

# CLINICAL EVALUATION STUDY



Health Innovation Hub Ireland



## About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health and is supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise. We offer companies the opportunity for pilot and clinical evaluation studies and we provide the health service access to innovative products, services and devices that they may not otherwise be exposed to.

and outcomes. We assess all concepts for healthcare innovation from those on the frontline – from clinician to porter. We encourage healthcare professionals to get in touch with HIHI if they have an idea or solution to how something in your job might work better.



Dr Tara Dalton, CEO

Cork based Altratech is a cutting-edge biotech company comprised of a team of 20 scientists and engineers, including nine PhDs, focused on developing advanced molecular detection technologies.

Over the past seven years, they have pioneered a unique bio-orthogonal alternative to PCR testing called Molecular Detection by Proxy. Their technology combines nanotechnology, CMOS semiconductors, and PNA chemistry to detect and quantify viral RNA, DNA, antigens, or antibodies from any sample with minimal preparation.

Altratech is committed to building technology infrastructure that enhances the future of decentralized healthcare by providing rapid, accurate, and connected viral diagnostics.

HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways



## The Healthcare Challenge

Traditional viral diagnostic tests require sample collection and analysis in clinical settings, creating barriers in terms of accessibility, convenience, and timely diagnosis. The COVID-19 pandemic has highlighted these challenges, particularly for individuals in remote areas or those without easy access to healthcare facilities.

Delayed results often cause anxiety, while the process of attending clinics poses risks of spreading infection. The need for rapid, home-based diagnostics that deliver accurate results and contribute to public health efforts has become more pressing than ever.



# The Healthcare Solution



Altratech's solution is a home-based viral diagnostic platform that offers users the ability to quickly and accurately test for infectious diseases such as COVID-19, HIV or others, from the comfort of their homes.

By using Molecular Detection by Proxy, their assay provides highly sensitive and specific results, enabling early detection and self-monitoring.

This decentralisation of healthcare allows users to perform diagnostic tests without the need for medical personnel, reducing the burden on healthcare systems and enabling faster interventions.

## HIHI Role

Health Innovation Hub Ireland (HIHI) provided crucial support during the clinical evaluation stage of Altratech's viral diagnostic solution. HIHI managed the project, recruited relevant participants, and organised usability sessions. Additionally, HIHI assisted with data analysis and report preparation, ensuring that Altratech received comprehensive insights to refine its product. HIHI's involvement was instrumental in helping Altratech tailor their technology to meet real-world clinical and user needs.



## Outcome Report

The usability study involved twenty participants, including healthcare professionals and young adults, who tested Altratech's viral diagnostic tool. Fifteen participants used the mobile app in combination with paper instructions, while five relied solely on the paper instructions to interact with the prototype. The study assessed user satisfaction, comprehension of instructions, and confidence in interpreting results. The key outcomes were:

- High user satisfaction with the app's functionality and ease of navigation.
- Identified areas where instructional clarity could be improved, particularly for manual use without app assistance.
- Valuable feedback that will guide the refinement of the diagnostic test interface and instructional materials for future iterations.

The report highlighted key insights that will be used to improve the usability of Altratech's viral diagnostic tool. The feedback identified challenges with instruction comprehension and ease of use, particularly for users relying on the paper instructions alone.

These findings will guide design enhancements to ensure that the diagnostic tool is user-friendly and accessible to a broader demographic, ultimately improving its effectiveness in home-based disease detection. The collaboration with HIHI provided Altratech with actionable data that will drive future product development.

