



Standard Specification for Physical and Chemical Properties of Industry Reference Materials (IRM)¹

This standard is issued under the fixed designation D5900; 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 specification covers the chemical and physical quality specifications or requirements, or both, for Industry Reference Materials (IRMs) as cited in Practice D4678 and other standards.

1.2 IRMs, as evaluated and referenced in Practice D4678, are vitally important to conduct product, specification, and development testing in the rubber and carbon black industries.

1.3 Before a new lot of material can be accepted as an IRM, it must comply with the specifications prescribed in this specification. However, these specifications are only part of the requirements. Other requirements as given in Practice D4678 shall be met before a candidate material can be formally accepted as an IRM.

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

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

D88 Test Method for Saybolt Viscosity

D92 Test Method for Flash and Fire Points by Cleveland Open Cup Tester

D97 Test Method for Pour Point of Petroleum Products

D280 Test Methods for Hygroscopic Moisture (and Other Matter Volatile Under the Test Conditions) in Pigments

D287 Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method)

D445 Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity)

D611 Test Methods for Aniline Point and Mixed Aniline Point of Petroleum Products and Hydrocarbon Solvents

D1278 Test Methods for Rubber from Natural Sources—Chemical Analysis

D1416 Test Methods for Rubber from Synthetic Sources—Chemical Analysis³

D1500 Test Method for ASTM Color of Petroleum Products (ASTM Color Scale)

D1519 Test Methods for Rubber Chemicals—Determination of Melting Range

D1646 Test Methods for Rubber—Viscosity, Stress Relaxation, and Pre-Vulcanization Characteristics (Mooney Viscometer)

D1747 Test Method for Refractive Index of Viscous Materials

D1951 Test Method for Ash in Drying Oils and Fatty Acids³

D1959 Test Method for Iodine Value of Drying Oils and Fatty Acids³

D1960 Test Method for Loss on Heating of Drying Oils³

D1965 Test Method for Unsaponifiable Matter in Drying Oils, Fatty Acids, and Polymerized Fatty Acids³

D1980 Test Method for Acid Value of Fatty Acids and Polymerized Fatty Acids³

D1982 Test Method for Titer of Fatty Acids

D1993 Test Method for Precipitated Silica—Surface Area by Multipoint BET Nitrogen Adsorption

D2007 Test Method for Characteristic Groups in Rubber Extender and Processing Oils and Other Petroleum-Derived Oils by the Clay-Gel Absorption Chromatographic Method

D2140 Practice for Calculating Carbon-Type Composition of Insulating Oils of Petroleum Origin

D2161 Practice for Conversion of Kinematic Viscosity to Saybolt Universal Viscosity or to Saybolt Furol Viscosity

D2501 Test Method for Calculation of Viscosity-Gravity Constant (VGC) of Petroleum Oils

D3037 Test Method for Carbon Black—Surface Area by

¹ This specification is under the jurisdiction of ASTM Committee D11 on Rubber and is the direct responsibility of Subcommittee D11.20 on Compounding Materials and Procedures.

Current edition approved May 1, 2012. Published June 2012. Originally approved in 1996. Last previous edition approved in 2010 as D5900 – 10a. DOI: 10.1520/D5900-12.

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 Withdrawn. The last approved version of this historical standard is referenced on www.astm.org.

Nitrogen Adsorption³

- D3157 Test Method for Rubber from Natural Sources—Color
- D3194 Test Method for Rubber From Natural Sources—Plasticity Retention Index (PRI)
- D3280 Test Methods for Analysis of White Zinc Pigments
- D4004 Test Methods for Rubber—Determination of Metal Content by Flame Atomic Absorption (AAS) Analysis
- D4075 Test Methods for Rubber Compounding Materials—Flame Atomic Absorption Analysis—Determination of Metals
- D4315 Test Methods for Rubber Compounding Material—Zinc Oxide
- D4569 Test Method for Rubber Compounding Materials—Determination of Acidity in Sulfur
- D4570 Test Method for Rubber Chemicals—Determination of Particle Size of Sulfur by Sieving (Dry)
- D4571 Test Methods for Rubber Compounding Materials—Determination of Volatile Material
- D4572 Test Method for Rubber Chemicals—Wet Sieve Analysis of Sulfur
- D4574 Test Methods for Rubber Compounding Materials—Determination of Ash Content
- D4578 Test Methods for Rubber Chemicals—Determination of Percent Sulfur by Extraction
- D4678 Practice for Rubber—Preparation, Testing, Acceptance, Documentation, and Use of Reference Materials
- D4934 Test Method for Rubber Compounding Materials: 2-Benzothiazyl Sulfenamide Accelerators—Insolubles
- D4936 Test Method for Mercaptobenzothiazole Sulfenamide Assay by Reduction/Titration
- D5289 Test Method for Rubber Property—Vulcanization Using Rotorless Cure Meters
- D5712 Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method
- D6499 Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products
- D7427 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

