FAQ Regarding Use of KN95 Respirators Available Through the Department of Public Health

Does DPH have N95 respirators and KN95 respirators available for distribution?

Yes, as to both, but DPH has a very limited supply of N95 respirators.

NIOSH-approved N95 respirators filter out more airborne particles than the KN95 respirators in the DPH warehouse. Accordingly, N95 respirators will be distributed to professionals who need the most protection in environments where there are aerosol generating procedures, including intubations, CPR or nebulizer treatments.

DPH has KN95 respirators available for use by individuals who do not work directly in such aerosol generating environments.

What is the difference between a N95 respirator and a KN95 respirator?

Filtering facepiece respirators are subject to various regulatory standards around the world. N95 respirators are regulated by the United States National Institute for Occupational Safety and Health (NIOSH). KN95 respirators are regulated by the Government in China.

A comparison of the specifications for a N95 respirator and a KN95 respirator can be found here.

There is a shortage of NIOSH approved N95 masks in the United States. If you do not have access to N95 respirators, then you can consider using a KN95 mask as an alternative.

Has DPH tested the KN95 respirators received from China to determine the filtration efficiency?

Yes. Initial testing of KN95 respirator material was conducted at the Massachusetts Institute of Technology (MIT). We have worked with the Advanced Functional Fabrics of America, Inc. (AFFOA) to obtain further statistical characterization of respirator performance. AFFOA coordinated testing at MIT campus and MIT Lincoln Laboratory where comparable conclusions about mask quality were obtained. Two key measurements were taken for each material: 1. Filter material performance and 2. Filter material pressure drop.

- 1. The purpose of evaluating filter performance is to measure the reduction in concentrations of specific aerosols, such as the COVID-19 virus, in air that passes through the filter.
- 2. Pressure drop, also known as breathing resistance, measures the resistance air is subjected to as it moves through the respirator.

Summary results for tested respirators can be found here. These masks were not tested in an accredited National Institute for Occupational Safety and Health (NIOSH) testing laboratory, and thus are not NIOSH approved or certified.

Has DPH tested the KN95 respirators received from China to determine the resistance to penetration of fluids?

Yes. The Department of Public Health worked with the Advanced Functional Fabrics of America, Inc. (AFFOA) and the MIT Lincoln Laboratory to test each masks' resistance to penetration of fluids. This test was set up to establish the ability of the mask's material to resist the penetration of blood and bodily fluids. Surgical masks are considered a Class II medical device and are regulated by the Food and Drug Administration (FDA). As such, surgical mask products must comply with performance and quality specifications, described in 21 CFR 878.4040.

Limited testing of resistance to fluid penetration was conducted on the KN95 masks, in a procedure that is similar to the method described in ASTM F1862: Standard Test Method for Resistance of Surgical Mask Penetration by Synthetic blood.

This specific test is critical to determine whether the mask can protect the wearer from exposure to bodily fluids, including large droplets expelled by sick patients when sneezing or coughing.

According to ASTM F 1862, surgical masks are tested on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, 160 mm Hg). Fluid resistance may be claimed if the device passes ASTM F1862 at the corresponding level. Surgical masks that show passing results at higher velocities are more fluid resistant.

These masks were not tested in an accredited FDA testing laboratory, and thus cannot be considered FDA approved or certified, according to the tests reported by DPH. Other properties such as bacterial filtration efficiency (BFE) or latex particle filtration efficiency (PFE) which are required for surgical masks were not tested by the state.

Summary results for tested masks can be found here.

Should the KN95 respirators from DPH be used to protect an individual performing an aerosol generating procedure on a COVID-19 positive individual?

No. The initial results for the tested KN95 materials indicate that the filtration efficiency is below the 95% filtration standard set by the FDA and NIOSH.

Can the KN95 respirators available from DPH be used in a hospital setting, nursing facility setting or other healthcare setting?

Yes, KN95 may be used in the hospital setting. Hospitals should prioritize using N95 respirators for aerosol generating procedures, including intubations, CPR or nebulizer treatments.

How should the KN95 mask fit to provide protection?

The respirator must form a seal with the wearer's face, so that air passes through the filter (instead of around the edges) before it is inhaled. To ensure a proper seal, the wearer should ensure the respirator edges do not touch any facial hair. Clean-shaven is ideal for a good seal.

How can I order KN95 respirators from DPH?

If you anticipate a supply shortage within the next 5 days and are unable to source KN95 respirators through your normal supply chain, then you may request a several days bridge supply through the Department of Public Health at the following link: https://www.mass.gov/info-details/personal-protective-equipment-ppe-during-covid-19#requesting-ppe

What types of individuals/groups can request KN95 respirators from DPH?

- o Hospitals
- o Nursing Homes
- o Community Health Centers
- o Emergency Medical Services
- o Local Public Health
- Other health facilities