

Title: **NON PRESCRIPTION READING GLASSES**  
 Protocol Number: **KOHL'S – 903-K**

Test Property	Test Method	Samples	Test Principle / Requirements	Rating (Section or exec. Summary which failed items can be referenced)
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<b>LABELING</b>				
General Labeling Provisions	FDA 21 CFR 801.1 - 801.15	All Samples	<ul style="list-style-type: none"> <li>Name and place of business of manufacturer, packer or distributor</li> <li>Intended uses (labeled or advertised)</li> <li>No misleading statements</li> <li>Adequate directions for use</li> <li>Prominence of required label statements</li> </ul>	
Labeling Requirement For Over-the-Counter Reading Glasses	FDA 21 CFR 801.60 - 801.62	All Samples	<ul style="list-style-type: none"> <li>Principal display panel</li> <li>Statement of identity</li> <li>Declaration of net quantity</li> <li>Use of impact resistant lenses In reading glasses</li> </ul>	
Country Of Origin Marking	19 CFR 134	All Samples	<ul style="list-style-type: none"> <li>Shall indicate country of origin legibly and permanently and in a conspicuous place.</li> <li>Must be in a close proximity and in comparable size to the name of country or locality other than the country of origin appears on the marking</li> <li>Must be visible at point of purchase</li> </ul>	
Non-Prescription Ready-to-wear Magnifying Spectacles or Glasses	New York Code, Title 8, Article 144 - 7127	All Samples	"ATTENTION; READY-TO-WEAR NON-PRESCRIPTION GLASSES ARE NOT INTENDED TO REPLACE PRESCRIBED CORRECTIVE LENSES OR EXAMINATIONS BY AN EYE CARE PROFESSIONAL. CONTINUOUS EYE CHECK-UPS ARE NECESSARY TO DETERMINE YOUR EYE HEALTH STATUS AND VISION NEEDS."	
#Verify Label Claims	Visual Check	All Samples	The labeling must comply and valid with all claims.	
Adult Tracking Label: **If space limitations exist, contact Kohl's Quality Assurance & Product Integrity teams to discuss minimum required information <a href="mailto:mr.qa.pi@kohls.com">mr.qa.pi@kohls.com</a>	Kohl's Requirement	All	Can be included on packaging when necessary: Kohl's Assigned Factory Number Manufacture Date (Month/Year) UPC #	

<b>PHYSICAL CHARACTERISTICS</b>				
Frame Size Measurement	Standard Measure	3 samples	As approved/ product specification/ as claimed/ as measured (+5% / -0%)	

<b>CONSTRUCTION/LENS MATERIAL QUALITIES</b>				
Kohl's Workmanship Review	Visual Check / Actual Use	All Samples	<ul style="list-style-type: none"> <li>All components shall be provided as claimed and shall not be deformed or fractured.</li> <li>All hardware shall be provided</li> <li>All welds shall be smoothly finished and free from pits and splatter</li> <li>All components shall not contain any</li> </ul>	

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			burrs or sharp edges (Test by touch or sight) <ul style="list-style-type: none"> <li>Product shall not contain any loose components or unsecured fastening where rigidity is required</li> </ul>	
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**CONSTRUCTION/LENS MATERIAL QUALITIES (Cont.)**

