Designation: D7427 – 14

Standard Test Method for Immunological Measurement of Four Principal Allergenic Proteins (Hev b 1, 3, 5 and 6.02) in Natural Rubber and Its Products Derived from Latex[1]

This standard is issued under the fixed designation D7427; 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 an immunological method known as an immunoenzymetric assay to quantify the amount of 4 principal *Hevea brasiliensis [Hev b]* allergenic proteins [Hev b 1, Hev b 3, Hev b 5 and Hev b 6.02] in natural rubber and its products[2] derived from latex using monoclonal antibodies specific for epitopes on these proteins. Since these assays quantify the levels of only 4 of the known 14 officially acknowledged allergens potentially present in natural rubber latex containing products, the sum of the four allergen levels shall be viewed as an indicator of the allergen burden and not as a measure of the total allergen content that can be released from the product.

1.2 For the purpose of this test method, the range of allergenic protein will be measured in terms of nanogram to microgram quantities per gram or unit surface area of a natural rubber containing product.

1.3 The test method is not designed to evaluate the potential of natural rubber containing materials to induce or elicit Type I (IgE-mediated) hypersensitivity reactions.

1.4 This test method should be used under controlled laboratory conditions to detect and quantify the level of 4 allergenic proteins found in natural rubber containing products. It should not be used to describe, appraise or assess the hazard or risk of these natural rubber containing materials or products under actual in use conditions.

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

1.6 *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:*[3]

D1193 Specification for Reagent Water

D4483 Practice for Evaluating Precision for Test Method Standards in the Rubber and Carbon Black Manufacturing Industries

D4678 Practice for Rubber—Preparation, Testing, Acceptance, Documentation, and Use of Reference Materials

D5712 Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method

D6499 Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

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

3. Terminology

3.1 *Definitions:*

3.1.1 *accepted reference value (ARV)*—value that serves as an agreed upon reference for comparison and which is derived as *(1)* a theoretical or established value, based on scientific principles, *(2)* an assigned or certified value, based on experimental work of some national or international organization, or *(3)* a consensus or certified value, based on collaborative experimental work under the auspices of a scientific or engineering group.

3.1.1.1 *Discussion*—ARV is an average industrial reference material (IRM) property or parameter value established by way of a specified test program. In this standard, the ARV as defined in the IRMs for the reference antigens and capture and detection antibodies is determined by analyzing a high and low

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[2] This procedure has not been validated for condoms, particularly lubricated condoms, which could contain surfactants or other ingredients that could interfere with the assay.

[3] 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.

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control in an inter-laboratory study and using the assigned values of these high and low controls to verify that the assay is in control and that the reagents are performing properly.

3.1.2 *accuracy*—the closeness of agreement between a test result and an accepted reference value.

3.1.3 *allergens*—protein antigens which induce allergic immune reactions typically mediated through IgE antibodies.

3.1.4 *analyte*—any element, ion, compound, substance, factor, infectious agent, cell, organelle, activity (enzymatic, hormonal, or immunological), or property the presence or absence, concentration, activity, intensity, or other characteristics of which are to be determined.

3.1.5 *antibody*—an immunoglobulin, a protein that is produced as a part of the humoral immune response which is capable of specifically combining with antigen.

3.1.5.1 *Discussion*—Any of numerous Y-shaped protein molecules produced by B lymphocytes as a primary immune response, each molecule and its clones having a unique binding site that can combine with the complementary site of an antigen, as on a virus or bacterium, thereby signaling other immune responses. (See *monoclonal antibody*.)

3.1.6 *antigen*—any substance that can stimulate the production of antibodies within an organism and combine specifically with them.

3.1.7 *background absorbance*—the absorbance reading in the solution resulting from non-specific interactions caused by the presence of chemicals, ions, etc., other than the analyte being measured.

3.1.8 *binding capacity—within the context of this document*, refers to the number of Hev b allergen molecules that a primary capture antibody can bind reproducibly under standardized assay conditions (pH, ionic strength, protein matrix, time, temperature).

