

Considerations for Choosing A DTC Fecal Collection Device

Optimizing for Sample Integrity, Safety, and Scale



Oftentimes, it's wise to trust your gut, but when it comes to choosing a fecal collection device for direct-to-consumer (DTC) companies, it's better to have the facts. Following the COVID-19 pandemic, consumers turned to at-home sample collection for a convenient and private way to test themselves for various health conditions. With the right test, users can receive accessible health information without ever leaving the comfort of their homes, but this does not come without complications. DTC testing takes sample collection out of the hands of professionals, and instead leaves collection entirely in the hands of the user, so choosing the right device is critical.

The shape, size, or strength of a sample is just the tip of the iceberg when it comes to deciding on a fecal collection device. DTC companies have several critical factors to evaluate, including sample quality, user-friendliness, and shipping logistics. Companies that consider these factors work to guarantee their users' safety and ensure sample integrity. With so many considerations and new fecal collection devices emerging on the market, it can be difficult to know which device is right for your application.

DEVICE DESIGN AND USER-SAFETY

Any at-home fecal collection device should be simple and straightforward to make the collection process as easy as possible. Devices should ensure safety for both the user and supply chain personnel. Choosing a device that ensures safety for the laboratory staff and shipper is crucial so that the personnel will not be harmed if an error occurs. DTC companies should ideally view user safety as a top priority and select a collection device that has safeguards in place to limit the risk of exposure for all.

It is important for a company to be conscious of its demographic when choosing a device. While most collection devices are intended to be user-friendly, many have complex designs and lengthy instructions, leaving room for user error. A complicated design will likely be more difficult for certain age ranges, which increases the company's liability risk. When a user performs an athome test, the device may contain a preservative that can accidentally be ingested or spilled, affecting both the user and the sample. When potential user errors are eliminated, there is less of a liability for the company, and a higher likelihood that the sample will be usable.

Some devices require the swab to be removed from the tube after stirring it in the solution. This step poses risks and potentially exposes the user to pathogens during removal. Other devices require the solution tube to sit with the lid off during the test, where it can easily be knocked over and spilled. Although fancy designs look nice, they are not necessary. At the end of the day, safe sample collection is the only thing that matters. A collection device designed around the user minimizes potential collection errors and reduces the probability of a wasted sample.

COMPARE COLLECTION DEVICES BY APPLICATION

A good product design is not just based on looks, but on how well the product meets the needs of the user. The fecal collection devices listed in Table 1 are designed specifically for unsupervised sample collection and at-home testing applications.

Recommendation Chart

	Bunny Wipe™	SafeCollect™ Swab Collection Kit	Fecal Collection Tube	Fecal Collection Tube (with beads)
User-Friendly	✓	✓		
Custom Barcoding		✓		
User-Safety	✓	✓	✓	✓
Automation Friendly		√		
16S	✓	✓	✓	√
Shotgun	✓	✓	✓	✓
Long-Read Sequencing	✓	√	✓	

Table 1: DNA/RNA Shield™ Fecal Collection Devices

PATHOGEN INACTIVATION

When choosing a device, the key component is a reliable reagent that inactivates viruses and pathogens. Choosing a reagent that inactivates pathogens helps make samples safe, non-biohazardous and ready for transport. Without the need to identify samples as biohazardous material, companies can limit complications and reduce excessive shipping costs.

Pathogen inactivation also determines the lab's biosafety level (BSL). The CDC identifies laboratories as BSL-1 to BSL-4 based on the type of sample being processed. As biosafety levels increase, so do the restrictions, safety enhancements, and costs. When pathogens are rendered non-infectious, samples can be handled in a lower-level laboratory with less constraints and barriers, further reducing costs.¹

DOWNSTREAM APPLICATIONS

Homogenization, also known as lysing, is another top consideration. This refers to the rupture of the cell membrane, resulting in the release of cell contents.² Unbiased results are imperative and can only be achieved through efficient homogenization. This ensures accurate downstream analysis in applications such as nucleic acid quantification and sequencing.

For DTC companies with sensitive downstream applications, using a reagent that preserves sample integrity from the time of collection is essential. Microbial cells can quickly grow and change, so if the microbial profile cannot be frozen in time, the results from downstream applications such as Next-Gen Sequencing, arrays, and PCR may be biased and incorrectly interpreted.³ Reagents such as DNA/RNA Shield™ prevent microbial bloom and ensure unbiased results by snapshotting the microbial profile at the time of collection.

ANALYSIS METHOD

DTC companies can use different analysis methods to make recommendations based on various characteristics. The choice of sequencing technique determines the ability to detect organisms relevant to the gut microbiome:

 16S/ITS targets a specific region of the bacterial and fungal gene and yields the names of microbial groups to even the species level. The primers typically target

- regions V1-V2, V1-V3, V3-V4, V4 for bacteria or ITS2 for fungi. This type of analysis readily demonstrates the diversity and relative abundance of groups of bacteria and fungi in the microbiome.
- Shotgun Metagenomic sequences DNA from all organisms present in the sample. This high-resolution analysis method yields comprehensive information on genera, species, and strains of bacteria as well as fungi, archaea, and viruses, and allows insights into the functional potential of the microbiome.
- Metatranscriptomic is a type of sequencing that provides a comprehensive profile by identifying all active microbes, their functions, and how they interact with one another. Metatranscriptomic analysis shows the genes that archaea, eukaryotes, DNA, and RNA viruses are expressing.

TRANSPORTING SAMPLES

When transporting biological samples, it is necessary to preserve sample integrity from the time of collection to the time it takes to reach the lab. Isolation, inactivation, and temperature requirements are all factors that impact the costs and complexity of shipping samples. Even a slight shift in temperature can affect the nucleic acids present in biological samples. A cold chain is often used to prevent temperature changes, which imposes higher costs and stricter regulations. Today, FedEx's smallest cold-shipping box is priced at \$49.35, which excludes actual shipping costs and additional dangerous goods fees.⁴

Fortunately, with the help of innovative preservation technologies, reagents can store samples at ambient temperatures, eliminating the need for a cold chain. This alleviates shipping costs and protects the DNA and RNA present in any biological sample.

CHOOSING A DTC FECAL COLLECTION DEVICE

With so many options on the market addressing different needs, it may seem daunting to choose the right device. Zymo Research's Collection Kits and Devices are the most trusted devices for fecal collection and can be used for many different applications.

References

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