

Family Medicine 1020  
West Broadway Minneapolis,  
MN 55411 612.302.8200  
Phone

## North Memorial Clinic

UNIVERSITY *of* MINNESOTA, PHYSICIANS

### BP AC Public Statement of Patrick Keenan MD:

**Introduction:** Thank you for allowing me to make a statement at this meeting. It's exciting to be here discussing even the possibility of an over-the-counter rapid HIV test.

**Financial Disclosure:** OraSure Technologies paid for my flight and hotel so I could attend t.his meeting. Otherwise, I have no disclosures.

**Background:** In Minneapolis we have done operational research on the use of OraQuick in the outreach setting, using both whole blood and oral fluid. We did a CDC-funded project from July 2002 through August 2004. When we started the project, OraQuick was still an investigational test. We have also had rapid HIV testing outreach projects for the Minnesota Department of Health since 1999.

I have presented at CDC workshops on Implementation of Rapid HIV Testing (September 2002) and on Quality Assurance in Rapid HIV Testing (April 2003). We helped the CDC to film a video at our clinic on Quality Assurance in OraQuick Testing.

In the past 3 years our outreach workers have done over 5000 OraQuick tests in diverse settings such as homeless shelters, chemical "dependency programs, home visits, etc. So I feel we know this test well, and I would like to tell you of our experience with OraQuick.

### Technical simplicity:

I would first like to comment on the technical simplicity of the OraQuick test. We found that with a minimum of training (basically the time it takes to demonstrate one run-through of the test -- 30 to 60 minutes), people from diverse backgrounds such as being a printer, bus driver, chef, or bar tender were able to do the test well. We trained 14 workers. Of course, to train a good outreach worker, we had to cover lot of other topics as well such as universal precautions, HIPP AA, and pre and post test counseling. In fact, we felt that the teaching of the OraQuick testing procedure itself was the easiest part of training.

Of course, even this brief amount of training is a lot different from the anticipated over-the-counter use we're talking about today. How people would do with NO previous training certainly needs to be studied. But it is a fact that you don't have to be a laboratorian to perform this test.

### Robust nature of test:

Second, I would like to say that the OraQuick is a robust test. Our team demonstrated, sometimes inadvertently, that this test held up to the temperature extremes of Minnesota weather, without a loss of accuracy.

OraQuick seems a consistently manufactured test. We did controls every day for two years and never had an invalid control. In the 5000+ tests we have done, we have had only 7 invalid tests. Five were blank with no lines at control or test areas. The other two had been dropped on the floor.

Sometimes for training purposes we made use of test devices that had expired' dates. We found that the control and test lines became much fainter after several months. So use of expired test devices is a real concern with OTC use because it could lead to false negative tests.

**Posttest Counseling Issues:**

The information that would accompany the OTC test must emphasize the possibility of a false positive test. In Minnesota we tested the highest risk persons we could find. We had about a 1 in 200 to 300 rate of true positives. Our rate of false positives was the same, about 1 in 200. So our Positive Predictive value was 50%. In a lot of populations, this is the kind of PPV you might expect.

**Medical "Knowledge Gap:"**

From personal experience I think there is a knowledge gap between the public health community (that knows a lot about rapid HIV testing) and the rest of the medical community (which does not). And I speak of this coming from a primary care department in an academic center. My concern is that a person with a reactive rapid HIV test might see their doctor and receive inappropriate confirmatory testing. The most important element of the packaging should specify that a Western blot test is needed for confirmation. The person with a reactive test should be encouraged to impart this information to his or her physician.

If over the counter HIV testing becomes a reality, I would recommend an effort be made to educate primary care physicians about rapid HIV testing. (For example, talks "at state and regional meetings and perhaps a mailing from their professional organization. )

**Conclusion:**

In conclusion, the United States would benefit from having an over the counter, technically simple, rapid HIV test. There remain many questions to be answered and much work to be done before implementation of such a test. But I think it's the right time to start addressing these issues.

Patrick Keenan MD  
University of MN  
Dept Family Medicine and Community Health  
1020 West Broadway  
Mpls, MN 55411  
612-302-8200  
pkeenan@umphysicians.umn.edu

November 3, 2005

Honorable Committee members of FDA Advisory Committee

I am:

Dr. Waheed N. Khan

President Azko, Inc.

