課題 **Sealtratech**

Altratech Ltd, Cork, Ireland www.altratech.com

AN IMPORTANT INNOVATION

Altratech introduce a completely new method of molecular detection. This is a first-of-kind, multianalyte DNA, RNA, antibody and antigen diagnostic. It delivers concurrent serology and nucleic acid detection. The technology is compliant with the challenging demands of WHO REASSURED criteria, especially in providing a commercially viable diagnostic tool for the developing world.

The innovation is in the process of being productised with The Cambridge Design Partnership (UK) into a fully automated, portable, stand-alone instrument for Point of Care and Point of Need. It will not require medically qualified personnel to operate. This innovation provides substantial advantages over existing, more complex, expensive and less portable Point of Care systems.

THE COMPANY

Based in Ireland, Altratech has a multidisciplinary team of 17 scientists and engineers with expertise in microfluidics, chip design, biology, physics and chemistry. The company's intellectual property is protected by a family of 40 proprietary international patents and there are a further 12 patent applications filed. In addition to these patents, Altratech holds one patent jointly with the U.S. National Institute of Health, with whom it has collaborated on PNA probe design and synthesis.

The Company's industry partners include: On-Semiconductor (US) for CMOS chip fabrication, AMI-Schott (US) for PNA wafer spotting, and Cork University Hospital (IRE) and St Cecilio Hospital (Spain) for clinical trials. Altratech's patent attorneys are Brown Rudnick (US), and its auditors are BDO.

The Company's promoters have strong track records in microfluidics and in chip design and have built and sold previous companies to Life Technologies and Silicon Labs. To date Altratech has raised circa US\$20M, receiving funding from the EU MEDLoC, the EU Horizon 2020 and the US BARDA DRIVe programs. The Company's investors include Kernel Capital, Infinity Capital and Claret Capital. In October 2024, Altratech was a successful applicant to the European Innovation Councils prestigious Accelerator Program and awarded €10.5M. The Company is now seeking a strategic partner from within the life science industry and is open to investment and licensing arrangements.

Altratech CEO Dr. Tara Dalton will be speaking at the Precision Med TRI-CON San Diego March 11 -13 where the Company will have a stand and live prototype demonstrations.

A New Method for Multianalyte Point of Care Diagnostics

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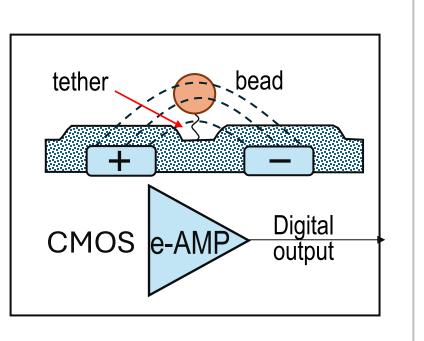
PROPRIETARY MATERIALS

Altratech developed several proprietary have technologies published in peer review publications which, in combination, allow for exceptional specificity, sensitivity and multiplexing capability in a portable format.

Digital CMOS Sensor Chip:

Single paramagnetic beads are specifically tethered by the target to our proprietary sensor and quantitatively detected by employing fringe-field sensing. This Sensor Chip replaces Optical Detection with Electronic Detection.

> Fig 1: The CMOS sensor 'fringe-field' capacitive sensing principle, and electronic signal amplification.

