ViveST®

Sample Storage and Transportation Device

Product Insert

Cat No. VSL24C **24 Test**

Summary and Explanation of the Device

Standard methods of biological sample storage and transport have several disadvantages for analytes that are unstable at ambient temperatures or higher humidity. ViveST® provides the ability to store up to 1.5 mL of biological sample at ambient temperature. This device utilizes an absorbent matrix onto which a biological sample can be loaded and dried. The matrix is housed in a screw-top tube so that the sample is self-contained during storage and shipping. The tube also contains a DriCap® Desiccator that acts as an indicator for moisture inside the ViveST device.

Device Principle

Using the ViveST Sample Storage and Transportation Device, a liquid biological sample is added to an absorbent matrix and allowed to dry. The sample can be stored or transported as needed in the dried state. When required, the sample is reconstituted into a liquid state so that the dried analytes are released from the matrix. The reconstituted sample can then be recovered for downstream testing.

Intended Use/Indications for Use

This product is intended to be used to maintain a biological sample in a dried state for storage and transport. Upon reconstitution, the sample can be used for downstream testing. Each user must validate the use of ViveST.

Materials Provided

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

Component	Description	Quantity
ViveST	Tube containing fibrous matrix and DriCap Desiccator	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
Sterile Syringes	BD 3 mL Luer-Lock™, individually-wrapped
Tubes	At least 1 mL with a screw-cap, for sample recovery/storage
Rack	For tubes used in recovery
Workstation	Biological safety cabinet, laminar flow hood or equivalent
Personal Protection	Powder-free disposable gloves, laboratory coat, safety glasses
Waste	Biohazard waste container

Warnings and Precautions

- 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 a DriCap Desiccator 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.[1,2]
  - 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).
  - 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	Σ	Contains sufficient for n tests
	Use by	REF	Catalogue number
LOT	Batch code		Consult instructions for use
	Do not reuse		Caution/Attention, see instructions for use
	Manufacturer	EC REP	Authorized Representative
CE	European Conformity	IVD	For *In Vitro* Diagnostic Use

Sample Loading Procedure

1. Place desired number of ViveST into a biological safety cabinet or laminar flow hood.
2. Observe the DriCap™ Desiccator in each ViveST. Use only a ViveST containing a DriCap Desiccator that is deep blue in color.

   Warning - Do not use if the DriCap Desiccator appears light-blue, white or pink in color.
3. Label the ***cap*** of each ViveST with a sample identifier.
   - The matrix is attached to the cap; therefore, the sample identifier should be placed on the cap. Labeling only the tube may lead to sample confusion.
4. Remove the cap from each ViveST and place it on the work surface of the hood so that the absorbent matrix is pointing upward.
   - Retain the ViveST tube in the hood out of the way.
5. Slowly pipette appropriate volume (up to 1.5 mL) of liquid biological sample onto the top of the ViveST matrix.
   - Initially adding 1 drop of sample may help to begin proper absorption.
   - It is acceptable to lightly touch the matrix with the pipette tip.
   - Record the exact sample volume for sample recovery procedure.
6. Air dry the loaded matrix.
   - Do NOT place the matrix into the ViveST tube until the matrix has completely dried.
   - Samples will dry faster if placed in an air ventilation instrument, such as a laminar flow hood or biological safety cabinet, near the circulating vent.
   - Generally, about 8 hours are required for drying when using a laminar flow hood. This time may vary due to various environmental factors such as airflow speeds, temperature, and humidity. At relative humidity >60%, drying time may need to be extended.
   - For individual laboratory validation, follow the ViveST Drying Time Validation Protocol available on the ViveBio website at www.vivebio.com.
7. Screw the cap onto the ViveST so that the matrix is contained within the tube.

   Warning – The matrix must be completely dry before replacing it into the ViveST.
8. The ViveST containing a dried sample may be stored or shipped at ambient temperature. Users should validate length of storage time for their specific application.
   - Ship the ViveST containing the dried sample following 2009 UN Model Regulations and WHO 2009-2010 Guidance.[3,4]
9. Proceed to the Sample Recovery Procedure for instructions on reconstitution of the sample.

