

# ASTM D4991

# Testing for Purillex<sup>®</sup>

# Containers

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TECHNICAL NOTE

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# TECHNICAL NOTE

## ASTM D4991 Testing for Purillex® Containers

### SUMMARY



Many customers in the fields of tissue engineering and cell therapy come to Savillex when their standard, off-the-shelf labware fails during shipment. Failures are most common after air shipments and are evidenced by liquid leaks detected upon receipt. A live tissue or cell sample being shipped to a hospital or clinic as part of treatment can be a catastrophic failure that can lead to damaged samples, surgical delays, and poor patient outcomes. Therefore, those selecting containers for critical CGT applications should pay attention to containers tested to ASTM shipping test standards.

The ASTM D4991-07(2015) Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method is a standard test method that covers the testing of empty rigid containers

under differential pressure conditions like those which can occur during air transport. It is an essential test for those considering using bottles, jars, vials, or other containers for critical shipping applications, particularly when maintaining sterility is required. However, the test is difficult for standard containers to pass and is often necessary for the most vital applications like hazardous liquid shipment. This technical note describes the testing of Savillex Purillex® Bottles and Jars at an independent lab to meet the requirements of ASTM D4991.

### ASTM D4991-07(2015) TESTING

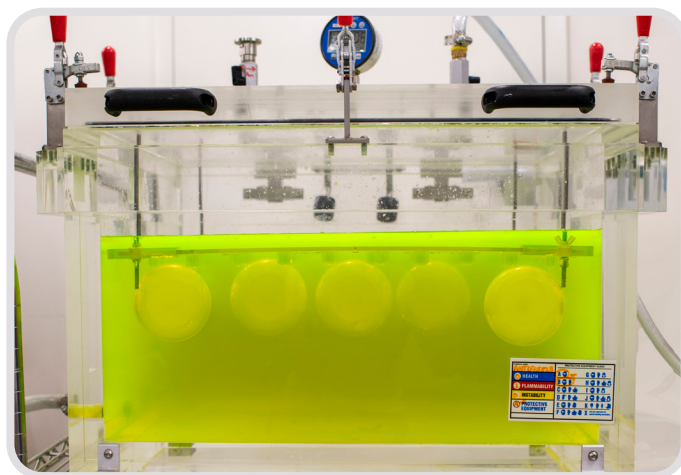
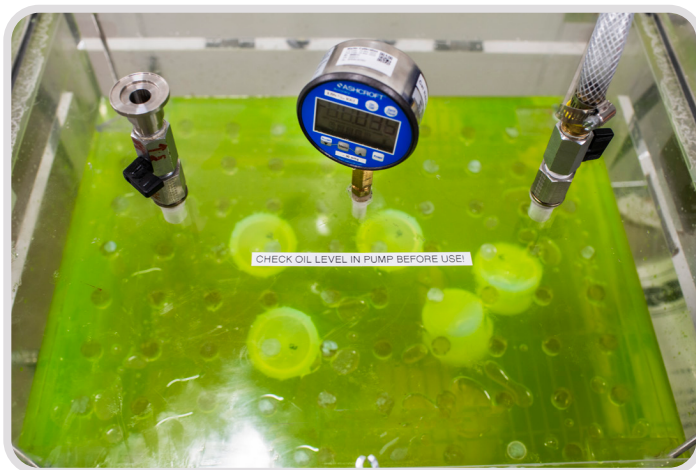
#### TEST PREPARATION

Five (5) 1000 mL Purillex PFA Bottles and five (5) 120 mL Purillex Jars were used in testing. These empty, rigid containers were prepared by sealing the closures using the operational torque setting, which simulates actual usage and the same torque used during Container Closure Integrity Testing (CCIT). The containers were then immersed in an ethylene glycol-water solution in a sealed, transparent test chamber.

## TEST PROCEDURE

The test chamber was subjected to a gradually increasing partial vacuum, slowly rising to 28.16 in Hg. During de-pressurization, the containers were observed for signs of leakage in the form of air bubbles leaking from the closure seal.

The vacuum chamber was maintained at this setting for 30 minutes. Once testing was completed, each container was removed from the chamber, dried off, and inspected for the presence of fluid within the container. Passing containers show no signs of bubbles during de-pressurization and no signs of fluid leaking into the container.



*Purillex PFA Bottles and Jars ASTM D4991 testing*

## CONCLUSION

All containers passed the D4991 testing with no leaks observed. The ASTM D4991 test method is an important method for testing containers for critical shipping applications. Although the test is a difficult one for standard containers, Purillex bottles and jars easily passed. This is due to their ferrule-style closures, durable construction, and closure torque settings validated by CCIT.

[Click here](#) to learn more about Purillex containers - built for the life sciences.