10500 Rockville Pike #1124

North Bethesda, MD 20852

Tel: (301) 564-5613 Fax: (301) 340-8322

Before I say anything about over the counter Home use of HIV test Kits, I would like to state that I do not have any interest or shares in the companies making the mv tests available in the Market these days. I have studies extensively practically all of the HIV tests available in the market. I am an Infectious Disease specialist from Children's Hospital Washington D.C. I have studies on HIV/AIDS problems in Dominican Republic, Haiti and here of course.

I submitted a paper on the subject of OTC use of HIV tests to mv /STD Education/Trainer Network (ENT) Meeting in April 7,2005. Unfortunately it was not accepted for presentation. I am attaching a copy of the abstract to be presented to the committee.

I will go over the points, which I made in the paper, which are still very relevant today as they were last year or year before.

Title: *HIV/AIDS* Testing in Privacy of Borne like the Glucose monitoring and Pregnancy Tests.

Names of presenter . Waheed N. Khan

Abstract of the Presentation.

At present HIV diagnostic tests are performed in laboratories, hospitals, specialty clinics and doctor's office with strict adherence to the rules set by the Food and Drug Administration (FDA). This has not been very productive. One third of aU suspected people with HIV do not know their HIV status with the result that HIV/AIDS continue to be a serious problem with 40,000 new cases of HIV positive people are added every year in this country. Even though being HIV positive is not a death sentence like it used to be; life saving treatment is available now if HIV is detected early enough. Being HIV positive is a reportable event and combined with the stigma attached to being HIV positive is a strong deterrent for people to get themselves tested. Quite often those who get tested under peer pressure do not go back to get results. An example is when Borne Access test for HIV -1 became available a few years ago in the pharmacies, 30 thousand people paid \$40/test, sent in the test card but never called to get the results; reason they were afraid that in this day and age with caller ID some one would know who is call for the HIV test results. There are number of FDA approved HIV tests are available in the market; OraQuick (HIV-I) and OraQuick Advance (with oral fluid) are a good example. These tests come with well written, easy to understand, well-illustrated instructions so an average person can do the test. The test results are visually determined and no equipment or complex procedures are involved. The FDA has restrictions on these tests that trained technicians- only at clinics or hospitals perform them. These tests are so simple and easy to perform and they compare well with over the counter Glucose Monitoring and Pregnancy tests. There are 16 million diabetics in this country and they all perform sugar test at home by pricking their finger for a drop of blood to perform the test. There have been no adverse reaction reports on these millions of tests performed in the privacy of a borne. As a matter of fact doctors keep reminding their patients to keep up and monitor their sugar levels to take correct dose of Insulin. The main reason given for the FDA restrictions is the fear that people might commit suicide after they know that they are "HIV positive. There are 80,000 suicides per year in this country (CDC figure) and they are not related to being HIV positive. In fact I am not aware of even one report. There could be pre and post counseling to a prospective user of the HIV test by a clinic of his/her choice on the phone. The British Journal of Medicine came out with their recommendation last in February 05 that pre counseling be dropped from the test procedure.

Agreement: Your signature on this proposal indicates agreement with the following:

Signature: Signed Waheed N. Khan Date: 4/7 /05

Testimony on HIV Testing Over the Counter  
November 3rd, 2005 Blood Products Advisory  
Committee Hearing

My mom and my dad are grateful. Grateful that I know. Grateful that I have the knowledge I need to keep myself healthy. Grateful because I now know I need tools to keep me healthy and vibrant for years to come.

Good Morning, My name is Tom Donohue. I am a 26 year old from State College, Pennsylvania. I am the executive director and founder of a non-profit organization called Who's Positive. Who's Positive is committed to raising the awareness of HIV and its consequences. Our organization foregrounds the reality of living with HIV through the first-hand accounts of young adults coping with the disease. Who's Positive strives to remind the public that this is a virus with no cure. Through the stories of those living with HIV, Who's Positive hopes to reduce the transmission of HIV among teens and young adults - a population with one of the fastest growing infection rates.

I am grateful that I know. Two years ago I was diagnosed with HIV. It was one moment of passion of intimacy of irresponsibility that was responsible for my infection. I live in a rural town where my one local AIDS service organization services 2 counties with 4 employees. Where young people are afraid to get tested in fear someone may recognize ones destination may be "The AIDS Project" I live in a community surrounded by students and stigma; one main barrier which prevents young people from getting tested for HIV.