3.1.9 *blocking solution*—a non-reactive protein solution used to prevent nonspecific antibody adsorption and to reduce background absorbance.

3.1.10 *calibration*—the standardization of an instrument setting or an assay configuration.

3.1.11 *calibration material/calibrator*—a material (for example, solution) of known quantitative/qualitative characteristics (for example, concentration, activity, intensity, reactivity) used to calibrate, graduate, or adjust a measurement procedure or to compare the response obtained with the response of a test specimen/sample.

3.1.12 *concentration range*—the recommended analyte concentration range in nanograms per mL to micrograms per mL that produces an absorbance reading from 0.1 to 2.0–3.0 units (depending on the instrument).

3.1.13 *data reduction algorithm*—a mathematical process that converts assay-response data (for example, absorbance units) into interpolated dose results.

3.1.13.1 *Discussion*—The dose–response relationship in the assay is defined by the standard, reference, or calibration curve.

3.1.14 *detection limit//limit of detection*—the smallest quantity of an analyte that can be reproducibly and a statistically significant manner distinguished from the variance of the background, or a zero calibrator in a given assay system.

3.1.14.1 *Discussion*—It is usually defined at the 95 % confidence interval and has also been called the lower detection limit or positive threshold of the assay; this term is not synonymous with analytical sensitivity.

3.1.15 *enzyme linked immunosorbent assay (ELISA)*—an immunological test method to quantify antigen or antibody levels using an enzyme as the detection mechanism.

3.1.16 *epitope/determinant—(1)* the minimum molecular structure of the antigenic site that will react with an antibody; *(2)* any site on an antigen molecule at which an antibody can bind; the chemical structure of the site determining the specific combining antibody.

3.1.17 *IgE*—human IgE is an immunoglobulin of the approximate molecular weight of 190 000, which exists normally in monomeric form and constitutes approximately 0.0005 % of the total serum immunoglobulins.

3.1.17.1 *Discussion*—It (IgE) binds with high affinity to FcεR1 receptors on mast cells and basophils and FcεRII receptors on a number of cells. IgE mediates the release of vasoactive mediators following the binding of allergen.

3.1.18 *immunoenzymetric assay (IEMA)*—a two-site non-isotopic immunological test method that employs two antibodies, a primary antibody to capture and a secondary enzyme conjugated antibody to detect the analyte of interest.

3.1.19 *immunoglobulin*—a glycoprotein composed of two heavy and two light chains that functions as an antibody. Human immunoglobulins have been subdivided into different isotypes (IgM, IgG, IgA, IgD, IgE), each of which possess a unique set of antigenic markers, physiochemical properties, and each of which produce a different pattern of effector functions (receptor binding, complement activation, opsonization).

3.1.19.1 *Discussion*—All antibodies are immunoglobulins, but it is not certain that all immunoglobulins possess antibody function.

3.1.20 *industry reference materials (IRM)*—materials that have been prepared according to a specified production process to generate a uniform lot; the parameters that define the quality of the lot are evaluated by a specified measurement program.

3.1.20.1 *Discussion*—IRMs are divided into two types according to the production process for generating the material.

3.1.21 *linearity*—the ability (within a given range) of an assay to provide results that are directly proportional to the concentration [amount] of the analyte in the test sample.

3.1.22 *monoclonal antibody*—antibody produced by cells created through the fusion of an antibody producing cell (B-lymphocyte) with immortal cancer cells.

3.1.22.1 *Discussion*—This fusion process produces a hybrid (hybridoma) that expresses properties of both cells. The cells are all identical since they derive from a single cell and are called "monoclonal."

3.1.23 *parallelism*—extent to which the dose–response relationship between two materials (that is, calibrator versus unknown specimens) is constant for the examined range of concentrations.

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3.1.23.1 *Discussion*—Parallelism is a property (and a requirement) of quantitative immunoassays in which the calibrator and test sera produce parallel dose–response curves.

