

# SHANXI HONGJIN PLASTIC TECHNOLOGY CO., LTD.

## PROTOCOL FOR SHELF LIFE DETERMINATION STUDY

### 1.0 Purpose:

Conduct shelf life determination for Nitrile Examination Gloves, Black as per EN455-4, so as to determine its shelf life.

### 2.0 Standard:

2.1 EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

2.2 EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

2.3 EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

### 3.0 Samples Information:

Size: M

**Product Name:** Nitrile Examination Gloves, Black

**Product Lot No. and quantity:** Random sample three production lots from production lines (about 15 cases per lot, and 1000 pieces/ case), conduct shelf life determination study per item 5.1-5.3.

### 4.0 Instruction of Sampling Testing:

According to EN455-1 and EN455-2, sample gloves individually from three production lots and conduct the following testing and record the testing data under the condition of time zero, accelerated aging or real time shelf life determination.

Item	Criteria	Quantity and Acceptance Criteria
Length (mm)	$\geq 240\text{mm}$	13 pieces, median
Width (mm)	$95\pm 10\text{mm}$	13 pieces, median
Thickness (mm)	Middle Fingertip $t_f$	13 pieces
	Test piece $t_x$	
Force at Break (N)	$\geq 6\text{N}$	13 pieces, median
Watertightness	---	G-I, AQL1.5, sampling 200 pieces (Ac7, Re 8)
Notes: 1. Condition of sampling testing: Temperature: $23\pm 2^\circ\text{C}$ , Humidity: $50\pm 5\%$ 2. Samples shall be conditioned at least 16 hours before testing.		

If all the testing results comply with the criteria requirements, then the lot of products will be accepted. On the contrary, it will be rejected.

### 5.0 Shelf Life Determination Study:

#### 5.1 Time Zero Testing:

5.1.1 It is estimated to conduct time zero testing for gloves from May 13, 2021. The testing will be conducted and recorded per item 4.0 after the randomly sampled gloves are conditioned. Analyze

the testing data so as to ensure that original testing data for the gloves for shelf life determination comply with standard requirements.

5.1.2 If it is determined that the time zero testing result comply with standard requirements, start accelerated aging shelf life determination study and real time study.

**5.2 Accelerated Aging Shelf Life Testing:**

5.2.1 As per Annex B in EN 455-4, 4 different temperatures and 5-time point at each temperature are used for accelerated aging shelf life testing, and the testing is continued at least 120 days. The selected temperature and days are as follows:

# \ Temp	80°C	70°C	60°C	50°C
1	1 Day	1 Day	5 Days	22 Days
2	2 Days	3 Days	15 Days	35 Days
3	3 Days	7 Days	22 Days	55 Days
4	4 Days	8 Days	35 Days	90 Days
5	5 Days	10 Days	42 Days	120 Days

5.2.2 As per the arrangements in the above table, the schedules for each testing are as follows:

Temp	80°C	70°C	60°C	50°C
Testing Period	Estimated testing period is: 2021.05.13-18	Estimated testing period is: 2021.05.13-23	Estimated testing period is: 2021.05.13-06.24	Estimated testing period is: 2021.05.13-09.10

5.2.3 Conduct accelerated aging for 3 lots of products at each selected temperature and time, and make relative testing and records as per item 4.0 after completing accelerated aging. Analyze and evaluate each testing data after each testing.

**6.0 Standard for Shelf Life Determination**

6.1 Shelf life determination for accelerated aging shelf life testing: After completing relative testing required in item 5.1 and 5.2, if each testing data comply with EN 455-1 and EN 455-2, then it is acceptable to claim that the shelf life of the gloves is 3 years.

6.2 It is not acceptable to claim that the shelf life of the Gloves is 5 years till the real time testing is completed.

**7.0 Record and Files:**

Details for shelf life determination study refer to corresponding testing report, and the testing data and report shall be filed permanently.

Prepared by: *Xiao Weili* / QA Director

Date: May 10, 2021

Reviewed by: *Wu Zhigang* / General Manager

Date: May 10, 2021

# SHANXI HONGJIN PLASTIC TECHNOLOGY CO., LTD.

## PERFORMANCE TESTING REPORT AT TIME ZERO

### Purpose:

As per EN455-4, carry out performance test at time zero to verify and determine whether the product of Nitrile Examination Gloves, Black conform to associate standard requirements, and provide basic data for determining shelf life of the product.

