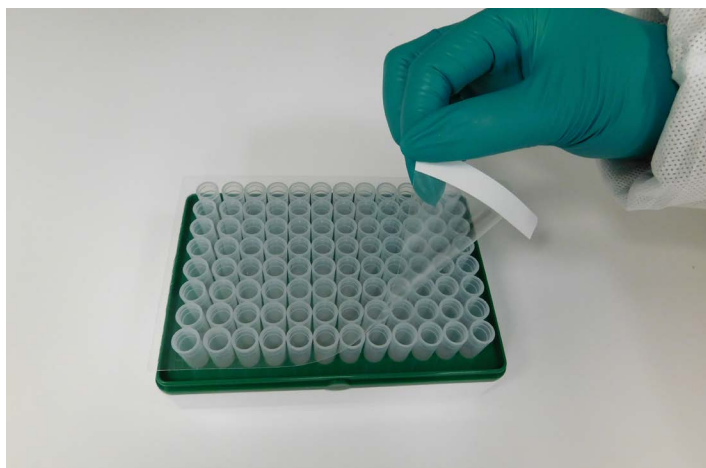


Alternate Storage Procedure for BAX® Lysis Reagent in Cluster Tube Racks



Use of Adhesive Seals with 4°C storage

When utilizing the BAX® System Prep Xpress to dispense BAX® System Lysis Reagent into multiple racks of cluster tubes, it has been asked to determine if an alternate method of sealing the tubes for storage could be used. Adhesive seals from VWR were evaluated to determine if these would be an acceptable alternative. Hygiena™ has determined that cluster tube racks with BAX® System Lysis Reagent can be sealed with VWR adhesive seals and stored at 4°C for up to two weeks.

Objective:

The purpose of this internal study was to determine if full-plate adhesive seals could be used with Simport cluster tube racks containing 200 µL of BAX® System Lysis Reagent. These seals would be used as a cheaper and easier alternative to the cluster tube caps for 4°C storage.

Methodology

The BAX® System Lysis Reagent was prepared as indicated in the User Guide using lysis buffer (L/N: 60719) along with protease (L/N: 136820). Six racks of Simport cluster tubes (96 tubes/rack) were then filled with 200 µL of lysis reagent using the BAX® System Prep Xpress and the “BAX Lysis – 6 racks” program. The tubes were then sealed with VWR adhesive seals (VWR P/N: 60941-062) using a Speedball Deluxe 4" Brayer. The seals were then trimmed to allow for the proper fit of the lid. The initial weight of each rack was recorded, and the racks were stored at 4°C. After eight (8) days, the racks were removed and re-weighed. Each rack was visually inspected for uneven and edge-effect evaporation. Racks were returned to 4°C and re-weighed and inspected again after fourteen (14) days.

Following the fourteen-day storage, random strips were selected for testing with pure culture or ground beef post-enrichment spikes using either *Salmonella* Typhimurium or *Escherichia coli* O157:H7 and compared with freshly prepared lysis reagent. All lysates were prepared as per the BAX® System User Guide and tested with *Salmonella* (KIT2006) or *E. coli* O157:H7 Exact (KIT2039) BAX® System Real-Time PCR Assays.

Results

The table below shows the results of weight measurements of the 4°C stored racks. The overall difference of 0.2% between initial and final weights is well within the tolerances of the BAX® System (+/-10%). In addition, no uneven or edge-effect evaporation was observed.

Cluster Tube Rack	Initial Weight (g)	8-day Weight (g)	Difference (g)	14-day Weight (g)	Difference (g)	% Difference	Observations
1	146.72	146.60	-0.12	146.40	-0.32	-0.2	No visible change
2	147.79	147.66	-0.13	147.51	-0.28	-0.2	No visible change
3	148.08	147.96	-0.12	147.80	-0.28	-0.2	No visible change
4	146.78	146.55	-0.23	146.42	-0.36	-0.2	No visible change
5	147.42	147.22	-0.20	147.14	-0.28	-0.2	No visible visible change
6	147.74	147.60	-0.14	147.46	-0.28	-0.2	No visible change

BAX® System results (Figure 1) showed no difference in detection or CT values in either assay as compared to freshly prepared lysis reagent as seen in the representative results below.

(Note: Shown are 6 replicates per culture and post-enrichment spikes in ground beef).

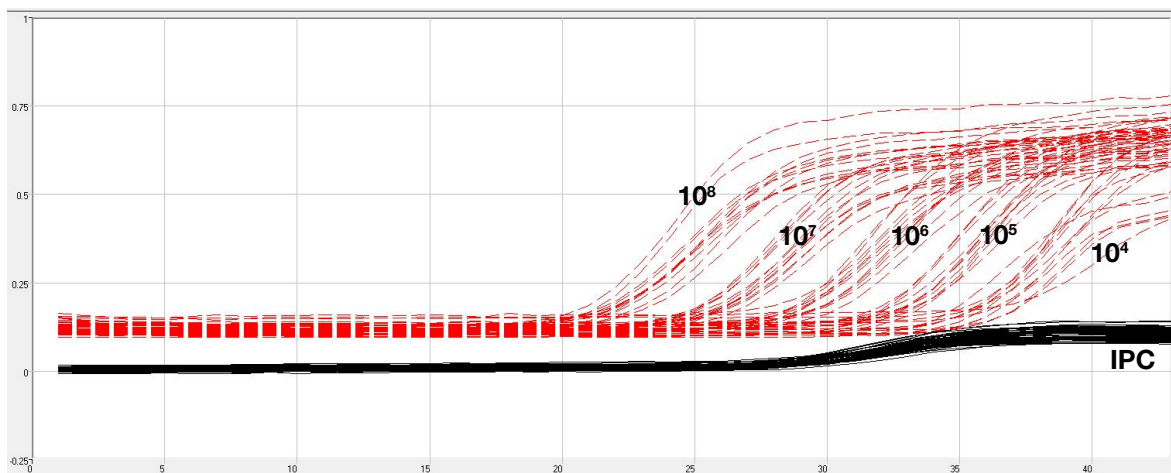


Figure 1. BAX® System results from serial dilutions of spiked cultures containing from 10^8 to 10^4 organisms in ground beef (IPC = internal positive control)

Conclusions

The results of this study demonstrate that the BAX® System Lysis Reagent can be dispensed into Simport cluster tube racks and sealed with VWR adhesive seals and then stored for up to two weeks at 4°C. There is no effect on assay results when using the adhesive seals and results are consistent with performance claims.