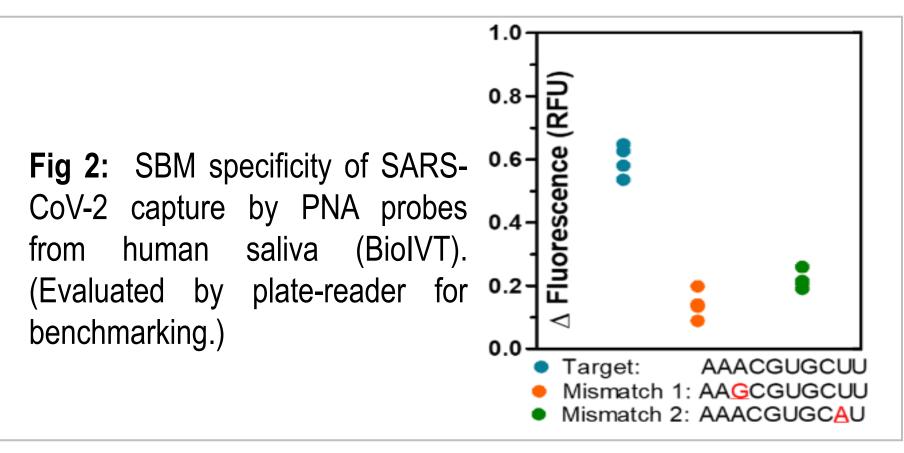


PNA Probes:

Peptide Nucleic Acids are synthetic mimics of DNA which can be used as probes in diagnostic assays. Altratech have designed PNA probes for specific target capture directly from biological samples, eliminating centrifugation.

Improved chiral PNAs have been co-developed and synthesized in FMOC chemistry with the US National Institute of Health.

PNA probe design flexibility allows for multiple applications through modification of the input PNA. PNA probes are known for their excellent specificity, e.g. Single-Base-Mismatch specificity:



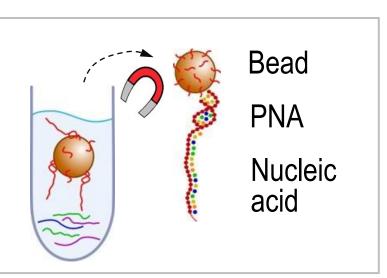
Antigenic Peptide Sequences:

These are synthesized with the same FMOC chemistry as the PNA probes and are used for specific antibody capture from the raw sample.

Superparamagnetic Beads:

PNA-coated superparamagnetic beads with captured Target are magnetically removed from the sample.

Fig 3: (a) Human saliva sample in vial. (b) Capture & extraction of SARS-CoV-2 RNA.



PROTOTYPE & HARDWARE

Integrated Prototype:

The fully integrated prototype (Fig 4) combines the operational Detection Module (A) which is built, and the Sample Preparation Module (B), which is currently being developed with the Cambridge Design Partnership (UK).