3. Significance and Use

3.1 IRMs are vitally important in product and specification testing, in research and development work, in technical service work, and in quality control operations in the rubber and carbon black industries. They are especially valuable for referee purposes. Many ASTM rubber standards for the evaluation of natural or synthetic rubber require the use of specific IRMs in their test recipes for better laboratory repeatability and reproducibility.

3.2 New material lots that have been selected as candidates for IRM approval shall conform to the appropriate specifications given in this standard and meet requirements given in Practice D4678 before the lots may be accepted as IRMs.

3.3 The chemical and physical IRM specifications shown will ensure some consistency in IRM properties from one lot to the next. However, the specifications cannot ensure exact inter-lot consistency.

TABLE 1 Specification for IRM 1—Tetramethyl Thiuram Disulfide (TMTD)

Property	ASTM Designation	Limits
Melting point, °C	D1519	142 min
Ash, %	D4574	0.10 max
Loss on heating at 105°C, % loss	D4571	0.5 max
Wet sieve analysis, % retaining on 100 mesh screen	D4572	0.05 max

4. Specifications

4.1 The following are specifications for Industry Reference Materials (IRMs).

4.2 *Specification for IRM 1⁴—Tetramethyl Thiuram Disulfide (TMTD):*

4.2.1 Material description: Appearance is light buff to white powder. Specific gravity is 1.5. This material is commonly used in certain ASTM rubber test recipes as an accelerator in sulfur vulcanization.

4.2.2 Specifications are given in Table 1.

4.3 *Specification for IRM 2⁵—Benzothiazyl Disulfide (MBTS)*

4.3.1 Material description: Appearance is cream-colored powder. Specific gravity is 1.5. This material shall contain 2 ± 0.2 % mineral oil. This material is commonly used as an accelerator in certain ASTM rubber test recipes in sulfur vulcanization.

4.3.2 Specifications are given in Table 2.

4.4 *Specification for IRM 3⁶—N-tert-butyl-benzothiazole Sulfenamide (TBBS)*

4.4.1 Material description: Appearance is light tan or beige pellets approximately 1/8 in. long. Specific gravity is 1.28.

4.4.2 Specifications are given in Table 3.

4.5 *Specification for IRM 21⁶—Stearic Acid*

4.5.1 Material description: Appearance is a fine powder or flakes.

4.5.2 Specifications are given in Table 4.

4.6 *Specification for IRM 31⁶—Sulfur*

4.6.1 Material description: Appearance is light to pale yellow powder.

4.6.2 Specifications are given in Table 5.

4.7 *Specification for IRM 43⁷—Naphthenic Process Oil:*

4.7.1 Material description: Appearance is translucent dark liquid. Specific gravity is 0.9. This material is commonly used in certain ASTM rubber test recipes as a process oil. This oil has been hydrotreated.

4.7.2 Specifications are given in Table 6.

4.8 *Specification for IRM 91⁸—Zinc Oxide (ZnO):*

4.8.1 Material description: Appearance is a white powder. Specific gravity is 5.6. This material is commonly used in

⁴ Lot IRM 1a is no longer available; IRM 1b has not been approved.

⁵ A lot IRM 2a has been depleted. Lot IRM 2b has not been approved.

⁶ An approved lot has been reserved and is available from Akron Rubber Development Lab Inc., 300 Kenmore Blvd., Akron, OH 44301, website: www.ardl.com.

⁷ No approved lot of IRM 43 has been established.

⁸ An approved lot has been reserved and is available from R. E. Carroll, Inc., P.O. Box 5806, Trenton, NJ 08638-0806.