Cosmetic Quality Of The Lens	With Reference to ANSI Z80.3 Section 4.8	All Samples	<ul style="list-style-type: none"> <li>Visually inspect the lens at about 12" from an open-shaded 40W incandescent clear lighting against a dark background</li> <li>Shall be reasonably free of pits, scratches, grayness, water marks, bubbles, cracks, striae, inclusions and local irregularities which produce aberrations that would impair or prevent the normal use of the lens as intended</li> </ul>	
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*Impact Resistance Of The Lens	FDA 21 CFR 801.410	Refer to Annex A	Under 21 CFR 801.410(c)(3), it is required to test a statistically significant sample of over-the-counter glass lenses from each production batch. And FDA accepts the Acceptable Quality Level (AQL) of 6.5, General Inspection Level II. (See Annex A) <p>A lens will be considered as not complying with the requirements when it has fractured as one of the followings:</p> <ul style="list-style-type: none"> <li>(i) It cracks through its entire thickness, including a laminar layer;</li> <li>(ii) It cracks across a complete diameter into two or more separate pieces, or</li> <li>(iii) Any lens material visible to the naked eyes becomes detached from the ocular surface;</li> <li>(iv) The test ball passes through the lens.</li> </ul> <p><b>In lieu of testing, Certification Statement (See Annex B) dated within one year can be submitted for review.</b></p> <p>Note: Supplier shall maintain the records of testing for a period of three (3) years from the date of shipment, and copies will be forwarded to FDA upon request.</p>	
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**PERFORMANCE**


*Single-Vision Ready-to-Wear Near-Vision Spectacles (if applicable)	ANSI Z80.31	4 Samples	Shall comply with the requirements of ANSI Z80.31	
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Normal Use/Functionality	Actual Use	1 Sample	Shall withstand 500 cycles of normal use. No structural failure. No loose parts. Temple arms, hinges and nose pads must be functional as intended after testing.	
Impact Resistance	ASTM F963	1 Samples	Shall be functional after 4 drops from 3 feet height.	
Effects Of Extreme Temperature (Environmental)	Kohl's TM 30	1 Sample	24 Hours @ 0° F (-18°C) and 24 Hours @ 180° F (82°C). No fractured, crazed or delaminated lens. No frame damage or flaws. Any marking on the frame should remain permanent and legible.	
*Blue Light Blocking verification (If claimed)	With reference to ANSI Z80.3 Section 4.10.5	1 Sample	The blue light transmittance from 380nm-500nm shall not exceed x +0.5%  Note: x = the claimed blue light transmittance If no claim made, report as data	
*Abrasion resistant test of spectacle lens (If claimed)	With reference to ISO 8980-5	1 Sample	Rub the lens surface with the prepared tool applying the force of (5±1) N for 25 cycles. A cycle is defined as one stoke in one direction, followed by a return stoke in the opposite direction. A stroke is defined as one pass in one direction on the surface being tested. The center of the abrasion track shall pass within ±2mm of the geometric center with a stroke length of (30±5)mm. .The test shall be conducted at a rate of (1±0,1) cycle per second.  -The surface tested shall be free of visible abrasion.  Note: Test on both front and back surfaces	
*Boiling Water Test (Applicable to Tinted Lens)	Visual Check	1 Sample	Tinted lens is boiled in water for a period of 10 minutes. No fractured, crazed or delaminated lens.	
*Boiling Salt Water and Cross-Cut Adhesion Test (Applicable to Coated Lens)	ASTM D3359 (Mod.) Visual Check	1 Sample	<ul style="list-style-type: none"> <li>Coated lens is boiled in 1% saline water for a period of 10 minutes. No fractured, crazed or delaminated lens.</li> <li>1" long X-cut is made in the coating at the clean and dried center position. Any peeling or removal of coating along the incisions or at their intersection by the tape should be not more than 1/16".</li> </ul>	
Flammability	With reference to ANSI Z80.3 Section 5.3	1 Sample	No part of the reading glasses shall ignite within the specified test period. Deformation or any other deterioration, other than ignition, is permitted.	

