Designation: D7661 – 10

Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms[1]

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 non-lubricated 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D3492 Specification for Rubber Contraceptives (Male Condoms)

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 non-lubricated 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 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.

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[1] This test method is under the jurisdiction of ASTM Committee D11 on Rubber 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.

[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.

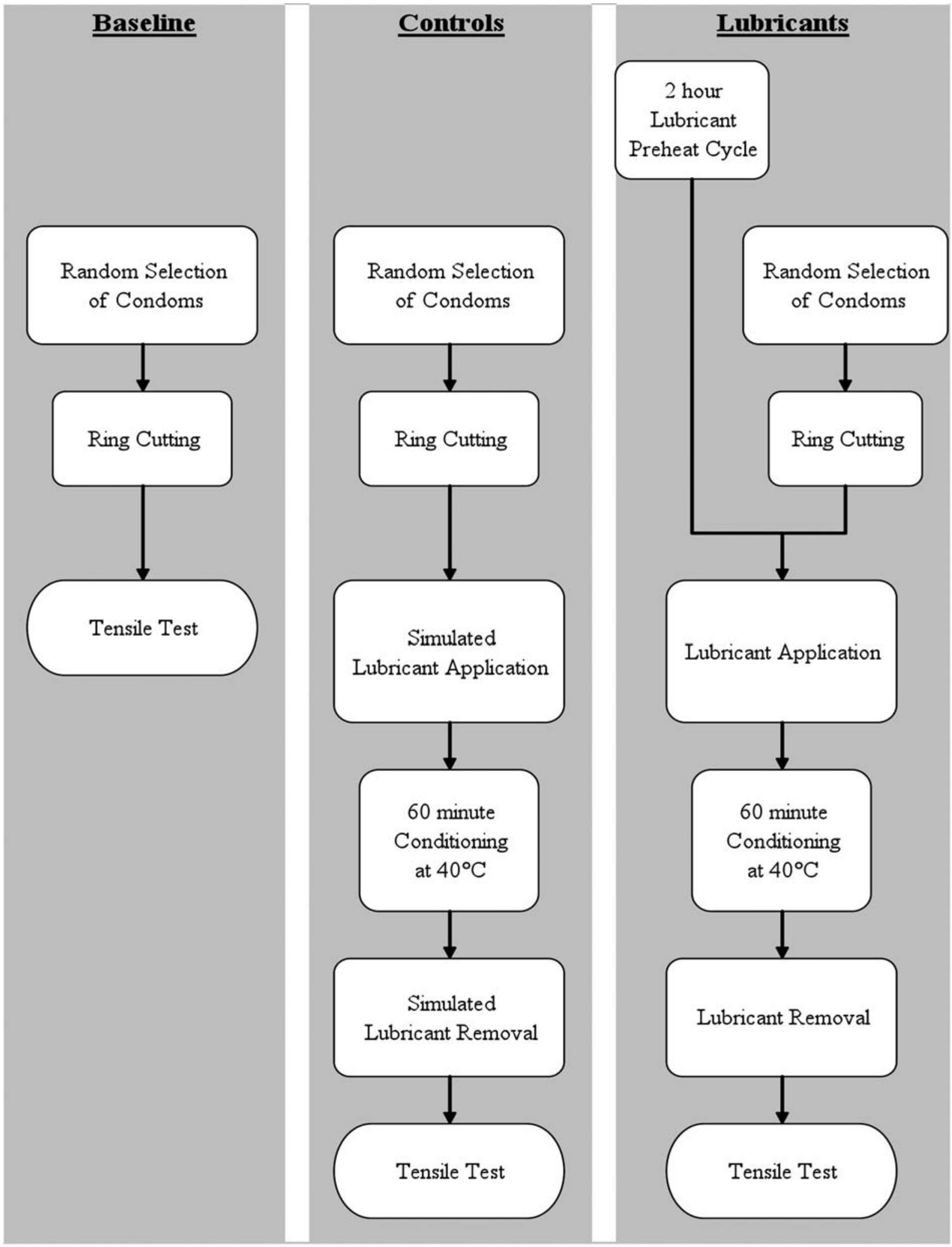

FIG. 1 Flow Chart for the Tensile Test Component of the Lubricant Compatibility Test

