ALFA SCIENTIFIC DESIGNS, INC.

White Paper

ALFA's Patented
Semi-Quantitative Collection Tube

Enhances the Accuracy of Fecal Tests

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MK-05-7603 Rev A

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Introduction of Alfa's Semi-quantitative Fecal Sample Collection Tube

While great strides have been made in rapid, point-of-care testing, these advances have focused on the chemistry and fluid dynamics of the test itself. By ignoring sample collection, the industry risks missing out on a simple means to enhance the accuracy and reliability of testing. Traditional collection tubes (**Figure 1C**) do not control the amount of specimen introduced into the test solution. The scientists at Alfa Scientific Designs, Inc. recognized the importance of collecting an appropriate amount of stool specimen to ensure test accuracy and to avoid false positives. In response they developed and patented[1] a sample collection tube designed to minimize sample overload and decrease the rate of false positive test results. The semi-quantitative collection tube (**Figure 1A**) relies on an internal metering device that ensures the test fluid is not overloaded by sample. By achieving this semi-quantitative balance of sample and test fluid, the reliability of results is greatly improved and expenditures on unnecessary and invasive medical examinations are avoided.

Eliminate Sample Loss and Spillage with ALFA's Patented Secure Design

The traditional, singly sealed sample tubes ubiquitous among iFOB sampling devices are prone to leakage if handled roughly in the shipping process. With the novel sample collection tube design, sample security issues are alleviated by securing both ends of the tube with two sealing mechanisms. With a sample closure ferrule providing an internal seal and the screw top serving as the traditional closure, the sample collection device (**Figure 1A & 1B**) ensures tight control over the test sample.

Test solution flow is necessarily unidirectional to avoid contamination with the excess sample held back by the metering device. Therefore, ALFA devised a unique breakaway sample dispensing port at the opposite end of the sample tube. This port is protected by a secondary closure to ensure the port is not breached until the test cartridge is ready for sample addition. The resulting product offers the greatest degree of sample security on the market, again reducing the monetary and time expenditures associated with breached sample tubes.

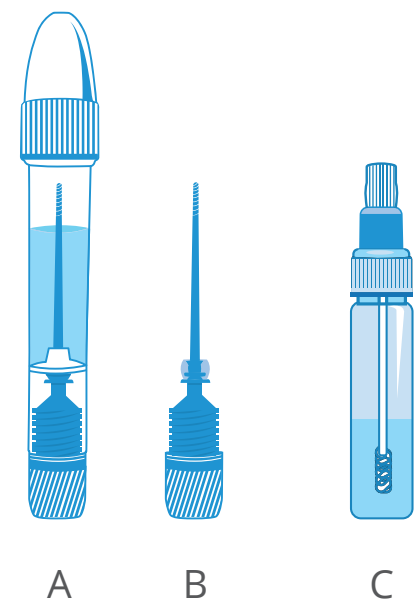


Figure 1: The uniquely designed, patented sample collection tube **(A)** features a doubly sealed sample introduction mechanism and protective covering over the breakaway sample dispensing port.The sampling device **(B)** utilizes a closure ferrule designed to prevent leakage from the internal chamber into the outer closure. By comparison, the traditional sample tube **(C)** offers only a single closure and no control over the amount of sample introduced to the sampling tube.

Features and Benefits of the Semi-quantitative Fecal Sample Collection Tube

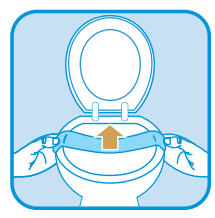
FEATURE	BENEFITS
Internal sample metering system	Allows for semi-quantitative sampling
	Increases test accuracy
	Decreases incidence of false positives
Screw cap and closure ferrule	Eliminates sample loss and spillage
Snap cap outflow port with protective screw cap	Added sample security
	Ease of use

The Semi-quantitative Collection Tube is Easy to Use

While the benefits of the semi-quantitative collection tube are numerous, the actual sampling procedure is unchanged from a traditional fecal sampling device. Simply unscrew the cap with the sampling stick attached, sample as directed, and return the screw cap to its original position. The sampling tube does all the work of controlling sample input with no added requirements on the part of the user.

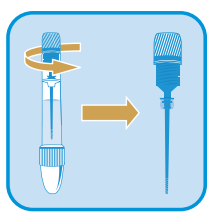
Quick Guide

Remove tape covers from back sides of the collection paper.

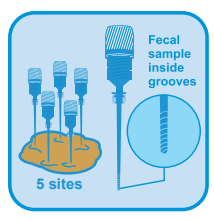


Loosely place paper so it sags at the back portion of the toilet bowl, affix tape, and then lower the seat.

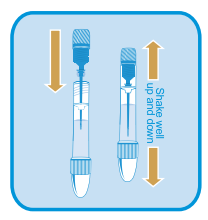
Deposit stool specimen on collection paper.



Unscrew and remove sampler from the collection tube.



Using the grooved tip of sampler, pierce the stool in at least 5 different sites.



Insert sampler with specimen back into collection tube, firmly tighten, and shake the tube to mix the liquid. Flush remaining stool and paper.

Conclusion

By carefully considering the deficiencies of a typical fecal sampling device, the scientists at Alfa Scientific Designs, Inc. have designed and patented a greatly improved sampling device. With careful control over sample introduction to the test solution, the semi-quantitative sample tube ensures a proper sample to solution ratio, effectively decreasing the incidence of false positive results. Dual closure mechanisms at both sample introduction and the outflow port provide the highest level of sample security and integrity, minimizing expenditures on re-sampling or re-testing. All of these improvements are available with no added complexity to the sampling procedure since the tube does all of the work. For these reasons, the semi-quantitative fecal sampling tube is simply one of the best available sampling device on the market.

References

1. Zhou, et. al., U.S. patent numbers S D477,669S; 6,780,160 B2; 6,922,370 B2; 7,048,693 B2.