TABLE 2 Specification for IRM 2—Benzothiazyl Disulfide (MBTS)

Property	ASTM Designation	Limits
Melting point, °C	D1519	165 min
Ash, %	D4574	0.7 max
Loss on heating at 105°C, % loss	D4571	0.5 max
Wet sieve analysis, % retained on 100 mesh screen	D4572	0.1 max

TABLE 3 Specification for IRM 3—N-tert-butyl-benzothiazole Sulfenamide (TBBS)

Property	ASTM Designation	Limit/Target
Assay, %	D4936	96 min
Melting Point, Initial, °C	D1519	108 min
Melting Point, Final, °C	D1519	109 min
Volatile Matter, %	D1416	0.1 max
Ash, %	D4574	0.2 max
Insolubles in Methanol, %	D4934	0.3 max

TABLE 4 Specification for IRM 21—Stearic Acid

Property	ASTM Designation	Limit/Target
Mineral Acid		None
Acid Value	D1980	193 to 199 min
Titer, °C	D1982	66 min
Iodine Value, %	D1959	1.0 max
Loss on Heating, %	D1960	0.2 max
Ash, %	D1951	0.05 max
Fat, Unsaponifiables and Insoluble, %	D1965	0.5 max

TABLE 5 Specification for IRM 31—Sulfur

Property	ASTM Designation	Limit/Target
Organic Material, %		0.05 max
Volatile Matter, °C	D4571	0.5 max
Ash, %	D4574	0.3 max
Insoluble in CS ₂ , %	D4578	0.3 max
Acidity, %	D4569	0.005 max
Dry analysis, % retained on 100 mesh screen	D4570	0.0 max
Dry analysis, % retained on 200 mesh screen	D4570	5 to 10

TABLE 6 Specification for IRM 43—Naphthenic Process Oil

Property	ASTM Designation	Limits/Targets
Clay-gel absorption chromatographic analysis	D2007	
% Asphaltenes		0.3 max
% Polar compounds		6.0 max
% Saturated hydrocarbon		35.1 to 65.0
Viscosity @ 100°C, mm ² /s	D88 and D2161	16.8 ± 1.2
Viscosity-gravity constant	D2501	0.889 ± 0.002

many ASTM rubber test recipes as an activator and in ASTM test recipes for testing halogenated elastomers as a vulcanizing agent.

4.8.2 Specifications are given in **Table 7**.

4.9 *Specification for IRM 241⁶—Butyl Rubber*

4.9.1 Material description: Appearance is pale white solid rubber. This is a copolymer of isobutylene and isoprene (IIR). The rubber shall be stabilized with a non-staining antioxidant suitable for long-term storage. Specific gravity is 0.92. This

TABLE 7 Specification for IRM 91—Zinc Oxide (ZnO)

Property	ASTM Designation	Limits/Targets
Surface area, m ² /g	D4315 and D3037	4.3 ± 0.3
% Zinc oxide	D3280	99.5 min
% Lead	D4075	0.08 max
% Cadmium	D4075	0.08 max
Loss on heating @ 105°C % loss	D280	0.50 max
Wet sieve analysis, %, retains on 45 µm	D4315	0.10 max

TABLE 8 Specification for IRM 241—Butyl Rubber

Property	ASTM Designation	Limits/Targets
Mooney Viscosity mL 1 + 8 125°C (unmassed)	D1646	51 ± 1
Volatile matter, %	D1416	0.30 max
Ash, %	D1416	0.50 max

TABLE 9 Specification for IRM 901—Petroleum Oil

Property	ASTM Designation	Limit/Targets
Viscosity: cst @ 99°C	D445	19.23 ± 1.11
Gravity, API @ 16°C	D287	28.8 ± 1.0
Flash pt. COC, °C	D92	243 min
Aniline point, °C	D611	124 ± 1
Viscosity-gravity Constant	D2140	0.790 – 0.805
Naphthenics Cn%	D2140	27 (avg)
Paraffinics Cp%	D2140	65 min

TABLE 10 Specification for IRM 902—Petroleum Oil

Property	ASTM Designation	Limits/Targets
Viscosity: cst @ 99°C	D445	20.35 ± 1.15
Gravity, API @ 16°C	D287	20.0 ± 1.0
Flash pt. COC, °C	D92	232 min
Aniline point, °C	D611	93.0 ± 3.0
Viscosity-gravity constant	D2140	0.865 ± 0.005
Naphthenics Cn%	D2140	35 min
Paraffinics Cp%	D2140	50 max

material is commonly used for the quality control monitoring of Mooney viscometers in accordance with Test Methods **D1646**.

4.9.2 Specifications are given in **Table 8**.

4.10 *Specification for IRM 901⁸—Petroleum Oil:*

4.10.1 Material description: Appearance is a dark liquid. Specific gravity is 0.8. This oil is a severely solvent refined heavy paraffinic petroleum oil. Its CAS registry number is 64741-88-4. This oil is commonly used in ASTM oil immersion tests. Typical properties are as follows: Aromatics, Ca in accordance with Test Method **D2140** is 3 %; pour point in accordance with Test Method **D97** is –12°C; color in accordance with Test Method **D1500** is L3.5; refractive index in accordance with Test Method **D1747** is 1.4848; and UV absorption @ 260 nm is 0.8.

