



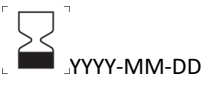
DISCOVERY PATCH®
SWEAT COLLECTION SYSTEM

INSTRUCTIONS FOR USE

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SYMBOLS GLOSSARY

Symbol	Symbol Title	Explanatory Text
	Manufacturer	Indicates the medical device manufacturer
	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Use by	Indicates the date after which the medical device is not to be used
 www.epicorebiosystems.com	Consult electronic instructions for use	Indicates the need for the user to consult the electronic instructions for use
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Non sterile	Indicates a medical device that has not been subjected to a sterilization process
	Quantity	Indicates the amount or number of contents
	Does not contain latex	Indicates the absence of natural rubber latex

INDICATIONS FOR USE

The Discovery Patch® Sweat Collection System is designed to collect sweat during on-body wear for biomarker research. The Discovery Patch is intended for use by researchers and healthcare professionals for the collection of sweat in home and professional healthcare settings for biomarker research. The Discovery Patch is intended for use on patients ≥18 years of age.

CONTRAINDICATIONS

The Discovery Patch is not intended for use on:

- Subjects with a history of allergic responses to skin adhesives
- Damaged or diseased skin
- Open wounds
- Women who are pregnant, lactating, or trying to become pregnant. Discovery Patch has not been tested on pregnant women.

WARNINGS

- If serious skin reactions occur, discontinue use of Discovery Patch.
- Individuals with an allergy to adhesives or silicone should not wear the Discovery Patch.

PRECAUTIONS

- Discovery Patch is not sterile.
- The Discovery Patch is intended for single-use only.
- Do not apply the Discovery Patch if it appears damaged.
- Do not use Discovery Patch if package appears damaged or torn.
- Do not wear the Discovery Patch over regions of the body with excessive body hair. Excessive body hair should be trimmed prior to use.
- No creams or lotions should be applied to the skin prior to application of the Discovery Patch.
- Upon removal, subjects may experience transient redness of the skin, which typically resolves within a few hours or up to a day.

STORAGE AND HANDLING

- Storage temperature range: 15 – 30°C (59-86°F)
- Storage relative humidity range: 40 – 60% RH
- Ensure your hands are clean and dry before handling the Discovery Patch and any components. Gloves are recommended for healthcare professionals when handling the Discovery Patch.

SYSTEM OVERVIEW

This guide describes important steps required to apply the Discovery Patch to the skin and to perform extraction of the collected sweat.

BACKGROUND

The Discovery Patch Sweat Collection System (Figure 1) consists of a soft, skin-interfaced microfluidic patch and extraction apparatus that collectively facilitate the rapid capture and extraction of sweat into quantifiable volumes for research of various biomarkers. The soft mechanical properties, the flexible layout, and the small size of the microfluidic patch facilitates attachment onto various body locations (e.g., forearm, upper bicep, lower back, and thigh) while minimizing risks of sample contamination, sample evaporation, and leakage. An extraction apparatus supports efficient transfer of the collected sweat from the microfluidic patch and into a container where it can be stored and prepared for biomarker analysis.

These instructions for use introduce the key features and capabilities of the Discovery Patch Sweat Collection System and present the methodologies required for patch application, sweat collection, and sweat extraction using the system.