America has the tools to fighting and ending this epidemic. I come before you today in support of an over the counter rapid HIV test and to urge your immediate attention and approval to moving forward with this proposal. An over the counter test will break down barriers for some many young people. It will allow smaller rural communities who do not have access to quick reliable testing to go out *ta* their local drug store and get tested in the convenience of their own home and while getting results back in 20 minutes. I believe this will significantly reduce the amount of young people who are unaware they are HIV positive; ultimately resulting in prevention of more infections.

This committee must recognize the responsibility it has to my friends and my peers; to your friends, your family and especially your children of giving an extra tool for them to empower themselves to get tested. Young people continue to bear the brunt of the global HIV/AIDS epidemic, with youth under age 25 accounting for more than half of all new HIV infections each year~

Through my work with Who's Positive, I go to different schools and universities throughout the United States to share my personal story about being HIV positive. We use a peer to peer approach as a prevention tool which has been very successful. Since finding out about an OTC test I've used this opportunity as a forum to open dialog with young people on the issue. The majority of young folks see this as an additional resource; an alternative of facing ones actions and behaviors to a stranger face to face. They see it as a true confidential and anonymous test. They see it as a way to **help** remove the social stigma surrounding HIV/AIDS as a way to reduce the amount of young people who don't know their status and a way to reduce the number of infections among young people.

Some shared concerns. Many were uneducated. They were unfamiliar with a rapid test and it's accuracy. Some expressed concern with being alone if they were to find a positive result - who would they turn to what resources would be available for them~ While raising these concerns most still supported the concept.

As I end my comments I do not end my fight, my journey through this tough world of the unknown. Knowing your status is important, to you, your family, your friends and your partners. I am a very lucky Uncle of three and brother of one. My parents and family are saddened and challenged by my actions which put me in the situation I am in, but they are relieved I know my status, I now have the tools to keep me healthy, I have the knowledge and the responsibility from not infecting others and most importantly to me; I may live a bit longer to enJoy those moments with the ones I love simply because I empowered myself to know my status early enough in my Journey to fight HIV/AIDS.

At my request due to our limited available funding I thank OraSure Technologies for providing transportation and accommodations to allow us the opportunity to give you this perspective.

Donohue Testimony on HIV Testing Over the Counter  
November 3rd, 2005

In the fight with all these folks together until a cure is found. I thank you for your time and I request these remarks be submitted for the record.

Thomas M. Donohue, Jr.  
Executive Director, Founder  
Who's Positive  
[www.whospositive.org](http://www.whospositive.org)

Submitted by Thomas M. Donohue  
Executive Director, Who's Positive  
State College, PA

PUBLIC COMMENT Provided by  
James Sykes, The AIDS Institute  
Before the Blood Products Advisory  
Committee Food and Drug  
Administration Gaithersburg,  
Maryland November 3-4, 2005

Distinguished Committee Members:

My name is James Sykes and I am representing The AIDS Institute, a national public policy organization. Thank you for considering my public comments regarding over-the counter (OTC) home-use HIV test kits.

The AIDS Institute supports efforts by the Centers for Disease Control and Prevention (CDC) to increase access to and availability of HI V testing. The goal of HI V testing is two-fold. First, that an individual become informed of his or her HIV status so that appropriate medical evaluation and treatment can be sought. Unlike the early domestic HIV epidemic, today improved treatment options are available to people living with HIV. In many instances HIV has become a chronic disease. Second, people who are aware of their HIV status may be less likely to transmit the virus to others. This is an important public health consideration.

The introduction of the HIV rapid test in recent years has expanded HIV testing and increased testing access and availability. One of the advantages of the rapid test is the relative immediacy of receiving the test result. More conventional testing is hampered by relatively poor client return rates, often resulting in clients not receiving test results.

The AIDS Institute supports the concept of GTC home-use HIV testing kits. Such an approach will further increase access to and availability of HIV testing. This approach can play a role in the overall HIV domestic testing system. In particular, the approach may be appealing to individuals who resist seeking HIV testing in public health settings and private medical practice. For these individuals, use of an OTC home-use HIV test kit may be the only approach by which they become aware of their HIV status.

There are a number of issues The AIDS Institute believes must be addressed prior to the implementation of this approach.

1. The absence of direct counseling in the OTC home-use HIV test kit setting will require the provision of clear information with the kit including: appropriate use of the kit, HIV prevention, and a statement that HIV infection is a treatable disease.
2. Likewise, the absence of direct counseling with this method will need to be addressed by provision of a toll-free twenty-four hour, seven-day a week telephone number staffed by qualified counselors. The counselors will need to be prepared to answer questions about the test kit and its use; HIV prevention and local referral options for medical and psychosocial evaluation and assistance.
3. The CDC will need to address how this approach may impact HIV case reporting and HIV surveillance data.

