

Stabilization of SARS-CoV-2 Viral Ribonucleic Acid (RNA) in Specimens

Virucidal Specimen Collection System for SARS-CoV-2 Testing

SAFER™ Stabilization Fluid preserves viral RNA at room temperature and pressure for up to 7 days. It allows for accurate molecular detection of RNA viruses, like SARS-CoV-2, by preventing false negatives caused by sample degradation.

Features

1. Proven 36% more detection of cases compared to gold-standard diagnostic methods.
2. Inactivates SARS-CoV-2 virus in 45 seconds, guarding the safety of professionals.
3. Convenient, preserves samples at room conditions for up to 7 days without refrigeration.
4. Guanidine-free, does not release cyanide with disinfectants needed for lab platforms.
5. Compatible for use with automation platforms for mass testing.

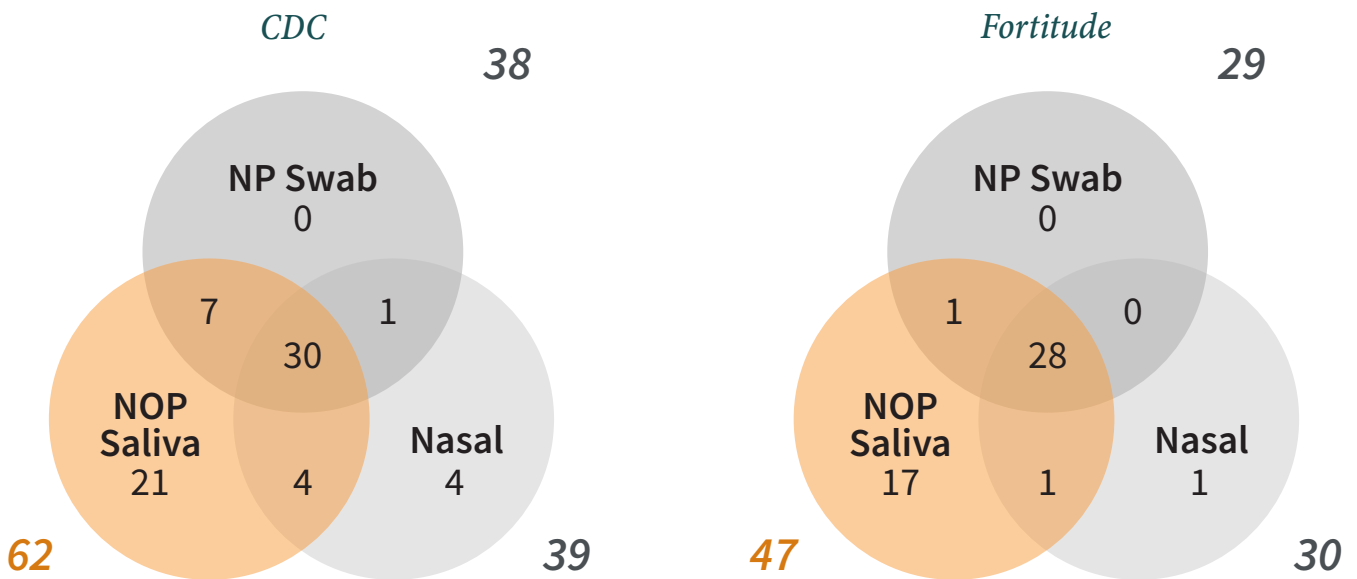


Figure 1. Number of positive diagnoses in tested patients for 3 sample types: Naso-oropharyngeal (NOP) Saliva, Nasopharyngeal Swab, and Nasal Swab.¹ NOP Saliva is more sensitive, detecting 36% more positives than NP Swabs.