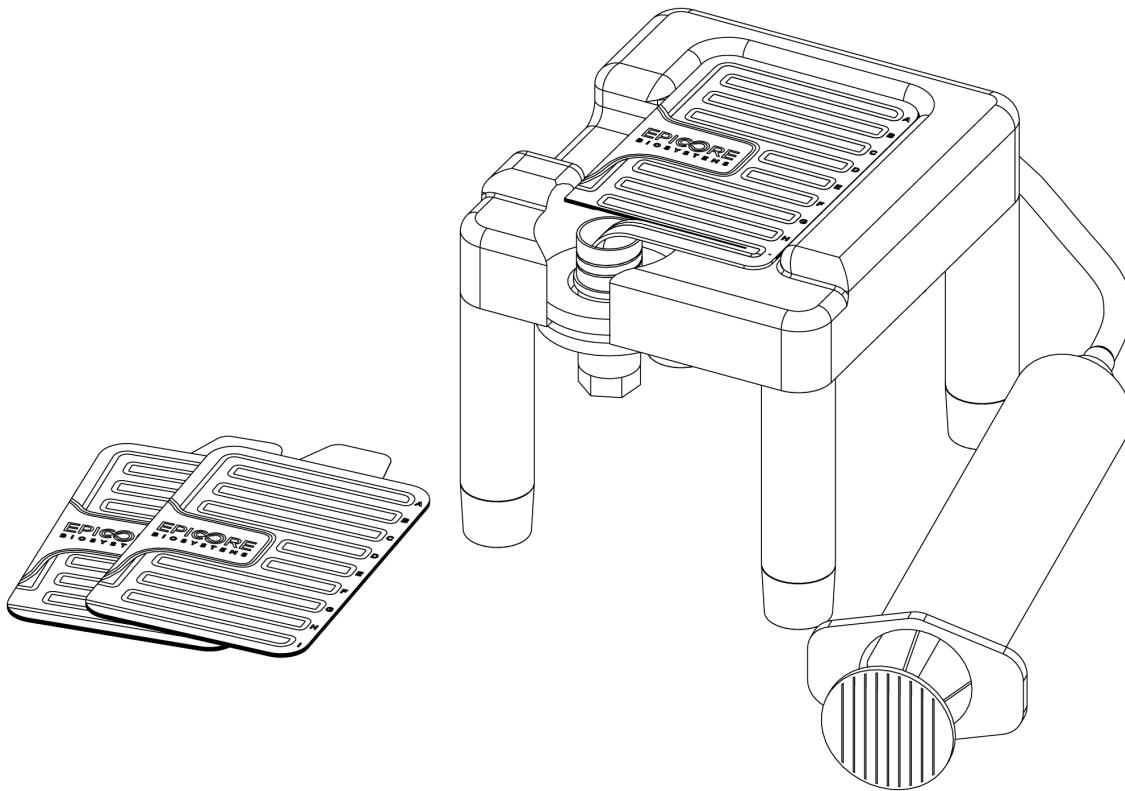


Figure 1: Discovery Patch Sweat Collection System

SYSTEM COMPONENTS

The Discovery Patch Sweat Collection System consists of:

- i) wearable microfluidic patch herein referred to as Discovery Patch,
- ii) sweat extraction apparatus for removal of collected sweat from the Discovery Patch herein referred to as Extraction Fixture,
- iii) vial for safe storage of collected sweat in preparation for analysis.

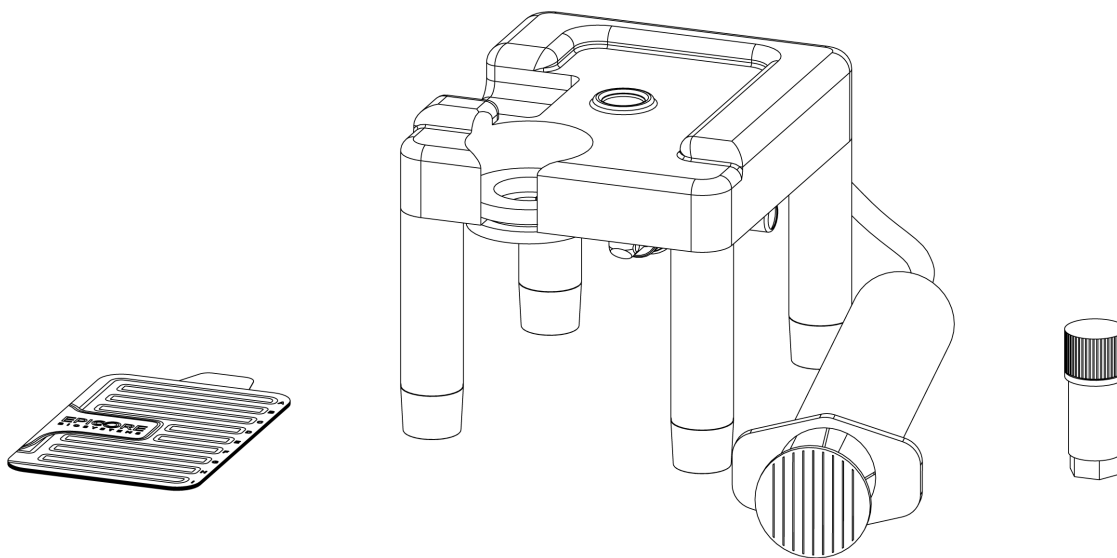


Figure 2: Components of the Discovery Patch Sweat Collection System: Discovery Patch (left), Extraction Fixture (middle), and Vial (right)

DISCOVERY PATCH

The Discovery Patch is a single-use, flexible wearable microfluidic patch that is designed to be soft and compatible for wear on the skin. The Discovery Patch is available in two variants, designed for either an optimized sweat collection efficiency or an emphasis on the ability to evaluate and analyze sweat rate data.

