

Smart Notes

QA

Are collection devices other than nasopharyngeal swabs used to obtain a sample for detection of SARS-CoV-2?

Yes, the FDA has provided Emergency Use Authorization (EUA) guidance for collection devices other than nasopharyngeal swabs. The Thermo Scientific™ Samco™ Clicktainer™ Vials are a specimen collection container that may be validated in your lab as a saliva or sputum collection device used in a SARS-CoV-2 detection kit.

Background

As testing for SARS-CoV-2 continues, there has been ongoing research on best practices for obtaining a sample. According to CDC guidelines, to obtain an adequate sample for SARS-CoV-2 testing using a nasal swab, the sample must be collected by a trained healthcare provider. There can be some discomfort during the procedure to collect the sample and the contact between patient and healthcare provider adds risk to both parties. Saliva and sputum can be used as an alternative sample for SARS-CoV-2 detection and research has shown that saliva is preferable to other sample types. Both sample types can be collected in a less invasive way using a sterile specimen container included as the collection device in a SARS-CoV-2 detection kit. This would allow a patient to receive the collection device and obtain a sample for SARS-CoV-2 testing.

The Clicktainer Vials are a Class 1 medical device that are designed to collect patient samples such as saliva or sputum. The Clicktainer Vials come sterile with a Sterility Assurance Level (SAL) of 10^{-4} and offer improved sample protection by providing a leak-tight seal, easy-to-grip surfaces and straight-sided design for easy handling. The Clicktainer Vials are leakproof tested* in accordance with BS EN 14254 and pressure tested to 95 kPa in accordance with BS EN 14401. The Clicktainer Vials have clearly designed labels with fields to capture good clinical practices information for sample collection. There are a wide range of cap colors and packaging configurations that can be customized to fit your needs.



What is unique about using the Clicktainer Vials for saliva or sputum sample collection?

The Clicktainer Vials come with an audible multi-click seal system that helps ensure that the container is fully closed and therefore, leakproof (Figure 1). This feature makes the product easy to use for collection of saliva or sputum samples that may be validated for use in SARS-CoV-2 testing and will help facilitate and enable large-scale testing needs.

Time is of the essence in SARS-CoV-2 testing and Thermo Fisher Scientific is here to help.

Clicktainer Vials are leakproof, easy to use with an audible multi-click seal, and are designed with user safety in mind making them a perfect tool for sample collection in this extreme time of need.

We can meet any of your SARS-CoV-2 needs, visit our [online tools](#).

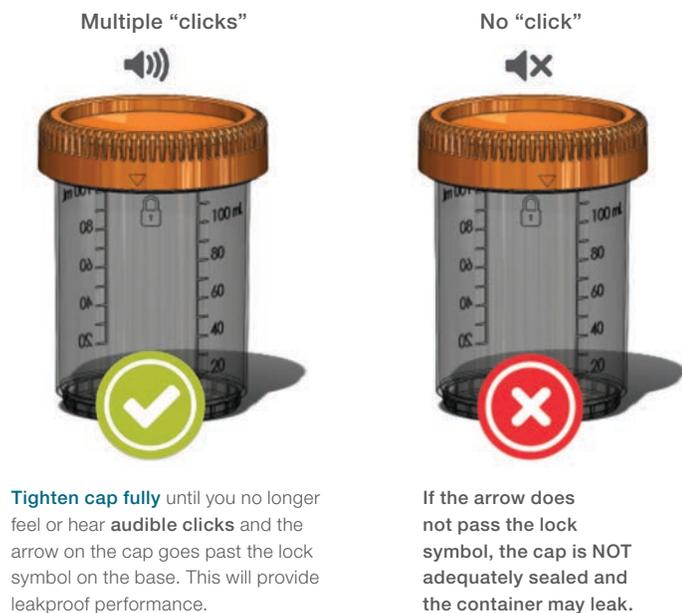


Figure 1. Image depicting the Instructions For Use (IFU) for the Clicktainer Vials.



*The term "leakproof" applies to Thermo Scientific Samco Clicktainer products, 90 mL / 53 mm and 120 mL / 53 mm, that meet the following criteria: a) a vacuum test that draws 95 kPa of pressure within a sealed chamber with no leakage; b) leak testing in accordance with BS EN 14254, which involves filling the container with a dye, placing for 2 minutes on a roller mixer followed by 1 hour inverted in a water bath with no leakage. Note: these tests, using other liquids, may not yield the same results. To ensure safe usage, customers are advised to test Thermo Scientific Samco Clicktainer Vials under conditions of their planned applications. Thermo Scientific Samco Clicktainer Vials are leakproof at ambient temperature and pressure when used with their Clicktainer closures.

Find out more at thermofisher.com/clicktainer