



FUTURE  
DIAGNOSTICS

# A.S.S.U.R.E.D. 2.0

## Are We Close To A Perfect Test?

- ✓ Affordable
- ✓ Sensitive
- ✓ Specific
- ✓ User-friendly
- ✓ Rapid and robust
- ✓ Equipment-free
- ✓ Deliverable

About Senzo: Senzo Health is a diagnostics technology company developing future testing solutions for healthcare and industry, based in London, Cambridge and the USA.

## A.S.S.U.R.E.D.

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A.S.S.U.R.E.D. is a truly amazing framework to think about diagnostics.

The Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, Deliverable to end-users (A.S.S.U.R.E.D.) criteria for point-of-care diagnostics were originally developed in 2003 by the World Health Organization (WHO) to guide affordable test development for resource-limited settings which lacked access to laboratories for population-scale diagnostics.

The A.S.S.U.R.E.D. proposal simplified something the industry had always known but had struggled to articulate: a positive or negative result was not enough. For a diagnostic test to make a difference, it has to identify disease, simply, quickly, reliably, and affordably, for anybody, anywhere. It has to be a test of record, that patients, professionals, and providers can trust and act upon.



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**CURRENT AND EMERGING MEDICAL CHALLENGES, FROM INFECTIOUS DISEASES, TO ANTIMICROBIAL RESISTANCE, TO THE RISING BURDEN OF CHRONIC CONDITIONS NEED A NEW TYPE OF DIAGNOSTIC.**

## **PROBLEMS:**

The global health landscape has undergone significant shifts since the A.S.S.U.R.E.D. criteria were first introduced over 20 years ago.

Pandemics have highlighted the critical importance of self-tests. Antimicrobial resistance threatens to undermine the effectiveness of existing treatments. A Sexually Transmitted Infection epidemic has shown the limitations of a centralized healthcare and laboratory system. As populations age and the prevalence of chronic diseases increases, healthcare systems are under mounting pressure to manage these conditions effectively while controlling costs.

Decentralized testing will play a key role in addressing these challenges by improving access to timely and accurate diagnostic information.

## **SOLUTIONS:**

A.S.S.U.R.E.D. is no longer relevant only to developing healthcare systems lacking central lab coverage. These current and emerging medical challenges need a new type of diagnostic.

As systems transition to decentralized, accessible, personalized, and accurate testing, it is becoming clear that the A.S.S.U.R.E.D. standard can guide diagnostic development for modern healthcare.

A.S.S.U.R.E.D. 2.0 could set a new vision for the industry. Maintaining the standard, but upgrading the mission, from supporting developing systems to supporting all systems, spanning a wide range of the most important diagnostic test targets and applications.

## THE SENSITIVITY CHALLENGE:

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Rapid diagnostic tests, particularly lateral flow antigen assays, have made significant strides in meeting many of the A.S.S.U.R.E.D. criteria. These tests are typically affordable, easy to use, and provide quick results without the need for sophisticated equipment.

However, as is well known, their weakness is in their sensitivity - or lack thereof - particularly when it comes to detecting low levels of pathogens in the early stages of infection. This can lead to false-negative results, which from STIs to RTIs, delay diagnosis, hinder timely treatment, curtail containment, and enable transmission.

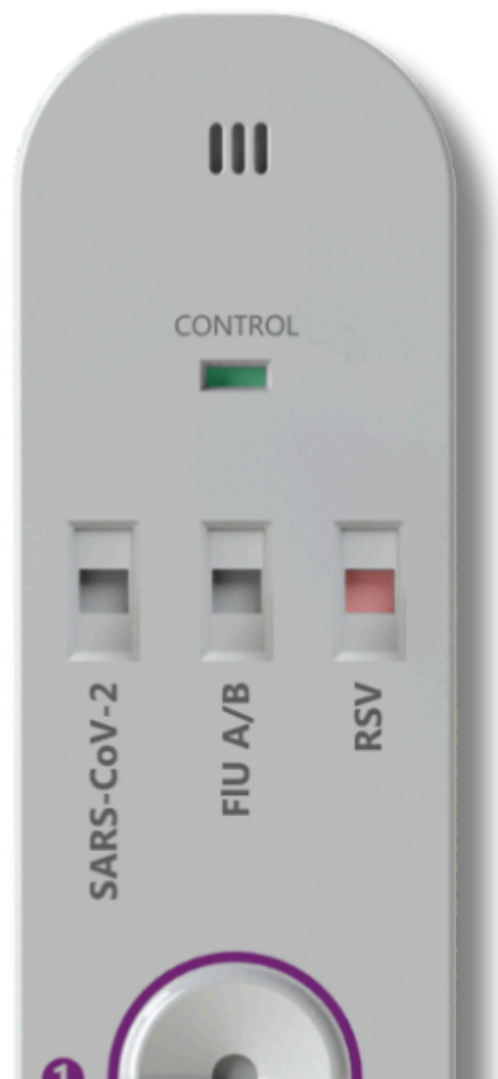
Improving the sensitivity of rapid tests while maintaining their simplicity and associated affordability is a key in the mission to develop a truly A.S.S.U.R.E.D. diagnostic. The ability to detect infections early when viral loads are low is arguably more important than confirming the presence of an infection at its peak when levels are at their highest. But, enhancing sensitivity often requires more complex technologies, instrumentation, or sample preparation steps, which increase cost and complexity - solve one problem, create another.