One patch variant is designed to collect the greatest volume of sweat in the shortest amount of time. This rapid collection of sweat is enabled by a “solid” skin-side adhesive design, with widespread adhesive coverage across the majority of the backside of the patch. This patch variant may be used when the goal is to collect sweat as fast as possible, where any comparisons of sweat rate (either intra or inter-subject) are not of interest.

A second patch variant allows for the sweat rate of the wearer to be evaluated. This is made possible by a “patterned” skin-side adhesive design which features stripes of adhesive across the width of the patch. This patch

variant should be used when sweat rate (either intra- or inter-subject) is of interest.

Both Discovery Patch variants feature the following:

- A **removable liner** that protects an acrylic adhesive present on the back of the patch
- A **skin-side adhesive** used to adhere the patch to the skin surface
- A **sweat collection area** bordered by adhesive where sweat is to be collected from the skin
- A **sweat inlet** at the base of the patch where sweat enters the patch microchannels
- A **network of microchannels** where sweat travels through and is contained within the patch
- **Volume tick marks** used for estimating patch fill volume
- A **channel outlet** at the end of the microchannel where sweat is transferred from the patch and into a sample storage vial during the extraction process

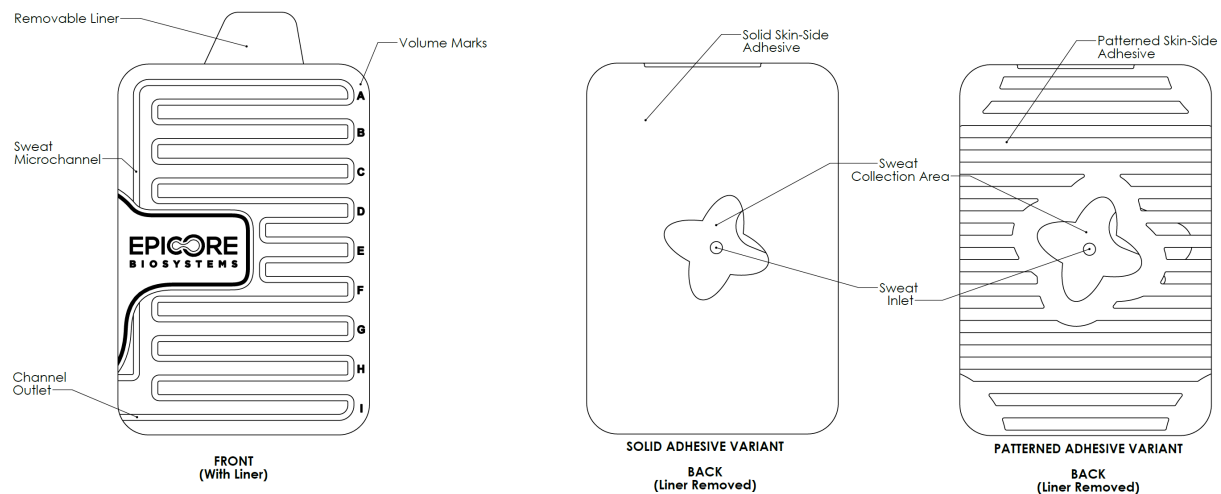


Figure 3: Key Features of the Discovery Patch

Dimensions (L x W x H)	2.4" x 1.6" x 0.034"
Weight	2 grams

Table 1: Discovery Patch Specifications

The Discovery Patch may be placed at various anatomical locations for regional sweat capture and analysis. As the wearer begins to sweat, the excreted sweat pooling in the Discovery Patch's collection area propagates through a network of microchannels driven by the natural pressure gradients of the sweat glands.

