Participant Information Sheet

HBV blood collection evaluation: Microsample vs Venous Blood

Sponsor: The University of Auckland
Lead Prof. M. Cather Simpson:
Study Site: Auckland City Hospital / Community Outreach locations
Study Contact Person email: natasha@orbisdiagnostics.com
Ethics committee ref.: 2026 FULL 23886

You are being invited to take part in a study about hepatitis B virus (HBV) infection testing. It's completely up to you whether you take part. If you say no, that's okay—your care won't be affected. If you say yes now, but change your mind later, you can stop at any time.

This information sheet explains what the study is about, what taking part would involve, and what the risks and benefits might be. We'll talk through it with you and answer any questions. You also can take time to discuss it with your family, whānau, friends, doctor or with us.

If you decide to take part in the study, you will need to sign the consent form at the end of this document before you can participate in the study. You'll get a copy of this information sheet and the consent form to keep.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Taking part in this study is completely your choice. You do not have to participate. Choosing not to participate will not affect your healthcare in any way. If you decide to take part now but change your mind later, you can withdraw from the study at any time without giving a reason. You may also ask to have your data withdrawn up to one month after your study visit.

WHAT IS THE PURPOSE OF THE STUDY?

This study is being done to compare two ways of collecting blood samples – microsampling and venous blood draw – for testing using an HBV test. We want to see if a new test developed by Orbis Diagnostics (the Orbis HBV Triplex Assay) gives similar results using blood from these different types of sample collection methods. The results could help make HBV testing easier and more accessible in clinics and community settings in the future.

Up to 100 people will take part in this study, all within the North Island of Aotearoa New Zealand. The study involves just one visit. At that visit, two types of blood samples will be taken - one from the upper arm (microsample) and two from a vein (venous blood draw).

There is no treatment or medicine involved in this study. The blood samples will be tested using a new HBV Triplex Assay developed by Orbis Diagnostics, and the results will be compared with standard lab tests. This approach helps us check how well the new test works with different blood sample types.

WHO CAN TAKE PART IN THE STUDY?

You've been invited to take part in this study because you either have been diagnosed with HBV, have had the HBV vaccine or have shown no immune response to HBV in previous testing.

You can take part if you:
- Are 18 or older
- Have HBV or have been vaccinated
- Can give both microsample and venous blood samples in the same visit
- Can give consent

You can't take part if you:
- Are under 18
- Have a bleeding problem
- Got the HBV vaccine in the last 8 weeks
- Can't give consent

No changes to your medications or lifestyle are needed.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You will attend one study visit in which a small blood sample will be taken from your upper arm (microsample) and another (two tubes) from a vein in your arm to compare results using a new HBV test. You will have the choice of sampling from one or both arms. The volume of blood may be smaller or greater than for your standard testing procedure.

WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

Your microsample will be used only for this study. Any leftover venous blood may be stored securely for possible repeat testing during this study. If you give permission, it may also be used in future research to help improve or modify the HBV test. If you do not give consent for future use, the sample will be safely destroyed after the study ends.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with storing your tissue should be discussed with your family/ whānau, as appropriate. A karakia should be discussed as well. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples, citing whakapapa and advising their people to consult before participating in research in which this type of situation occurs. However, it is acknowledged that individuals have the right to choose.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The risks are low and mainly relate to blood collection. You may feel brief discomfort, bruising, or light-headedness. There's a very small risk of infection at the site where blood is taken.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct benefits to you, but the study may help improve access to simpler HBV testing in the future.

WILL ANY COSTS BE REIMBURSED?

There are no costs associated with this study. You will receive a $40 voucher to thank you for your participation.

WHAT IF SOMETHING GOES WRONG?

As this research study is for the principal benefit of its commercial collaborator Orbis Diagnostics, if you were injured in this study, you won't be eligible for compensation from ACC.