Researchers are exploring various approaches to overcoming this hurdle, from advanced materials to amplification to targeting new disease biomarkers. By harnessing these technological improvements, it may be possible to engineer the perfect test; a lateral flow antigen diagnostic that achieves high sensitivity without sacrificing the other A.S.S.U.R.E.D. criteria.

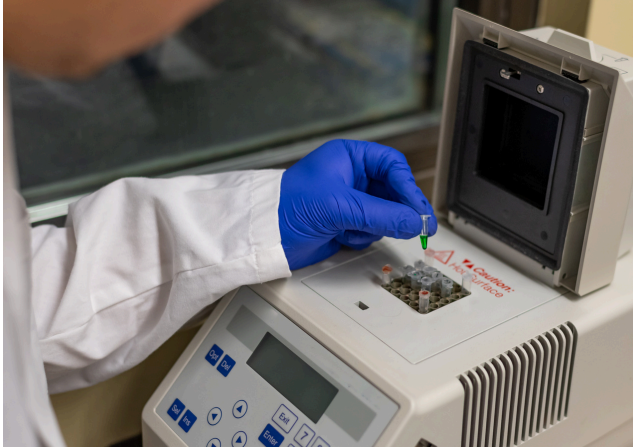
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# A TRULY A.S.S.U.R.E.D. TEST:



The vision of a fully A.S.S.U.R.E.D. rapid test holds immense potential for transforming healthcare delivery and outcomes.

A highly sensitive lateral flow assay that maintains the affordability, user-friendliness, and accessibility of current tests would enable widespread, decentralized testing in a range of settings, from primary care clinics to community-based screening programs, to over-the-counter home-use.

A.S.S.U.R.E.D. is no longer just the solution to developing healthcare systems, it is the solution to many of the core problems affecting every modern healthcare system.

Solving the sensitivity problem currently faced by near-A.S.S.U.R.E.D. diagnostics will improve the early detection and management of infectious diseases, allowing for targeted treatment and infection control.

Finally, integrating A.S.S.U.R.E.D. tests with digital health platforms could enable real-time disease surveillance, facilitating rapid response to emerging outbreaks guiding public health decision-making and policy.



## FUNDING, COLLABORATION, PATHWAYS, AND POLICY:



To realize the full potential of A.S.S.U.R.E.D. diagnostics, several barriers must be overcome.

Funding and incentives are needed to drive research and development efforts targeting the development of truly A.S.S.U.R.E.D. tests.

Collaborative partnerships between academia, industry, and government agencies to pool resources and expertise need to be strengthened.

Regulatory pathways need to be updated to support the development and commercialization of this standard without compromising quality control, safety or efficacy.