During collection, the extent of sweat filling can be readily observed according to the annotated tick marks printed along the right edge of the Discovery Patch. Each letter (A through I) corresponds to an estimate of sweat volume collected as shown in Figure 4.

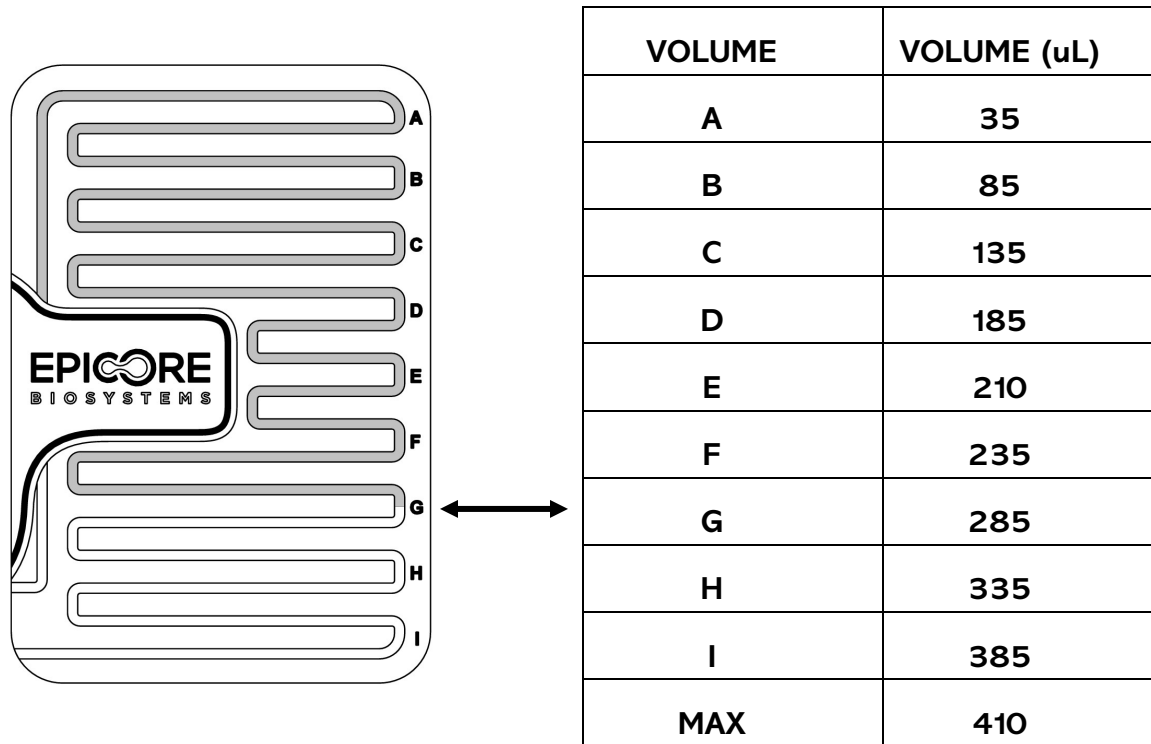


Figure 4. Partially filled Discovery Patch filled to Volume Mark “G” (left) and Approximate Fill Volume Reference Table (right). Patch shown currently contains approximately 285 uL of sweat.

EXTRACTION FIXTURE

The Extraction Fixture is used to transfer sweat collected and stored within the patch to a container for analysis. The fixture features:

- An **extraction platform** where the patch is placed after removal for extraction
- **Patch cavity** for easy alignment of the patch for extraction
- An **extraction ridge** surrounding the **extraction cutout** connected to the valved **extraction tubing** system and **syringe** to enable sweat extraction
- A **vial holder** where the container for extracted sweat is supported during the extraction process

