

VISP FAQ for participants

February 2025

What is VISP or VISR?

Participants who receive a human immunodeficiency virus type 1 (HIV-1) vaccine in a study may produce antibodies against HIV-1. On standard antibody-based HIV tests, which work by detecting the presence of HIV antibodies, vaccine-induced seropositivity (VISP) may cause a former participant to test positive for HIV even if they have not acquired HIV. This is referred to as VISP or vaccine-induced seroreactivity (VISR).^{1,2}

People who have received an HIV-1 vaccine during an HIV-1 vaccine study should get a special HIV-1 test that looks for the virus itself, which is generally known as a polymerase chain reaction (PCR) test. An HIV-1 PCR test is not affected by antibodies induced by the vaccine 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?

Some people use the words vaccine-induced seroreactivity (VISR). It has exactly the same meaning as 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 study.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 former 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; formerly known as Janssen) 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>.

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?

It is possible. The presence, duration, and frequency of vaccine-induced seropositivity (VISP) vary between different experimental vaccines.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)

How long does VISP last?

If a participant receives an investigational human immunodeficiency virus (HIV) vaccine, they may or may not make antibodies against HIV. If they do make antibodies, the antibodies may go away quickly or they may last for many years after the last study vaccination.¹ Based on data from Johnson & Johnson (J&J; formerly known as Janssen) HIV-1 vaccine studies, >90% of participants still have vaccine-induced seropositivity (VISP) at 6.5 years after the first vaccination.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. It may be possible to pass the antibodies through a blood transfusion or organ donation, and therefore you might not be able to donate blood or organs. If a former participant gets pregnant, they might pass the antibodies to the baby. The antibodies from the vaccine that are passed on to the baby are temporary and go away over time. These antibodies are not harmful to the baby. If you are pregnant or have recently given birth and suspect you have VISP, speak to your doctor about getting your newborn tested with a human immunodeficiency virus (HIV) test that looks for HIV nucleic acid (polymerase chain reaction [PCR]), not for HIV antibodies.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-1 infection status.¹

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

How can I explain this situation to my health care provider?

If anyone asks you to get tested for human immunodeficiency virus (HIV), tell them that you have been in an HIV vaccine study and that you might have vaccine-induced seropositivity (VISP). You can also tell them about the informational website WhatIsVISP.com.

Explain that if you are being tested with an HIV test that is looking for antibodies, the test might look as if you have acquired HIV even if you have not. Therefore, you could get an incorrect diagnosis of HIV infection.

If possible, you should get all your HIV tests done at the study site where you received the HIV-1 vaccine or through the VISP HIV Testing Service (see table below). If this is not possible, then you will have to explain to the health care provider requesting an HIV test that you will need a polymerase chain reaction (PCR) test that looks for the HIV virus. Give the provider the contact information of your study site or the VISP HIV Testing Service. In case the health care provider does not understand the situation of VISP, it is better to say “no” to the HIV test and contact your former study site or the VISP testing service for your country (see table below) for assistance to get you the correct test.¹

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

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 you were vaccinated
Peru	https://www.hvtn.org/participate/visp-and-hiv-testing.html
Thailand	Please contact the study site (doctor) where you were vaccinated
Uganda, Rwanda, or Kenya	Please contact the study site (doctor) where you were vaccinated
USA (including Puerto Rico)	https://www.hvtn.org/participate/visp-and-hiv-testing.html

What are the different NATs?

You may encounter various terms or abbreviations referring to nucleic acid tests (NATs), and these are clarified below. NATs determine the presence of tiny pieces of human immunodeficiency virus (HIV) itself. These are components of the genetic material of the virus and are different from the antibodies that are identified in the standard HIV 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: 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

For ease of understanding, we only mention the term “PCR” on the vaccine-induced seropositivity (VISP) website.

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 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 a blood sample. Finally, some are self-tests that anybody can do and use 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. Over the years, these tests have improved in detecting an infection with HIV. Currently, the most commonly used are called fourth-generation tests
- Western blot: a test that detects proteins (such as antibodies) using their size and ability to attach to a membrane
- Rapid tests: tests based on an HIV EIA but commercialized in a kit allowing any health care practitioner to use them. They generally are among the simplest to use and provide results in <30 minutes
- Self-tests: tests based on an HIV EIA but commercialized in a kit allowing any individual to use them at home. They generally are among the simplest to use and 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>.