



# Wait, Wait, Don't Test Me!

**IF YOUR PATIENT REFUSES AN HIV TEST**, could there be a legitimate reason? When a person says “no” to the test because of participation in an HIV vaccine clinical trial, pay attention.

The CDC recommends opt-out HIV testing as a valuable tool to identify HIV positive individuals and interrupt the transmission of HIV. All available tools to identify and counsel HIV-infected individuals should be pursued. However, one important population of persons must be considered in any such policy: participants in HIV vaccine trials.

By 2008, more than 30,000 individuals worldwide had participated voluntarily in experimental HIV vaccine trials. The CDC recommendations pose some complex issues for these individuals, as many will test positive in antibody-based screening assays. In the last five years, almost all HIV vaccines have elicited some reactivity in commercially based assays. All of these vaccine study participants are HIV-negative by RNA/DNA assays.

We don't know how long experimental vaccine recipients will retain these antibodies; some have demonstrated seropositivity for more than 15 years after their trial concluded. With HIV tests, including EIA, Western Blot and rapid tests detecting antibodies, not the virus, HIV vaccine trial participants risk being falsely labeled as HIV positive as a result of HIV testing.

Not only does an incorrect HIV diagnosis cause unwarranted distress to the patient, false diagnoses impact HIV reporting to government and health organizations, potentially calling those statistics into question. Revealing the presence of antibodies to the patient, even if it is not in the form of a false diagnosis, can compromise his or her “blind” participation in the study. This is important because “blinded” participation is necessary for accurate conclusions about the vaccine's efficacy.

During the informed consent process, HIV vaccine trial participants are asked to have all HIV testing performed at their trial sites. The vaccine trial study design requires that sites regularly test participants and provide testing to any participant or former participant on request. Validated algorithms to define HIV infection for vaccination are avail-

able at all HIV Vaccine Trials Network sites. Physicians may encounter patients who decline HIV tests because of study participation, and their requests should be respected.

Using the CDC database of HIV testing sites, (available at [www.hivtest.org](http://www.hivtest.org)) every HIV testing site within 25 miles of each HIV Vaccine Trials Network study site was sent information about vaccine-induced seropositivity to raise awareness of the importance of HIV testing only at the study site.

You can decrease the risk of an incorrect diagnosis in HIV vaccine trial participants by learning if there are HIV vaccine trials in your area and by asking patients if they are participating in such a trial. If a patient who is a trial participant needs an HIV test, coordinate the test with the participant's trial site.

Apply these best practices to avoid the potential for incorrect diagnosis.

- Inform the patient of his or her legal rights surrounding HIV testing. He or she must consent to—and has the right to refuse—an HIV test (trial participants are advised not to be tested outside the trial site).
- Ask patients if they are participating in an HIV vaccine trial—even if they don't fit your perceptions of study participants.
- Familiarize yourself with HIV vaccine trials happening in your area. Visit [www.hvtn.org](http://www.hvtn.org) for information.
- If you need HIV test results on a patient who is an HIV vaccine trial participant, contact the participant's trial site. Coordinate the HIV test through the trial site. The site can perform RNA or DNA HIV testing that provides accurate results to you and the participant. **HIV**



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