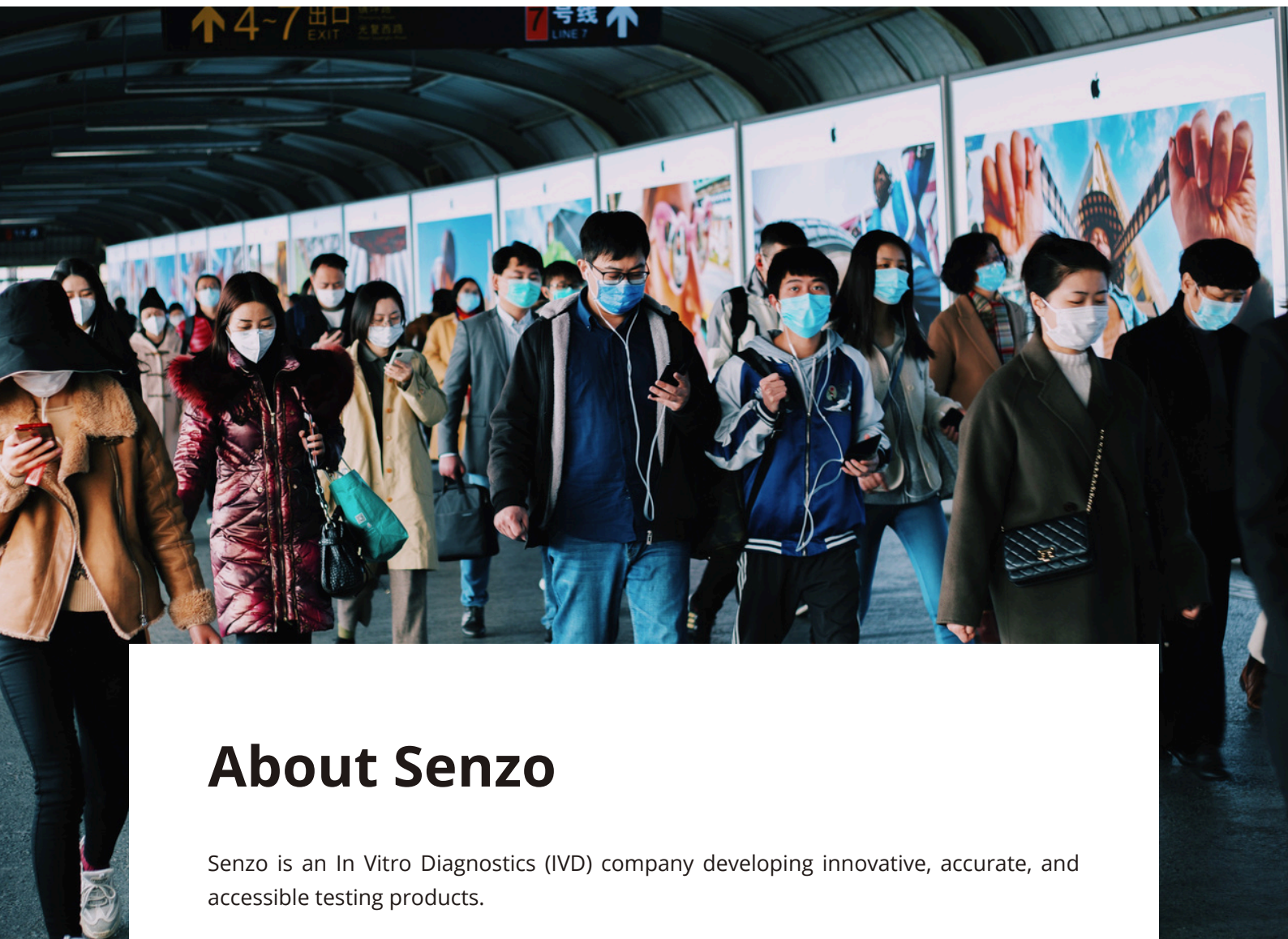
Policy must be created on how to rapidly integrate these tests into existing healthcare systems, ensuring that they are readily available and accepted by both healthcare providers and patients.

## MAKING IT REAL:

As we confront the evolving challenges of modern healthcare, a new criteria - an A.S.S.U.R.E.D. 2.0 accreditation - could help clarify an important path forward. The development of a truly A.S.S.U.R.E.D. diagnostic combining high sensitivity with affordability, user-friendliness, and deliverability, could change how, when, and where we are able to identify illness, making healthcare personalized and proactive.

The realization of this goal will require concerted efforts from researchers, policymakers, and healthcare stakeholders, but the potential benefits - in terms of improved patient outcomes, outbreak preparedness, health system efficiency, and ultimately lives saved - demand that investment.





## About Senzo

Senzo is an In Vitro Diagnostics (IVD) company developing innovative, accurate, and accessible testing products.

Senzo was founded with the vision of utilising novel technologies, with a focus on enhanced sensitivity, to create mobile, point-of-care and self-testing products and devices with the ability to accurately, quickly, and cost-effectively conduct testing where and when healthcare professionals and patients need it most.

Senzo is creating game-changing products and systems which bring testing to the patient, eliminating the need for the current slow, expensive central-lab testing paradigms. With insights generated at the point of care, patients can make better decisions faster, and healthcare professionals can identify life-threatening diseases at an earlier stage, improving treatment outcomes and saving lives.

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