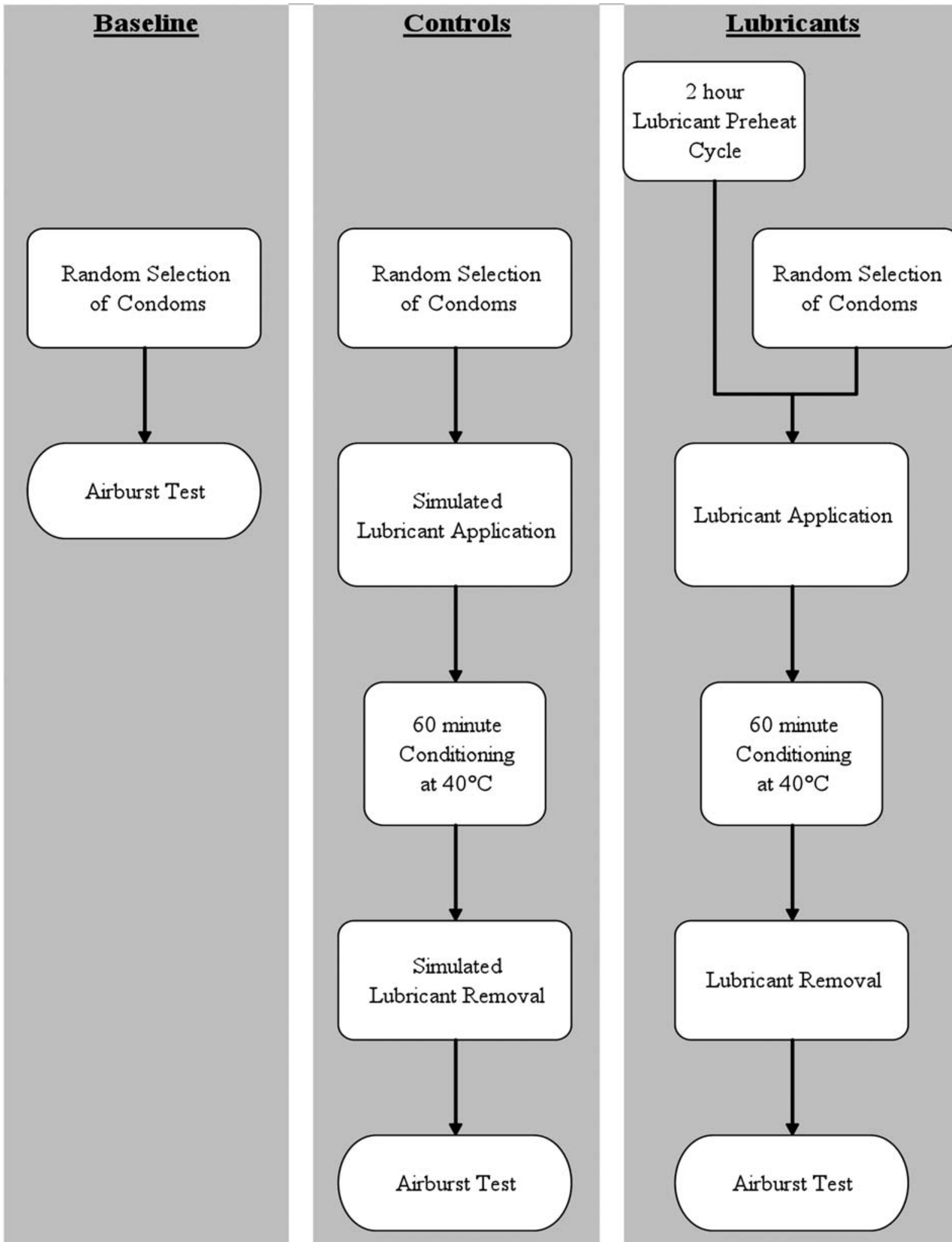

FIG. 2 Flow Chart for the Airburst Test Component of the Lubricant Compatibility Test

5. Apparatus

5.1 *Environmental chamber or oven,* capable of maintaining 40 ± 2°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.

7.1.3 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 9.6 and for airburst properties as per 10.6.

7.2.1.2 *Control Group*—Condoms are tested as per 9.2-9.6 and 10.2-10.6. In other words, the lubricant preheat cycle (9.1 and 10.1) 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 9 and 10 with a lubricant for which condom compatibility is unknown.

7.2.1.4 *Mineral Oil Group*—Condoms are tested as per Sections 9 and 10 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. Procedure for Tensile Testing

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

9.1 *Lubricant Preheat Cycle:*

9.1.1 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.

9.1.2 Measure and dispense the volume of lubricant determined in 9.1.1 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.

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

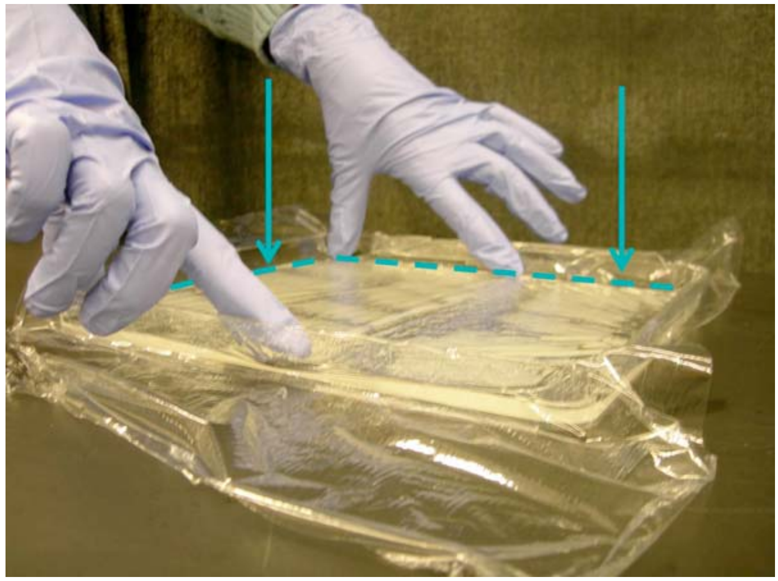

FIG. 3 Tuck Plastic Wrap Inside Dish

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

9.1.5 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 ± 2°C. Record the actual length of time that the dish and beaker are in the chamber/oven.

9.2 *Ring Specimens:*

9.2.1 During the lubricant preheat cycle (9.1), randomly select a minimum of 20 non-lubricated NRL condoms from a single finished lot of one brand for tensile testing.

9.2.2 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.

9.3 *Lubricant Application:*

9.3.1 At the conclusion of the lubricant preheat cycle (9.1), remove the lubricant from the oven. Uncover the dish and beaker of preheated lubricant.

9.3.2 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.

9.3.3 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.

9.3.4 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.

9.3.5 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.

9.4 *Ring Conditioning*—Immediately condition the dish of rings for 60 ± 5 min in an environmental chamber or oven maintained at 40 ± 2°C.

9.5 *Lubricant Removal:*

9.5.1 Lay one low-lint tissue wipe onto the bench top. Place a second low-lint tissue wipe on top of the first one. This set of two wipes will be called Blotting Paper #1.

9.5.2 Repeat 9.5.1, yielding a second set of blotting paper adjacent to the first set (Blotting Paper #2).

9.5.3 Repeat 9.5.1 again, yielding a third set of blotting paper adjacent to the second set (Blotting Paper #3).

9.5.4 At the conclusion of ring conditioning (9.4), remove the dish of rings from the oven and immediately remove the plastic wrap from the dish.

9.5.5 Remove a preconditioned ring from the dish. Hold one end of the ring with the non-dominant hand. Position the ring between two fingers of the dominant hand. Gently slide the two fingers down the ring to remove excess lubricant. Avoid pulling or stretching the ring. See Fig. 4.

