



Designation: D7661 – 23

Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms¹

This standard is issued under the fixed designation D7661; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers procedures used to detect a shift in physical properties of natural rubber latex (NRL) condoms after immersion in a personal lubricant. “Personal lubricants” are lubricants such as liquids or gels that are applied by the consumer at the time of condom use.

1.2 This test method does not attempt to address compatibility of lubricants applied to a condom at the time of manufacture (“manufacturer lubricants”). It shall be the responsibility of the condom manufacturer to verify the long-term stability (shelf life) of any manufacturer lubricant that is packaged within the individual condom wrapper. Other regulatory requirements may apply.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

D3492 Specification for Rubber Contraceptives (Male Condoms)

¹ This test method is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

3. Summary of Test Method

3.1 This test method measures the change in tensile and airburst properties, specifically force at break, percent elongation at break, airburst pressure, and airburst volume, of NRL condoms and condom rings after 60 min of immersion in a liquid or gel lubricant. Condoms (up to the open end) and rings cut from condoms are immersed in personal lubricant, heated to body temperature, cleaned of excess lubricant, and tested for both tensile and airburst properties. Those properties are then compared to control condoms and rings that are subjected to the same procedures without adding lubricant. For comparison purposes, baseline testing is also performed on condoms directly from their packages. A final group exposed to mineral oil is also included to validate the laboratory's test technique.

3.2 A flow chart of the lubricant compatibility tensile test component is shown in **Fig. 1**. A flow chart of the lubricant compatibility airburst test component is shown in **Fig. 2**. Each step of the process shall be performed immediately after the conclusion of the previous step.

4. Significance and Use

4.1 Weakening of natural rubber latex is known to occur after contact with certain lubricants, particularly petroleum-based products.^{3,4} This procedure was developed as a screening method for lubricant manufacturers to determine whether or not a particular personal lubricant has a significant effect on the tensile and airburst properties of an NRL condom.

4.2 This test method is designed for use on NRL condoms that meet the criteria of Specification **D3492** and can: (1) have a ring specimen cut in compliance with Appendix X1 of

³ White, N., Taylor, K., Lyszkowski, A., Tullett, J., and Morris, C., Dangers of lubricants used with condoms, *Nature*, 1988, Sep 1;335(6185):19.

⁴ Voeller, B., Coulson, A., Bernstein, G., and Nakamura, R., Mineral oil lubricants cause rapid deterioration of latex condoms, *Contraception*, 1989, Jan;39(1):95-102.

