

Topic	Question	Answer
HIV TESTING AND HIV VACCINE RESEARCH	What is VISP/VISR?	Participants who receive an HIV vaccine in a clinical trial may produce antibodies against the HIV proteins in the vaccine. This is referred to as Vaccine Induced Seropositivity (or Vaccine Induced Seroreactivity). On conventional HIV tests, which work by detecting the presence of HIV antibodies, VISP/R may cause a participant to test positive for HIV even in the absence of actual HIV infection. A HIV nucleic acid test is not affected by vaccine seropositivity and therefore will distinguish between VISP/R and an HIV infection.
HIV TESTING AND HIV VACCINE RESEARCH	How long will VISP/R last?	If a participant receives an experimental HIV vaccine, they may or may not make antibodies to the HIV proteins expressed in that vaccine. If they do develop VISP/R, the antibodies may wane quickly, or they may remain present for many years after last study vaccination. Based on data from Janssen HIV vaccine studies, >90% participants still have VISP/R at least 5.5 years post-last vaccination and VISP/R is highly present across a range of different 4th gen Ag/Ab tests
HIV TESTING AND HIV VACCINE RESEARCH	Can VISP/R be passed from one person to another?	Participants that have VISP/R cannot pass the antibodies from one person to another by kissing or participating in sexual contact. It may be possible that the antibodies could be passed through a blood transfusion or organ donation, although antibodies transferred in this manner are temporary. If a participant becomes pregnant during or after the study and has VISP, we don't know if the antibodies could be passed to the baby.
HIV TESTING AND HIV VACCINE RESEARCH	What is the VISP/R HIV Testing Service?	The Sponsor provided post-study VISP HIV Testing Service allows a participant to receive an HIV nucleic acid test at no cost for as long as VISP/R is present in their bodies. Post-study testing is for determining HIV infection status.
EU VISP Service	Pharmacist is needed to register on the MAP platform. What if there is no pharmacist at the site?	This is a feature of the MAP portal programming. Due to complexities of the MAP platform background programming, use of 'pharmacist' and 'drug' on the Lab Kit Delivery contact details page cannot be changed. For the VISP Testing service, this page is used for entry of the name and address for lab kit delivery. This can be the same name and address as the HCP who registers and does not have to be a pharmacist nor a different person to the registered HCP.
EU VISP Service	Physicians have to wait for registration approval?	Yes. Parexel will verify the license number to make sure that only eligible HCPs get access to the system.
EU VISP Service	Physician have to wait for the lab kit delivery for blood draw? Is it required to have 2 visits at the site to get a test?	At least one visit will be required (for the actual blood draw). The VISP request and result dissemination could theoretically also be done via phone. For the very first VISP request, an additional on-site visit is required to enable the HCP to verify the participant's identity and eligibility for the VISP service. Once a ppt is registered in the MAP portal, the platform will "recognize" former participants and eligibility will not have to be approved again, so the HCP can immediately request a lab kit or HIV test for that same participant.
EU VISP Service	How long is it expected for a HCP to get MAP portal access?	The inbox is carefully monitored and access should be given quickly, however please be mindful that time is needed to verify HCP license number. Access could take up to 1 hour.
EU VISP Service	Can the HCP also be the kit recipient or is a 2nd person needed to be added to the portal?	The HCP can be the kit recipient; no other person is needed.
EU VISP Service	Where can I find instructions on how to order a lab kit?	These instructions are included in the "how to navigate through MAP" guide that the HCP will be able to download from the MAP portal after registering.
EU VISP Service	How long can blood samples be kept onsite and at what temp before shipment?	It is preferred to ship the samples on the same day. If that is not possible, store the tubes overnight in a fridge (4 to 8 degrees Celsius) and ship the next day. Shipping is done at ambient temperature
EU VISP Service	Is any sample processing required or samples can be shipped directly?	Samples can be shipped directly
EU VISP Service	Is it possible to order more kits in advance to make turnaround shorter than two weeks?	Yes, is possible. Alternatively, HCP can use own tubes (details available on MAP platform) and download & print shipping labels from MAP as well.
EU VISP Service	Is it planned to have a website also in local languages?	The website can be translated through Google Translate, if needed