Date Tested: 2021.05.13

### Samples Tested:

Size: M

Product Name: Nitrile Examination Gloves, Black

Product Lot No.: 21051309141A

21051311141A

21051313141A

### Standards:

EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 21051309141A:**

#### **1. PERFORMANCE TESTING AT TIME ZERO----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Conditioning: At least 16 hours

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	96	6.3
2	M	235	0.09	0.11	97	6.3
3	M	240	0.10	0.11	96	6.2
4	M	238	0.10	0.11	97	6.1
5	M	241	0.09	0.12	97	6.1
6	M	233	0.09	0.11	96	6.1
7	M	241	0.10	0.12	97	6.0
8	M	241	0.10	0.12	97	5.9
9	M	240	0.09	0.11	97	5.8
10	M	242	0.10	0.11	97	5.7

11	M	238	0.09	0.12	97	5.7
12	M	240	0.10	0.12	97	5.7
13	M	242	0.09	0.11	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

## 2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

## 3. FINAL RESULTS of LOT NO. 21051309141A:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## II. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 21051311141A

### 1. PERFORMANCE TESTING AT TIME ZERO----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded results for force at break shall conform to the values of at least 6N.

Conditioning: At least 16 hours

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	237	0.10	0.12	97	6.4
2	M	244	0.09	0.11	97	6.3
3	M	242	0.10	0.12	97	6.2
4	M	240	0.10	0.11	97	6.2
5	M	240	0.09	0.12	96	6.1
6	M	242	0.09	0.11	97	6.1
7	M	242	0.10	0.12	97	6.1
8	M	242	0.09	0.12	97	5.9
9	M	233	0.09	0.11	96	5.9
10	M	239	0.10	0.11	97	5.8
11	M	234	0.09	0.12	97	5.7
12	M	245	0.10	0.12	97	5.7
13	M	238	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the It is It is It is showed from the above data that the performance testing of samples conform to the

specification (Force at Break  $\geq 6N$ ).

## 2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

## 3. FINAL RESULTS of LOT NO. 21051311141A:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## III. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 21051313141A

### 1. PERFORMANCE TESTING AT TIME ZERO ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded results for force at break shall conform to the values of at least 6N.

Conditioning: At least 16 hours

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.10	0.12	97	6.5
2	M	247	0.09	0.11	97	6.4
3	M	243	0.09	0.11	96	6.3
4	M	236	0.10	0.11	96	6.3
5	M	240	0.09	0.12	97	6.1
6	M	245	0.09	0.11	97	6.1
7	M	236	0.10	0.12	97	6.1
8	M	237	0.09	0.11	97	5.9
9	M	241	0.09	0.11	96	5.9
10	M	242	0.10	0.11	97	5.8
11	M	246	0.09	0.12	97	5.7
12	M	243	0.10	0.12	97	5.7
13	M	239	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

## 2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### 3. FINAL RESULTS of LOT NO. 21051313141A:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### IV. FINAL RESULT FOR PERFORMANCE TESTING AT TIME ZERO:

Through the performance test at time zero on 3 lots products (Lot No: 21051309141A, 21051311141A, 21051313141A) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: *Xiao Weili*  
Xiao Weili / QA Director

Date: May 14, 2021

Reviewed by: *Wu Zhigang*  
Wu Zhigang / General Manager

Date: May 14, 2021

# SHANXI HONGJIN PLASTIC TECHNOLOGY CO., LTD.

## PERFORMANCE TESTING REPORT @ 80°C FOR 5 TIME POINT

### Purpose:

As per EN455-4, carry out accelerated aging property test at 80°C for 5-time point (namely 1 day, 2 days, 3 days, 4 days, and 5 days) to verify and determine the shelf-life of Nitrile Examination Gloves, Black.

**Date Tested:** 2021.05.13-18

### Samples Tested:

Size: M

**Product Name:** Nitrile Examination Gloves, Black

**Product Lot No.:** 21051309141A

21051311141A

21051313141A

### Standards:

EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C OF LOT NO. 21051309141A**

#### **1. Accelerated Aging Condition: 80°C@ 1 day      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	235	0.10	0.12	97	6.4
2	M	245	0.09	0.12	97	6.3
3	M	240	0.10	0.11	97	6.2
4	M	245	0.10	0.11	96	6.2
5	M	240	0.09	0.12	97	6.1
6	M	230	0.09	0.11	96	6.1
7	M	241	0.10	0.12	97	6.1
8	M	240	0.09	0.11	97	6.0
9	M	230	0.09	0.11	97	6.0
10	M	235	0.10	0.11	97	5.9

11	M	240	0.09	0.12	96	5.8
12	M	241	0.10	0.12	97	5.7
13	M	247	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **2. Accelerated Aging Condition: 80°C @ 2 days      Conditioning: At least 16 hours**