4.10.2 Specifications are given in **Table 9**.

4.11 *Specification for IRM 902⁸—Petroleum Oil:*

4.11.1 Material description: Appearance is a light yellow, translucent liquid. Specific gravity is 0.8. This oil is a severely hydrotreated naphthenic distillate. Its CAS registry number is 64742-52-5. This oil is commonly used in ASTM oil immersion tests. Typical properties are as follows: Aromatics, Ca in

TABLE 11 Specification for IRM 903—Petroleum Oil

Property	ASTM Designation	Limits/Targets
Viscosity: cst @ 38°C	D445	33 ± 1.1
Gravity, API @ 16°C	D287	22.0 ± 1.0
Flash pt. COC, °C	D92	163 min
Aniline point, °C	D611	70.0 ± 1.0
Viscosity-gravity constant	D2140	0.880 ± 0.005
Naphthenics Cn%	D2140	40 min
Paraffinics Cp%	D2140	45 max

accordance with Test Method **D2140** is 12 %; pour point in accordance with Test Method **D97** is – 12°C; color in accordance with Test Method **D1500** is L2.5; refractive index in accordance with Test Method **D1747** is 1.5105; and UV absorbance @ 260 nm is 4.0.

4.11.2 Specifications are given in **Table 10**.

4.12 *Specification for IRM 903⁸—Petroleum Oil:*

4.12.1 Material description: Appearance is a light yellow, translucent liquid. Specific gravity is 0.8. This oil is a severely hydrotreated naphthenic distillate. Its CAS registry number is 64742-52-5. This IRM is commonly used in ASTM oil immersion tests. Typical properties are as follows: Aromatics, Ca in accordance with Test Method **D2140** is 14 %; pour point in accordance with Test Method **D97** is – 31°C; color in accordance with Test Method **D1500** is L0.5; refractive index in accordance with Test Method **D1747** is 1.5026; and UV absorbance @ 260 nm is 2.2.

4.12.2 Specifications are given in **Table 11**.

4.13 *Specification for IRM 905⁸—Petroleum Oil:*

4.13.1 Material description: Appearance is an amber liquid. Specific gravity is 0.88. This oil is a severely solvent refined heavy paraffinic petroleum oil. Its CAS registry number is 64741-88-4. This oil is commonly used in ASTM oil immersion tests. Typical properties are as follows: Aromatics, Ca in accordance with Test Method **D2140** is 4 %; pour point in accordance with Test Method **D97** is – 5°C; color in accordance with Test Method **D1500** is L1.0; and refractive index in accordance with Test Method **D1747** is 1.4808.

4.13.2 Specifications are given in **Table 12**.

4.14 *Specification for IRM 913⁶—Ammoniated Latex Antigenic Protein*

4.14.1 Material description: Sealed vial for hypodermic extraction—500 test quantity.

4.14.2 Specifications are given in **Table 13**.

4.15 *Specification for IRM 914⁶—Rabbit Anti AL Antisera*

4.15.1 Material description: Sealed vial for hypodermic extraction—7500 test quantity.

4.15.2 Specifications are given in **Table 14**.

4.16 *Specification for IRM 915⁹—Mouse monoclonal antibody Hb1-5*

4.16.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.16.2 Specifications are given in **Table 15**.

4.17 *Specification for IRM 916⁹—Mouse monoclonal antibody Hb1-1*

TABLE 12 Specification for IRM 905—Petroleum Oil

Property	ASTM Designation	Limit/Targets
Viscosity: cst @ 99°C	D445	11.35 ± 0.55
Flash pt. COC, °C	D92	243 min
Aniline point, °C	D611	115 ± 1.0
Pour Point, °C (typical)	D97	–15
ASTM Color (typical)	D1500	L 1.0
Refractive Index (typical)	D1747	1.4808
Aromatics, C _A (%) (typical)	D2140	4

TABLE 13 Specification for IRM 913—Ammoniated Latex Antigenic Protein

Property	ASTM Designation	Limit/Target
Source	D6499	Ammoniated NR Latex (high and low)
Protein Amount	D5712	Stock solution should be adjusted to 1 mg protein per ml
AA Analysis	D5712	The correlation coefficient of AA composition between batches should be at least 0.90.
SDS-PAGE	D6499	Full distribution of NR proteins (between 5 kDa and 200 kDa)
Western blot profile	D6499	Full distribution of NR antigens (between 5 kDa and 200 kDa)
Inhibition ELISA	D6499	Adjust antigen content based on D6499 determination.