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<b>ANALYTICAL</b>				
*Toxicology (Plastic Components)	FDA 21 CFR 170-189	1 Sample	MSDS document review <u>or</u> must comply with applicable requirements of FDA.	
*Lead In Scrapable Surface Coating	CPSC-CH-E1003-09	1 Sample	≤90 ppm (0.0090% by weight). (CPSA – 16 CFR 1303)	
*Nickel Spot Test – Metal Frame (Qualitative)	<u>PD CR 12471</u>	1 Sample	Negative test result (Applicable to direct & prolong skin contact metallic components only)	
*Lead in Accessible Plastic Component	EPA SW 846 Method # 3050B/3051A /3052 (Mod.)	1 Sample	Lead ≤ 200ppm (0.02% by weight)	
* CA Prop 65	Refer to Protocol 1300	All Samples	All samples shall be reviewed against the requirements of California Proposition 65 to determine if additional testing or labeling is required.	
Polycarbonate eyewear products (prescription glasses and sunglasses, over-the-counter (OTC) reading glasses, non-prescription sunglasses, and safety glasses)  <i>*Implement for SP21 Shipments</i>	Acetonitrile extraction & LC/MS/MS	1 Sample	<b>Bisphenol A (BPA):</b> PC Temple ≤ 25 µg/g PC Nose pad ≤ 68 µg/g PC Frame ≤ 120 µg/g PC Lens ≤ 302 µg/g SUD 2020-04-17 by OEHHA	<i>If pass below BPA requirements, Prop 65 warning is not needed. If fail requirements need to discuss with Kohl's PI to use Prop 65 Warning</i>
BPA in sunglasses Accessible coating and plastic only		1 samples	<b>Client requirement</b> Product shall carry an appropriate warning label   <b>WARNING:</b> This product can expose you to chemicals including Bisphenol A, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to <a href="http://www.P65Warnings.ca.gov">www.P65Warnings.ca.gov</a>	



**KOHL'S TEST PROTOCOL**

Approved: Aug 21, 2020

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**Annex A: Impact Resistance Test (21 CFR 801.410)**

Test sample size for Pairs of Reading Glasses (L.H.S. Lens & R.H.S. Lens)

Lot or Batch Size (Pairs of reading glasses)	Test sample size (Pairs of reading glasses) required
2 - 8	2
9 - 15	3
16 - 25	5
26 - 50	8
51 - 90	13
91 - 150	20
151 - 280	32
281 - 500	50
501 - 1200	80
1201 - 3200	125
3201 - 10000	200

**Annex B**

Certification Statement of Impact Resistance

" \_\_\_\_\_ " (Name of manufacturer or seller) hereby guarantees that the articles listed herein are impact-resistant within the meaning of 21 CFR 801.410 and have been tested pursuant to that section. Impact-resistant lenses are not unbreakable or shatterproof. Records of testing will be maintained for a period of three (3) years from the date of shipment, and copies will be forwarded to FDA upon request.  
(Signature and street address of manufacturer or seller)

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Protocol Version	Description of Change	Revised by / Date	Approved by / Date
903-A	Initial Release	Elizabeth Armstrong DRAFT	Ro Jain DRAFT
903-B	Added composite testing requirements for phthalates testing	Elizabeth Armstrong DRAFT	Ro Jain DRAFT
903-C	Separate the test line of Prop 65 to supplementary protocol	John Wong Mar 07, 2013	Ro Jain Apr 15, 2013
903-D	Removed Cadmium in Accessible Plastic Component	Birkoff Chen Jan 30, 2014	Jeetendra Shelatkar Jan 30, 2014
903-E	Price Adjustment on lead content test	Candy Chan Jul 30, 2014	Jeetendra Shelatkar Aug 4, 2014
903-F	Added blue light test line	Teana Robinette April 4, 2019	Teana Robinette April 4, 2019
903-G	Updated method for blue light testing	Elizabeth Armstrong April 30, 2019	Elizabeth Armstrong April 30, 2019
903-H	Added Annex B	Cindy Ng Jun 13, 2019	Elizabeth Armstrong June 13, 2019
903-I	Updated Cosmetic Quality of the lens to be correct section number	Charlene Swanson June 21, 2019	Charlene Swanson June 21, 2019
903-J	Added adult tracking label requirements	Elizabeth Armstrong June 15, 2020	Elizabeth Armstrong June 15, 2020
903-K	Added BPA requirements	Elizabeth Armstrong Aug 21, 2020	Elizabeth Armstrong Aug 21, 2020