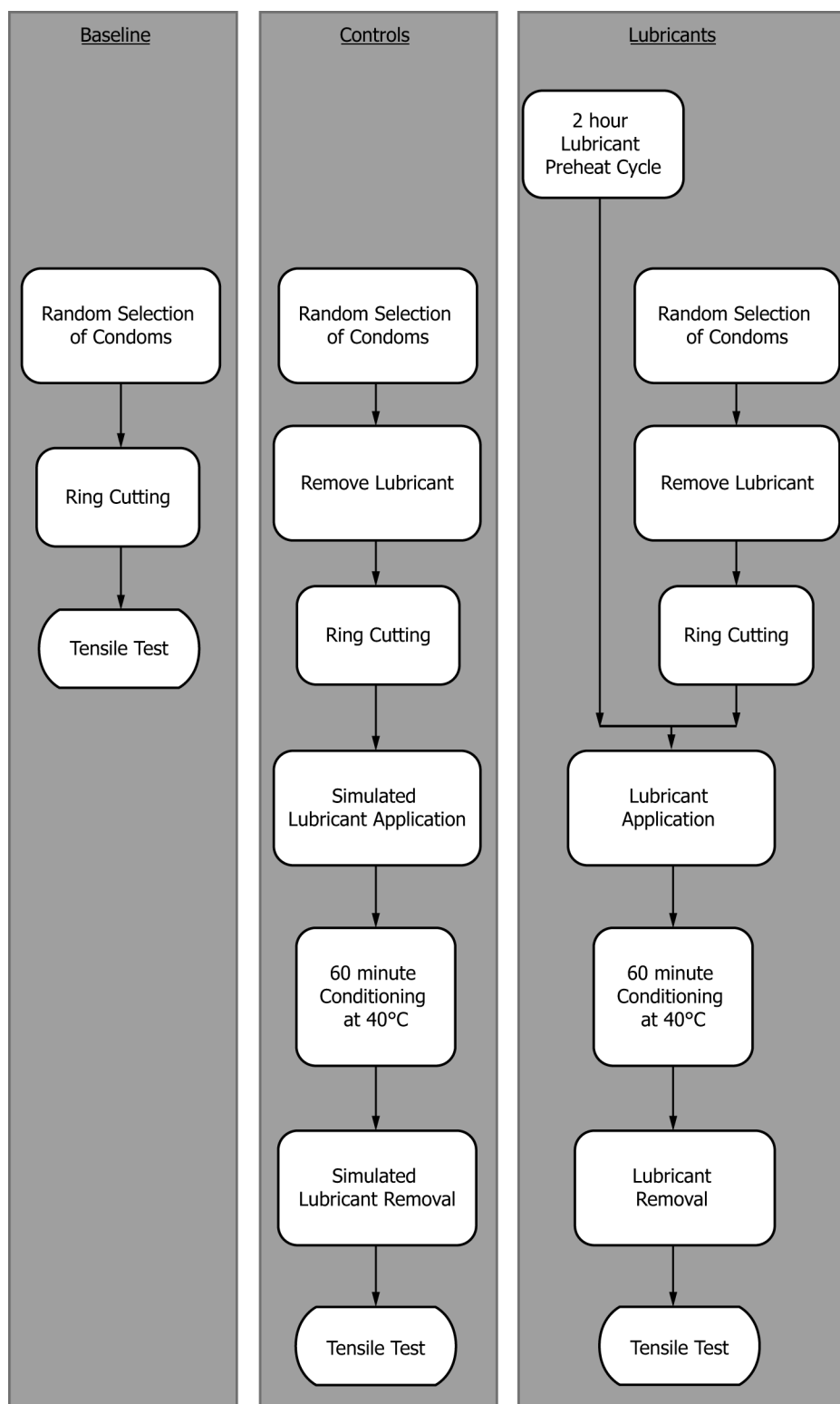


FIG. 1 Flow Chart for the Tensile Test Component of the Lubricant Compatibility Test

