Development of a rapid testing platform for infectious diseases

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Abstract

We demonstrate that after 5 minutes of measurement, AI nanopores can detect SARS-CoV-2 in saliva with a sensitivity and specificity of 90% and 96%, respectively. The test method using AI nanopores can also identify SARS-CoV-2 variants with high accuracy. The AI nanopore platform enables the development of new rapid tests for infectious diseases simply by changing the nanopore diameter and the training data.

Background & Results

Tests for infectious diseases caused by viruses and bacteria commonly employ methods based on antigen–antibody reactions or the polymerase chain reaction (PCR). Although the antigen–antibody test is simple and rapid, it has low sensitivity and specificity; the PCR test has high-sensitivity and specificity but requires a skilled pretreatment and is often time-consuming. The development of simple, high-sensitivity, high-specificity, high-throughput, low-cost, and rapid tests for infectious diseases is urgently demanded.

Nanopores are through-holes fabricated on a silicon substrate using semiconductor technology (Fig.1). When a virus or bacterium passes through a nanopore, it initiates a single ionic current-time waveform specific to that entity, which contains information about the volume, structure, and surface charge of the virus or bacterium. As AI can distinguish waveforms that are difficult to distinguish with the human eye, it can identify the type of virus or bacterium on an individual level.

Using AI nanopores (a fusion of AI and nanopores), we successfully discriminated cultured SARS-CoV, MERS-CoV, SARS-CoV, and HCoV-229E with high accuracy. We also accurately discriminated cultured influenza A viruses (type A) and SARS-CoV-2. After filtrating saliva samples collected from patients, we learned and tested PCR-positive and PCR-negative samples using AI nanopores (Fig. 2). Pretreatment by filtration alone retained many contaminants in both the positive and negative clinical specimens. We developed and implemented a machine learning method that extracts viral waveforms from the contaminant-derived waveforms. The sensitivity and specificity improved with measurement time, reaching 90% and 96%, respectively, after 5 minutes of measurement.

Significance of the research and Future perspective

Testing platforms that can respond immediately to new infectious-disease outbreaks will play a role in minimizing the spread of infectious diseases and economic losses. On AI nanopore platforms, viruses and bacteria can be tested simply by adjusting the nanopore diameter and training data to suit the test target, after a simple filtration pretreatment.

The currently developed AI nanopore platform can be constructed into an integrated device using semiconductor technology, paving the way for infectious-disease testing using a smartphone. The device can test for a wide variety of viruses and bacteria with a single measurement. The integrated system of nanopores, AI, and IT will instantly inform users of the time, location, and type of an infectious disease, thereby guarding the safety, security, and health of societies worldwide (Fig. 3).

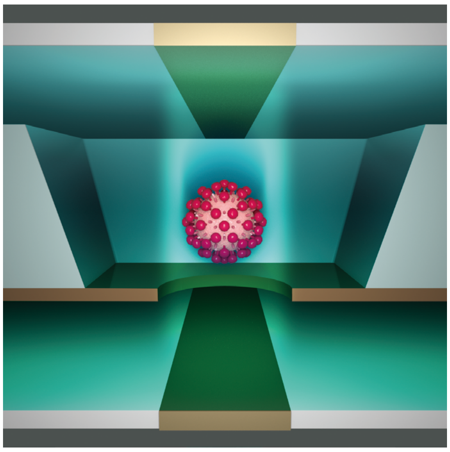

Fig. 1

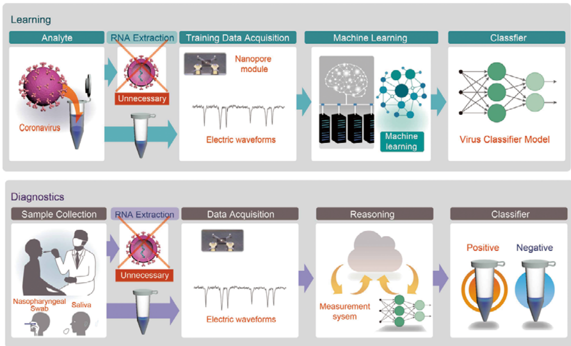

Fig. 2

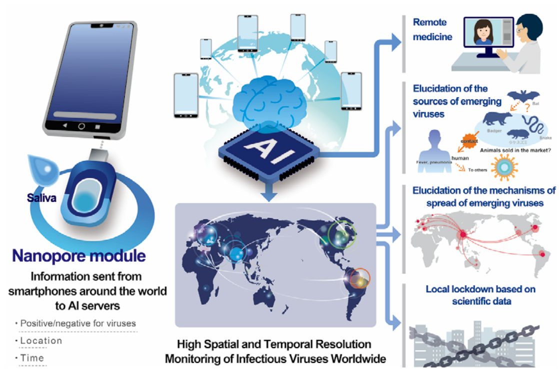

Fig. 3

Patent Japanese Patent No. 6971499, 6985687, 6807529, 6638913, 6762494, 6719773

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