However, although Orbis Diagnostics is not the Sponsor of this study, the company has satisfied the Northern A Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

An initial decision whether to compensate you would be made by the Sponsor, the University of Auckland, and/or by the Orbis Diagnostics Insurer. If they decide not to compensate you, you may be able to take action through the Courts for compensation.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

1. Collecting your information
   We will collect information about you during the study, including your test results and basic details like your age. If needed, we may also collect information from your medical records. You can only take part if you agree to this collection of information.
2. Identifying you
   We will give you a study code to protect your identity. This study code number will be used on all your test results and study data. A separate, secure list will link your name to this number in case we need to match up your data later.
3. Who can see your information?
   Only approved members of the research team will see your personal (identifiable) information. Your de-identified (coded) data may be seen by:
   - Study staff and researchers

- Independently contracted statistics experts
- Health agencies or ethics committees (for audits)
- Lab staff testing your samples
- Your doctor, specialists or other health care professionals directly involved in your assessment and care, if any test results may affect your health. If you return a positive HBV test your GP or other medical care provider will be contacted to follow up with additional testing and/or treatment. If you are pregnant and return a positive HBV test, your GP or other Lead Maternity Care provider will be contacted to ensure that a birth dose of Hepatitis B vaccine is offered to your newborn baby. If results show you have no antibody protection you will be counselled about the possibility of vaccination or a booster.
- If you test positive for HBV, you may benefit from long-term monitoring for complications provided free of charge for everyone through the Hepatitis Foundation of New Zealand. You may also benefit from antiviral treatment, which is fully funded for individuals eligible for funded healthcare in NZ.
- If required by law, your information could be shared for safety reasons or public health.

4. Storage and security
   Your information will be stored securely at the University of Auckland. Coded study data will be entered into a secure online system and stored by the sponsor in encrypted, cloud-based storage. All data storage, including signed consent forms confidentially stored at Orbis Diagnostics follow Aotearoa New Zealand and international privacy rules.
5. Future use of your information
   If you agree, your coded data may be used for future HBV research to improve testing methods. Your name will not be attached to this data. You can choose whether or not you allow this on the consent form.
6. Can I see or withdraw my data?
   Yes. You can ask to see or correct your information at any time. If you withdraw from the study, no new information will be collected. Data already collected may still be used, unless you ask us to delete it before the analysis is done.
7. Māori data and cultural care
   We acknowledge that health information for Māori participants is a taonga (treasure). Formal Māori consultation has been performed and recommendations for additional measures to improve Māori rights and interests in relation to data and tissue have been adopted. In recognising the sacredness of data and tissue, we affirm our commitment to respectful, transparent, and culturally grounded research that upholds the mana of all Māori participants.
8. Ownership Rights.
   The information collected in this study may help create new discoveries or commercial products, such as improved HBV testing methods that may be used both nationally and internationally. These rights will belong to the University of Auckland and Orbis Diagnostics. You and your family will not receive any payment, financial benefit, or rights to these discoveries or products.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind, you can withdraw at any time by telling a member of the study team. No new data or samples will be collected after that point. You can also ask us to delete your data and destroy your leftover blood sample, unless the study analysis has already been completed.

CAN I FIND OUT THE RESULTS OF THE STUDY?

If you would like a summary of the study results in plain English, you can request this at any time. Results will be available after the study is completed and analysed—this may take up to 12 months after the final participant visit.

The study will also be listed on a public clinical trial registry, and results may be published in scientific journals or presented at conferences. No personal information will be included.

WHO IS FUNDING THE STUDY?