3.1.24 *precision*—the closeness of agreement between independent test results obtained under prescribed conditions; agreement between replicate measurements.

3.1.24.1 *Discussion*—Precision has no numerical value but is expressed in terms of imprecision—the standard deviation (SD) or the coefficient of variation (CV: SD/mean) of the results in a set of replicate measurements.

3.1.25 *precision profile*—the precision of an assay across the analyte concentration range of interest.

3.1.25.1 *Discussion*—A precision profile is constructed by determining the standard deviation (or coefficient of variation) of replicate measurements (within assays, between assays, or between specimen dilutions within an assay) spanning the entire analyte concentration range, albeit without the exact knowledge of the true analyte concentration that is contained in the serum specimens. When the CV_{dose} (*Y*-axis) is graphed against the dose (*X*-axis), a precision profile plot is generated. The precision profile is also referred to as the "imprecision profile" by some investigators.

3.1.26 *primary antibody*—the antibody used first in an assay sequence that is specific for the antigen and is sometimes referred to as the capture antibody that binds the analyte of interest from a biological specimen.

3.1.27 *proficiency testing (PT)*—an independent (non-manufacturer sponsored) program in which challenge specimens are sent to participating laboratories to be evaluated in assays that measure a spectrum of analytes.

3.1.28 *qualitative assay*—an assay system that produces an indication of the presence or absence of an analyte but does not provide a precise estimate of the concentration of that analyte.

3.1.28.1 *Discussion*—A positive test result implies only that the assay signal exceeds the analytical threshold or positive cutoff point that has been set to obtain an arbitrary combination of diagnostic sensitivity and specificity.

3.1.29 *quantitative assay*—an assay system that produces an accurate and reproducible estimate of the concentration of an analyte in the test specimen.

3.1.29.1 *Discussion*—Its (quantitative assay) analysis involves interpolation from a calibration curve, which is referenced to a readily available standard reference preparation.

3.1.30 *quality control response*—level of analyte produced by an assay for a quality control specimen that has a previously defined analyte concentration range as defined by the manufacturer.

3.1.30.1 *Discussion*—Assay performance was evaluated by determining the agreement in Hev b 1, 3, 5 or 6.02 levels obtained for two quality control extracts containing a high or low level of each Hev b allergen, following analysis in multiple laboratories participating in the multi-center study.

3.1.31 *reference solution*—the solution against which the test sample is being compared.

3.1.32 *relative standard deviation (RSD)*—the coefficient of variation which is the standard deviation divided by the mean.

3.1.33 *repeatability*—precision under conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time.

3.1.34 *repeatability limit (r)*—the value below which the absolute difference between two individual test results obtained under repeatability conditions may be expected to occur with a probability of approximately 0.95 (95 %).

3.1.34.1 *Discussion*—The repeatability limit is 2.8 (~1.96 · square root of 2) times the repeatability standard deviation. This multiplier is independent of the size of the inter-laboratory study.

3.1.35 *reproducibility*—precision obtained under conditions where test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment.

3.1.36 *reproducibility limit (R)*—the value below which the absolute difference between two test results obtained under reproducibility conditions may be expected to occur with a probability of approximately 0.95 (95 %).

3.1.36.1 *Discussion*—The reproducibility limit is 2.8 (~1.96 · square root of 2) times the reproducibility standard deviation. This multiplier is independent of the number of laboratories participating.

3.1.37 *secondary antibody—in an IEMA*, it is the enzyme conjugated antibody used second in a sequence that is specific for the analyte or interest and that completes the sandwich of the analyte.

3.1.38 *standard solution*—the preparation containing a standard analyte that is used as a reference to which the unknown sample being measured is compared.

3.1.39 *substrate*—the material or substance upon which an enzyme reacts.

3.1.40 *titer*—the strength of an antibody in solution that takes into consideration its concentration and affinity.