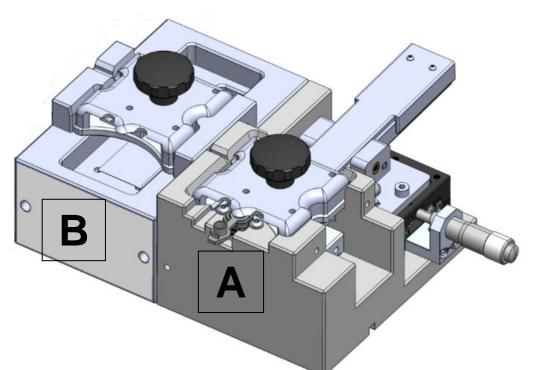
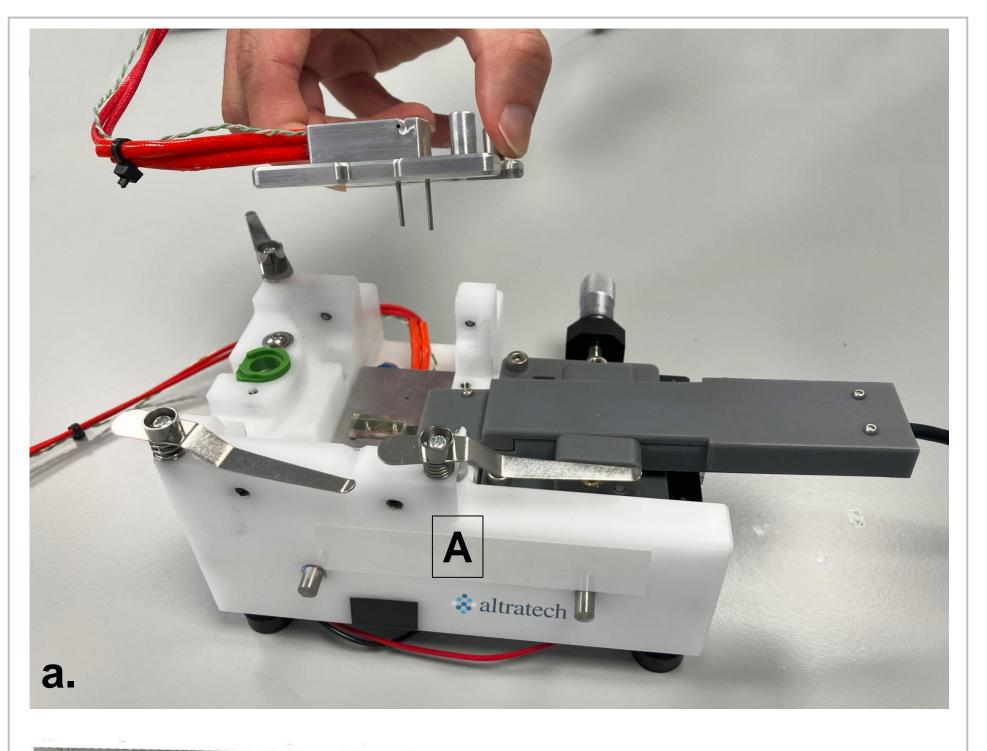
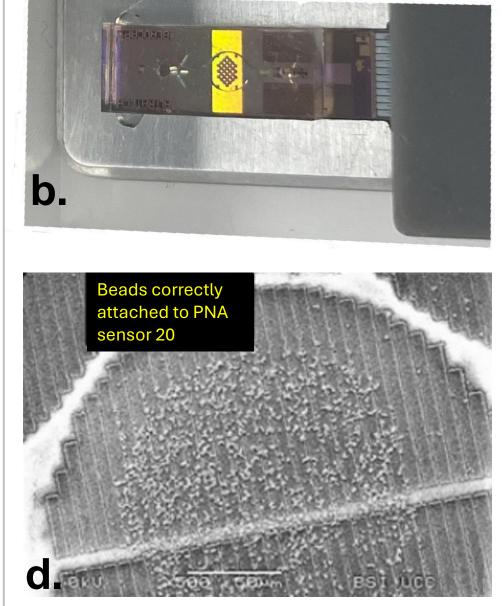
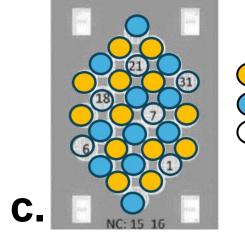


Fig 4: **A** Detection Module. **B** Sample Preparation Module.

Detection Module (A) is fully operational in the laboratory. This unit automates the assay and has improved detection levels through electromagnetic mixing and hardware improvements (Fig 5).







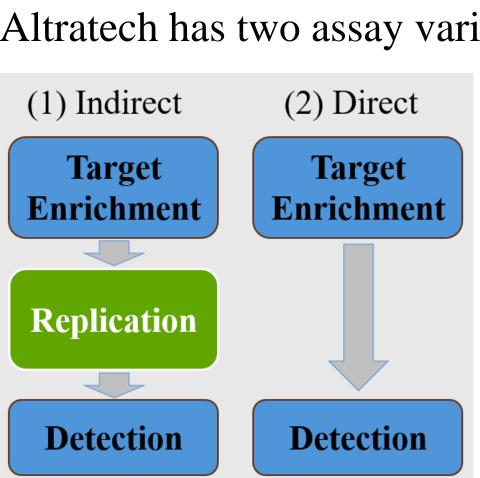
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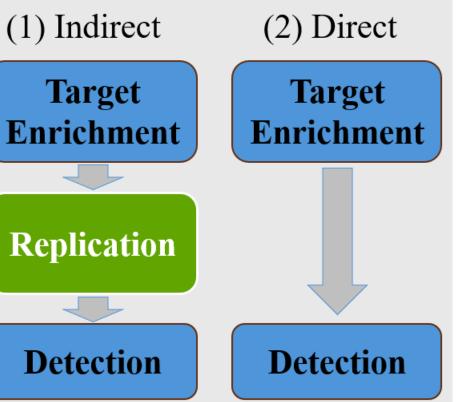
- a. The Prototype, Detection Module (A) with cover removed.
- b. The digital CMOS chip with 30 capacitive sensors in the microfluidic channel.
- c. The 30 Sensor spotting pattern.
- d. SEM photo of one sensor with specifically captured beads.

