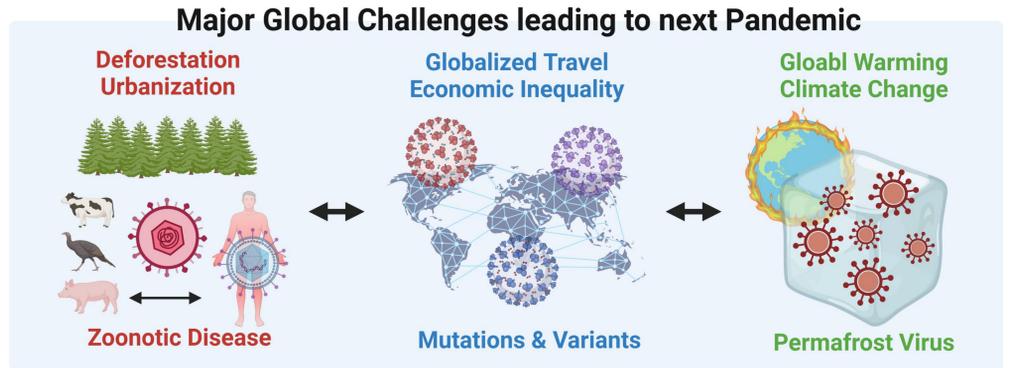


Background

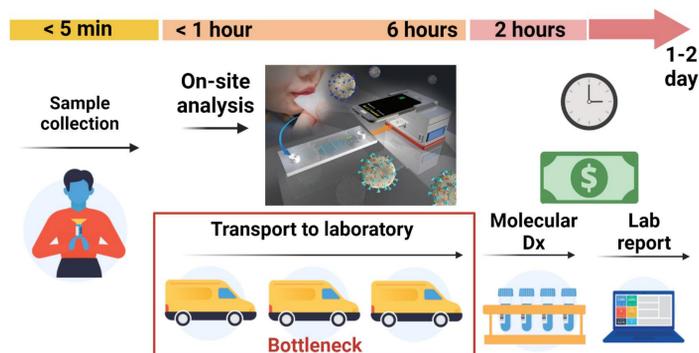
The frequency and degree of epidemics and pandemics will increase, primary due to deforestation during urbanization, globally connected society and climate change. To address these global challenges, development of sustainable diagnostics and supply of those to wildlife, livestock and human populations are necessary. The COVID-19 pandemic has demonstrated a significant gap between availability of diagnostics and current needs. The fundamental limitation originates from reliance upon polymerase chain reaction (PCR), which requires temperature cycling, labor-intensive protocols for extraction and purification, and long turnaround time. This prevents government from effectively controlling the spread of disease due to delayed information and suboptimal surveillance of emerging variants. Point-of-care or portable diagnostic can be a promising alternative to existing laboratory-based PCR tests since it can bypass the sample transport and allow the fast and accurate surveillance of newly emerging zoonotic infectious viruses at patients' location. Here, two portable diagnostic system for variant identification and multiplex detection were introduced in terms of their novelty, improvements over previous lineages. We would like to identify the current position of our system in the history of diagnostic equipment development and discuss a sustainable next-generation version to prepare for a future global pandemic.

Future Work Approach



Global Surveillance System through Sustainable Next Generation Diagnostics

Generation	Typical Prototype	Analyte	Aid of	Price	Specialty
1st	Lateral Flow i.e. Pregnancy Test	Antibody & Antigen (moderate sensitivity)	Simple Chemistry	Inexpensive	Fast 10 min
2nd	Microfluidics Microelectronics	Purified Nucleic Acid (Highly sensitive)	Additional Step of Extraction & Purification	Expensive	Slow Several Hours
3rd	Palm-Size Device	Unpurified Nucleic Acid (automatic processing in machine) Single Sample Types	Simple Heating Novel Enzyme Disposable Cartridge Relatively Small Instrument	Costly	Deliverable To User 1 Hour
4th & Next	Wearable Implantable Device	Multiple Targets Single-Nucleotide Sensitivity Differential Diagnostic i.e. COVID, Flu, RSV	Universal Chemistry i.e. Lysis, Amplification, and Detection in one pot Communication Technology	\$ 10/test \$ 100 instrumentation	At-Home Test Repetitive Test Continuous measurement 1 Hour