# AACC

Advancing  
Clinical Laboratory  
Science Worldwide

October 21, 2005

Donald W. Jelm  
Center for Biologics Evaluation  
and Research Food and Drug  
Administration 1401 Rockville  
Pike Rockville, Maryland 20852

Dear Mr. Jelm:

The American Association for Clinical Chemistry, Inc. (AACC) offers the following comments for your November 3, 2005, Blood Products Advisory Committee discussion concerning home-use test to detect HIV-1 antibodies.

As laboratory professionals, we believe that testing of biological specimens, either for diagnosis or for monitoring a known condition, is best done by trained laboratory professionals. We also recognize, however, that home-tests can play an important role in health care. Thus, AACC recommends that the FDA carefully consider the associated risks and benefits before approving an HIV home-test, including:

- How the test performs in its intended setting - do the individuals performing the test consistently get accurate results?
- What is the likelihood of obtaining false-positive or false-negative results and how are those issues addressed? (Is a confirmatory test required for positive results?)
- Is counseling required?
- What mechanisms are in place to encourage compliance?
- What impact will the test have on public health reporting?

By way of background, AACC is the principal association of professional laboratory scientists including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (314) 302-1503, or Vince Stine, Director, Government Affairs, at (202) 835-8721.

Sincerely,

  
Mitchell G. Scott, PhD  
President, AACC

SF  
AIDS  
FOUNDATION

Testimony Presented to the Blood Products Safety Advisory Committee,  
U.S. Food and Drug Administration

Presented by Ernest Hopkins, Director of Federal Affairs,  
San Francisco AIDS Foundation

November 3, 2005

Today, the Blood Products Safety Advisory Committee is considering criteria that the U.S. Food and Drug Administration (FDA) should use when evaluating applications for over-the-counter (OTC) home-use rapid HIV test kits. We appreciate the opportunity to provide comments on this critical issue.

First, let me explain that the San Francisco AIDS Foundation generally supports the availability of at-home HIV rapid test kits. We believe that the availability of such a product could play a key role in increasing access to HIV testing and in helping many Americans more rapidly determine their HIV status. According to the federal Centers for Disease Control and Prevention, it is estimated that 25-30% of the estimated 1.1 million Americans living with HIV are not aware that they are infected. We must continue to develop innovative and creative approaches that will significantly reduce the number of people in our country who are unaware that they are HIV-positive. At-home HIV test kits should be a part of this larger effort.

In particular, home-use HIV test kits could be especially helpful and useful for individuals who are uncomfortable seeking an HIV test at a physician's office or HIV testing clinic but who desire speedy test results and prefer the privacy and anonymity of testing at home. They could also be used by those who feel they do not have the time to spend waiting at a physician's office or HIV testing clinic and would be far more likely to get tested if they could get speedy HIV test results at home.

We do recognize that potential misuses of this product-such as a person somehow coercing or forcing a spouse or sexual partner to take such a test or an individual attempting to gather a sample from someone else to be tested without his or her consent-raise significant concerns. We believe, however, that the benefits of such a product outweigh these risks.

That all being said, we also believe that the FDA needs to apply rigorous criteria in reviewing such products to ensure that they are as effective as possible and do not produce negative health outcomes for those who purchase and use the product. Specifically, we recommend that the committee support the following criteria:

- (1) The kits must ensure that those who purchase and use the product are able to easily and correctly interpret the results. It is critical that the person taking the test is able to easily understand the results and has ample and easily accessible information that helps him/her understand what the results mean. The fact that a negative test result could still mean the person is actually infected (because of the window period between infection and the creation of antibodies) must be clearly explained in language that is easily understood. Similarly, the remote chance that test results could be inaccurate needs to be explained in clear terms that will be understood by all who use the product.
- (2) The companies who sell these products must ensure that individuals who test positive have immediate access to emotional support and counseling. For many individuals, testing positive for HIV can create significant emotional distress. Individuals who find out they are HIV -infected should have 24-hour phone access to trained emotional support counselors who can assist them with dealing with the array of reactions they may have.
- (3) Individuals who use the product must have an easy and reliable mechanism to obtain referrals to HIV treatment and prevention services in their local community. It is critical that people who opt to use a home-use HIV test kit be able to quickly link to HIV programs in their local area. Those who test positive should be able to quickly identify resources in their area that will assist them in getting a confirmatory test and to obtain HIV care, treatment and support. Those who test negative or have inconclusive results should also be able to easily get information about organizations they can turn to for additional information about HIV/AIDS.
- (4) The product should include information about the risks posed by other sexually transmitted diseases and about how to prevent the spread of both mv and other STDs. If a consumer is concerned enough to buy an at-home HIV test because they believe they may be at risk for HIV, they may also be at risk for other STDs. We believe the manufacturer has a responsibility to help educate consumers about this potential risk and to provide clear and comprehensive information about how individuals can best protect themselves from getting HIV or other STDs.
- (5) This information and these resources should be made available in a variety of languages. In order to be effective, as many individuals as possible must be able to understand what their results mean and where they can receive additional support and referrals. At a minimum, materials, emotional support and referrals should be made available in Spanish.