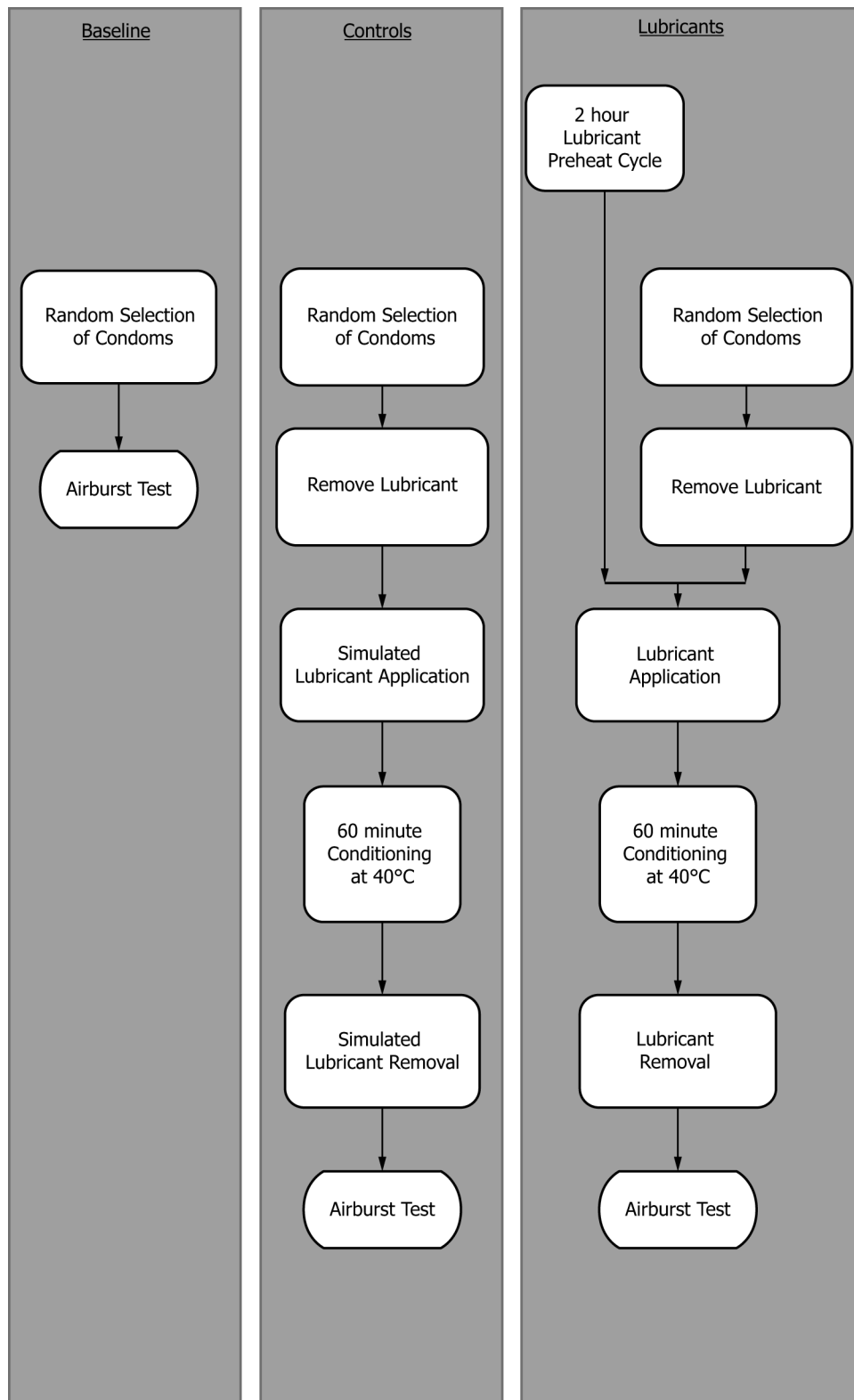


FIG. 2 Flow Chart for the Airburst Test Component of the Lubricant Compatibility Test

Specification **D3492** and (2) be tested for burst properties in compliance with Annex A2 of Specification **D3492**.

4.3 This test method is not to be used to determine the safety of either the test lubricant or NRL condom. This test method is to be used only to determine if the tensile or airburst properties of the NRL condom have been significantly affected by the test lubricant.

5. Apparatus

5.1 *Environmental chamber or oven*, capable of maintaining $40 \pm 2^\circ\text{C}$.

5.2 *Airburst tester and clamping mount*, capable of inflating a condom as specified in Annex A2 of Specification **D3492**.

5.3 *Tensile tester and roller grips*, capable of testing ring specimens according to Appendix X1 of Specification **D3492**.

5.4 *Ring-cutting die, mechanical press, and replaceable cutting surface*, for cutting ring specimens from condoms, compliant with Appendix XI of Specification **D3492**.

6. Materials

6.1 *Test lubricant*, for which compatibility with NRL condoms is unknown.

6.2 *Mineral oil*, meeting the current requirements of the U.S. Pharmacopeia. The mineral oil is expected to cause significant degradation in the NRL condom physical properties when the test method is properly performed.

6.3 *Solvents, including water, isopropyl alcohol (IPA), and mild detergent*, for cleaning laboratory equipment and supplies after each lubricant group has been tested.

6.4 *Cornstarch*, to assist in dimensional measurements and tensile testing (optional).

6.5 *Shallow dishes with tight-fitting lids*, in number sufficient to hold 20 condom rings and 20 whole condoms.

6.6 *Low-lint laboratory-grade paper towels*, for removing lubricant from test samples after oven conditioning.

6.7 *General laboratory supplies*, including beakers, graduated cylinder, plastic wrap, rubber bands, foam-tipped swabs, stir rods, plastic food-storage bags, ruler, powder-free exam gloves, Petri dishes, felt-tipped permanent marking pen, and cellophane tape.

