

Heat Stability of PRO-Clean™ Protein Residue Test

Introduction

PRO-Clean™ is a ready-to-use, high sensitivity, rapid test for detection of protein residues on surfaces after cleaning. Hygiena™ has studied the effects of storing devices under high heat to determine device performance.

Method

Devices were stored in their packaging at a constant temperature of 37°C (98.6°F) for up to four weeks. Control devices were stored at 4°C over the same period. Devices were tested at multiple timepoints by inoculating swabs with a known amount of bovine albumin serum (BSA) protein standard around the limit of detection. Devices were activated and incubated at 22°C for 10 minutes. Devices were studied for the loss of detection of the protein sample.

Results and Discussion

PRO-Clean™ devices stored at 37°C and 4°C detected BSA at low concentrations across all timepoints.

Table 1. PRO-Clean™ Devices Stored at 37°C vs 4°C		
Storage Temperature	37°C	4°C
Storage Time (Days)	20µg BSA per swab	20µg BSA per swab
0	Detected	Detected
7	Detected	Detected
14	Detected	Detected
21	Detected	Detected
28	Detected	Detected

Conclusions

Devices which endure temperature abuse above 4°C for up to 4 weeks performed equivalently to devices stored under appropriate conditions.