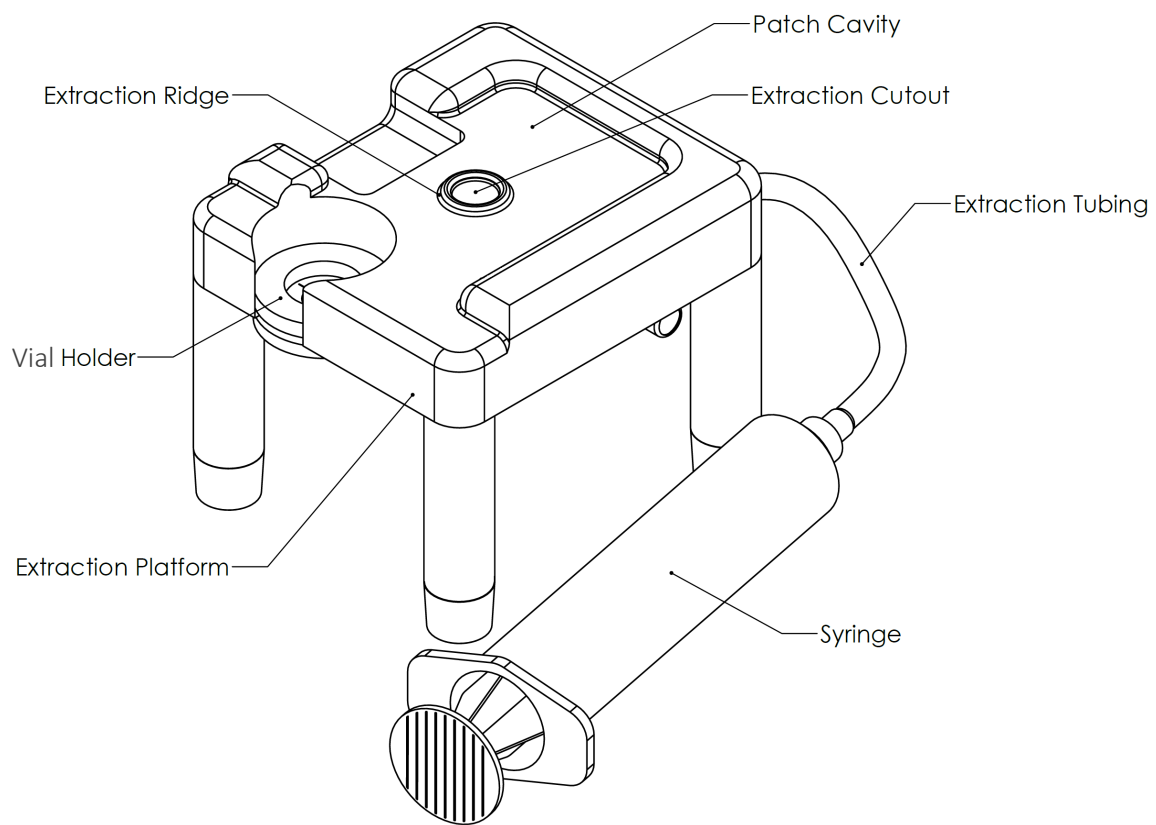


Figure 5: Key Features of the Extraction Fixture

The patch cavity of the Extraction Fixture aligns the extraction cutout with the patch's sweat inlet. Air is pushed through the patch, which pushes all contained sweat through the patch microchannel until it exits the device at the sweat extraction port and into a storage vial. A valve integrated with the extraction tubing allows the syringe to be refilled in place without pulling in sweat while a patch is on the extraction platform.

SAMPLE STORAGE VIALS

Off-the-shelf sample storage vials may be included with the Discovery Patch Sweat Collection System. Extracted sweat is deposited and stored within these vials until the sweat is ready to be analyzed. Vials provided by Epicore fit a cutout in the Extraction Fixture which support the vial during the sweat extraction process.

Note that any vial used other than provided by Epicore may not fit the Extraction Fixture.

DIRECTIONS FOR USE

INSPECT DEVICE

The Discovery Patch System is shipped ready for use. The patch does not require cleaning prior to use. Patches with damage, cracks, tears, or other defects should be discarded. Once inspected, the Discovery Patch is ready for use. The Discovery Patch can be labeled at the bottom with a soft-tip permanent marker if desired.

SUBJECT PREPARATION AND PATCH APPLICATION

1. Put on a clean pair of nitrile gloves
2. Inspect placement locations for hair follicles, and shave with an electric trimmer if necessary
3. Wipe all placement locations with fresh alcohol wipes, and allow the skin to dry completely for 2 minutes, or dry with paper towels if necessary. Patch must be applied prior to the onset of sweating.
4. If desired, label the bottom of each patch using a permanent marker
5. Remove the liner from the back of the patch
6. Apply the patch to the desired body location and apply uniform pressure for 10 seconds
7. Repeat as needed with additional patches

SWEAT CAPTURE

1. Sweat must be collected during an activity associated with a sufficient sweat rate to fill the patch
2. Once sweat collection activity is completed (or desired amount of sweat has been collected), continue to patch removal. Patch should be removed as soon as possible after collection.