9.5.6 Flip ring upside down and repeat the gentle sliding of fingers down the ring.

9.5.7 Lay the ring onto Blotting Paper #1.

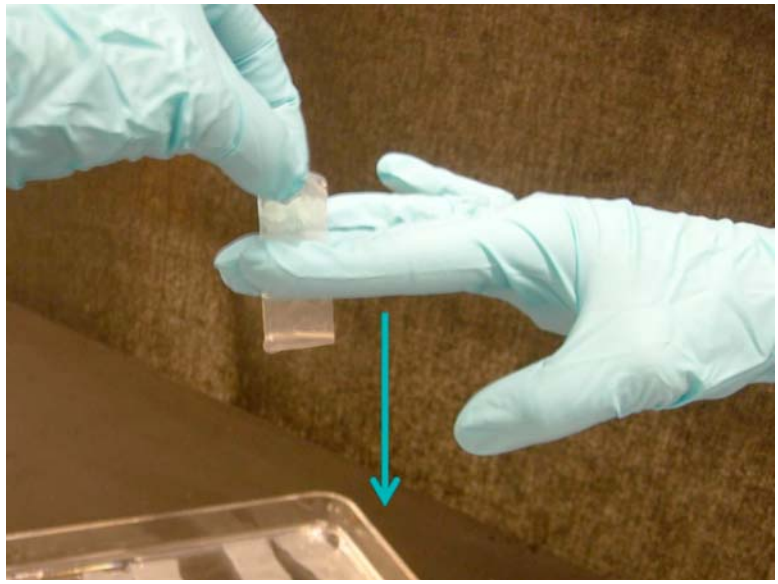

FIG. 4 Gently Slide Fingers Down Ring

9.5.8 Repeat 9.5.5-9.5.7 for all rings, laying them out in rows on one half of Blotting Paper #1. Rings should not contact one another.

9.5.9 Fold Blotting Paper #1 over the rings. See Fig. 5.

9.5.10 Blot excess lubricant from the rings as follows: place hands in the middle of Blotting Paper #1. Exert gentle pressure while sliding hands from the center of the folded wipes to the edges, doing so three times (so that each ring is pressed three times with the same blotting paper). See Fig. 6.

9.5.11 Pick up each ring from Blotting Paper #1 and lay onto one half of Blotting Paper #2. Rings should be laid in rows, but should not contact one another.

9.5.12 Fold Blotting Paper #2 over the rings.

9.5.13 Place hands in the middle of Blotting Paper #2. Exert gentle pressure while sliding hands from the center of the paper to the edges, doing so three times (so that each ring is pressed three times with the same blotting paper).

9.5.14 Pick up each ring and lay flat onto Blotting Paper #3. Rings are now ready for tensile testing.

9.6 *Tensile Test:*

9.6.1 Remove one ring from Blotting Paper #3 and lay flat onto a clean surface. Carefully measure the distance between the folded edges of the ring to the nearest 0.5 mm and record the results. Multiply the laid-flat width by 2 to obtain the circumference of the ring specimen, which is necessary to calculate elongation at break.

9.6.2 Conduct ring testing as per X1.4.5-X1.4.6 of Specification D3492. Record the force (N) and separation of the rollers (mm) at break.

NOTE 6—Placement of the ring on the roller grip may be facilitated as follows (optional): dip thumb and finger into a dish of cornstarch. Insert finger through ring. Gently roll the ring between the thumb and finger to distribute the cornstarch on both the inside and outside of the ring. See Fig. 7.

9.6.3 Repeat 9.6.1-9.6.2 for all rings.

10. Procedure for Airburst Testing

NOTE 7—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 8 ± 0.5 mm in the shallow dish (this may be done using water and a ruler).

NOTE 8—A 225- by 225-mm dish requires approximately 400 mL of lubricant to yield a depth of 8 mm.

10.1.2 Measure and dispense the volume of lubricant determined in 10.1.1 into a glass beaker, and then transfer one third 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 9—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 two thirds of lubricant with plastic wrap and a rubber band.

NOTE 10—Multiple dishes may be needed to accommodate 20 condoms. The number of dishes required will depend on the size of each dish. For example, a 225- by 225-mm dish will fit four condoms side by side as described in 10.3.4. Therefore, 5 dishes of this size are required for 20 condoms.

10.1.5 Repeat 10.1.1-10.1.4 for the remaining shallow dishes and beakers.

10.1.6 The covered dish(es) and beaker(s) of lubricant shall be preheated for a minimum of 2 h in an environmental chamber or oven maintained at 40 ± 2°C. Record the actual length of time that the dish(es) and beaker(s) are in the chamber/oven.