4. Summary of Test Method

4.1 This standard defines a general laboratory method called the immunoenzymetric assay. The first step in the method involves the extraction of a latex-containing product using a procedure previously described in Test Methods D5712 and D6499. In brief, the latex product is extracted for 2 h in an aqueous buffer, typically at 5 to 10 mL per gram with agitation such as rotation or shaking. Following the extraction process, the extract is recovered and the level of 4 Hev b allergens is quantified using a two-site, non-competitive binding immunoenzymetric assay (IEMA) (**1**).[4]

4.2 The general IEMA design is based on the use of a monoclonal antibody which is specific for a single Hev b allergenic protein that is attached to a microtiter plate by adsorption. This "capture" antibody has also been called the primary antibody in the assay system. Following blocking of the microtiter plate, the "unknown or test" extracts of the latex

[4] The boldface numbers in parentheses refer to the list of references at the end of this standard.

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TABLE 1 Characterized Latex Allergens

NOTE 1—Hev b 1, 3, 5. and 6.02 have been set in boldface because these are the allergenic proteins that are quantified by the immunoenzymetic assays covered in this standard.

Name	Description	MW (kD)	Plant Family	Crossreactivity to Food
Hev b 1	**Rubber elongation factor**	**58/14.6**	**—**	**Papain, fig**
Hev b 2	Beta 1/3 glucanase	34–36	PR-2[A]	—
Hev b 3	**Prenyltransferase**	**24–27**	**—**	**—**
Hev b 4	Microhelix	110/115	—	—
Hev b 5	**Acidic protein**	**16**	**—**	**Kiwi**
Hev b 6.01	Hevein preprotein (Prohevein)	20	PR-3	Avocado, banana, chestnut
Hev b 6.02	**Hevein protein (Mature hevein)**	**4.7**	**PR-3**	**Avocado, banana, chestnut**
Hev b 7	Patatin homologue	43–46	—	Potato
Hev b 8	Hevea Profilin	14–14.2	Profilin	Pollens, celery
Hev b 9	Hevea Enolase	51	—	Molds
Hev b 10	Mn Superoxide Dismutase	22–26	—	Molds
Hev b 11	Class I Chitinase	33	PR-3	Banana, avocado
Hev b 12	Lipid Transfer Protein	9.4	PR-14	Peach, stone fruit
Hev b 13	Esterase	42	—	—
Hev b 14	Hevamine	30	—	—

[A] PR = pathogenesis-related.

product are pipetted into replicate wells in the plate. In a different part of the plate, calibrators with pre-defined levels of the relevant Hev b allergenic protein are pipetted in replicate to produce a calibration curve. These calibrators can be either reference proteins or working calibrators that have been cross-validated against the reference proteins. Additionally, two control extracts with pre-defined ranges are pipetted in replicates into their wells in the plate and these serve as positive controls to verify that the assay is in control. Accepted reference values are assigned by the manufacturer to these two control preparations. These controls permit the assessment of assay agreement between laboratories by determining the range and coefficient of variation of the quality control response (see 3.1.30). Following the incubation of the extract with the insolubilized capture antibody, the plate is washed and a horseradish peroxidase enzyme-labeled secondary or "detection" antibody is pipetted into all wells in the plate. This detection antibody binds to a second determinant or epitope on the Hev b allergenic protein that is already bound to the primary capture antibody. As such, the two antibodies are a matched pair that form a "sandwich" around the target Hev b allergen. Following the conjugated second antibody incubation, the plate is washed to remove unbound labelled antibodies and substrate is pipetted into all wells in the plate. The clear substrate is enzymatically converted to a colored product. The extent or intensity of the color is assessed in a microtiter plate reader at an appropriate wavelength. The final measured optical density in each well is proportional to the amount of enzyme-labeled detect antibody bound, which in turn is proportional to the amount of the Hev b allergenic protein bound. Interpolation of the unknown optical density from the calibration curve permits determination of the concentration of the Hev b allergenic protein in the test extracts.

