SAMPLE REPORT

Performance Assessment of International Respirator Masks

Increasing COVID-19 Cases Causing PPE Shortages

With the number COVID-19 cases increasing, providers continue to struggle to procure both N-95 masks and gowns. 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 N-95 masks and gowns you have procured meet industry standards. ECRI’s laboratories have the equipment on hand to test both 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 and to test the water repellency of medical gowns according to the method described by AAMI PB70.

ECRI Can Help

Let ECRI help provide assurance that N-95s masks and gowns 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 a Respirator Mask

Product Overview:
Test: Modified NIOSH TEB-APR-STP-0059
Date Tested: August 21, 2020
Manufacturer: Jiangsu Pinzheng Medical Device Technology Co.
Model Tested: KN95
Country of Certification: China
Standard of Claimed Conformance: GB2626-2006

These findings apply to the KN95 mask. The packaging for this product indicates that it meets GB2626-2006 (Chinese standard for respirator masks).

Methods:
Twenty respirators were submitted for evaluation. The ten samples were randomly sampled and tested using modified versions of NIOSH Standard Test Procedures TEB-APR-STP-0059 for particulate filtration efficiency testing, TEB-APR-STP-0003 for exhalation resistance testing, and TEB-APR-STP-0007 for inhalation resistance testing. We report the maximum and minimum filtration efficiency observed for each mask throughout the duration of the test.

The overall minimum and maximum filter efficiency was 87.62 % and 99.70 %, respectively. Five respirators measured more than 95%. Five respirators measured less than 95%.
## Results:

### Filter Efficiency:

<table>
<thead>
<tr>
<th>Respirator Mask Sample</th>
<th>Flow Rate (Lpm)</th>
<th>Initial Filter Resistance (mmH2O)</th>
<th>Minimum Observed Percent Leakage (%)</th>
<th>Maximum Observed Percent Leakage (%)</th>
<th>Filtration Efficiency Range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>6.4</td>
<td>8.63</td>
<td>10.55</td>
<td>91.37 – 89.45</td>
</tr>
<tr>
<td>2</td>
<td>85</td>
<td>6.4</td>
<td>9.53</td>
<td>11.74</td>
<td>90.47 – 88.26</td>
</tr>
<tr>
<td>3</td>
<td>85</td>
<td>13.4</td>
<td>0.39</td>
<td>1.02</td>
<td>99.61 – 98.98</td>
</tr>
<tr>
<td>4</td>
<td>85</td>
<td>11.3</td>
<td>0.30</td>
<td>0.76</td>
<td>99.70 – 99.24</td>
</tr>
<tr>
<td>5</td>
<td>85</td>
<td>12.6</td>
<td>0.38</td>
<td>0.80</td>
<td>99.62 – 99.20</td>
</tr>
<tr>
<td>6</td>
<td>85</td>
<td>11.5</td>
<td>0.49</td>
<td>1.26</td>
<td>99.51 – 98.74</td>
</tr>
<tr>
<td>7</td>
<td>85</td>
<td>7.9</td>
<td>6.31</td>
<td>9.68</td>
<td>93.69 – 90.32</td>
</tr>
<tr>
<td>8</td>
<td>85</td>
<td>8.2</td>
<td>5.81</td>
<td>9.01</td>
<td>94.19 – 90.99</td>
</tr>
<tr>
<td>9</td>
<td>85</td>
<td>6.2</td>
<td>10.7</td>
<td>12.38</td>
<td>89.30 – 87.62</td>
</tr>
<tr>
<td>10</td>
<td>85</td>
<td>12.9</td>
<td>0.42</td>
<td>1.25</td>
<td>99.58 – 98.75</td>
</tr>
</tbody>
</table>

Minimum Filtration Efficiency: **87.62**  
Maximum Filtration Efficiency: **99.70**

### Inhalation Resistance:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Maximum Permissible Resistance (mm H2O)</th>
<th>Actual Measured Resistance (mm H2O)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>35</td>
<td>13.4</td>
<td>PASS</td>
</tr>
<tr>
<td>2</td>
<td>35</td>
<td>6.2</td>
<td>PASS</td>
</tr>
</tbody>
</table>

### Exhalation Resistance:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Maximum Permissible Resistance (mm H2O)</th>
<th>Actual Measured Resistance (mm H2O)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25</td>
<td>6.4</td>
<td>PASS</td>
</tr>
<tr>
<td>2</td>
<td>25</td>
<td>5.8</td>
<td>PASS</td>
</tr>
</tbody>
</table>
Conclusion:

This respirator mask's performance is NOT equivalent to an N95 respirator mask with respect to its filtration efficiency. The filtration efficiency requirement of N95 masks is $\geq 95\%$.

Product Photos:

![Product Photos]

Sample 1:

- **Country of Origin**: China
- **Manufacturer name**: Jiangsu Pinzheng Medical Device Technology Co., Ltd
- **Model/Product no**: KN95
- **Mfg Lot no/date**: n/a
- **Standard it complies w/**: GB2626-2006
**Disclaimer:**

1. The intent of this assessment is to determine whether the respirator mask samples tested meet basic particulate efficiency and breathing resistance performance requirements specified for N95 respirator masks certified by NIOSH.

2. The results of this assessment are not equivalent to NIOSH certification testing and should not be construed as being part of the official NIOSH respirator approval process.

3. This assessment is based on a convenience sampling of the respirator mask model identified, and is not based on a random sampling of a given production lot or lots. As such, respirators tested may not be representative of all respirators with the same model designation or certification mark.

4. This assessment is not a confirmation that the respirator model conforms to any or all of its specifications in accordance with its certification mark.

5. The assessment did not look at respirator mask fit to the face, and fit testing will be necessary for the wearer to confirm that the respirator mask fits appropriately.

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