

Test anxiety

The FDA has approved an HIV viral load test, but some experts claim that no one knows what the test results will mean

by Bob Roehr

Food and Drug Administration approval for the Amplicor test to measure HIV viral load has brought as many questions as answers for people with AIDS and their physicians. Beyond the bromide of "low is good, high is bad," there are no definitive guidelines for using the test in clinical management of HIV disease.

Amplicor, approved on June 3, is manufactured by a subsidiary of the pharmaceutical company Hoffmann-LaRoche. It uses polymerase chain reaction (PCR) technology in a laboratory environment and is sensitive enough to measure as few as 400 copies of the virus per milliliter.

Roche is offering two free tests to people who are HIV positive as part of its initial marketing effort. The offer began June 17 and runs for 60 days. Patients and physicians can access the program by calling 1-888-TEST PCR.

Martin Delaney, executive director of Project Inform in San Francisco, calls approval of the test "profound. It gives us a tool to measure a clear-cut goal in HIV disease for the first time." He believes it would be "crazy" to try to use recently approved therapies like protease inhibitors and nevirapine "without the concurrent use of the viral load marker."

Ernest Hopkins, head of treatment advocacy for the National Association of People with AIDS, says his group will initiate a "major alert" to its member organizations "to encourage people to take advantage" of the free offer.

But Richard Klein, an FDA official in the Office of AIDS and Special Health Issues, is skeptical. "Everybody says it [the test] is absolutely necessary to manage your drugs. Based on what? I keep asking people that—as to why it is necessary and how to interpret it. And nobody has an answer."

"If you are looking at using the test to manage drugs," Klein says, "what number should you use as your pivot point? How do you know when you should switch the drug? When it goes up? How much?"

Then there are the test's apparent anomalies. Under standard conditions an effective therapy should knock down viral load and raise CD4

counts. But Klein said a scatter graph presented at the FDA hearing on the test "had 20 percent of the dots [patients] where they both went up or they both went down. Nobody could interpret what that meant."

Klein is concerned that nobody knows whether the viral load test will show different results if taken during different parts of the day or the week. Experience has shown that CD4 levels can vary substantially during the daily cycle of body functions. Viral load may follow this pattern.

Klein cites testimony from a National Institutes of Health researcher on the rigor NIH had to implement to get continuity from lab to lab with its viral load testing. "[He] doesn't think commercial labs around the country are working together to make sure you are going to get the same results all the time," Klein said.

"Everybody is assuming that because [the test] is out there, and because they hear about it, that everybody knows the answers to those questions," Klein said. "People agonize over those numbers without knowing what they mean. But people agonize over everything—CD4s, antigen levels. You are looking at this little picture and don't know what the whole picture is."

Klein believes the manufacturer made the Amplicor test more widely available than its approval for research purposes indicated, in order to help create a market. And he claims the ploy has worked, because treatment activists latched onto it and helped push for full market approval, despite there being little data available as to what the test means as a clinical management tool.

Spencer Cox of the Treatment Action Group in New York shares the frustration with Amplicor: "There is not much data on using it to monitor responses to therapy. A lot of doctors feel that they don't know enough about what it means to use it accurately."

Cox is also skeptical of the manufacturer's "marketing scheme."

"I don't want people falling into the trap of thinking, oh my god, I had one test and it came in at 115,000, I have to do something right now," he said. He urges people with AIDS to think of RNA testing as "a long-term strategy, it's not a one-shot deal."

Log Cabin Republicans spokesman David Greer says, "The administration finally gets it. You can't just appoint somebody who doesn't know the community intimately. She was caught extremely off guard during the whole same-sex marriage thing." He believes that "Richard Socarides is much better able to handle the issues when they get hot."

Columnist Richard Mohr is "delighted to see Marsha Scott gone; the only thing she managed to accomplish was to snooker our weak and groveling national organizations."

Activist Michael Petrelis says, "As far as I could tell, Scott's mission was to undercut legitimate anger at the president's betrayal of gay and AIDS promises. I wonder why not a single Democratic gay leader lambasted Clinton for appointing a heterosexual to be the gay liaison. Imagine the uproar if he had appointed a man to be a liaison to women's groups, or a white person to serve the needs of African Americans."

But Petrelis finds little comfort in Socarides' sexual orientation: "He is a Democrat who happens to be gay. Other than working to convince gay voters to cast ballots for Clinton in November, what is Socarides' agenda?"

Bob Roehr

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Socarides replaces Scott as Clinton's gay liaison

Marsha Scott is leaving as liaison to the gay and lesbian community, exactly one year after becoming the first Clinton administration official to occupy that post. Richard Socarides, a gay man, will move from the Department of Labor to assume Scott's responsibilities.

According to *The Washington Post*, Scott will "go to Chicago to help handle [Democratic National] convention VIPs, meaning everyone from dignitaries to Cabinet members to FOBs [friends of Bill] to big contributors."

Community reaction to the move was predictable.

Keith Boykin says he is "disappointed she is leaving, she has done a good job." The executive director of the National Black Gay and Lesbian Leadership Forum was a member of the White House staff who worked with Scott. He "hopes [Socarides] is able to meet the challenge."

Helen Gonzales is "sad" to see Scott go. "She played an important role in providing access to our community." Gonzales hopes that Socarides will have "the same type of access" to the president that Scott did.