4.3 This standard describes the IEMA generic procedure. There are in fact 4 separate IEMAs which are covered by this standard. These are IEMAs that quantify Hev b 1, Hev b 3, Hev b 5 and Hev b 6.02 in extracts, each with their own unique primary capture and secondary detection antibodies and calibrators.

5. Significance and Use

5.1 IgE-mediated allergic reactions to protein allergens in natural rubber latex derived from the *Hevea brasiliensis* tree emerged in the 1990s as a concern with occasional allergic manifestations. Symptoms encompassing hives, uriticaria, rhinitis, asthma and anaphylaxis have all been reported in latex allergic individuals exposed to products derived from natural rubber latex.

5.2 Since no safe level of Hevea latex allergen exposure is known, avoidance is the primary mode of treating latex allergy.

5.3 As a result of investigations conducted by many scientists across the world, fourteen latex allergens have so far been identified and categorized by the Allergen Nomenclature Sub-Committee of the International Union of Immunological Societies (IUIS) as Hev b 1 to Hev b 13 (Table 1) (see Specification D1193). Reported sensitization rates for these allergenic Hev b proteins vary among the many reports as a result of differences in the study populations, IgE antibody assay methods and the quality of the Hev b allergens used as calibrators and quality control reagents in the analysis. Most studies, however, agree that Hev b 1 and Hev b 3 are important allergens for individuals (for example, children with spina bifida) who are exposed through mucosal contact as a result of multiple surgeries or latex catheter use for an extended period of time. Additionally, investigators performing sensitization studies also agree that Hev b 5 and Hev b 6.02 are important allergens that may elicit sensitization in genetically-predisposed individuals who are exposed to natural rubber latex (**2-4**). On the basis of these clinical studies, assays for these four allergenic proteins (that is, Hev b 1, Hev b 3, Hev b 5 and Hev b 6.02) have been developed and they are thus the subject of this standard. Adoption of immunoenzymetric assay reagents and standard proteins needed to quantify other latex allergens (other than Hev b 1, 3, 5, and 6.02) in extracts of natural rubber latex products will require separate documentation and validation.

5.3.1 From the historical context, a number of assays have been developed to quantify the level of protein allergens and

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allergen in natural rubber latex containing products (see Practices D4483 and D4678).

5.3.2 The *modified Lowry* assay for total protein, Test Method D5712, was the first assay of this type. It assesses the level of total protein as an indirect indicator of allergenicity of latex-containing products. This assay does not discriminate between the allergenic and non-allergenic proteins.

5.3.3 The second assay to be developed involved the use of human latex-specific IgE antibody in a *competitive inhibition immunoassay* format to estimate the overall allergenic potency of a natural rubber product extract (**5**, **6**). The extract is incubated with human serum containing latex-specific IgE antibody and then this mixture is incubated with a solid phase latex allergosorbent. Latex allergenic proteins, if they are present, bind to the latex-specific IgE antibody in solution and they thus inhibit IgE antibody binding onto the latex allergosorbent. Allergosorbent bound IgE is then quantified and the extent of competitive inhibition of IgE binding is a measure of latex allergens. While this assay provides an estimate of the allergenicity or level of natural rubber allergens extractable from a product, difficulty in procuring reproducible lots of latex specific IgE containing human serum has precluded widespread use of this assay. For this reason, this assay has not been put forth as an ASTM standard.

5.3.4 A third assay design is similar to the human IgE based competitive inhibition immunoassay, but it employs rabbit antiserum instead of human serum containing IgE anti-latex. The *competitive inhibition enzyme linked immunosorbent assay* (ELISA) has been adopted as Test Method D6499. It measures latex proteins that elicit immune responses, but it cannot distinguish between latex allergens (IgE inducing) from non-allergenic antigens (non-IgE inducing).