Sample Recovery Procedure

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

   Warning – If the DriCap Desiccator is discolored, proceed with caution as this indicative that the matrix did not completely dry prior to capping or that the ViveST device was exposed to moisture.

3. Inside the hood, label a sample recovery tube to match the sample identifier for each ViveST. Uncap the tube for recovery of each sample. Place recovery tube into a tube rack until needed.
   - Place the sample recovery tube screw caps in a clean area of the hood until ready for further use. Do NOT discard the caps.
   - Pipet appropriate volume of molecular grade water into each recovery tube.
4. Prepare a sterile syringe by removing its wrapping. Remove the plunger from the barrel of the syringe.
   - Place the removed plunger in a clean area of the hood until ready for further use. Do NOT discard the plunger.
5. Uncap one ViveST and transfer the matrix into the syringe barrel.
   - Pressing the matrix against the inside of the syringe barrel mouth should direct enough pressure to break the matrix free from the cap.
   - Holding the matrix against the syringe barrel with a sterile pipette tip may also aid in releasing the matrix.
   - If necessary, gently press the matrix into the syringe barrel using the cap, a pipet tip or the syringe plunger.
6. Rehydrate the matrix with molecular grade water as described below:
   - Insert the syringe plunger and depress until the matrix is fully compressed.
   - Place the syringe barrel into a recovery tube containing the appropriate volume of molecular grade water.
   - While holding the tip of the syringe in the water, pull the syringe plunger upward to draw the entire volume of water into the syringe to rehydrate the matrix.
   - Ensure that there are no air bubbles in the syringe that may inhibit water from completely absorbing into the matrix.

     NOTE: It may take a few minutes for the water to be fully absorbed.
7. Rest the syringe in the recovery tube and allow the rehydrated matrix to incubate at room temperature for 10 minutes.
8. Perform steps 6 & 7 for each ViveST.
9. While keeping the tip of the syringe in its recovery tube, use the syringe plunger to depress with firm, even pressure until the plunger has completely compressed the matrix. This action will expel the reconstituted sample into the recovery tube.
   - A volume approximately equal to the volume of water used should be collected in the recovery tube.
10. Remove the syringe, including the matrix, from the recovery tube and dispose in a proper biohazard waste container.
11. Cap each labeled recovery tube containing the reconstituted sample.
12. Repeat Steps 9 - 11 for each reconstituted sample.
13. Continue with testing or store samples using your standard sample storage conditions.

Function of the DriCap Desiccator

The DriCap Desiccator is included to act as an indicator for moisture inside the ViveST device. It is NOT intended to aid in the drying of the samples on the matrix. If the environment inside the ViveST device is exposed to moisture, the DriCap Desiccator will change from a deep blue color to varying shades of light-blue, pink or white. A ViveST device, whose desiccant is not a deep blue color, should not be used for biological sample loading.

After loading, the matrix should be completely dried prior to being secured in the ViveST tube. After storage and/or shipment of biological samples on ViveST, the user should observe the color of the desiccant and proceed with caution if the desiccant is not a deep blue color as this is indicative that the matrix did not completely dry prior to capping or that the ViveST device was exposed to moisture.

Test Limitations

- Limited validation studies have been performed evaluating the use of ViveST with a number of sample types and downstream assays. The user is responsible for confirming the performance characteristics of any downstream assay when used in combination with samples recovered from the ViveST Sample Storage and Transportation device.
- The DriCap Desiccator in NOT intended to dry samples. Samples must be completely dry before securing the matrix in the ViveST tube.
- Drying time may vary depending on environmental conditions and sample types loaded on the ViveST device. Each user should confirm the ideal drying time for each sample type in their laboratory environment (details provided in the **Drying Time Validation Protocol** available on the ViveBio website at www.vivebio.com.).

References

1. 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.
2. 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.
3. United Nations: Recommendations on Transport of Dangerous Goods Model Regulations. UN document, 2009, section 2.6.3.
4. World Health Organization: Guidance on Regulations for the Transport of Infectious Substances 2009-2010. WHO document, 2008.

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