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 20°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.09	0.12	97	6.5
2	M	250	0.09	0.11	97	6.3
3	M	247	0.09	0.12	97	6.2
4	M	243	0.10	0.11	96	6.2
5	M	243	0.10	0.12	97	6.1
6	M	240	0.09	0.11	97	6.1
7	M	238	0.10	0.12	96	6.1
8	M	240	0.09	0.11	97	6.0
9	M	235	0.09	0.11	97	6.0
10	M	240	0.10	0.11	96	5.9
11	M	246	0.09	0.12	97	5.8
12	M	234	0.10	0.12	97	5.8
13	M	235	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 2 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 80°C @ 3 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	244	0.10	0.12	96	6.4
2	M	242	0.09	0.11	97	6.4
3	M	242	0.09	0.11	97	6.2
4	M	240	0.10	0.11	97	6.2
5	M	240	0.09	0.12	96	6.2
6	M	235	0.10	0.11	96	6.1
7	M	234	0.10	0.12	97	6.1
8	M	240	0.09	0.11	97	6.0
9	M	240	0.09	0.11	96	6.0
10	M	246	0.10	0.11	97	5.8
11	M	240	0.09	0.12	97	5.8
12	M	242	0.10	0.12	97	5.7
13	M	240	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break ≥6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 3 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can

be used normally.

**4. Accelerated Aging Condition: 80°C @ 4 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	247	0.10	0.12	97	6.4
2	M	240	0.09	0.11	97	6.3
3	M	245	0.09	0.11	96	6.2
4	M	242	0.10	0.11	97	6.2
5	M	245	0.09	0.12	97	6.2
6	M	242	0.09	0.11	96	6.2
7	M	240	0.10	0.12	97	6.2
8	M	235	0.09	0.11	97	6.1
9	M	245	0.09	0.11	97	6.0
10	M	242	0.10	0.11	97	5.9
11	M	242	0.09	0.12	97	5.7
12	M	243	0.10	0.12	96	5.7
13	M	240	0.09	0.11	97	5.6
Median Value						6.2

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 4 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 80°C @ 5 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length	Thickness (mm)	Palm	Force at
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		(mm)	Test Piece	Middle Fingertip	Width (mm)	Break (N)
1	M	242	0.09	0.12	97	6.4
2	M	235	0.09	0.11	96	6.3
3	M	240	0.09	0.11	97	6.2
4	M	236	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	245	0.09	0.11	96	6.1
7	M	231	0.10	0.12	97	6.1
8	M	240	0.09	0.11	97	6.0
9	M	240	0.09	0.11	96	6.0
10	M	242	0.10	0.11	97	5.9
11	M	240	0.09	0.12	97	5.8
12	M	247	0.10	0.12	97	5.7
13	M	241	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 5 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 6. FINAL RESULTS of LOT NO. 21051309141A :

Final performance-testing results of samples at conditions of 80°C@ 1 day, 80°C@ 2 days, 80°C@ 3 days, 80°C@ 4 days, 80°C@ 5 days conform to associate standard requirements, and can be used normally.

## II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C OF LOT NO. 21051311141A

### 1. Accelerated Aging Condition: 80°C @ 1 day Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length	Thickness (mm)	Palm	Force at
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		(mm)	Test Piece	Middle Fingertip	Width (mm)	Break (N)
1	M	242	0.10	0.12	97	6.3
2	M	241	0.09	0.11	97	6.3
3	M	240	0.09	0.11	96	6.3
4	M	237	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	243	0.09	0.11	96	6.1
7	M	241	0.10	0.12	97	6.1
8	M	245	0.09	0.11	96	6.0
9	M	235	0.09	0.11	96	6.0
10	M	238	0.10	0.11	96	5.8
11	M	245	0.09	0.12	97	5.8
12	M	241	0.10	0.12	97	5.7
13	M	243	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **2. Accelerated Aging Condition: 80°C @ 2 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	96	6.5
2	M	240	0.09	0.11	97	6.4
3	M	240	0.09	0.12	97	6.2
4	M	242	0.10	0.11	96	6.2
5	M	240	0.09	0.12	97	6.1
6	M	243	0.09	0.11	97	6.1

7	M	250	0.10	0.12	97	6.1
8	M	235	0.09	0.11	97	6.1
9	M	245	0.09	0.11	97	6.1
10	M	240	0.10	0.11	96	6.0
11	M	234	0.09	0.12	97	5.8
12	M	243	0.10	0.12	96	5.7
13	M	240	0.09	0.12	96	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	3

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C@ 2 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 80°C @ 3 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli      Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	237	0.10	0.12	97	6.5
2	M	245	0.09	0.11	97	6.3
3	M	240	0.09	0.12	97	6.3
4	M	242	0.10	0.11	96	6.2
5	M	243	0.09	0.12	97	6.2
6	M	241	0.09	0.11	97	6.1
7	M	240	0.10	0.12	96	6.1
8	M	242	0.09	0.11	97	6.1
9	M	240	0.09	0.11	97	6.0
10	M	235	0.10	0.11	97	5.8
11	M	242	0.09	0.12	97	5.8
12	M	234	0.10	0.12	96	5.7
13	M	240	0.09	0.11	97	5.6

