport boxes with ventilation holes were created and provided to staff to ensure proper drying of DBS cards while in transit between sites and offices (Fig. 1b). If the specimen was transported within four hours of collection, the card flap was folded over the blood spot without touching it, the card was placed onto a sheet of glassine paper in the transport box and covered with the lid. Once the specimen was dried completely, the labeled card was placed with the completed test requisition form directly into a business-size envelope without desiccant or humidity indicators and sent by standard first-class mail to the Wadsworth Center laboratory. At sites where specimens for rapid test confirmation were collected by venipuncture, blood was collected in blood draw tubes containing EDTA and shipped to the Wadsworth Center at ambient temperature. Upon receipt at the laboratory, all specimens were checked for proper labeling and quality. Specifically, the specimens were checked for sufficient quantity of blood, to ensure that the blood spot had dried properly, did not have serum rings or appear to be clotted, layered, supersaturated, scratched or abraded. The specimens were assigned an accession number, placed in a plastic bag with a desiccant packet, and stored at 4 °C until testing was performed. Specimens were typically tested within one week, but stability studies conducted in the laboratory indicated that storage at elevated temperatures without desiccant had no effect on Western blot reactivity for up to one