- (6) **These test kits must be priced appropriately to ensure maximum utilization and benefit.** If at-home test kits are expensive, they will be used by a much smaller segment of the population and our goals of helping more Americans identify their HIV -status will be undermined. Especially given the disproportionate impact of HIV on those with lower incomes, it is critical that these products be priced to ensure that as many people at risk for HIV have access to them as possible.

We sincerely appreciate the opportunity to speak on these important issues. The San Francisco AIDS Foundation hopes to work with the FDA and the United States Health and Human Services Agency to ensure that these products are made available in the near future and that the criteria we have outlined are met.

-end

# **Over-the-Counter HIV Testing**

## A Consumer Advocate Strategy

November 3, 2005

Anything Over 3 Minutes Is Forever.



## 1.0 Implications of an aTe Rapid HIV Test -A Manufacturer's Experience

MedMira launched its over-the-counter (GTC) rapid HIV test in Hong Kong and Macao in January 2005.

Drawing on our first-hand experience gained in the field, we would like express our thoughts on the implementation, management, and monitoring of a rapid HIV test for home use in the United States.

First, it is important that the "right" rapid HIV tests be considered for GTe.

- It is vital that the strict regulatory practices developed by the United States Food & Drug Administration (FDA) for rapid HIV testing in professional settings be carried through into a consumer home-test option.
- No HIV test, either rapid or traditional, will give truly accurate results 100% of the time, depending on a number of factors.
- Each test has an inherent accuracy in its ability to detect true HIV positive and negative cases, but this accuracy can be influenced by factors such as the ability of the user to follow the testing directions, obtain and apply the specimen, etc.
- It is important to consider the capabilities of test; whether it may be prone to false-negatives due to its technology limits (as is the case with one FDA-approved rapid HIV test containing only a reagent control where a procedural and reagent control line is critical) or whether tests that use specimen types other than traditional blood specimens may be affected by interfering factors (such as the usage of caffeine, alcohol, tobacco).

Second, it is important to consider certain issues surrounding the use of rapid HIV tests by the general public:

- Reasonable access routes for consumers to counseling and treatment and, more importantly, ensuring that they are used. This is critical to the health and welfare of the individual using the test.
- Impact of OTC rapid HIV tests on public health and welfare, with regard to partner notification, results reporting and tracking of the epidemiology of HIV infections to public health agencies.
- Potential liability issues both to the manufacturer and the public healthcare system if/when false results are obtained.
- Impact of an OTC rapid HIV test on Adverse Event identification and investigation (according to 21 CFR 803).

## 2.0 The Consumer Advocate System - An Overview

What if someone tests negative for HIV, but there was a problem with that particular test, or the test procedure was performed incorrectly, and that person was actually HIV-positive, and then unknowingly infected someone else?

Or someone who is knowingly HIV -positive purposely infects someone else?

What if the specimen to be tested is not collected properly, is not a sufficient amount, is not suitable, or is not added to the test at all?

Or perhaps someone misinterprets the results and is HIV-positive when they think they are negative?

What about consumers that face a high level of stress and anxiety either before or after conducting the test at home and mayor may not have emotional support available to them?