PATCH REMOVAL

1. Put on a clean pair of gloves to avoid contamination of the sample
2. Begin removal by carefully lifting a corner of the patch. Gently lift the rest of the patch away from the skin, working from the outside of the patch in towards the center.
3. Set patch aside, and take care to keep the sweat inlet and channel outlet openings away from any wicking materials (e.g. paper, cloth)
4. Repeat Steps 2 and 3 for all remaining patches
5. Extract the sweat as soon as possible after patch removal (time dependent based on biomarker research interest) using the extraction fixture

SWEAT EXTRACTION

1. Put on a clean pair of gloves
2. Wipe the top of the extraction fixture surfaces with 70% isopropyl alcohol (IPA) and a lint-free wipe and allow to dry for 2 minutes
3. Withdraw the plunger of the extraction fixture syringe to maximum capacity
4. Unscrew the cap of one sample storage vial and place it in the vial holder of the extraction fixture
5. Select a patch and cut between the two rows at volume marker I as shown in image B of Figure 6 so that the final row forms a tail
6. Place the patch in the patch cavity of the extraction fixture so that the patch inlet is over the extraction hole and the patch tail extends over the vial
7. Fold the tail down so that the channel outlet is inside the vial, as shown in image C of Figure 6.

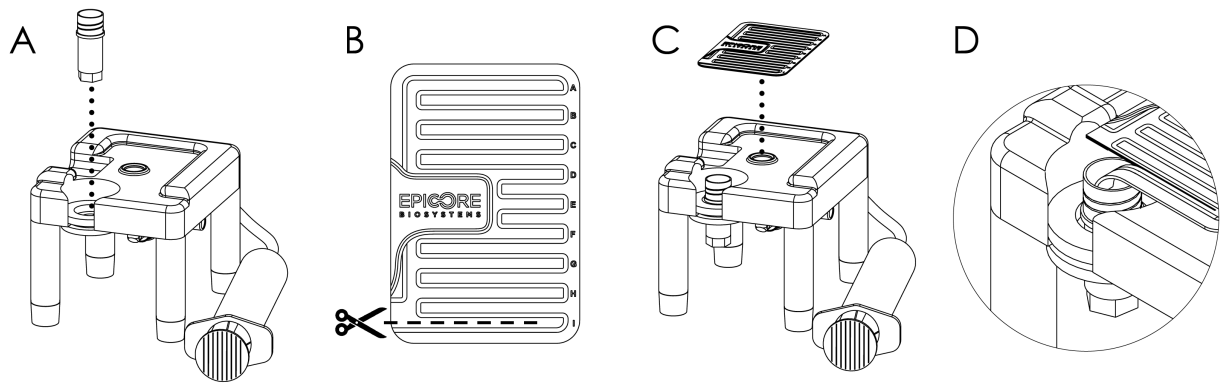


Figure 6: Preparing Patch for Sweat Extraction: A) Uncap and insert vial into the holder B) Cut patch to create a tail, C) Place patch in patch cavity, D) Fold tail so it bends down into the cryovial

8. Using your thumb, press down and hold slight pressure over the entire extraction ridge to maintain a seal between the patch and the fixture throughout the sweat extraction process
9. With the other hand, grasp the syringe and firmly press on the syringe plunger to push the sweat out of the patch and into the vial; watch the front and back boundaries of the collected sweat and adjust the pressure on your thumb and the syringe so that the sweat flows neatly through the microchannels
10. Remove the patch from the extraction fixture and discard
11. Remove the vial from the fixture and replace the cap
12. Wipe the surfaces of the extraction fixture with IPA
13. Repeat steps above for all patches and remaining subject collections

SWEAT SAMPLE STORAGE AND TRANSPORTATION

If sweat samples will not be analyzed immediately after extraction, samples should be frozen for storage. Samples can be stored at -20°C for up to a month and at or below -70°C for longer durations. Vials provided by Epicore are rated for temperatures between -90°C and +121°C.

SUPPORT

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