The final product will be a small form-factor, lowcost cartridge and wireless reader unit (Fig 6). This miniaturisation is made possible through the solid-state nature of the device and by replacing Optical Detection with our CMOS enabled Electronic Detection.



Fig 6: Cartridge & Wireless Reader Unit.





The indirect approach facilitates rapid progress towards improved assay sensitivity. As upstream advances in Target Enrichment are implemented, the direct method with no replication step, will supplant the indirect approach when the sensitivity levels are comparable.

Fig 7: Linearity of direct detection demonstrates ability of this approach.

Fig 8:









14 February 2025

ASSAY METHOD

Altratech has two assay variants: (1) Indirect & (2) Direct:

Indirect Detection:

Incorporates a single enzymatic step, which tags and replicates the target. This provides for improved sensitivity, which is critical for applications assessing low-titre samples. **Direct:**

Without the requirement for an enzymatic step, this variant allows direct detection of target molecule and quantification (current $R^2 = 0.96$).

INDIRECT: NUCLEIC ACID DATA

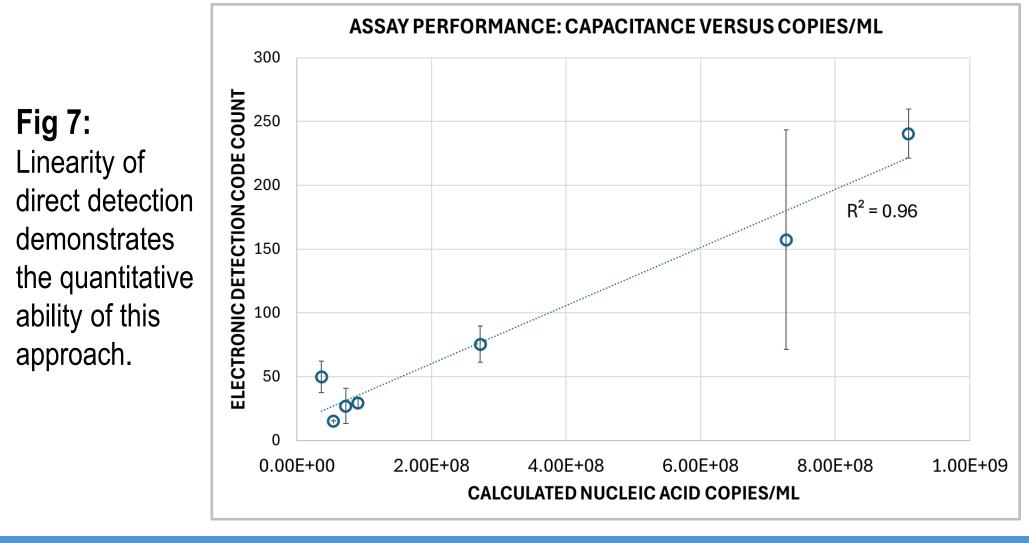
• Current Limit of Detection: 1E4 cp/mL (SARS-C0V-2). • **Targeting** 1000 copies/mL by end of Q1 2025.

• Capable of achieving 100 copies/mL sensitivity with further engineering refinement.

DIRECT: NUCLEIC ACID DATA

• Current LOD: 1E6 copies/ml (Synthetic SARS-COV-2). • **Targeting** 1E4 copies/ml by end of Q3 2025.

• Capable of achieving 100 copies/ml sensitivity with further engineering and target enrichment development.



DIRECT: ANTIBODY DATA

Altratech have demonstrated the replacement of the enzyme in a commercially-available HIV antibody test with a superparamagnetic, PNA-coated reporter bead allowing detection and quantification on specific sensors on our proprietary CMOS silicon chip.

