Designation: F2981 – 15

Standard Test Method for Verifying Nonporous Flexible Barrier Material Resistance to the Passage of Air[1]

This standard is issued under the fixed designation F2981; 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 is to be used to verify a specific material design property. Some flexible barrier materials are designed to have a resistance to the passage of air through the membrane structure. These materials are characterized as nonporous. This test method provides a means to verify this property by challenging a material with a given volume of air under pressure over a specific time period.

1.2 This test method is not intended to measure the diffusion properties of a material nor to identify or quantify the presence of pinhole damage to the design that may result in leaks.

1.3 *Units*—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]

E171 Practice for Conditioning and Testing Flexible Barrier Packaging

2.2 *ISO Standards:*[3]

ISO 11607-1 Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

ISO 5636-5 Paper and Board—Determination of Air Permeance and Air Resistance (Medium Range)—Part 5: Gurley Method

2.3 *TAPPI Standard:*[4]

TAPPI Test Method T 460 om-06 Air Resistance of Paper (Gurley Method)

3. Significance and Use

3.1 This material challenge is presented in ISO-11607-1 Annex C as a normative test method to demonstrate that a material is nonporous and satisfies the microbial barrier requirements.

4. Apparatus

4.1 *Gurley Cylinder-type Densometer,* or equivalent apparatus compliant with ISO 5636-5.

4.1.1 *Air Volume and Pressure,* as standardized in TAPPI T-460 and ISO 5636-5.

4.2 *Clock or Timer.*

4.3 *Dimensional Scale,* in 0.1 millimeter increments.

5. Conditioning

5.1 Conditioning of samples will depend on the material under evaluation. If conditioning before testing is appropriate, normal and desirable, then condition the test specimens following ASTM E171.

6. Preparation and Procedure

6.1 Measure and cut sample of material to be tested approximately 50 mm × 50 mm square. Other cut sizes of samples can be used if easier to manipulate and position in holder without damage, wrinkling or introducing leaks.

6.2 Prior to inserting the material, ensure that the column is raised in the ready position. Loosen the wheel on the bottom of densometer and place the web between the clamps. By inserting the material samples with the smoother side facing upward toward the cylinder, the risk of leaking around the clamp is minimized.

6.3 Rotate the wheel to the right to tighten until the material is secure. (See Fig. 1.)

[1] This test method is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Packaging and is the direct responsibility of Subcommittee F02.20 on Physical Properties.

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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] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from Technical Association of the Pulp and Paper Industry (TAPPI), 15 Technology Parkway South, Norcross, GA 30092, http://www.tappi.org.

FIG. 1

6.4 Release the stop and guide the cylinder downward until it rests on the oil level inside the cylinder. Wait a minimum of 5 seconds to allow cylinder to settle into position. Record starting time.

6.5 Measure the position of the cylinder from position A to B in mm. (See Fig. 2.)

6.6 Record this distance as the starting distance.

6.7 Leave apparatus in position for one hour and record end of test time.

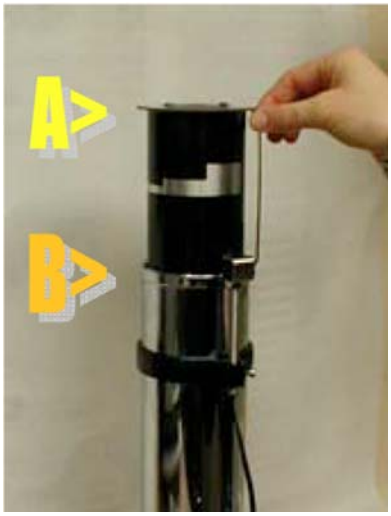

FIG. 2

6.8 Measure the position of the cylinder from position A to B in mm. Record end test distance.

6.9 Calculate and record the difference between start and end distance measurements.

6.10 If the difference is less than or equal to 1 mm, the materials are verified as nonporous.

6.11 When a material designed to be nonporous has results greater than 1 mm, check for anomalies.

6.11.1 Check position of test sample and holder for air leaking around sample.

6.11.2 Check that material is not damaged. Excessive wrinkling of material may create fractures in the structure.

7. Results

7.1 Record results as pass/fail.

7.2 List any deviations from specified procedure.

8. Precision and Bias

8.1 The precision of this test method is based on an inter-laboratory study of ASTM WK30771, Standard Test Method for Verifying Nonporous Flexible Barrier Material Resistance to the Passage of Air conducted in 2013. Ten laboratories participated in this study. Two samples of each of the three materials listed below were tested. Materials 1 and 2 are designed to be non-porous. Material 3 is designed to be porous. All samples were correctly identified as either porous or nonporous based on the outcome of each test. The results are shown in Table 1. Details are recorded in ASTM ILS927.

8.1.1 *Material 1: Extrusion Coated Film*—12 µm polyester/50 µm low density polyethylene.

8.1.2 *Material 2: Film*—38 µm Ethylene vinyl acetate.

8.1.3 *Material 3: Paper*—80 grams per square meter.

8.2 At the time of the study, there was no reference for determining the bias for this test method, therefore no statement on bias is being made.

9. Keywords

9.1 flexible material; Gurley; impermeability; nonporous; porosity

TABLE 1 Tests for Nonporous Characteristic Measured Correctly

Total Specimens Tested	False Positives	False Negatives	Confidence Interval
60	0	0	95% – 100%