



Designation: F3169 – 16

Standard Test Method for Leak Detection in Blister Packaging by Vacuum Deflection Method by Laser Measurement¹

This standard is issued under the fixed designation F3169; 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 *Test Packages*—This test method can be applied to non-porous blister packs sealed with flexible films such as those used in pharmaceutical packaging. Such blister packs typically consist of thermoformed polymer or cold formed aluminum trays that contain a number of individual blister pockets into which tablets or capsules are placed. The trays are then sealed with a polymer, paper-backed or foil-based flexible laminate lidding material.

1.2 *Leaks Detected*—This test method detects leaks in blister packs by measuring the deflection of the blister pack surface in response to an applied vacuum. This deflection of the blister pack surface results from the difference in pressure between the gas inside the blister pack and the applied vacuum. Air loss from within a blister pocket as a result of a leak will alter this pressure differential causing a measureable variation in blister pocket deflection. This test method requires that the blister packs are held in appropriate tooling inside a suitable test chamber.

1.3 *Test Results*—Test results are reported qualitatively (pass/fail). Appropriate acceptance criteria for *deflection*, *height*, and *collapse* values are established by comparing non-leaking packs with those containing defects of a known size. Suitably sized defects in the laminate, tray material, and seal can be detected using this test method. The sensitivity of this test method depends upon a range of factors including blister pocket headspace, blister pocket size, lidding material type, lidding material thickness, lidding material tension, printing, surface texture, test conditions, and the values selected for the pass/fail acceptance criteria. The ability of the test to detect 15 μm , 50 μm , and catastrophic sized holes in four blister pack designs was demonstrated in a study.

1.4 The values stated in SI units are to be regarded as standard and no other units of measurement are included in this test method.

1.5 *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

D996 Terminology of Packaging and Distribution Environments

F17 Terminology Relating to Flexible Barrier Packaging

3. Terminology

3.1 For definitions used in this test method, see Terminologies **D996** and **F17**.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *blister pack, n*—forming material, encapsulated product, and sealed lidding material.

3.2.2 *blister pocket, n*—sealed cavity in the forming material that contains product.

3.2.3 *collapse, n*—difference in height of the blister pocket profile in one plane before and after the reduced vacuum has been applied.

3.2.4 *deflection, n*—difference in height of the blister pocket profile in one plane before and after the initial vacuum has been applied.

3.2.5 *height, n*—difference in height of the blister pocket profile in one plane after initial vacuum when compared against blister pack surface height.

3.2.6 *profile, n*—surface of the lidding material measured at regular intervals across the blister pocket.

4. Summary of Test Method

4.1 The test blister packs are located in the test chamber in appropriate tooling to prevent them from moving under vacuum. The chamber is then sealed and the profile of every

¹ This test method is under the jurisdiction of ASTM Committee **F02** on Primary Barrier Packaging and is the direct responsibility of Subcommittee **F02.40** on Package Integrity.

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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.