3M | Attest™
Sterilization Solutions

VH2O2

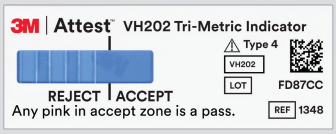
Color Stability of Chemical Indicators (CIs) for Vaporized Hydrogen Peroxide (VH2O2) Sterilization Before Use

Background

Chemical Indicators (CIs) for monitoring vaporized hydrogen peroxide (VH2O2) sterilization processes are understood by the sterilization assurance industry to be susceptible to color change when stored outside their native packaging under ambient lighting. Users of VH2O2 CIs in healthcare facilities are mindful that most of these CIs require storage in their native packaging away from ambient light and chemicals. Despite not being recommended by manufacturers and the practice being inconsistent with labeling storage requirements, it is a known practice that users may store these CIs in open containers or bins on workstations for easy access during the pack-and-prep operations in the Sterile Processing Department (SPD).

Purpose

The purpose of this study is to evaluate and compare the performance of the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E (Type 4) to 6 different VH2O2 CIs (Type 1 and Type 4) with respect to stability of the CIs initial (unexposed) color under ambient lighting.



3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348 (Type 4) — Unprocessed

Objective

The study objective was to quantitatively measure the reactive chemistry color change of the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E (Type 4) in comparison to 6 different Type 1 and Type 4 VH2O2 CIs when each has been kept under ambient lighting. This condition simulates a use case where the CIs are stored in ambient lighting, outside their native packaging. This condition reflects how a user might transfer the CIs from their native packaging to an open storage container or bin located on the table surface of their clean workspace station of the SPD.

Method

A minimum of thirty (30) CIs of each type were placed “face-up” in a workspace so that the reactive chemistry of each CI was exposed to the ambient lighting in the workspace. The workspace lights were left on continuously for 8 weeks. At the time intervals specified (0 days, 1 week, 2 weeks, 4 weeks, 6 weeks, 8 weeks) the reactive chemistry of the CIs tested was measured using the Xrite colorimeter to determine the L a*b* color values which were then compared to the color change required for an ACCEPT or PASS result of the specified CI. The use of a colorimeter to measure the color change of the CIs provided an objective numerical result.

Results

Over the testing period of 8 weeks, significant color change was observed in all of the Type 1 and Type 4 VH2O2 CIs tested in this study except for the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E (Type 4). A table containing actual test CI images from each of the tested time intervals is attached.[1]

Discussion

In this study there were instances where the CIs shifted their color towards the endpoint color when they were stored outside of their native packaging, under ambient lighting. Some CIs changed color so extensively they would be rendered obviously unusable. Some CIs changed to the point where the color would be equivalent to using indicators that have been effectively “pre-exposed”, leading to the possibility that an inadequate sterilization process could generate a “PASS” or “ACCEPT” indicator result.

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Conclusion

The 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E (Type 4) is the most color stable of all competitive VH2O2 CIs tested, including ASP, Steris and SPS, and won't change color before sterilization, under ambient light for 8 weeks.[1,2]

Important Study Limitations

As documented in the Method sections above, the CIs tested in this study were stored outside their native packaging and outside their instructions for use, including the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E (Type 4). The findings should not be interpreted to support or promote any practice inconsistent with manufacturer labeling storage requirements. Always follow manufacturer's storage requirements for VH2O2 CIs as per their instructions for use.

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References

1. Charts - Color Stability of Chemical Indicators (CIs) for Vaporized Hydrogen Peroxide (VH2O2) Sterilization Before Use EN_GL_70-2011-8066-1.
2. Reference 3M Study EM-05-692861.