# FAST, SIMPLE, LOW-COST POINT-OF-CARE DIAGNOSTICS FOR COVID-19 AND OTHER INFECTIOUS DISEASES

Buchser, William, Lalli, Matthew, Milbrandt, Jeffrey, Mitra, Robi

Gill, John

T-019442

**Technology Description**

A team of Washington University researchers has developed a low-cost molecular diagnostics kit and reader that could provide rapid, widespread screening and surveillance for SARS-CoV-2 and other infections. This technology utilizes a reverse-transcription loop-mediated isothermal amplification (RT-LAMP) assay to analyze saliva samples without the RNA extraction step, thus removing many of the current bottlenecks to molecular testing for COVID-19, and many other infections for where diagnostic RNA or DNA can be detected in saliva. Demonstrated proof of concept for COVID-19 indicates the potential for at-home, rapid testing for many other infections, such as sexually transmitted infections, various flu strains, tropical diseases, etc.

The testing capacity of PCR diagnostic tests for COVID-19 (the current gold standard) is limited by shortages of critical reagents, supplies and labor—nasal swabs, RNA extraction kits, analytical instruments and trained medical and laboratory personnel for collecting samples and performing assays. This new, easy-to-use, RT-LAMP kit and reading device reduces those bottlenecks with a simple, rapid, 1-step, single-tube, fluorescent nucleic acid assay that yields positive results in ~15 minutes and negative results in 25 minutes directly on a saliva sample without costly RNA purification. This point-of-care system does not require expensive instruments or trained personnel to collect samples, perform the reaction or interpret the results. It could enable widespread, rapid, frequent and reliable testing in a variety of settings to potentially curtail the ongoing COVID-19 pandemic, as well as transform testing for other infections such as HIV and other STIs, flu strains, and tropical diseases.

**Overview of Point of Care Kit and Reader**
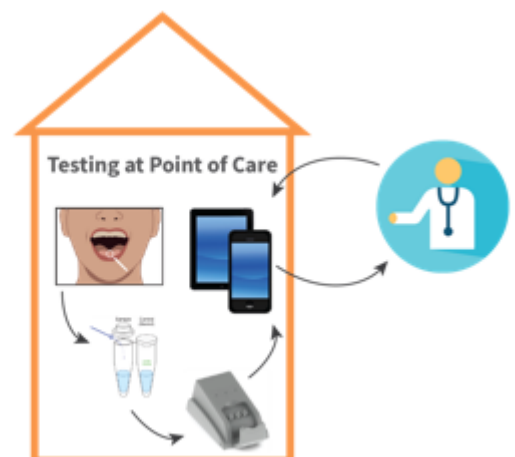


*A test kit supplies reagents and loops for collecting saliva sample. Individuals access software that provides simple walk-*

*through instructions for performing the assay. The reader device analyzes results in less than half an hour.*

**Stage of Research**

The inventors optimized the LAMP reagent and primer mix and tested it on contrived saliva controls using a prototype low-cost reader device. They demonstrated rapid and sensitive detection of $<10^2$ viral genomes per reaction. They have also performed proof-of-concept validation on 117 clinical samples showed high sensitivity and specificity. ([Lalli et al](#). and [Bramley et al.)](#)

**Applications:**

- **Point-of-care or in-home diagnostics**:
  - widespread screening and surveillance for SARS-CoV-2 in clinics, brick and mortar pharmacies, restaurants, airports, meat/food processing facilities, offices, homes or work sites
  - potential for multiplexing to concurrently diagnose other infectious diseases (e.g., influenza, respiratory syncytial virus, HIV, other STIs)
  - potential for using any body fluid for detection

**Key Advantages:**

- **Easy sample collection and preparation:**
  - direct analysis of saliva samples using 1-step, single-tube, single-temperature chemistry without an RNA extraction step
  - real-time reader device designed for ease-of-use and integrated with software that provides simple walk-through instructions
  - reduces bottlenecks caused by shortages of specialized nasal swabs, instruments, reagents and trained personnel to collect samples and perform assays
- **Inexpensive:** expected costs <$100/reader and $3/assay for reagents
- **Rapid results:**
  - initial demonstration detects viral loads with 95% sensitivity at 100 particles per microliter in 20 minutes
  - molecular testing with 100% specificity
  - software can communicate results to hospital or other centralized facility

**Patents:** Application pending

**Publications:**

- John C Bramley, Jason E Waligorski, Colin L Kremitzki, Mariel J Liebeskind, Alex Yenkin, Xinyuan E Xu, Matthew A Lalli, Jane A O'Halloran, Philip A Mudd, Stacey House, Robi Mitra, Jeffrey D Milbrandt, William J Buchser, medRxiv 2020.10.19.20215319; doi: https://doi.org/10.1101/2020.10.19.20215319 [Low-Cost Manually Assembled Open Source Reader for Isothermal Pathogen Detection from Saliva using RT-LAMP: SARS-CoV-2 Use Case .](#)
- Lalli, M. A., Chen, X., Langmade, S. J., Fronick, C. C., Sawyer, C. S., Burcea, L. C., ... & Mitra, R. D. (2020). [Rapid and extraction-free detection of SARS-CoV-2 from saliva with colorimetric LAMP](#).

**Related Web Links:** Buchser [Profile](#) and [Lab](#); Milbrant [Profile](#) and [Lab](#); Mitra [Profile](#) and [Lab](#)