

Summary and Explanation of the Device

Standard methods of biological specimen storage and transport have several disadvantages, such as low-temperature or low-volume requirements. ViveST™ provides the ability to store up to 1mL of viable biological specimen at ambient temperature for use in specimen storage and transportation.^{1,2} This device utilizes an absorbent matrix on which a biological specimen can be loaded and dried. The matrix is housed on the screw-cap of a microcentrifuge tube such that the sample is self-contained during storage and shipping. The tube also contains a DriCap® Desiccator that acts as a quality control indicator for dryness during shipping and storage.

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Device Principle

The ViveST Sample Storage and Transportation Device consists of two kits: the Sample Storage and Transportation Device Kit and an optional Accessory Kit. In the Sample Storage and Transportation Device Kit, a biological specimen is added and allowed to dry on an absorbent matrix. During the drying process, water in the biological sample is evaporated but biological analytes including proteins, virions and nucleic acids remain in the matrix. The samples can then be stored or transported as needed in the dried state. The Accessory Kit is utilized to reconstitute the samples into a liquid state. During reconstitution, the dried analytes are released from the matrix and contained in molecular grade water. Reconstituted samples can then be processed as usual for molecular or immunoassay tests.

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Materials Provided

Store all components at Room Temperature (15-25°C, out of direct sunlight).

Component	Description	Quantity
Sterile Syringes	Individually-wrapped Luer-Lock™, 3mL	24
Recovery Tubes	8mL flat-bottom sterile tube with screw cap	24










Materials Required, but Not Provided

Item	Description
Pipette	1000 µL
Pipette Tips	1000 µL, sterile DNase- and RNase-free, with aerosol barrier
Water	Molecular grade
Rack	For recovery tubes
Workstation	Biological safety cabinet or laminar air flow
Personal Protection	Powder-free disposable gloves, laboratory coat, safety glasses
Waste	Biohazard waste container

Warnings and Precautions

- For Research Use Only. Not for *in vitro* Diagnostic Use.
- This kit supplies sufficient consumables and reagents for the number of tests indicated.
- Do not use the components of this kit beyond the expiration date printed on the box.
- Use only a ViveST containing DriCap Desiccators with a deep blue color. Do not use a ViveST if the DriCap Desiccator appears light-blue, white or pink in color.

- Use good laboratory practices and universal precautions relating to the prevention of transmission of blood borne pathogens.^{3,4}
 - Use disposable powder-free gloves to handle all materials as though capable of transmitting infectious agents.
 - Immediately clean any spills suspected of potentially containing infectious agents with 0.5% w/v sodium hypochlorite (10% v/v bleach).
 - Dispose of all specimens and materials that come in contact with specimens as though they contain infectious agents.
 - In the event that materials known or suspected of containing infectious agents are ingested or come in contact with open lacerations, lesions or mucous membranes (eyes, nasal passages, etc.), consult with a physician immediately.

Symbology Table			
Symbol	Meaning	Symbol	Meaning
15°C / 25°C	Temperature limitation		Contains sufficient for n tests
	Use by		Catalogue number
	Batch code		Consult instructions for use
	Do not reuse		Caution/Attention, see instructions for use
	Manufacturer		Date of Manufacture

Sample Recovery Procedure

Note – This protocol requires a ViveST that was previously loaded and dried. Refer to the ViveST Sample Storage and Transportation Device kit package insert for sample loading instructions.

1. Place the ViveSTs containing dried samples into a clean biological hood.
2. Observe the DriCap Desiccator inside each ViveST. Continue recovery only for a ViveST containing a DriCap Desiccator that is a deep blue color.

Warning - Do not use if the DriCap Desiccator appears light-blue, white or pink in color.

3. Inside the hood, uncap a recovery tube for each sample to be recovered and place into the tube rack.
 - Place the recovery tube screw caps in a clean area of the hood until ready for further use. Do NOT discard the caps.
4. Prepare a sterile syringe by removing its wrapping and removing the plunger.
 - Place the removed plungers in a clean area of the hood until ready for further use. Do NOT discard the plungers.
5. Uncap one ViveST and transfer the matrix into the syringe barrel.
 - Pressing the matrix against the inside of the syringe barrel mouth should apply enough pressure to break the matrix free from the cap.
 - Holding the matrix against the syringe barrel with a pipette tip may also aid in releasing the matrix.
6. Place the syringe barrel into a recovery tube.
7. Draw 1 mL of molecular grade water into a pipette tip.

8. Using the pipette tip, gently push the matrix until it is touching the bottom of the syringe barrel. Pipette the water onto the matrix.
 - Do not squeeze the matrix when placing it to the bottom of the syringe barrel or when pipetting the water.
 - The water should be completely absorbed by the matrix. If some water leaks into the recovery tube, aspirate it using the pipette tip and re-pipette onto the matrix.
9. Rest the syringe in the recovery tube and allow the matrix to incubate at room temperature for 10 minutes.
10. Perform steps 4 - 9 for each ViveST.
11. While keeping the tip of each syringe in its recovery tube, insert the syringe plunger into the syringe barrel and depress with firm, even pressure until the plunger has completely compressed the matrix.
 - A volume of approximately 1 mL should be collected in the recovery tube.
12. Remove the syringe from the recovery tube and dispose of all components, including the matrix, in a proper biohazard waste container.
13. Cap and label each recovery tube containing reconstituted sample.
14. Continue with testing or store samples using your standard plasma storage conditions.

Function of the DriCap Desiccator

The DriCap Desiccator is intended for use as quality control of sample dryness as well as the storage and shipping environments. It is NOT intended to aid in drying of the samples on the matrix. The matrix should be completely dried prior to being secured in the ViveST. If the matrix is not properly dried, the DriCap Desiccator will change from a deep blue color to varying shades of light-blue, pink and white. If any of the crystals in the desiccant are pink or white, the sample should not be used for further testing due to possible analyte degradation.

Test Limitations

- Limited validation tests of ViveST have only been performed using human EDTA plasma and human serum as the biological specimen.
- The DriCap Desiccator is NOT intended to dry samples. Samples must be completely dry before securing the matrix in the ViveST.

References

1. RM Lloyd, Jr., DA Burns, JT Huong, RL Mathis, MA Winters, M Tanner, A De La Rosa, B Yen-Lieberman, W Armstrong, A Taege, DR McClernon, JL Wetshtein, BM Friedrich, MR Ferguson, W O'Brien, PM Feorino and M Holodniy. Dried-plasma transport using a novel matrix and collection system for human immunodeficiency virus and hepatitis C virus virologic testing. *J Clin Microbiol*, 47(5), May 2009, p. 1491-96.
2. M Zanoni, R Cortes, RS Diaz, MC Sucupira, D Ferreira, LA Inocencio, C Vilhena, C Loveday, RM Lloyd, Jr., M. Holodniy. Comparative effectiveness of dried plasma HIV-1 viral load testing in Brazil using ViveST for sample collection. *J Clin Virol*, 49(4), Dec 2010, p. 245-8.
3. National Committee for Clinical Laboratory Standards. Protection of laboratory workers from infectious disease transmitted by blood, body fluids, and tissue; approved guideline. NCCLS Document M29-A Villanova (PA); NCCLS; 1997 Dec. 90p.
4. Centers for Disease Control and Prevention: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other blood borne pathogens in healthcare settings. *MMWR*, 1988; 37: 377-82, 387-8.

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