VISP FAQ for health care professionals

February 2025

What is VISP?

Human immunodeficiency virus type 1 (HIV-1) vaccine trial participants can test positive for HIV even if they are not infected with HIV because the investigational vaccine has induced antibodies against HIV-1. This is called vaccine-induced seropositivity (VISP) or, less commonly, vaccine-induced seroreactivity (VISR). A standard HIV antibody test could provide positive results for your patient for several years even though they are not infected with HIV.[1,2]

An HIV nucleic acid test (NAT; such as polymerase chain reaction [PCR]) is not affected by vaccine seropositivity and therefore will distinguish between VISP and an HIV infection.[1,2]

1. HIV Vaccine Trials Network. The right HIV test. Accessed February 26, 2025. https://www.hvtn.org/participate/visp-and-hiv-testing.html.
2. Janssen Infectious Diseases & Vaccines. VISP Testing Service. Accessed February 26, 2025. https://visptesting.com.

What is VISR?

VISR means vaccine-induced seroreactivity. It is a synonym of vaccine-induced seropositivity (VISP).[1]

1. Janssen Infectious Diseases & Vaccines. VISP Testing Service. Accessed February 26, 2025. https://visptesting.com.

Is there an HIV vaccine available?

As of December 2024, there is no approved or marketed human immunodeficiency virus (HIV) vaccine available anywhere in the world, although research for an HIV vaccine has been ongoing for >30 years. All people who have received an investigational HIV vaccine were participants in a clinical trial.[1]

1. Morgan Coulson. Why don't we have an HIV vaccine? Accessed February 26, 2025. https://publichealth.jhu.edu/2022/why-dont-we-have-an-hiv-vaccine.

Do all participants of an HIV vaccine trial have VISP?

Vaccine-induced seropositivity (VISP) can only be present in participants who have received a human immunodeficiency virus (HIV) vaccine during a study. The frequency of VISP in study participants depends on the type of vaccine that was administered. Most participants who have received the Johnson & Johnson (J&J) HIV-1 vaccine in a study are expected to have VISP. The participants who have received placebo do not have VISP.[1]

1. Bridge HIV. What you need to know about vaccine–induced sero–positivity (VISP). Accessed February 26, 2025. https://www.bridgehiv.org/trialsandvials/visp.

WHAT IS VISP?

Do people who have received an HIV vaccine from another company or research group as part of a study, but not the Johnson & Johnson (J&J) vaccine, also have VISP?

Yes, it is a possibility. But the presence, frequency, and duration of vaccine-induced seropositivity (VISP) vary from investigational vaccine to investigational vaccine.[1]

1. Bridge HIV. What you need to know about vaccine–induced sero–positivity (VISP). Accessed February 26, 2025. https://www.bridgehiv.org/trialsandvials/visp.

What are the clinical studies that used the Johnson & Johnson (J&J) HIV-1 vaccine, and where did they take place?

Study name	Study number	ClinicalTrials.gov identifier	Countries
Mensch	HIV-V-A002 / IPCAVD006	NCT02218125	USA (single site in Boston)
	HIV-V-A003	NCT02304185	USA (single site in Miami)
Approach	HIV-V-A004	NCT02315703	Rwanda
			South Africa
			Thailand
			Uganda
			USA
	HPX1002 / IPCAVD010	NCT02685020	USA (single site in Boston)
Traverse	HPX2004 / HVTN 117	NCT02788045	Rwanda
			USA
Ascent	HPX2003 / HVTN 118	NCT02935686	Kenya
			Rwanda
			USA
Imbokodo	HPX2008 / HVTN 705	NCT03060629	Malawi
			Mozambique
			South Africa
			Zambia
			Zimbabwe
Mosaico	HPX3002 / HVTN 706	NCT03964415	Argentina
			Brazil
			Italy
			Mexico
			Peru
			Poland
			Spain
			USA (including Puerto Rico)

WHAT IS VISP?

How long does VISP last?

If a former participant has developed vaccine-induced seropositivity (VISP), the antibodies may wane quickly or they may remain present for many years after the last study vaccination.[1] Based on data from Johnson & Johnson (J&J; formerly known as Janssen) human immunodeficiency virus type 1 (HIV-1) vaccine studies, >90% of participants still have VISP at 6.5 years after the first vaccination, and VISP is highly prevalent across a range of different fourth-generation antigen/antibody tests.[2]

1. Bridge HIV. What you need to know about vaccine–induced sero–positivity (VISP). Accessed February 26, 2025. https://www.bridgehiv.org/trialsandvials/visp.
2. Lavreys L. Vaccine-induced seropositivity/reactivity (VISP/R) in participants of the APPROACH study (HIV-V-A004). Presented at: HIV Vaccine Trials Network (HVTN) Annual Meeting; October 19, 2022; Seattle, WA, USA.

Can VISP be passed from one person to another?

