SAMPLE REPORT

General Design Assessment and Liquid Barrier Performance of Imported Isolation Gowns

Increasing COVID-19 Cases Causing PPE Shortages

With the number COVID-19 cases increasing, providers continue to struggle to procure both isolation gowns and N-95 masks. Many have had to resort to non-traditional international suppliers without any insight on product quality.

ECRI is uniquely positioned to provide your organization with assurance on whether isolation gowns and N-95 masks you have procured meet industry standards. ECRI’s laboratories have the equipment on hand to test both the water repellency of medical gowns according to the method described by AAMI PB70 and the efficiency of masks to assure that they perform at the level claimed using an identical machine that NIOSH uses for its N95 certification process.

This sample report demonstrates the performance of three isolation gowns purchased from Chinese manufacturers during hydrostatic pressure testing and water impact testing.

ECRI Can Help

Let ECRI help provide assurance that isolation gowns and N-95s masks that you have procured or are considering procuring via non-traditional suppliers will protect both your patients and staff.

For more information on our testing services, please contact us:
clientservices@ecri.org
610.825.2000 x5891
Performance Assessment of an Isolation Gown

Product Overview:
Manufacturer Name: Aruikon; Henan JoinKona Medical Products Stock Co., Ltd.
Model Name: Unknown
Model Number: JKJG0663Y2020
Gown Description: Blue, closed back design with waist tie and hook-and-loop closure at neck.
Material: 98% Polypropylene Non-woven, 2% Polyester film
Seams: Along the arms of the gown and shoulders
Cuff: Elastic fabric
Thumb hole: No
Size(s): XL

Methods:
Date Tested: August 24, 2020
The confirmatory tests performed are intended to judge the degree of liquid barrier performance provided by the gown and are not intended to serve as an assessment of gown production quality from the manufacturer.
Impact Penetration Test-
The first test studied impact penetration (AATCC 42). First, a piece of blotter paper was weighed and placed underneath a sample of the gown material. 500ml of water was allowed to spray downward onto the clamped sample, and the blotter paper was reweighed. A weight gain of less than 1.0g was the required penetration resistance for an AAMI Level 2 gown, while a weight gain of no more than 4.5g was required for an AAMI Level 1 gown. Three samples of the gown model were tested, with samples pulled from the abdomen, arm, and an area including a seam.

Hydrostatic Pressure Test-
For the hydrostatic pressure test (AATCC 127), eight samples (including tie attachments, if applicable, and at least two samples each of the abdomen, arm, and seam areas) were cut from the provided gowns. A column of water that can be adjusted from 0 – 50 cm was applied to the specimens to assess the water repellent barrier property of the gown. Pressure was increased at a rate of 60 mBar/min while the upper sample surface was visually scanned for evidence of water strikethrough. If three or more droplets of water were observed on the dry side of the sample, then the sample was noted to have failed at that pressure. The test was performed twice with four samples analyzed per test. Testing was stopped and the pressure was noted when either the product sustained 50 cmH2O or when one product sample failed.
Results:

**IMPACT PENETRATION TEST:**

<table>
<thead>
<tr>
<th>AAMI Requirement</th>
<th>Specimen</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Body</td>
<td>Body</td>
<td>Seam</td>
</tr>
<tr>
<td>Gain (grams)</td>
<td>&lt;1.0</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>Result</td>
<td>Level 2</td>
<td>Level 2</td>
</tr>
</tbody>
</table>

**HYDROSTATIC PRESSURE TEST:**

<table>
<thead>
<tr>
<th>Pressure (cmH₂O)</th>
<th>Specimen</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Body</td>
<td>Arm</td>
</tr>
<tr>
<td></td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>20</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>50</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*This is a test to estimate the AAMI equivalent barrier level, based on a limited number of samples using the hydrostatic pressure test described in the standard, and does not certify the AAMI level for the gown.

**Conclusion:**

The gown provided by Plymouth Hospital is a breathable SMS material with good coverage and closure features. The impact penetration samples all yielded 0.1g gain or less. All samples withstood 20 cm H₂O, but two samples failed the hydrostatic test prior to reaching 50 cmH₂O. Both tests therefore point to an AAMI Level 2 equivalence for this gown.

**Certification for Use:**

The general design, construction, and quality of this gown has been assessed on Plymouth Hospital’s behalf by ECRI -- an independent, nonprofit organization located in Plymouth Meeting, PA dedicated to improving the safety, quality, and cost-effectiveness of care across all healthcare settings (https://www.ecri.org/). The barrier performance of this gown meets the requirements for an AAMI Level 2 gown, which may be safely and reliably worn for low liquid contact medical use provided, as with other medical isolation gowns, which proper PPE technique is used and care is taken to avoid perforating the gown material.
**Product Photos:**

![Isolation Gown](image1)

![Packaging](image2)

**Disclaimer:**

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