Cleaning verification tests in endoscope reprocessing: not ready for prime-time

More healthcare associated outbreaks have been linked to contaminated endoscopes than any other medical device. Reprocessing of flexible endoscopes is particularly difficult and error-prone for several reasons: 1) endoscopes become heavily contaminated with microbial organisms during routine use, 2) endoscopes are heat-sensitive and cannot undergo high-temperature sterilization, and 3) endoscopes have long, narrow lumens that make physical removal of debris difficult. This third point is particularly important because thorough removal of organic material must occur prior to high-level disinfection (HLD).

The Association of perioperative Registered Nurses (AORN) recently recommended routine and daily use of cleaning verification tests (CVTs) to monitor effectiveness of endoscope cleaning. AORN published the CVT recommendation in their newest version of “Guidelines for Processing Flexible Endoscopes” [1]. This newsletter provides an overview of CVTs and DICON recommendations regarding their use.

What are cleaning verification tests (CVT)?

CVTs are non-culture, rapid assays to evaluate the adequacy of manual cleaning. CVTs are used after cleaning and before HLD. CVTs detect residual organic material; they do not specifically detect the presence of bacteria. There are two types of CVTs: 1) adenosine triphosphate (ATP) bioluminescence assays that detect the organic molecule ATP; and 2) bioburden assays that detect residual proteins, carbohydrates, or blood products. Examples of commercially available CVTs are shown in Table 1.

<table>
<thead>
<tr>
<th>Assay</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATP assays</td>
<td></td>
</tr>
<tr>
<td>Clean-Trace</td>
<td>3M (St. Paul, MN)</td>
</tr>
<tr>
<td>Glomax 2020</td>
<td>Promega (Madison, WI)</td>
</tr>
<tr>
<td>Pallchek</td>
<td>Pall Corp (Port Washington, NY)</td>
</tr>
<tr>
<td>Bioburden assays</td>
<td></td>
</tr>
<tr>
<td>Scope Check</td>
<td>Valisafe America (Tampa, FL)</td>
</tr>
<tr>
<td>EndoCheck</td>
<td>HealthMark Industries (Fraser, MI)</td>
</tr>
<tr>
<td>ChannelCheck</td>
<td>HealthMark Industries (Fraser, MI)</td>
</tr>
</tbody>
</table>


How are CVTs performed?

Different commercial assays use different sample collection methods. Some kits require users to swab the external or internal surfaces of the endoscope and perform tests directly on the swabs. In other cases, sterile water is flushed through the scope channels and collected for sampling. There is no consensus on optimal sampling method.
Adenosine triphosphate (ATP) tests

ATP is a molecule generated and used by all living cells. ATP is commonly referred to as “the energy currency of the cell.” ATP assays quantify the amount of ATP present in a test sample by using an enzyme (luciferase) that induces ATP to emit light. This emitted light can be quantified with a luminometer. The number of relative light units (RLU) detected with a luminometer is directly proportional to the number of ATP molecules present in a sample. However, the number of RLU detected does not directly correlate with the amount of bacteria present in a sample, because ATP can indicate the presence of micro-organisms or other organic material.

ATP assays were initially used to evaluate cleanliness of hospital room surfaces after cleaning, the quantification of bacteria in water, and the number of cells in tissue culture. Subsequently ATP assays were adapted to test for residual bacteria in endoscopes.

Potential Pitfalls of ATP Tests

- ATP assays do not detect low levels of bacterial contamination. The lower limit of detection of most commercial assays is approximately 1000 colony forming units (CFU) of bacteria [3]. Thus, ATP tests have poor sensitivity.
- ATP tests are not specific for bacterial contamination. RLU do not directly correlate with bacterial burden since ATP is also present in other types of organic material.
- The optimal RLU threshold to indicate inadequate manual cleaning is uncertain. Alfa et al proposed a threshold of >200 RLU to indicate inadequate manual cleaning based on a series of experimental and clinical validation studies [4]. However, other investigators have proposed lower thresholds [5].

Bioburden assays

Rapid bioburden assays use chemical reactions to detect proteins, carbohydrates and/or hemoglobin in 90 seconds or less. All assays use color change to indicate positivity.

Bioburden assays have many of the same potential pitfalls as ATP tests. Bioburden assays detect organic matter and are not specific for bacterial contamination. Likewise, empiric quantitative thresholds of protein, carbohydrate, and hemoglobin that indicate inadequate manual cleaning have been proposed [6] but optimal thresholds are uncertain [2]. Additionally, there is no consensus on whether assessing for one, two, or all 3 components (protein, carbohydrate, and/or hemoglobin) is most useful in identifying inadequately cleaned scopes.

Summary and Recommendations

- Manual cleaning is an essential step in endoscope reprocessing. Healthcare facilities must ensure that staff who perform endoscope reprocessing are trained to properly perform this function.
- CVTs are rapid, point-of-use tests that indicate presence of bioburden. CVTs are neither sensitive nor specific for bacterial contamination. Optimal test result thresholds to indicate inadequate cleaning are not known.
- Effectiveness of CVTs to improve safety of endoscope reprocessing has not be clearly demonstrated. Likewise, cost-effectiveness of CVTs is unknown.
- For all of the above reasons, we do not currently recommend use of CVTs.

References:


