NATIONAL CANCER INSTITUTE
Technology Transfer Center

Sensitive and Economic RNA Virus Detection Using a Novel RNA Preparation Method

Summary

The National Eye Institute seeks research and co-development partners and/or licensees to: (1) advance the production and uses of the new RNA preparation method; (2) manufacture reagent kits for testing in patients with suspected COVID-19 and other DNA/RNA viruses, and (3) manufacture reagent kits for patient biomarker profiles and inherited disease diagnostics.

NIH Reference Number

E-195-2020

Product Type

- Diagnostics

Keywords

- SARS-CoV-2, COVID, COVID-19, Virus, Biomarker, Extraction-free Detection, Chelating Resin, Chelex Resin, DNA/RNA diagnostic test, Infectious Diseases

Collaboration Opportunity

This invention is available for licensing and co-development.

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Description of Technology

DNA or RNA-based diagnostic tests for infectious diseases are critical in modern medicine. The current gold standard for COVID-19 detection is testing SARS-CoV-2 viral RNA by quantitative reverse transcription Polymerase Chain Reaction (RT-qPCR). This method involves patient sample collection with a nasopharyngeal swab, storage of the swab in a universal transport medium during transport to testing site, RNA extraction, and analysis of the extracted RNA sample. Collected patient samples – in addition to the possible presence of SARS-CoV-2 – also contain inhibitors for downstream enzymatic reactions, RNA degrading enzymes (e.g., RNase), and magnesium and calcium ions required for RNase activity. Active RNase in the patient sample reduces the amount of SARS-CoV-2

RNA in the sample; so the RNA needs to be extracted for analysis.

Researchers at the National Institutes of Health's National Eye Institute (NEI) developed a novel improved sample preparation method that eliminates the need for an RNA extraction step from the currently used method of detecting SARS-CoV-2. NEI researchers discovered that incorporation of a chelating agent into the RT-qPCR heating step ties up the magnesium and calcium ions needed for RNase activity – thereby increasing the amount of RNA produced for analysis. The new procedure also simultaneously removes potential inhibitors of RT-qPCR and inactivates SARS-CoV-2 infectivity. This removal improves workflow safety and eliminates the need for a BSL-2 testing facility. This is a versatile and safe method for RNA preparation for a variety of patient samples beyond SARS-CoV-2. It is suitable for standard clinical collection and testing on high throughput platforms for both DNA and RNA.

Inventors at the National Eye Institute are seeking research and co-development partners and/or licensees to: (1) advance the production and uses of the new RNA preparation method, (2) manufacture reagent kits for testing in patients with suspected COVID-19 and other DNA/RNA viruses, and (3) manufacture reagent kits for patient biomarker profiles and inherited disease diagnostics.

Potential Commercial Applications

- Improved COVID-19 diagnostic test
- Improved DNA or RNA-based diagnostic test for additional infectious diseases
- Safer preparation of patient samples
- Reagent kits for biomarker profiles and inherited diseases

Competitive Advantages

- Improved workflow safety
- Removes potential inhibitors of RT-qPCR
- Inactivates SARS-CoV-2 infectivity
- Increased RNA production for analysis
- Eliminates the need for an RNA extraction step

Inventor(s)

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Development Stage

- Clinical

Publications

Guan B, et al. Sensitive extraction-free SARS-CoV-2 RNA virus detection using a novel RNA 1 preparation method. [PMID: 33532808]

Patent Status

- **U.S. Provisional:** U.S. Provisional Patent Application Number 63/065,931, Filed 14 Aug 2020
- **PCT:** PCT Application Number PCT/US2021/045675, Filed 12 Aug 2021

Therapeutic Area

- Cancer/Neoplasm
- Infectious Diseases

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