



Barrier Protection of Medical and Surgical Gloves

Gloves are worn to protect patient and healthcare worker from infection transmission. They are also worn to protect against intermittent and splash contact with chemotherapy drugs, laboratory reagents, and other compounds that may be encountered in the healthcare setting. The increased focus on barrier protection gives rise to a discussion of current testing done to assess glove barrier effectiveness.

ASTM D5151-92 Standard Test Method for Detection of Holes in Medical Gloves In this test, required by FDA, a statistical sample of gloves on the production line is taken, attached to a measuring apparatus, filled with 1000 ml of water, and visually inspected for leaks. The percentage of gloves that leak is then measured and compared to the FDA requirements for AQL (acceptable quality level - the acceptable percentage of gloves that leak as defined by the FDA). Manufacturers can also test gloves for leaks by air inflation of each glove. Gloves are inflated for several minutes to test for holes.

Virus penetration FDA does not currently require virus penetration testing for medical and surgical gloves, but the ASTM ES-22-92 Standard Test Method for Viral Penetration (Bacteriophage Biopenetration) can be used to assess a glove's resistance to viral penetration. This test uses the bacteriophage PhiX174, a virus that is smaller than either the HIV or HBV viruses, and tests for passage of the phage through the glove material. One side of the glove is exposed to PhiX174, and tested at specified time intervals for the appearance of the virus on the other side. If virus is not detected after at least one hour of exposure, then the test is considered to pass. Although this test is not required, specific manufacturers may have viral penetration test data on hand.

Chemical permeation Medical and surgical gloves are not designed for immersion contact with chemicals, but they can protect against intermittent and splash contact with some chemicals such as cytotoxic drugs used in chemotherapy, some lab/diagnostic reagents, and some disinfectant/cleaning agents. FDA does not currently require chemical permeation testing for medical and surgical gloves, but ASTM F739-91 Permeation Breakthrough can be used to assess a glove's

resistance to chemical permeation. Compounds such as bleach, formaldehyde, glutaraldehyde, and others can be tested in this manner. A sample of the glove material is placed so that it functions as the barrier between two chambers in a specialized double-chamber apparatus. The chemical in question is placed in one chamber, and the other chamber is tested at specified time intervals for the appearance of the chemical in the other chamber. If the chemical is not detected after 8 hours of exposure, the test is considered to pass. If a glove wearer expects to come in contact with a specific chemical, the gloves under consideration should be tested for their permeation resistance to that particular chemical, rather than relying on a general perception of overall permeation resistance.

Note: All standards referenced should be reviewed for the latest active revision level.