



PEPFAR
U.S. President's Emergency Plan for AIDS Relief

HIV testing in PEPFAR-supported survey and surveillance activities

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This statement presents the policy of The Office of the U.S. Global AIDS Coordinator and Health Diplomacy (OGAC) regarding HIV testing (including informed consent, HIV testing strategy and return of HIV status information) in The United States President's Emergency Plan for AIDS Relief (PEPFAR)-supported (through technical assistance, funding and implementation support) survey and surveillance activities.

Informed consent

- All participants should provide informed consent to participate in all aspects of a PEPFAR-supported survey or surveillance activity, including testing for HIV infection (testing for the presence of HIV antibodies, antigens or virus). This applies to testing for HIV infection in survey and surveillance activities:
 - Irrespective of the survey or surveillance design: e.g. household-based surveys, facility-based surveys, sentinel surveillance, bio-behavioral surveys among key or priority populations.
 - Irrespective of the location or modality of testing: e.g. household-based HIV counseling and testing, venue-based testing, mobile testing, laboratory-based testing.
 - Irrespective of the testing strategy or assay format: e.g. rapid diagnostic tests, Western blot, enzyme immunoassay, polymerase chain reaction, viral load.
- Basic requirements for informed consent for testing for HIV infection in PEPFAR-supported survey and surveillance activities are defined by the Federal Policy for the Protection of Human Subjects (the "Common Rule").^{i,ii,iii} Additional requirements for informed consent may be applied by PEPFAR implementing agencies provided they are consistent with OGAC policy presented here, and Federal Policy on the Protection for Human Subjects.
- This policy is directed at testing for HIV infection that occurs in the context of PEPFAR-supported survey and surveillance activities, not testing for HIV infection in the context of routine service provision. HIV surveillance activities that collect results from testing for HIV infection offered as part of routine service provision (e.g. HIV testing for pregnant women attending antenatal services, HIV testing for newly registered cases of tuberculosis) may do so only if HIV testing clients provide informed consent for routine testing, or have the informed opportunity to opt-out of routine testing, as part of standard procedure and in accordance with national guidelines.

HIV testing strategy

- PEPFAR implementing agencies and funded partners involved with survey and surveillance activities will follow standardized, evidence-based HIV testing strategies outlined in the 2015 World Health Organization's *Consolidated Guidelines on HIV Testing Services*.^{iv}

- In addition, all testing for HIV infection in PEPFAR-supported survey and surveillance activities will conform to the PEPFAR Laboratory Technical Working Group recommendation that, if enzyme immunoassay (EIA)-based assays are utilized in the testing algorithm, all EIA positive specimens receive confirmation by a highly specific confirmatory test (e.g., Western blot, Geenius™ HIV 1/2 Confirmatory assay [Bio-Rad, France], INNO-LIA® HIV I/II Score [Fujireio Europe, Belgium]) to reduce the risk of false positive results.

Return of HIV status information

- All PEPFAR-supported survey and surveillance activities will provide participants the opportunity to receive final HIV status information generated by the activity. It is imperative from an ethical perspective, as well as a clinical and epidemic control perspective in the era of test and start, that participants have the opportunity to know their correct HIV status. This position comports with the core bio-ethical principles of Beneficence and Respect for persons.^v
 - “Final HIV status” refers to the classification of the participant with regards to the presence of HIV infection (negative, positive, not-determined—additional testing indicated) that is supported by the totality of information available to the survey or surveillance team. The totality of information that informs this classification includes information from any testing modality, location (e.g. household, clinic or laboratory), target biomarker (e.g. HIV antibodies, antigen or virus), assay format (e.g. rapid diagnostic tests, Western blot, EIA, polymerase chain reaction, viral load), or purpose (e.g. diagnosis, confirmation, surveillance), conducted in the context of the survey or surveillance activity.
- If participants receive multiple instances of testing for HIV infection as part of participation in the survey or surveillance activity (e.g. testing that involves different locations, targeted biomarkers, assay formats or purposes), participants will be provided the opportunity to receive final HIV status information that is informed by all instances of testing. Survey and surveillance staff should not have information about the final HIV status of a participant that the participant him/herself does not have the opportunity to receive.
- Participants in PEPFAR-supported survey and surveillance activities will be provided with the opportunity to receive final HIV status information immediately or with the minimum delay in order to facilitate the timely receipt of appropriate HIV-related services: linkage to HIV treatment for HIV-positive participants and appropriate prevention messages and services for HIV-negative participants.
- The opportunity to receive final HIV status information—irrespective of the context, targeted biomarker, assay format or purpose of the testing—will be actively provided and facilitated by the survey or surveillance team, without requiring participants to actively seek out the opportunity to receive testing results.

ⁱ Code of Federal Regulations. Title 45 – Public Welfare – Department of Health and Human Services – Part 46 – Section 116 – Protection of Human Subjects.

ⁱⁱ Code of Federal Regulations. Title 22 – Foreign Relations – United States Agency for International Development – Part 225 – Section 225 – Protection of Human Subjects.

ⁱⁱⁱ Code of Federal Regulations. Title 32 – National Defense – Department of Defense – Part 219 – Protection of Human Subjects.

^{iv} World Health Organization. *Consolidated Guidelines on HIV Testing Services*. Geneva, 2015.

^v National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, 1979.