7. Sampling Overview, Sample Groups, and Sample Size

7.1 Sampling Overview:

7.1.1 This test method shall be performed on three distinct brands of commercially available NRL condoms.

7.1.2 Each brand of condom should be non-lubricated, straight-walled, smooth condoms from a single finished lot.

7.1.2.1 If non-lubricated condoms are not available, condoms that are lubricated with silicone lubricant may be used in their place.

7.1.3 All condoms shall meet the requirements of Specification **D3492**.

7.2 Sample Groups:

7.2.1 Each of the three distinct brands of condoms shall be divided into four groups and tested for both tensile and airburst properties in the following order:

7.2.1.1 *Baseline Group*—Condoms are tested directly from the package for tensile properties as per **10.6** and for airburst properties as per **11.6**.

7.2.1.2 *Control Group*—Condoms are tested as per **10.2 – 10.6** and **11.2 – 11.6**. In other words, the lubricant preheat cycle (**10.1** and **11.1**) is unnecessary and the rings/condoms are placed in an empty dish (no lubricant) for conditioning in the oven. All other handling of the control rings/condoms should be exactly the same as for the test lubricant group (for example, covering with plastic wrap, conditioning in the oven, sliding fingers down rings/condoms to simulate removal of excess lubricant, blotting with low-lint tissue wipes, and so forth). There is no contact with lubricant in the control group.

7.2.1.3 *Test Lubricant Group*—Condoms are tested as per Sections **10** and **11** with a lubricant for which condom compatibility is unknown.

7.2.1.4 *Mineral Oil Group*—Condoms are tested as per Sections **10** and **11** with mineral oil, which is known to adversely affect the physical properties of NRL condoms. If this test method is properly conducted, significant degradation in airburst and tensile properties should be observed in this group.

7.3 *Sample Size*—The sample size for tensile testing shall be no fewer than 20 condoms per group. The sample size for airburst testing shall be no fewer than 20 condoms per group. A sample size of 20 per group is adequately powered to detect a 10 % change in airburst pressure, airburst volume, and percent elongation, as well as a 25 % change in force at break.

8. Cross-Contamination

8.1 It is important to test the four treatment groups in the order prescribed (beginning with baseline, then controls, then the test lubricant, and finally, the mineral oil) so as to reduce the possibility of cross-contamination of lubricants, especially mineral oil.

8.2 It is recommended that separate laboratory supplies (dishes, utensils, and so forth) be used for each lubricant group unless a thorough scrubbing of all reusable laboratory supplies is conducted using detergent and water.

8.3 It is expected that all laboratory equipment (including airburst and tensile equipment, as well as laboratory equipment handles, keypads, ruler, thickness gage, and so forth) will undergo a thorough cleaning using IPA and low-lint wipes after testing each lubricant group. Gloves shall also be changed between testing each lubricant group.

9. Sample Preparation – Lubricant Removal

9.1 As described in **7.1.2.1**, if non-lubricated condoms are not available, lubricated condoms may be used in their place. Lubricant should be removed from the outside of the condoms in the control, test lubricant, and mineral oil groups before beginning sample preparation (**10.1** and **11.1**). Lubricant should not be removed from condoms in the mineral oil group.

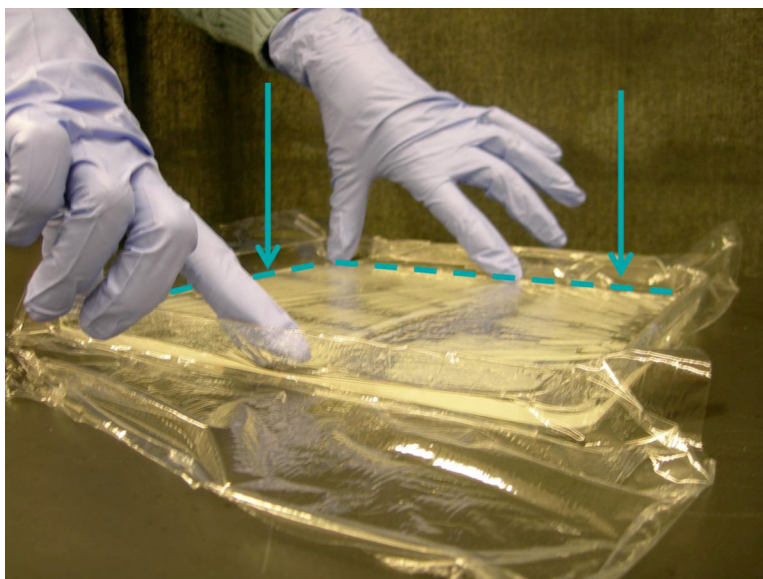


FIG. 3 Tuck Plastic Wrap Inside Dish

9.2 Remove lubricant using the blotting method outlined in 10.5. Start with 10.5.1 and end with 10.5.14 while skipping the steps described in 10.5.4–10.5.7.