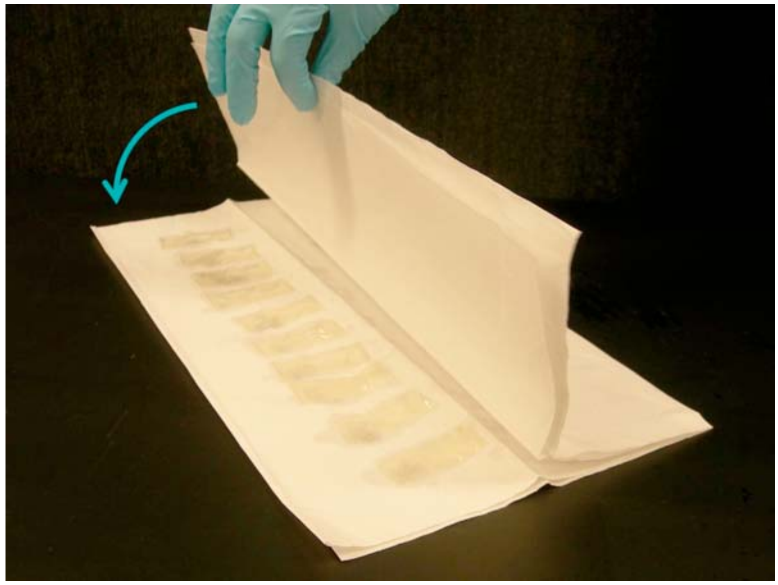

FIG. 5 Fold Blotting Paper #1 Over Rings

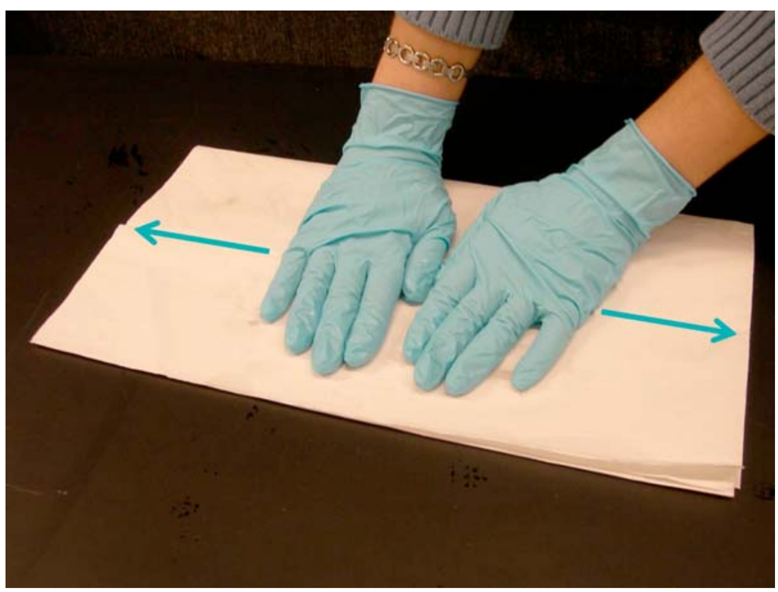

FIG. 6 Slide Hands Across Blotting Paper #1

10.2 *Condoms:*

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 airburst testing.

10.2.2 Carefully remove each condom from its individual packaging and gently unroll.

10.2.3 Using a ruler and felt-tipped permanent marking pen, make two small marks on the condom at lengths of 170 and 180 mm from the closed end, excluding reservoir tip (if any). See Fig. 8.

10.3 *Lubricant Application:*

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

10.3.2 Cut a length of cellophane tape and attach it to the inside of one condom across the bead 180 mm or more from the closed end. (Use the mark made in 10.2.3 as a guide.) Surface powders on the condom may need to be gently wiped away in order for the tape to adhere to the condom. The tape should be positioned so that the length of the tape is parallel to the length of the condom. See Fig. 9.

NOTE 11—Cellophane tape may be attached to the condoms during the lubricant preheat cycle, following 10.2.3.

10.3.3 Immediately lay the condom across the preheated lubricant in the shallow dish so that the condom is in contact with lubricant from the closed end up to the 170-mm mark.

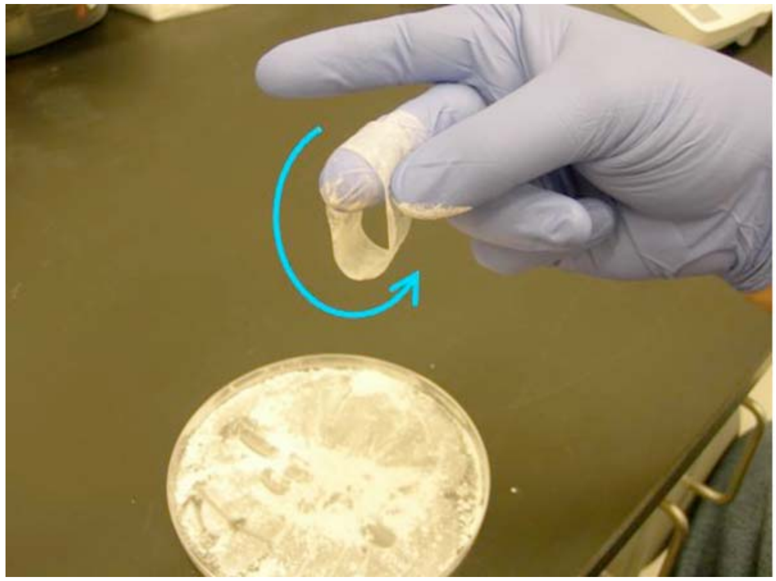

FIG. 7 Apply Cornstarch to Ring (Optional)

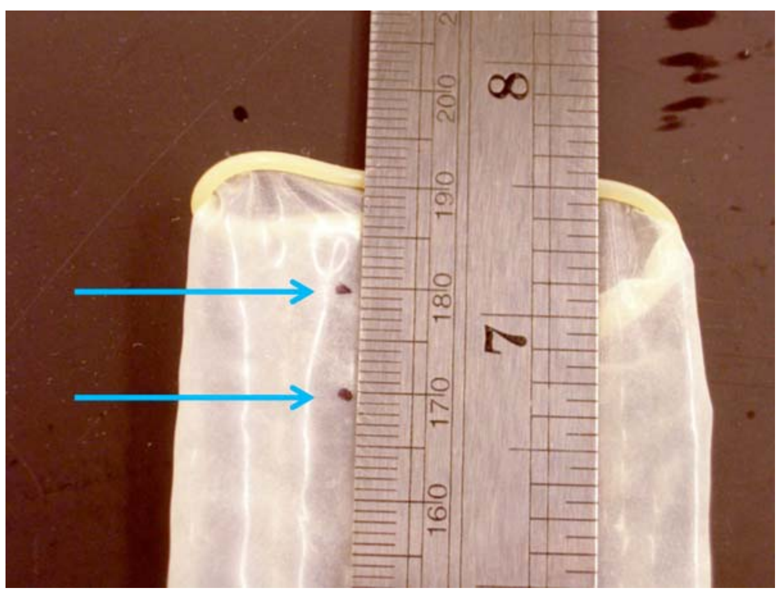

FIG. 8 Marks on Condom at 170 and 180 mm from Closed End

Affix the tape on the beaded edge of the condom to the wall of the dish to prevent lubricant from entering the open end of the condom.