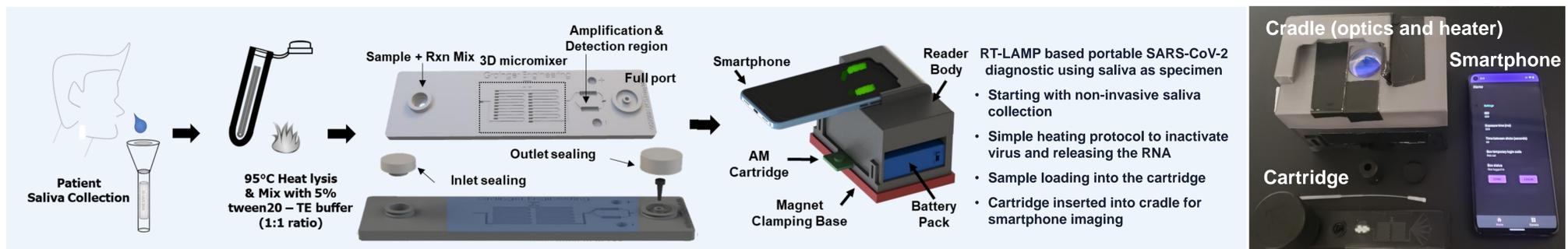


Reducing time-to-result compared to current centralized-lab-based testing

Methods

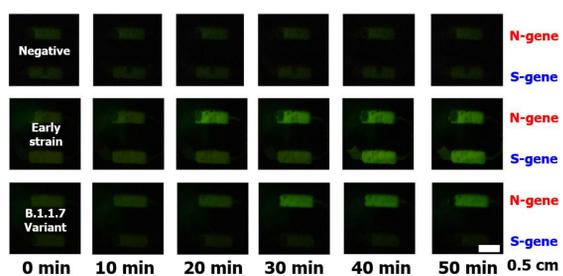
Point-of-care Setup

Actual Setup

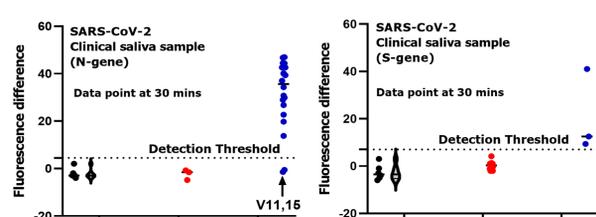


Results

On-cartridge spiked sample

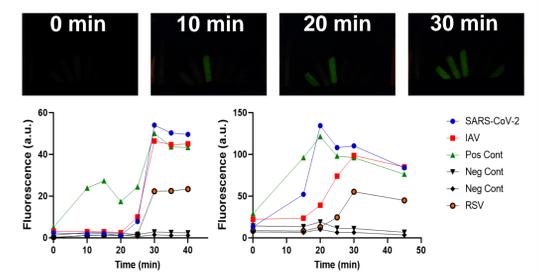


Clinical Study (n = 38)



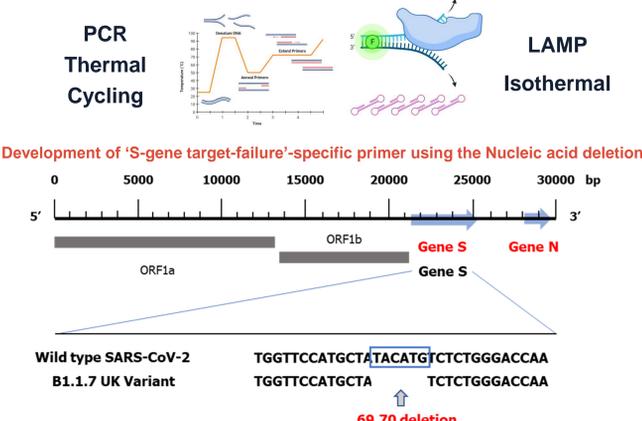
Summary
 ✓ 18/20 variant sample amplified for N-gene (90% sensitivity)
 ✓ 20/20 variant not amplified for S-gene (100% specificity)

Multiplex On-cartridge spiked sample



LAMP as Alternative to PCR & Primer Design

Primer Information



N-gene	
Primer	Sequence
F3	GTT CCT CAT CAC GTA GTC G
B3	GTT TGG CCT TGT TGT TGT T
FIP	GCC AGC CAT TCT AGC AGG AG-CAA CAG TTA AGA AAT TCA ACC CC
BIP	GAT GCT GCT CTT GCT TTG CT-ACC AGA CAT TTT GCT CTC AA
Loop B	GCT GCT TGA CAG ATT GAA CCA G
S-gene	
Primer	Sequence
F3	GGT GTT TAT TAC CCT GAC AAA G
B3	GTA CCA AAA ATC CAG CCT C
FIP	TGG AAC CAA GTA ACA TTG GAA AAG A-TTC TCA GAT CCT CAG TTT TAC ATT C
BIP	CTC TGG GAC CAA TGG TAC TAA GAG-GAC TTC TCA GTG GAA GCA
Loop B	AAC CCT GTC CTA CCA TTT AAT GAT G

Lineage of Diagnostic Tools

