XPRIZE SHINE - In-tube Fluorescent SARS-CoV-2 Saliva Test

Catherine A. Freije, Chloe K. Boehm, Sameed M. Siddiqui, Allen M. Goodman, A'Doriann Y. Bradley, Pardis C. Sabeti, Cameron Myhrvold

1,2 Broad Institute of Massachusetts Institute of Technology (MIT) and Harvard, Cambridge, MA 02142, USA.
2Harvard-MIT Program in Health Sciences and Technology, 77 Massachusetts Ave., Cambridge, MA 02139, USA.
3Computational and Systems Biology PhD Program, MIT, Cambridge, MA 02139, USA.
4Harvard T.H. Chan School of Public Health, 677 Huntington Avenue, Boston, MA 02115, USA.
5Department of Organismic and Evolutionary Biology, Harvard University, 26 Oxford Street, Cambridge, MA 02138, USA.
6Howard Hughes Medical Institute, Chevy Chase, MD 20815, USA.
7Massachusetts Consortium on Pathogen Readiness, Boston, MA, USA.
8Department of Organismic and Evolutionary Biology, Harvard University, 26 Oxford Street, Cambridge, MA 02138, USA.

XPRIZE Rapid Covid Testing

Catherine Freije

DISCLAIMER

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This protocol describes how to perform a SHINE in-tube fluorescent assay to detect SARS-CoV-2 RNA from a self-collected nasopharyngeal sample. This protocol is intended for point-of-care use. All enzymatic components are provided as a single-test freeze-dried pellet for shelf-stable storage, and all steps of the protocol are performed at ambient temperature. The protocol requires a transilluminator or another equivalent blue light emitting device. The protocol presented here is an improved version of the method presented in Arizti-Sanz J*, Freije CA*, et al. Integrated sample inactivation, amplification, and Cas13-based detection of SARS-CoV-2. bioRxiv (2020).

IMAGE ATTRIBUTION
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MATERIALS

Screw cap tube 5 mL sterile Thomas Scientific Catalog #1188R46

FastAmp® Viral and Cell Solution for Covid-19 Testing Solution B Contributed by users Catalog #4633

Reagent Mix A (In-tube SARS-CoV-2 resuspension mix) Contributed by users

Lyophilized Reagent Mix B (In-tube SARS-CoV-2 detection mix) Contributed by users

STEP MATERIALS

FastAmp® Viral and Cell Solution for Covid-19 Testing Solution B Contributed by users Catalog #4633

Screw cap tube 5 mL sterile Thomas Scientific Catalog #1188R46

Reagent Mix A (In-tube SARS-CoV-2 resuspension mix) Contributed by users

Lyophilized Reagent Mix B (In-tube SARS-CoV-2 detection mix) Contributed by users

The necessary volume of FastAmp Viral and Cell Solution is provided in the tube used for sample collection. All enzymatic components, reagents, and compatible buffers required for SARS-CoV-2 detection are included within Lyophilized Reagent Mix B and are reconstituted with Reagent Mix A (see protocol for details). A transilluminator or equivalent blue light emitting device is needed to visualize the assay results. A smartphone or smart device is necessary for automated interpretation of the SARS-CoV-2 detection results using the HandLens application.
PROTOCOL MATERIALS

- FastAmp® Viral and Cell Solution for Covid-19 Testing Solution B Contributed by users Catalog #4633

Step 1
- Screw cap tube 5 mL sterile Thomas Scientific Catalog #1188R46
- Reagent Mix A (In-tube SARS-CoV-2 resuspension mix) Contributed by users

Step 4
- Lyophilized Reagent Mix B (In-tube SARS-CoV-2 detection mix) Contributed by users

SAFETY WARNINGS

⚠️ Please take care with potentially infectious sample material that does not come into contact with the provided viral lysis solution contained within the saliva sample collection tube.

BEFORE START INSTRUCTIONS

Download the HandLens application on the user-provided smart device (smartphone, tablet, etc.). Clean workspace with disinfectant prior to starting the protocol.

Sample Collection and Viral Lysis

1. Expel approximately one drop of saliva into the sample collection tube and cap the tube. *Saliva collection tube contains necessary volume of FastAmp® Viral and Cell Solution.*

   - Screw cap tube 5 mL sterile Thomas Scientific Catalog #1188R46

2. Mix saliva sample and FastAmp® Viral and Cell Solution by vortexing the closed sample collection tube for 00:00:05.

   - FastAmp® Viral and Cell Solution for Covid-19 Testing Solution B Contributed by users Catalog #4633

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Oct 8 2020
3 Wait 00:05:00, incubating sample at Room temperature, before proceeding to Step 4.

4 Pipette 15 µL of Reagent Mix A into a single uncapped well of the 96-well plate containing lyophilized Reagent Mix B. Mix by pipetting up and down gently.

- **Reagent Mix A (In-tube SARS-CoV-2 resuspension mix)** Contributed by users
- **Lyophilized Reagent Mix B (In-tube SARS-CoV-2 detection mix)** Contributed by users

5 Add 5 µL sample-viral lysis mix to Reagent Mix A and B well. Mix by pipetting up and down gently. Recap sample.

6 Wait 01:30:00, incubating sample at Room temperature, before proceeding to Step 7.

7 **In-tube Fluorescent Readout and Automated Analysis**

Visualize the fluorescence of the sample using a transilluminator or equivalent blue light emitting device.

**Equipment**

- **13 x 12 cm mini Transilluminator**
  - NAME: Clare Chemical Research
  - BRAND: DR22A
  - SKU: SARS-CoV-2 Detection In-tube Fluorescent Readout and Automated Analysis

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8  With the user-provided smart device such as a smartphone, open the HandLens application and select in-tube as the test type.

9  Take a photo of the plate, and select upload. The result of the test will appear on the smart device screen.