10.3.4 Repeat 10.3.2-10.3.3 for additional condoms to fill the dish (see Note 10). Leave sufficient space between the condoms (5 to 10 mm) in case swelling occurs, for example, with petroleum-based lubricants.

10.3.5 Slowly dispense the lubricant from the preheated beaker directly onto the condoms in a zigzag fashion, beginning at the closed end of each condom and working toward the open end. Distributing the lubricant in this manner will force most of the air within the condom toward the open end, thereby facilitating complete immersion of the condoms in the lubricant. See Fig. 10.

NOTE 12—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 in the zigzag motion, as directed in 10.3.5. The lubricant will spread during heating; therefore, only minimal spreading of the lubricant across the condoms, with a foam-tipped swab or other clean utensil, is necessary.

10.3.6 Use a foam-tipped swab or other utensil to transfer any remaining lubricant from the walls of the beaker to the dish of condoms.

10.3.7 Repeat 10.3.2-10.3.6 for the remaining condoms and dishes of lubricant.

10.3.8 Cover each dish of condoms 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 and beyond the three empty walls of the dish. If necessary, fold the plastic wrap under the open end (beaded

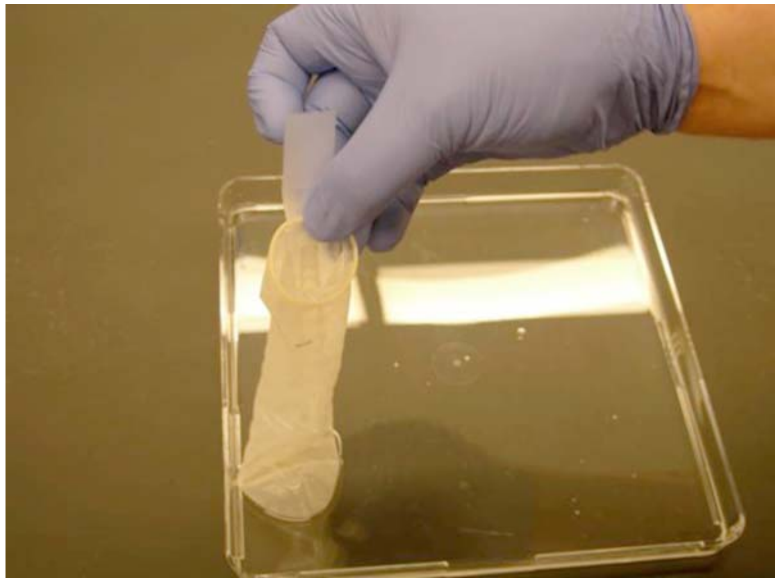

FIG. 9 Tape on Condom

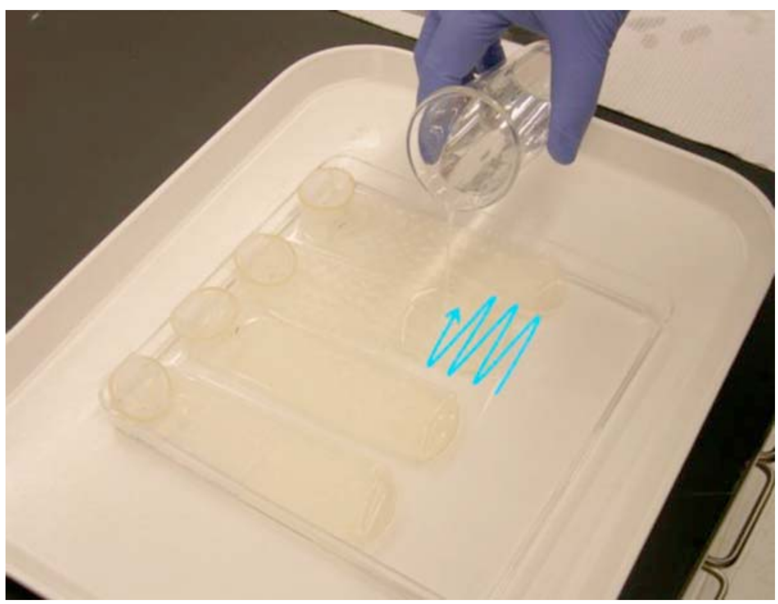

FIG. 10 Dispense Lubricant in Zigzag Fashion from Closed End to Open End of Each Condom

edge) of the condoms, which are taped to the fourth wall 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 condoms during conditioning. See Fig. 11. Note how the fingers tuck the plastic wrap to the edges and corners of the dish. Also, note how the open end of the condom is on top of the plastic wrap.

10.4 *Condom Conditioning*—Immediately condition the dish(es) of condoms for 60 ± 5 min in an environmental chamber or oven maintained at 40 ± 2°C.

10.5 *Lubricant Removal:*

10.5.1 Lay one low-lint tissue wipe onto the bench top. Place a second low-lint tissue wipe on top of the first one. This set of two wipes will be called Blotting Paper #1.

10.5.2 Repeat 10.5.1, yielding a second set of blotting paper adjacent to the first set (Blotting Paper #2).

10.5.3 Repeat 10.5.1 again, yielding a third set of blotting paper adjacent to the second set (Blotting Paper #3).

10.5.4 At the conclusion of condom conditioning (10.4), remove the condoms from the oven and immediately remove the plastic wrap from the first dish.

10.5.5 Gently lift one condom from the dish, peeling the tape from the dish and folding it onto itself as shown in Fig. 12. Do not attempt to remove the tape from the condom.