This study is funded by the University of Auckland in collaboration with Orbis Diagnostics, who developed the new HBV Triplex Assay being studied. Researchers involved in the study are based at the University of Auckland and at Orbis Diagnostics. Orbis Diagnostics is a startup company spun out of the University of Auckland to develop new diagnostic technology. This study is part of finding out whether the new diagnostics technology works well enough to be used widely. If the study results are positive, they will help turn the prototype test into a commercial product through Orbis Diagnostics.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern A Health and Disability Ethics Committeehas approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Principal Investigator	Study Contact Person
Name – Prof. M Cather Simpson Email - c.simpson@auckland.ac.nz	Name – Dr. Natasha Gordon Email - natasha@orbisdiagnostics.com

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kāmaka Waiora (Māori Health Team) at Auckland City Hospital by telephoning 09 307 4949 ext. 29200.

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

- Phone: 0800 555 050
- Fax: 0800 2 SUPPORT (0800 2787 7678)
- Email: advocacy@advocacy.org.nz
- Website: https://www.advocacy.org.nz

You also can contact the HDEC that approved this study on:

- Email: hdecs@health.govt.nz
- Phone: 0800 400 569 (Ministry of Health general enquiries)

Thank you for taking the time to read about and consider taking part in this study.

Approved by the Northern A Health and Disability Ethics Committee on 13th April 2026 for one year. Reference number 2026 FULL 23886.

Consent Form

HBV blood collection evaluation: Microsample vs Venous Blood

I have read the Participant Information Sheet or have had it read to me in a language I understand, and I fully comprehend what it says.	Yes ☐	No ☐
I have been given sufficient time to consider whether to participate in this study.	Yes ☐	No ☐
I have had the opportunity to consult a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	No ☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	No ☐
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without affecting my medical care.	Yes ☐	No ☐
I consent to collection and processing of my information, including information about my health, by research staff.	Yes ☐	No ☐
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my current provider's being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to a review of my relevant medical records by an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative, for the sole purpose of checking the accuracy of the information recorded for the study.	Yes ☐	No ☐
I understand that my participation in this study is confidential and that no material that could identify me personally will be used in any reports on this study.	Yes ☐	No ☐
I understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐
I know whom to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Email address (if yes above)

Declaration by participant:
I hereby consent to take part in this study.

Participant’s name: ____

Signature: _________________________ Date: _______________

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher’s name: ____

Signature: _________________________ Date: _______________

Appendix: Optional Future Use of Blood Samples

You are already taking part in a study about HBV infection testing. As part of that study, a blood sample will be collected from your arm (a venous blood sample).

We are asking for your permission to store any leftover blood from that sample after this study finishes. This choice is optional. You can still take part in the main study even if you do not agree to this storage of leftover blood.

WHY ARE WE ASKING TO STORE YOUR BLOOD SAMPLE?

Your leftover blood may help with future health research, including research on HBV infection detection, to improve testing methods. This future research may be done by our research team or by other approved researchers in Aotearoa New Zealand or overseas.

WHAT WILL HAPPEN TO THE SAMPLE?

- The sample will be stored securely by Orbis Diagnostics under oversight of the University of Auckland.
- It will be labelled with a study code, not with your name.
- It may be sent to an overseas laboratory for analysis.
- Any future research using your sample must be approved by an ethics committee.

YOUR CHOICES

You can choose:

- Whether or not your sample can be stored.
- Whether it can be used only for HBV research to improve testing methods.
- Whether your identifying information remains linked to the sample or is permanently removed (permanently de-identified).

If your identity is removed from the sample, it may not be possible to withdraw your consent later.

Questions about Future Unspecified Use of your Blood Sample

I agree for my tissue samples to be stored and used in future research but only on the same subject as the current research project: [HBV Test Comparison Study: Microsampling vs Venous]	Yes ☐	No ☐
I agree for my tissue samples to be stored and used in future research that is associated with HBV infection to improve testing methods which has been properly approved	Yes ☐	No ☐
I give permission for my tissue samples to be stored indefinitely	Yes ☐	No ☐
I want my identity to be kept with my tissue sample	Yes ☐	No ☐
I want my identity to be removed from my tissue samples and understand that in this case I will not be able to withdraw my consent in the future	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant’s name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher’s name:

Signature: Date: