

Timestrip® Virus Specimen Transport - Fridge Combo Product Spec Sheet



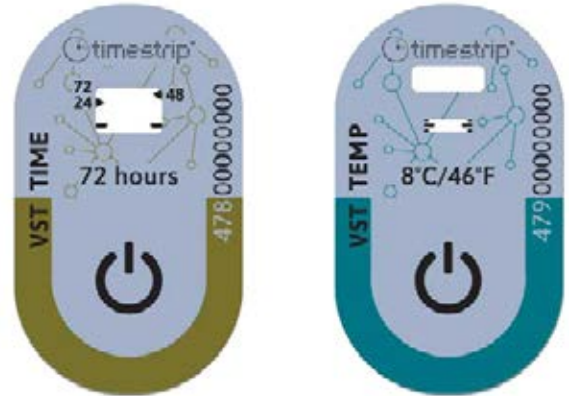
Timestrip® VST Fridge Combo (VST-TIMETEMP-728)

Timestrip® VST (Virus Specimen Transport) series has been specially formulated to provide an adequate quality control resolution for proper transport/storage of clinical viral specimens.

According to FDA & WHO regulations, Coronavirus specimens may be stored/transported/chilled between (2-8°C) for up to 72 hours after collection. In addition, virology specimen collection guidelines state similarly that “most viruses remain stable at 4°C for 2-3 days.”

Timestrip VST - Fridge Combo was developed to follow the required time limitations during chilled conditions together with a distinct indication when upper limits of chilled temperatures are breached beyond the stated 8 °C.

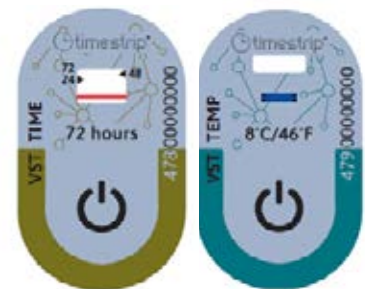
Timestrip VST - Fridge Combo is a complete solution composed of a single card with two indicators, TIME & TEMP. The first, is designed to indicate (aligning with regulation) when TIME of 72 hours has passed during chilled conditions (defined between 2-8°C). The second, is TEMP breach indication, signaling when temperatures exceed the regulated upper limit of 8 °C of chilled storage/transport.



Instructions for Use

After collection and insertion of a clinical specimen inside an adequate packaging, VST Fridge Combo can now be integrated simply quickly & safely.

1. Hold the VST Fridge Combo card in your hand
2. Firmly squeeze the button of the TIME indicator, between thumb and forefinger. Verify the appearance of a dark red thin line inside the white “indication window”
3. Firmly squeeze the button of the TEMP indicator, between thumb and forefinger. Verify the appearance of a complete blue coloration inside the small arming window. **This confirms that both indicators were activated.**
4. Immediately after activation of both buttons, refrigerate the Combo Card to temperatures of +6°C/43°F or below for a minimum of 10 minutes. (If the temperatures inside the chill environment are already at or below +6°C/43°F, stage 4 can be skipped.)
5. Soon after, peel off the liner from the back of the Combo Card and firmly adhere it to the packaged clinical specimen. **Ensure full adhesion to the specimen packaging.**
6. Immediately after adherence, the packaged clinical specimen (with the adhered complete card) needs to be placed inside regulated chill temperatures (between 2 – 8 °C) for immediate storage or transport.



Monitoring has begun.

In case the “indication window” of the TEMP-indicator and/or of the TIME-indicator is fully coloured, chilling conditions were breached.

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Storage Conditions (Unactivated)

Store indoors, at room temperature up to 30°C.

Shelf Life

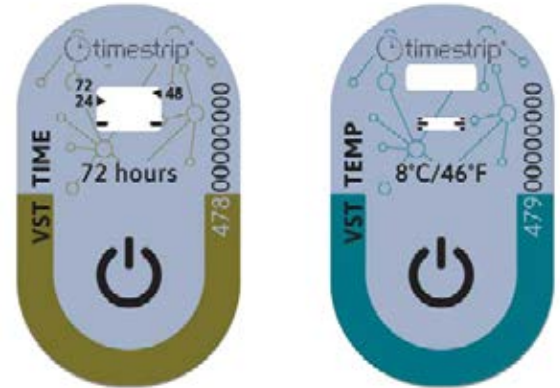
3 Years – for TIME indicator, the date of manufacture (MD) is stated on each pack. For the TEMP indicator, an expiry date is stated on each pack.

Product Construction

The indicators are constructed of polymeric assembly multilayer and aluminium-plastic laminate. TIME 72 HOURS encapsulates colored oils. TEMP 8° encapsulates colored liquid chemicals.

- TEMP 8° - Maximum weight of colorant is <0.5 mg.
- TEMP 8° - Liquid chemicals are listed in the Food Chemicals Codex and/or approved by the Food and Drug Administration (FDA) under Title 21, and/or considered generally recognized as safe (GRAS).
- All materials are non-toxic, latex, silicon and PVC free.

PRODUCT SPECIFICATIONS - TEMP 8° & TIME 72 HOURS	
Button Position	Button on Top (BOT)
Color of Progressing Front	Red for TIME 72 HOURS Blue for TEMP 8°
Adhesive	#14009//Time3
Other	Not suitable for immersion in water
Usage	The usage of the product in any assembly or production line must be agreed upon in advance, as it may alter performance specifications.
Remark	Run-time window length will vary slightly between production batches.



SPECIFICATIONS FOR TEMP 8°		
THRESHOLD TEMP	STOP TEMP*	RUN-OUT WINDOW**
+8°C/+46°F	+6°C/+43°F	2 Hours
* The temp at which the run-time advancement (the movement of the blue dye) will stop.		
** The run-out window starts at 1/2 hrs and ends at 2 hrs. The run-out window is calibrated to an isothermal temp of +2°C above the stated/printed threshold temp.		

PERFORMANCE SPECIFICATIONS FOR TEMP 8°	
Temperature Accuracy	± 1°C/2°F
Time Accuracy	± 15 % in time under isothermal conditions
Display	Continuous, irreversible
Usage	The usage of the product in any assembly or production line must be agreed upon in advance, as it may alter performance specifications.

PERFORMANCE SPECIFICATIONS FOR TIME 72 HOURS	
Run Time	72 Hours
Calibration Temperature	4 °C ± 1°C
Time Accuracy	± 15 % in time under isothermal conditions
Activation Force*	5 ± 2 kgf
* Activation is applied by firmly squeezing the blister. If the activation line doesn't appear within 2 min, re-squeeze the blister.	

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