10.5.6 Hold the open end of the condom with the non-dominant hand. Position the condom between two fingers of the dominant hand. Gently and loosely slide the two fingers down the condom to remove excess lubricant. It is necessary to

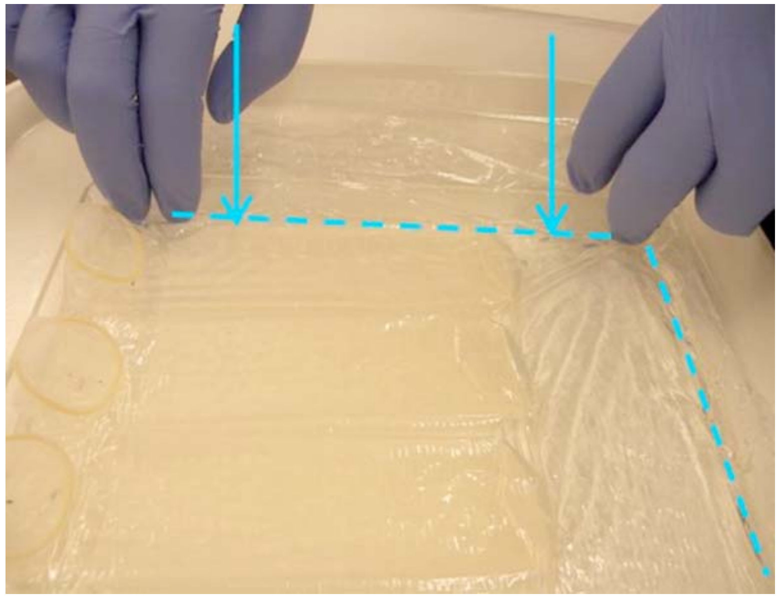

FIG. 11 Tuck Plastic Wrap Inside Dish

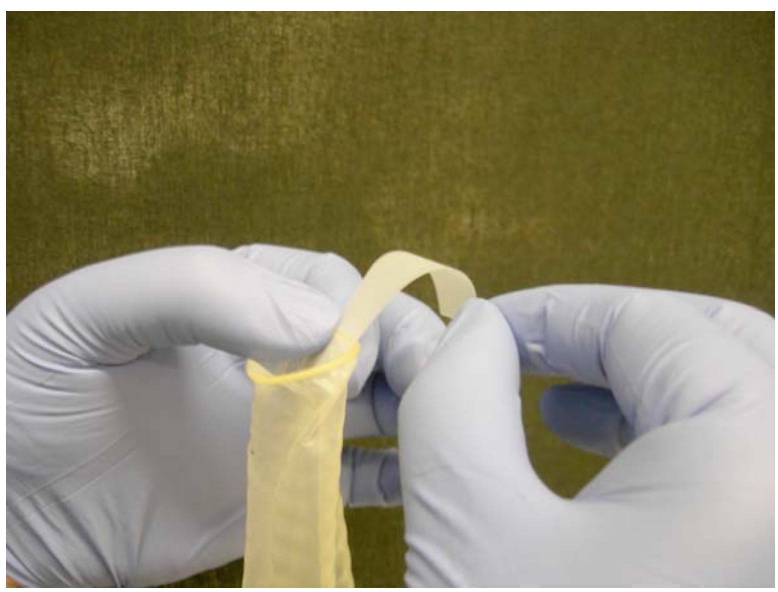

FIG. 12 Fold Tape onto Itself

allow air to escape from the open end of the condom while the fingers are gently sliding down. Therefore, do not pinch the open end completely closed while sliding down the condom. Following this technique will prevent pulling or stretching of the condom. See Fig. 13.

10.5.7 Slide fingers down the condom a second time using the technique in 10.5.6.

10.5.8 Lay the condom onto Blotting Paper #1.

10.5.9 Repeat 10.5.5-10.5.8 for as many condoms as will fit on one half of Blotting Paper #1. Condoms should be laid in rows but should not contact one another.

10.5.10 Fold Blotting Paper #1 over the condoms. See Fig. 14.

10.5.11 Blot excess lubricant from the condoms as follows: place hands in the middle of Blotting Paper #1. Exert gentle pressure while sliding hands from the center of the paper to the edges, doing so three times (so that each condom is pressed three times with the same blotting paper). See Fig. 15.

10.5.12 Pick up each condom from Blotting Paper #1 and lay onto one half of Blotting Paper #2. Condoms should be laid in rows, but should not contact one another.

10.5.13 Fold Blotting Paper #2 over the condoms.

10.5.14 Place hands in the middle of Blotting Paper #2. Exert gentle pressure while sliding hands from the center of the folded wipes to the edges, doing so three times (so that each condom is pressed three times with the same blotting paper).

10.5.15 Pick up each condom and lay flat onto Blotting Paper #3. These condoms are now ready for airburst testing.

10.5.16 Prepare new blotting paper for the next group of condoms as per 10.5.1-10.5.3

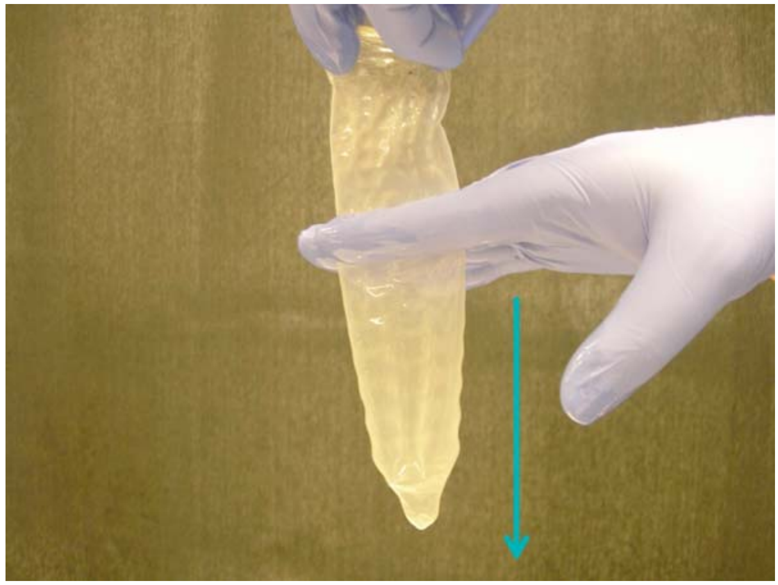

FIG. 13 Gently Slide Fingers Down Condom While Allowing Air to Escape from Open End