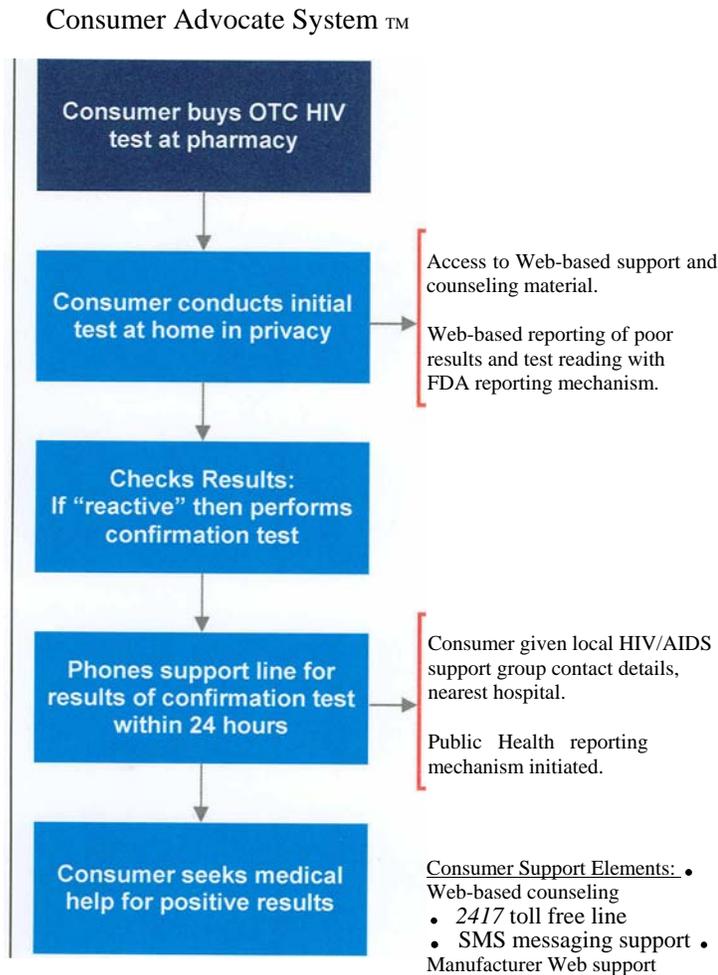
Will a person receiving HIV-negative results understand the concept of the "window period" and the need for retesting after a certain period of time without direct counseling?

These are serious concerns that must be addressed prior to FDA approval of OTC HIV testing.

Presently, the use of FDA-approved rapid HIV tests are regulated by systems and procedures that work hand in hand with current laboratory and professional healthcare services testing programs. Implementing a Consumer Advocate System™ (CASTM) in association with all OTC rapid HIV tests will serve to maintain standards and controls associated with current HIV testing practices, while preserving the integrity of public health. This system will provide consumers with additional protection, and access to professional counseling beyond a pre-recorded voice messaging system or a general pamphlet. It will help consumers help themselves.

## 2.0 The Consumer Advocate System - An Overview cont'd

The CASTM for aTC rapid HN tests would be implemented to ensure access to counseling and confirmation of initial rapid test results using a system similar to that employed by professional laboratories (see Chart I below).



The above diagram illustrates how a consumer would purchase a test package at a pharmacy that contains an "initial" test that is easy to use and a "confirmatory" test that the consumer will use if the initial results are Reactive. Confirmation results can be obtained in 24 hours, and the patient will obtain these results from and be counseled by a live, trained counselor. This system also enables reporting of positive cases from a reliable source to help monitor the virus' epidemiology in the United States.

### 3.0 Conclusion

In considering a CASTM, such as proposed here, government and manufacturers must also address privacy issues, tracking of the HIV epidemiology in the United States, quality control and management, and a strict process to ensure the right tests are approved for GTC use. Guidelines must be in place to address this serious issue, and a program such as proposed here with further input and development from the FDA and CDC may offer a viable solution.

### Contact Information

#### Media Relations

Andrea Young - Manager, Global Marketing Communications  
ayoung@medmira.com  
Phone: (902) 450-1588

#### General Inquiries

Phone: 1-877-633-6472 (North America only); or (902) 450-1588  
Fax: (902) 450-1580  
www.medmira.com

### Proposal & CDS Development Authors

#### Regulatory Mfairs

Ms. Robyn Cook, MSc  
Vice President, Process & Compliance  
rcook@medmira.com

#### Science & System Structure

Neeraj Vats, Ph. D.  
Vice President, Technology & Intellectual Property  
nvats@medmira.com

#### Consumer Mfairs & System Structure Giles

Crouch, MM  
Vice President, Sales & Marketing  
gcrouch@medmira.com

#### Communications

Andrea Young, BPR  
Manager, Global Marketing Communications  
ayoung@medmira.com