TABLE 14 Specification for IRM 914—Rabbit Anti-AL Antisera

Property	ASTM Designation	Limit/Target
Animal	D6499	Rabbits
Antigen	D6499	Ammoniated NR reference protein
Adjuvant Titer	D6499	Freund's complete and incomplete Minimum 1/8300
Western blot profile ^A	D6499	Reactivity with entire spectrum of SDS-PAGE ^B visible AL protein
Inhibition ELISA reactivity ^C	D6499	Comparative analysis of extracts from a minimum of 5 NR products

^A Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^B SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^C ELISA represents the enzyme linked immuno-sorbant assay.

4.17.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.17.2 Specifications are given in **Table 16**.

4.18 *Specification for IRM 917⁹—Hev b 1 Reference Protein*

4.18.1 Material description: Vials with lyophilized material—up to 1000 test quantity.

4.18.2 Specifications are given in **Table 17**.

4.19 *Specification for IRM 918⁹—Mouse monoclonal antibody Hb3-5*

4.19.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.19.2 Specifications are given in **Table 18**.

4.20 *Specification for IRM 919⁹—Mouse monoclonal antibody Hb3-10*

4.20.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.20.2 Specifications are given in **Table 19**.

⁹ An approved lot, IRM 915 to 924, has been reserved and is available from Scripps Laboratories, 6838 Flanders Drive, San Diego, CA 92121, website: www.scrippslabs.com.

TABLE 15 Specification for IRM 915—Mouse monoclonal antibody Hb1-5

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	rMBP-Hevb1 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/4000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Western blot profile ^B	D7427	Reactivity with FL ^C and Hev b 1 protein
Capture ELISA reactivity ^D	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^C Natural Rubber Latex designated as Field Latex.

^D ELISA represents the enzyme linked immuno-sorbant assay.

TABLE 16 Specification for IRM 916—Mouse monoclonal antibody Hb1-1

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	rMBP-Hevb1 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/3000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Western blot profile ^B	D7427	Reactivity with FL ^C and Hev b 1 protein
Capture ELISA reactivity ^D	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^C Natural Rubber Latex designated as Field Latex.

^D ELISA represents the enzyme linked immuno-sorbant assay.

TABLE 17 Specification for IRM 917—Hev b 1 Reference Protein

Property	ASTM Designation	Limit/Target
Source	D7427	r MBP-Hevb1
Protein amount	D7427	Stock solution should be adjusted to 1000 ng/mL
RP chromatography profile	D7427	One major peak detectable
Western blot profile ^A	D7427	One band detectable at molecular weight approximately 10-15 kDa
Capture ELISA reactivity ^B	D7427	Adjust antigen content based on D7427 determination

^A Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^B ELISA represents the enzyme linked immuno-sorbant assay.

4.21 Specification for IRM 920⁹—Hev b 3 Reference Protein

4.21.1 Material description: Vials with lyophilized material—up to 1000 test quantity.

4.21.2 Specifications are given in **Table 20**.

4.22 Specification for IRM 921⁹—Mouse monoclonal antibody Hb5-4

4.22.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.22.2 Specifications are given in **Table 21**.

TABLE 18 Specification for IRM 918—Mouse monoclonal antibody Hb3-5

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	rMBP-Hevb3 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/4,000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Western blot profile ^B	D7427	Reactivity with FL ^C and Hev b 3 protein
Capture ELISA reactivity ^D	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^C Natural Rubber Latex designated as Field Latex.

^D ELISA represents the enzyme linked immuno-sorbant assay.

TABLE 19 Specification for IRM 919—Mouse monoclonal antibody Hb3-10

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	rMBP-Hevb3 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/3000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Western blot profile ^B	D7427	Reactivity with FL ^C and Hev b 3 protein
Capture ELISA reactivity ^D	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^C Natural Rubber Latex designated as Field Latex.

^D ELISA represents the enzyme linked immuno-sorbant assay.

