

PHASIFY™ Sample Collection Kit (Saliva)

Intended Use

The PHASIFY™ Sample Collection Kit (Saliva) is intended for single use with the guidance of medical professionals to collect saliva samples. It facilitates the preservation, stabilization, and transportation of sample RNA at ambient temperature (15°C - 30°C) for up to 7 days. This RNA can be extracted and detected through molecular testing, such as RT-qPCR in the laboratory.

Principle

Medical professionals may instruct the patient to provide saliva into the Funnel, which is attached to the 5 mL Collection Vial. The 2.5 mL of Saliva Buffer in the Dropper Bottle is added to the Collection Vial to stabilize patient sample RNA for up to 7 days at ambient temperature, prior to downstream RNA extraction and RT-qPCR screening in a laboratory.

PHASIFY™ Sample Collection Kit (Saliva) - 100 Kit Case Contents

- 100 x Individual PHASIFY™ Sample Collection Kit (Saliva)
- 1 x User Manual

PHASIFY™ Sample Collection Kit (Saliva) - Individual Kit Contents

- 1 x 5 mL Collection Vial with Funnel
- 1 x Collection Vial Cap
- 1 x Dropper Bottle containing 2.5 mL of Saliva Buffer
- 1 x Patient Label
- 1 x Specimen Bag
- 1 x Quick Start Guide

Storage and Handling

Before collection

- The kit can be stored at 15-30°C for up to 12 months.
- Avoid direct sunlight.
- Do NOT use the test kit after expiration date indicated on the kit labels.
- All components should remain sealed before use.

After collection

- The collected sample can be stored at 15-30°C for up to 7 days.

Warnings and Precautions

- Saliva sample is potentially infectious.
- If Saliva Buffer is in contact with skin, eyes or mouth, flush with water immediately and seek medical help.
- Do NOT swallow any kit components.

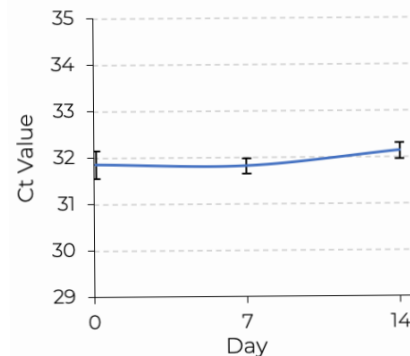
- All components in this kit are for one-time use only. Do NOT reuse.
- If the Saliva Buffer was spilled, flush the affected area abundantly with water upon disposal. Do NOT clean Saliva Buffer spills with bleach.
- Vial Cap may be a choking hazard. Keep away from children.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Instructions for patient saliva sample collection

1. Spit into the **Funnel** until the saliva level (excluding bubbles) reaches in between the two red lines labelled on the **Collection Vial**. Do not overfill.
2. Add all of the **Saliva Buffer** solution into the saliva-filled Collection Vial.
3. Unscrew the Funnel from the Collection Vial.
4. Close the tube tightly with the **Vial Cap**. Invert the vial 10 times to mix the sample and the Saliva Buffer thoroughly.
5. Fill in the patient information on the **Patient Label** (as instructed).
6. Stick the Patient Label onto the Collection Vial.
7. Place the labelled Collection Vial into the **Specimen Bag** and seal it.

Note: If collection was done in the laboratory, samples must have incubated in the Saliva Buffer solution for at least 10 minutes prior to extracting the nucleic acid.

Performance Evaluation



Verification data of spiked samples shows preservation of RNA over 14 days.

Disposal of Preserved Samples

Preserved samples will form reactive compounds when combined with bleach. Do NOT mix any preserved samples with bleach. Dispose any remaining preserved samples as per your institutions' hazardous chemical waste procedures.

Quality Control

Each lot of PHASIFY™ Sample Collection Kits (Saliva) is tested against predetermined specifications to ensure consistent product quality in accordance with PHASE Scientific's Quality Management System.

Disclaimers

This kit is intended for in vitro diagnostic use.

We reserve the right to change, alter or modify any product to enhance its performance and design.

Technical Support

For technical support, contact us at phasify@phasesci.com or +852 9135 2570.

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CE Registration



Caution, Consult accompanying documents



Temperature Limitation



Sufficient for Use



Keep away from sunlight



Keep away from moisture



Do not reuse



In-Vitro Diagnostic Medical Device



Batch code



Use by



Manufacturer