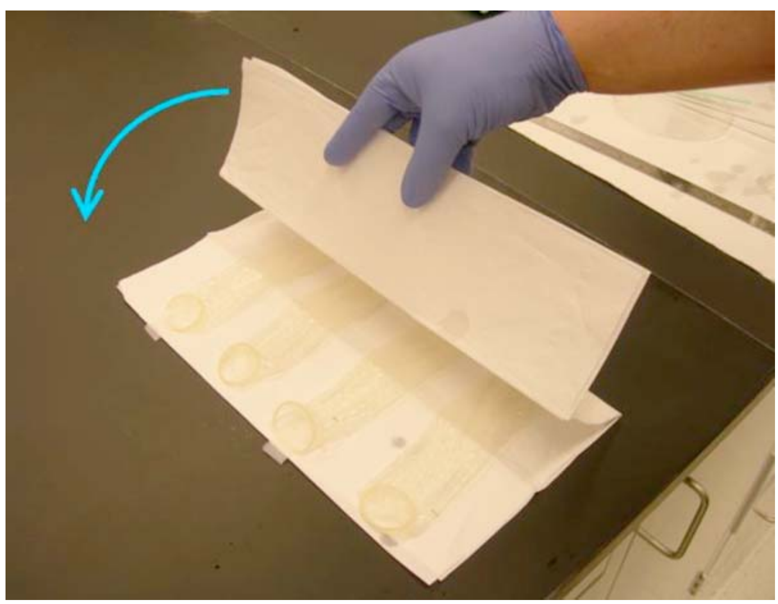

FIG. 14 Fold Blotting Paper #1 Over Condoms

10.5.17 Repeat 10.5.5-10.5.16 until all the condoms have been blotted.

10.6 *Airburst Testing*—Conduct air inflation testing as per Annex A2 of Specification D3492. Record the burst pressure (kPa) and burst volume (L) for each condom.

NOTE 13—Care should be taken in placing the "unrolled" condom on the test stem. Avoid stretching or distorting the condom when sliding it into position. Gently smooth out any wrinkles and air pockets, and make sure the reservoir tip remains intact.

11. Calculation

11.1 Calculate the elongation at break (%) as per X1.4.7.2 in Specification D3492 for each group of rings.

11.2 For each group of rings and condoms, calculate the mean and standard deviation of the following: breaking force (N), elongation at break (%), burst pressure (kPa), and burst volume (L).

11.3 Set the control group mean for each property at 100 %. Calculate the change in each property for the test lubricant group(s), the baseline group, and the mineral oil group as a percentage of the control group.

12. Report

12.1 Report the following information for each group of rings that were tested for tensile properties:

12.1.1 Sample identification;

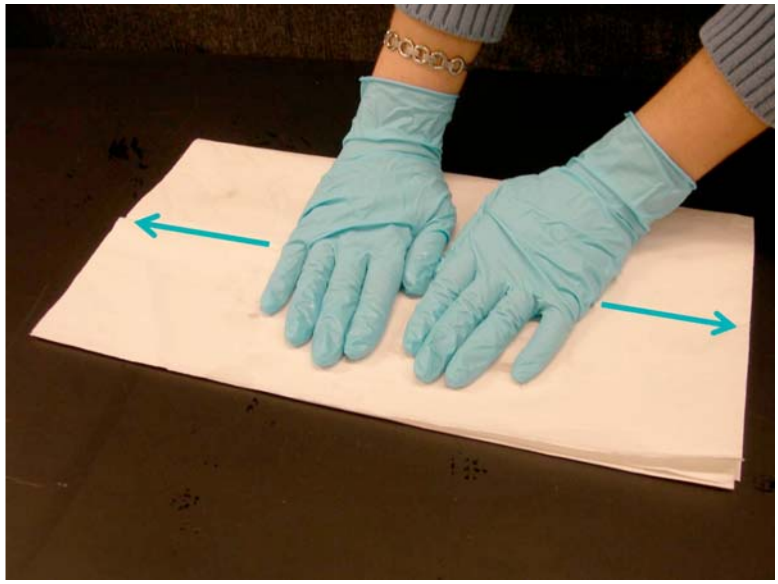

FIG. 15 Slide Hands across Blotting Paper #1

12.1.2 Date of testing;
12.1.3 Room temperature and relative humidity during tensile testing;
12.1.4 Roller circumference, mm;
12.1.5 Crosshead speed, mm/min;
12.1.6 Breaking force (N) and elongation at break (%) (means and standard deviations);
12.1.7 Changes in breaking force and elongation as a percentage of the control group.

12.2 Report the following information for each group of condoms that were tested for airburst properties:
12.2.1 Sample identification,
12.2.2 Date of testing,
12.2.3 Room temperature and relative humidity during airburst testing,
12.2.4 Barometric pressure,
12.2.5 Air flow rate,
12.2.6 Burst pressure (kPa) and burst volume (L) (means and standard deviations), and
12.2.7 Changes in burst pressure and burst volume as a percentage of the control group.

13. Precision and Bias

13.1 The precision of this test method is based on an interlaboratory study conducted in 2009.[5] A total of nine laboratories participated in this study testing condoms of three different manufacturers (A, B, and C), under five lubricant conditions (Baseline, Control, Water Based, Silicone, and Mineral Oil). The results from one of the participants had to be excluded from the statistical evaluation of precision because deviations from the testing protocol were reported. Every "test result" represents an individual determination, and all participants were asked to report 20 replicate test results for each condom/condition combination. Practice E691 was followed for the design and analysis of the data.

13.1.1 Repeatability Limit (*r*)—Two test results obtained within one laboratory shall be judged not equivalent if they differ by more than the "*r*" value for that material; "*r*" is the interval representing the critical difference between two test results for the same material obtained by the same operator using the same equipment on the same day in the same laboratory.

13.1.1.1 Repeatability limits are listed in Tables 1-4.

13.1.2 Reproducibility Limit (*R*)—Two test results shall be judged not equivalent if they differ by more than the "*R*" value for that material; "*R*" is the interval representing the critical difference between two test results for the same material obtained by different operators using different equipment in different laboratories.