10. Procedure for Tensile Testing

NOTE 1—Powder-free exam gloves should be worn during each step of the procedure.

10.1 Lubricant Preheat Cycle:

10.1.1 Determine the volume of lubricant necessary to yield a depth of 5 ± 0.5 mm in the shallow dish (this may be done using water and a ruler).

NOTE 2—A 225- by 225-mm dish requires approximately 250 mL of lubricant to yield a depth of 5 mm.

10.1.2 Measure and dispense the volume of lubricant determined in 10.1.1 into a glass beaker, and then transfer half of this volume into the shallow dish. If necessary, tilt the dish from side to side to spread the lubricant evenly across the bottom of the dish.

NOTE 3—For high-viscosity lubricants, it may be necessary to use a foam-tipped swab or other clean utensil to spread the lubricant across the bottom of the dish. Small areas lacking coverage are permissible, as the lubricant will continue to spread during preheating.

10.1.3 Cover the shallow dish with a tight-fitting lid to prevent evaporation during preheating.

10.1.4 Cover the beaker containing the remaining half of lubricant with plastic wrap and a rubber band.

10.1.5 The covered dish and beaker of lubricant shall be preheated for a minimum of 2 h in an environmental chamber or oven maintained at $40 \pm 2^\circ\text{C}$. Record the actual length of time that the dish and beaker are in the chamber/oven.

10.2 Ring Specimens:

10.2.1 During the lubricant preheat cycle (10.1), randomly select a minimum of 20 non-lubricated NRL condoms from a single finished lot of one brand for tensile testing.

10.2.2 Prepare one ring specimen from each condom as per Appendix X1 in Specification D3492.

NOTE 4—This procedure is intended for non-lubricated smooth NRL condoms; therefore sections X1.4.1.3 through X1.4.1.8 in Appendix X1 of Specification D3492 are not applicable.

10.3 Lubricant Application:

10.3.1 At the conclusion of the lubricant preheat cycle (10.1), remove the lubricant from the oven. Uncover the dish and beaker of preheated lubricant.

10.3.2 Immediately lay all rings in the preheated dish of lubricant. Rings should lay flat. Leave sufficient space between rings (5 to 10 mm) in case swelling occurs, for example, with petroleum-based lubricants.

10.3.3 Dispense lubricant from the preheated beaker directly on top of rings so as to completely immerse the rings in lubricant. Use a foam-tipped swab or other utensil to transfer any remaining lubricant from the walls of the beaker to the dish of rings.

NOTE 5—For high-viscosity lubricants, it may be helpful to transfer the preheated lubricant from the beaker into a plastic food storage bag. Cut a hole in one corner of the bag and squeeze out the lubricant onto the rings. The lubricant will spread during heating; therefore, only minimal spreading of the lubricant across the rings, with a foam-tipped swab or other clean utensil, is necessary.

10.3.4 Using a foam-tipped swab (or glass stir rod) and gentle pressure, briefly attempt to remove any large air bubbles trapped within the rings or lubricant or both. If the bubbles do not easily remove, leave them there.

10.3.5 Cover the dish of rings with plastic wrap in the following manner: position plastic wrap over the dish and let it fall onto the lubricant inside the dish. Avoid the formation of air bubbles by slowly smoothing the plastic wrap from the center of the dish to all four walls. Drape the excess plastic wrap over the walls of the dish. The plastic wrap should be in full contact with the lubricant all the way to the walls of the dish so as to create an even lubricant layer over the rings during conditioning. See Fig. 3. Note how the fingers tuck the plastic wrap to the edges and corners of the dish.