Former participants who have vaccine-induced seropositivity (VISP) cannot pass the antibodies from one person to another by kissing or participating in sexual contact. However, it may be possible to pass the antibodies through a blood transfusion or organ donation, although antibodies transferred in this manner are temporary. Additionally, there is a chance that antibodies could be passed from mother to child during pregnancy. The antibodies from the vaccine that are passed on to the baby are temporary. These antibodies are not harmful to the baby. Hence, newborns should be tested using a polymerase chain reaction (PCR) test (nucleic acid test [NAT]).[1]

1. HIV Vaccine Trials Network. The right HIV test. Accessed February 26, 2025. https://www.hvtn.org/participate/visp-and-hiv-testing.html.

What is the VISP HIV Testing Service?

Johnson & Johnson (J&J) provides a post-study vaccine-induced seropositivity (VISP) HIV Testing Service allowing former participants to receive a human immunodeficiency virus type 1 (HIV-1) nucleic acid test (NAT) at no cost for as long as VISP is present in their bodies. Post-study testing is for determining HIV infection status.[1]

1. VISP Testing Service. VISP questions and answers. Accessed February 26, 2025. https://visptesting.com/wp-content/uploads/2022/12/VISP-QA-for-Parexel-website-v2.063.pdf.

How can my patient with VISP get tested through the VISP HIV Testing Service?

If possible, former participants should get all their human immunodeficiency virus (HIV) tests done at the study site or through the vaccine-induced seropositivity (VISP) HIV Testing Service. Please see the table below for VISP HIV Testing Service contact information by country.

WHAT IS VISP?

VISP HIV Testing Service Contact Information by Region/country

Region/country	Contact
Europe	https://visptesting.com
Malawi, Mozambique, South Africa, Zambia, or Zimbabwe	https://www.hvtn.org/participate/visp-and-hiv-testing.html
Mexico, Argentina, or Brazil	Please contact the study site (doctor) where your patient was vaccinated
Peru	https://www.hvtn.org/participate/visp-and-hiv-testing.html
Thailand	Please contact the study site (doctor) where your patient was vaccinated
Uganda, Rwanda, or Kenya	Please contact the study site (doctor) where your patient was vaccinated
USA (including Puerto Rico)	https://www.hvtn.org/participate/visp-and-hiv-testing.html

What are the different NATs?

Nucleic acid tests (NATs) identify pieces of the human immunodeficiency virus (HIV) genome itself instead of antibodies that are identified in common/regular tests.

Overview of terms and abbreviations[1,2]:

- NAT (nucleic acid test): an overall term for tests that detect genetic material (nucleic acid like RNA or DNA)
- NAAT (nucleic acid amplification test): a NAT with “amplification,” which refers to the technology that is necessary to detect very small amounts of the nucleic acid
- PCR (polymerase chain reaction): refers to the technology used to amplify very small amounts of nucleic acid so that it can be detected
- DNA (deoxyribonucleic acid): a form of genetic material. Once HIV is inside a cell, its RNA is converted into DNA
- RNA (ribonucleic acid): a form of genetic material. The genetic material (or genome) of HIV is made of RNA
- DNA PCR (deoxyribonucleic acid polymerase chain reaction): a NAT that detects small amounts of DNA
- RNA PCR (ribonucleic acid polymerase chain reaction): a NAT that detects small amounts of RNA
- TNA (total nucleic acid) test: a test that detects both RNA and DNA

1. Centers for Disease Control and Prevention. Technical update for HIV nucleic acid tests approved for diagnostic purposes. Accessed February 26, 2025. https://stacks.cdc.gov/view/cdc/129018.
2. HIV i-Base. HIV testing and risks of sexual transmission, appendix 1: different types of HIV test. Accessed February 26, 2025. https://i-base.info/guides/testing/appendix-1-different-types-of-hiv-test.

WHAT IS VISP?

What are the different antibody tests?

Various human immunodeficiency virus (HIV) tests detect antibodies, and they are often called serological assays or immunoassays. Some are complex and done in a laboratory, and some are simpler tests done by a health care practitioner; both use blood. Finally, some are self-tests that anybody can do, based on a blood drop or saliva. Availability of different antibody tests varies from country to country. In general, tests based on antibodies could come back positive even if a person with vaccine-induced seropositivity (VISP) does not have HIV.

Overview of terms and abbreviations[1]:

- EIA (enzyme-linked immunoassay): a laboratory test that detects antibodies and antigens/proteins, such as those from HIV. There have been several generations of assays (with increasing performance), and the most commonly used are the fourth-generation tests
- Western blot: a test utilizing engineered proteins that are separated based on their size and transferred to a membrane to bind HIV-specific antibodies in the sample
- Rapid tests: tests based on an HIV EIA but commercialized in a kit allowing any health care practitioner to use them. They generally provide results in <30 minutes
- Self-tests: tests based on an HIV EIA but commercialized in a kit allowing any individual to use them. They generally provide results in <30 minutes

1. HIV i-Base. HIV testing and risks of sexual transmission, appendix 1: different types of HIV test. Accessed February 26, 2025. https://i-base.info/guides/testing/appendix-1-different-types-of-hiv-test.