The SAFER™ Stabilization Fluid is compatible for use with multiple sample types, including Naso-oropharyngeal (NOP) saliva, nasopharyngeal swabs, and oropharyngeal swabs. The SAFER™ Saliva Collection Kit is painless and non-invasive, making it suitable for use by adults, the children and the elderly even in the absence of medical professionals. SAFER™ Stabilization Fluid is validated to be compatible with multiple SARS-CoV-2 diagnostic test kits (Fortitude V2.1, Abbott Realtime SARS-CoV-2).

Reference:

[1] Kuo AJT, Choudhury Y, Tan IBH, et al. Validation of Saliva and Self-Administered Nasal Swabs for COVID-19 Testing (in prep, 2020).

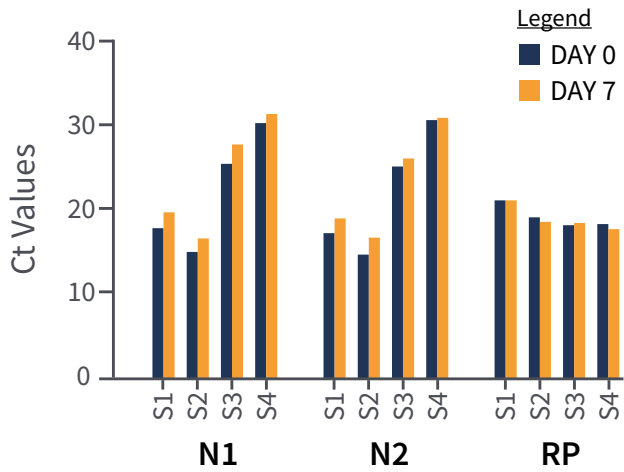


Figure 2. Stability of clinical specimens at room temperature. RNA was extracted from 4 clinical specimens (S1, S2, S3, S4) on Day 0 and Day 7. RT-PCR was performed on 2 SARS-CoV-2 gene targets N1 and N2, and RP (internal control).

Time	Control	SAFER™
45 seconds	$1.5 \times 10^5 \pm 0$	Undetectable
5 minutes	$1.5 \times 10^5 \pm 0$	Undetectable
1 hour	$1.6 \times 10^5 \pm 6.9 \times 10^4$	Undetectable

Table 1. Viral titre of SARS-CoV-2 samples with and without SAFER™ Stabilisation Fluid after 45 seconds, 5 minutes, and 1 hour.

Stability

The SAFER™ Stabilization Fluid stabilizes viral specimens for at least 7 days, when stored at temperatures as high as 37°C. Clinical specimens stored at room temperature over 7 days showed similar Ct values on 3 gene targets (N1, N2, and RP).


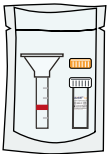
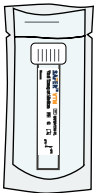
Inactivation of Virus

Validated by Duke-NUS Graduate Medical School and A*STAR, SARS-CoV-2 is inactivated by SAFER™ Stabilization Fluid in 45 seconds for safety (Table 1).

Taken together, SAFER™ Stabilisation Fluid:

- Provides more accurate results, reducing false negative results due to sample degradation.
- Eliminates need for cold chain transport and refrigeration.
- Suitable for use by the young and elderly in the absence of healthcare professional for mass testing.

Materials Supplied

Configurations	Components
 <p>SAFER™ Total Saliva Specimen Collection Kit for Home-use (Cat. No.: SAFER-SAL-01-B)</p>	2mL SAFER™ Stabilization Fluid /vial, a Funnel Collection Tube, and a Top Cap in a Clamshell Protective Case. Includes necessary packaging for triple bag protocol that keeps sample upright.
 <p>SAFER™ Clinic Saliva Specimen Collection Kit (Cat. No.: SAFER-SAL-01-P)</p>	2mL SAFER™ Stabilization Fluid /vial, with a Funnel Collection Tube, and a Top Cap in a sealed pouch.
 <p>SAFER™ VTM Viral Transport Medium for use with NP/ OP swabs (Cat.No.: SAFER-VTM-01)</p>	3mL SAFER™ Stabilization Fluid /vial only.

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