TABLE 20 Specification for IRM 920—Hev b 3 Reference Protein

Property	ASTM Designation	Limit/Target
Source	D7427	Field Latex (FL) ^A
Protein amount	D7427	Stock solution should be adjusted to 1000 ng/mL
RP chromatography profile	D7427	One major peak detectable
Western blot profile ^B	D7427	One band detectable at molecular weight approximately 20-25 kDa
Capture ELISA reactivity ^C	D7427	Adjust antigen content based on D7427 determination

^A Natural Rubber Latex designated as Field Latex.

^B Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^C ELISA represents the enzyme linked immuno-sorbant assay.

4.23 Specification for IRM 922⁹—Mouse monoclonal antibody Hb5-11

4.23.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.23.2 Specifications are given in **Table 22**.

4.24 Specification for IRM 923⁹—Hev b 5 Reference Protein

4.24.1 Material description: Vials with lyophilized material—up to 1000 test quantity.

4.24.2 Specifications are given in **Table 23**.

TABLE 21 Specification for IRM 921—Mouse monoclonal antibody Hb5-4

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	rMBP-Hevb5 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/3000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Capture ELISA reactivity ^B	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B ELISA represents the enzyme linked immuno-sorbant assay.

TABLE 22 Specification for IRM 922—Mouse monoclonal antibody Hb5-11

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	rMBP-Hevb5 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/3000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Capture ELISA reactivity ^B	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B ELISA represents the enzyme linked immuno-sorbant assay.

TABLE 23 Specification for IRM 923—Hev b 5 Reference Protein

Property	ASTM Designation	Limit/Target
Source	D7427	Natural Rubber Latex C-serum
Protein amount	D7427	Stock solution should be adjusted to 100 ng/mL
RP chromatography profile	D7427	One major peak detectable
Mass spectrometry profile	D7427	One major peak detectable at molecular weight approximately 16 kDa
Capture ELISA reactivity ^A	D7427	Adjust antigen content based on D7427 determination

^A ELISA represents the enzyme linked immuno-sorbant assay.

4.25 Specification for IRM 924⁹—Mouse monoclonal antibody Hb6.02-2

4.25.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.25.2 Specifications are given in **Table 24**.

4.26 Specification for IRM 925—Mouse monoclonal antibody Hb6.02-N3

TABLE 24 Specification for IRM 924—Mouse monoclonal antibody Hb6.02-2

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	Recombinant avidin-Hevb6.02 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/3000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Western blot profile ^B	D7427	Reactivity with FL ^C and Hev b 6.02 or Hev b 6.01 protein
Capture ELISA reactivity ^D	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^C Natural Rubber Latex designated as Field Latex.

^D ELISA represents the enzyme linked immuno-sorbant assay.

TABLE 25 Specification for IRM 925—Mouse monoclonal antibody Hb6.02-N3

Property	ASTM Designation	Limit/Target
Animal	D7427	Mouse
Antigen	D7427	Recombinant avidin-Hevb6.02 protein
Adjuvant	D7427	Freund's complete and incomplete
Titer	D7427	Minimum 1/3000
SDS PAGE Coomassie stain profile ^A	D7427	Two bands detectable
Western blot profile ^B	D7427	Reactivity with FL ^C and Hev b 6.02 or Hev b 6.01 protein
Capture ELISA reactivity ^D	D7427	Comparative analysis of extracts from a minimum of 5 NR products

^A SDS-PAGE represents sodium dodecylsulfate polyacrylamide gel electrophoresis.

^B Western blot represents the transfer of protein from SDS-Page to a membrane and subsequent antigen analysis using NR latex anti-sera.

^C Natural Rubber Latex designated as Field Latex.

^D ELISA represents the enzyme linked immuno-sorbant assay.

4.26.1 Material description: Vials with freezed material—up to 13 400 test quantity.

4.26.2 Specifications are given in **Table 25**.

4.27 Specification for IRM 926—Hev b 6.02 Reference Protein

4.27.1 Material description: Vials with lyophilized material—up to 1000 test quantity.

4.27.2 Specifications are given in **Table 26**.

5. Keywords

5.1 industry reference materials; IRM; reference materials

TABLE 26 Specification for IRM 926—Hev b 6.02 Reference Protein

Property	ASTM Designation	Limit/Target
Source	D7427	Natural Rubber Latex
Protein amount	D7427	Stock solution should be adjusted to 200 ng/mL
RP chromatography profile	D7427	One major peak detectable
Mass spectrometry profile	D7427	One major peak detectable at molecular weight approximately 4-5 kDa
Capture ELISA reactivity ^A	D7427	Adjust antigen content based on D7427 determination

^A ELISA represents the enzyme linked immuno-sorbant assay.

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