13.1.2.1 Reproducibility limits are listed in Tables 1-4.

13.1.3 The terms repeatability limit and reproducibility limit are used as specified in Practice E177.

13.1.4 Any judgment in accordance with 13.1.1 and 13.1.2 would have an approximate 95 % probability of being correct.

13.2 *Bias*—At the time of the study, there was no accepted reference material suitable for determining the bias for this test method; therefore, no statement on bias can be made.

13.3 The precision statement was determined through statistical examination of 9596 test results submitted by 8 laboratories on 3 condom types tested under 5 lubricant conditions.

13.3.1 Each of the three condom types was described as non-lubricated, straight-walled, smooth NRL condoms from a single finished lot (Condom A, Condom B, and Condom C).

13.4 To judge the equivalency of two test results, it is recommended to choose the condom material/lubricant combination that is closest in characteristics to the test material.

[5] Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:D11-1105.

TABLE 1 Burst Pressure (kPa)

Material	Average[A] $\bar{x}$	Repeatability Standard Deviation S_r	Reproducibility Standard Deviation S_R	Repeatability Limit r	Reproducibility Limit R
Baseline A	1.873	0.122	0.147	0.342	0.410
Control A	1.859	0.134	0.147	0.375	0.412
Water-Based A	1.789	0.173	0.186	0.484	0.521
Silicone A	1.676	0.143	0.182	0.402	0.509
Mineral Oil A	0.880	0.109	0.159	0.305	0.445
Baseline B	2.489	0.143	0.174	0.401	0.488
Control B	2.485	0.127	0.146	0.357	0.409
Water-Based B	2.348	0.139	0.168	0.389	0.469
Silicone B	2.312	0.140	0.191	0.392	0.534
Mineral Oil B	1.383	0.216	0.306	0.604	0.857
Baseline C	2.338	0.148	0.173	0.414	0.484
Control C	2.319	0.162	0.188	0.454	0.527
Water-Based C	2.228	0.146	0.170	0.408	0.477
Silicone C	2.177	0.174	0.229	0.486	0.642
Mineral Oil C	1.337	0.158	0.328	0.442	0.917

[A]The average of the laboratories' calculated averages.

TABLE 2 Burst Volume (L)

Material	Average[A] $\bar{x}$	Repeatability Standard Deviation S_r	Reproducibility Standard Deviation S_R	Repeatability Limit r	Reproducibility Limit R
Baseline A	37.646	2.318	3.083	6.489	8.634
Control A	38.583	2.617	3.105	7.327	8.695
Water-Based A	37.298	3.925	4.623	10.990	12.946
Silicone A	34.227	3.047	3.799	8.532	10.638
Mineral Oil A	18.454	4.637	7.438	12.983	20.828
Baseline B	37.073	2.600	2.933	7.281	8.211
Control B	37.438	1.909	2.603	5.345	7.288
Water-Based B	38.182	2.584	2.885	7.237	8.079
Silicone B	33.686	2.313	3.088	6.475	8.647
Mineral Oil B	21.731	3.936	5.070	11.020	14.195
Baseline C	38.828	2.266	2.619	6.345	7.333
Control C	38.810	2.696	3.011	7.548	8.430
Water-Based C	39.995	2.519	3.231	7.053	9.048
Silicone C	36.872	2.687	3.317	7.523	9.288
Mineral Oil C	22.318	3.342	7.234	9.357	20.256

[A]The average of the laboratories' calculated averages.

TABLE 3 Force at Break (N)

Material	Average[A] $\bar{x}$	Repeatability Standard Deviation S_r	Reproducibility Standard Deviation S_R	Repeatability Limit r	Reproducibility Limit R
Baseline A	60.02	9.49	10.29	26.57	28.82
Control A	59.86	9.68	10.58	27.10	29.62
Water-Based A	57.05	8.63	9.12	24.17	25.53
Silicone A	61.99	10.19	10.90	28.53	30.53
Mineral Oil A	9.93	3.01	7.11	8.42	19.91
Baseline B	85.23	9.83	13.68	27.52	38.31
Control B	84.70	9.23	13.18	25.84	36.90
Water-Based B	78.10	7.89	11.83	22.09	33.13
Silicone B	88.04	8.18	10.10	22.90	28.28
Mineral Oil B	18.94	3.20	10.24	8.96	28.68
Baseline C	84.71	11.24	12.99	31.48	36.37
Control C	83.45	11.94	12.83	33.43	35.92
Water-Based C	80.07	10.05	12.56	28.13	35.17
Silicone C	86.20	10.88	12.07	30.47	33.78
Mineral Oil C	14.23	3.85	7.28	10.77	20.37

[A]The average of the laboratories' calculated averages.

14. Keywords

14.1 compatibility; latex; lubricants; natural rubber; thin film

TABLE 4 Percent Elongation at Break (%)

Material	Average[A] $\bar{x}$	Repeatability Standard Deviation S_r	Reproducibility Standard Deviation S_R	Repeatability Limit r	Reproducibility Limit R
Baseline A	745.68	28.59	41.07	80.04	114.99
Control A	747.34	27.77	39.21	77.77	109.78
Water-Based A	745.75	26.97	39.61	75.52	110.92
Silicone A	749.01	30.48	42.48	85.33	118.94
Mineral Oil A	383.45	45.31	174.73	126.86	489.25
Baseline B	755.24	22.29	38.79	62.40	108.61
Control B	754.14	20.31	38.05	56.86	106.54
Water-Based B	749.77	18.01	33.05	50.44	92.55
Silicone B	754.75	18.60	42.21	52.07	118.20
Mineral Oil B	410.31	29.66	160.06	83.06	448.16
Baseline C	769.79	26.46	45.13	74.10	126.36
Control C	765.46	27.97	43.11	78.33	120.70
Water-Based C	769.69	24.81	44.02	69.46	123.24
Silicone C	771.07	24.84	44.00	69.54	123.21
Mineral Oil C	399.90	51.30	159.20	143.64	445.77

[A]The average of the laboratories' calculated averages.