5.3.5 The most recent assay, which is the subject of this standard, is the *two-site immunoenzymetric assay (IEMA)* which uses an insolubilized capture antibody to bind one of Hev b allergenic proteins from a latex product extract, and a second enzyme labeled detection antibody to detect bound allergens. Optical density responses are interpolated from reference curves constructed with known allergens. The performance characteristics of the reagents used in immunoenzymetric assays for Hev b 1, 3, 5 and 6.02 were investigated in the international collaborative study associated with the development of this standard and results are provided in Sections 15 through 17.

6. Interferences

6.1 Substances such as detergents or surfactants have the potential to prevent antibody binding to antigen and thus these additives could interfere in the IEMA. However, due to the sensitivity of the IEMA, these interferences often can be controlled by serially diluting the sample.

7. Apparatus

7.1 *96 Well Microtiter Assay Plate* (recommended high protein binding plates for optimal binding of capture antibody).

7.2 *Dilution Tubes,* low protein binding 12 × 75 mm (recommended polypropylene) test tubes for sample dilution.

7.3 *Mulitchannel Pipettors and Plastic Tips.*

7.4 *Analytical Balance.*

7.5 *Centrifuge* (capable of 1000× g) and appropriate tubes.

7.6 *Microtiter Plate Reader* and computer for data analysis.

7.7 *Microtiter Plate Sealing Tape.*

7.8 *Microtiter Plate Shaker.*

7.9 *Aspiration Device or a Microtiter Plate Washer.*

7.10 *End-Over-End Shaker.*

7.11 *Polypropylene Vessels,* for sample extraction.

8. Reagents and Materials

8.1 *Purity of Reagents*—Reagent grade chemicals shall be used in all tests. Unless otherwise indicated, it is intended that all reagents conform to the specifications of the Committee on Analytical Reagents of the American Chemical Society where such specifications are available.[5] Other grades may be used, provided it is first ascertained that the reagent is of sufficiently high purity to permit its use without lessening the accuracy of determination.

8.2 *Purity of Water*—Unless otherwise indicated, references to water shall be understood to mean reagent water as defined by specifications in Specification D1193.

8.3 *Buffers*—The buffers and solutions should be prepared before beginning the protocol. Preferably, all solutions containing protein are made in polypropylene tubes through the assay.

8.3.1 The Anti-Hev b coating buffer is a phosphate buffer of pH 6.0 to 9.0. The following buffer solutions may be used: sodium phosphate buffer or phosphate buffered saline or the equivalent of sufficient buffering capacity (at least 25 mM) to maintain the pH between 6.0 and 9.0. The procedure for phosphate buffered saline is provided below:

Phosphate Buffered Saline (PBS), pH 7.4; 1X Stock
1.5 mM KH_2PO_4—0.2 g
2.7 mM KCl—0.2 g
0.137 M NaCl—8.06 g
8.0 mM $Na_2HPO_4{\cdot}2H_20$—1.42 g

8.3.1.1 Dissolve ingredients in 800 mL of distilled water, adjust the pH to 7.4 if necessary and fill to 1000 mL. Alternatively, PBS can be purchased from a commercial source.

8.3.2 *PBS-BSA (Blocking Buffer)*—Add 0.5 g of BSA (bovine serum albumin) or BPLA (bovine plasma albumin) to 100 mL of PBS or the equivalent of sufficient buffering capacity (at least 25 mM) to maintain the pH between 6.0 and 9.0. Let the protein dissolve under gentle stirring at 25 ± 5°C. The amount needed for blocking one plate is approximately 30 mL. Store at 4 ± 3°C for a maximum of 2 weeks.

8.3.3 *Hev b 1 and Hev b 3 Assay Buffer*—The procedure for Hev b 1 and Hev b 3 Assay buffer is provided below:

[5] *Reagent Chemicals, American Chemical Society Specifications*, American Chemical Society, Washington, DC. For Suggestions on the testing of reagents not listed by the American Chemical Society, see *Annual Standards for Laboratory Chemicals,* BDH Ltd., Poole, Dorset, U.K., and the *United States Pharmacopeia and National Formulary,* U.S. Pharmacopeial Convention, Inc. (USPC), Rockville, MD.

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