Median Value	6.1
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It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 3 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 80°C @ 4 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	96	6.3
2	M	240	0.09	0.11	97	6.3
3	M	240	0.09	0.11	97	6.2
4	M	234	0.10	0.11	97	6.2
5	M	242	0.09	0.12	96	6.1
6	M	248	0.09	0.11	97	6.1
7	M	240	0.10	0.12	97	6.0
8	M	235	0.09	0.11	96	6.0
9	M	240	0.09	0.11	97	6.0
10	M	237	0.10	0.11	97	5.9
11	M	241	0.09	0.12	96	5.7
12	M	236	0.10	0.12	97	5.7
13	M	242	0.09	0.11	97	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 4 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 80°C @ 5 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	247	0.10	0.12	97	6.5
2	M	240	0.09	0.11	96	6.4
3	M	242	0.09	0.11	96	6.3
4	M	237	0.10	0.11	97	6.2
5	M	242	0.09	0.12	96	6.1
6	M	242	0.09	0.11	96	6.1
7	M	240	0.10	0.12	97	6.1
8	M	240	0.09	0.12	96	6.0
9	M	232	0.09	0.11	96	6.0
10	M	250	0.10	0.11	97	5.9
11	M	242	0.09	0.12	96	5.8
12	M	234	0.10	0.12	96	5.7
13	M	240	0.09	0.11	96	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq$ 6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 5 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051311141A :**

Final performance-testing results of samples at conditions of 80°C@ 1 day, 80°C@2 days, 80°C@ 3 days, 80°C@ 4 days, 80°C@ 5 days conform to associate standard requirements, and can be used normally.

### III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C OF LOT NO. 21051313141A

#### 1. Accelerated Aging Condition: 80°C @ 1 day Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.10	0.12	96	6.4
2	M	240	0.09	0.11	96	6.3
3	M	244	0.09	0.11	97	6.2
4	M	240	0.10	0.11	97	6.2
5	M	242	0.09	0.12	97	6.1
6	M	240	0.09	0.11	97	6.1
7	M	241	0.10	0.12	97	6.1
8	M	240	0.09	0.11	96	6.0
9	M	234	0.09	0.11	97	6.0
10	M	240	0.10	0.11	97	5.9
11	M	241	0.09	0.12	97	5.8
12	M	240	0.10	0.12	96	5.7
13	M	242	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 80°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 2. Accelerated Aging Condition: 80°C @ 2 days Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.09	0.12	97	6.4
2	M	240	0.09	0.11	97	6.3
3	M	242	0.09	0.12	96	6.3
4	M	240	0.10	0.11	96	6.2
5	M	241	0.09	0.12	97	6.1
6	M	238	0.09	0.11	97	6.1
7	M	244	0.10	0.12	96	6.1
8	M	241	0.09	0.11	97	6.0
9	M	240	0.09	0.11	96	6.0
10	M	242	0.10	0.11	97	5.9
11	M	242	0.09	0.12	97	5.8
12	M	243	0.10	0.12	97	5.7
13	M	235	0.09	0.11	96	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 2 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **3. Accelerated Aging Condition: 80°C @ 3 days      Conditioning: At least 16 hours**

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.09	0.12	97	6.3

2	M	240	0.09	0.11	97	6.3
3	M	242	0.09	0.11	97	6.2
4	M	240	0.10	0.11	97	6.2
5	M	242	0.09	0.12	97	6.1
6	M	241	0.09	0.11	96	6.1
7	M	242	0.10	0.12	97	6.1
8	M	240	0.09	0.11	96	6.0
9	M	242	0.09	0.11	96	6.0
10	M	235	0.10	0.11	97	5.9
11	M	239	0.09	0.12	97	5.8
12	M	240	0.10	0.12	97	5.7
13	M	230	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 3 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 4. Accelerated Aging Condition: 80°C @ 4 days Conditioning: At least 16 hours

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.3
2	M	239	0.09	0.11	97	6.3
3	M	240	0.09	0.11	97	6.2
4	M	242	0.10	0.12	97	6.2
5	M	243	0.09	0.12	96	6.2
6	M	240	0.09	0.11	96	6.1
7	M	241	0.10	0.12	97	6.1
8	M	240	0.09	0.11	96	6.0
9	M	242	0.09	0.11	97	6.0

10	M	241	0.10	0.11	97	5.9
11	M	244	0.09	0.12	97	5.8
12	M	240	0.10	0.12	96	5.7
13	M	243	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 80°C @ 4 DAYS:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 5. Accelerated Aging Condition: 80°C @ 5 days Conditioning: At least 16 hours

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.10	0.12	97	6.3
2	M	240	0.09	0.11	96	6.3
3	M	242	0.09	0.11	97	6.2
4	M	238	0.10	0.11	97	6.2
5	M	241	0.09	0.12	96	6.1
6	M	240	0.09	0.11	96	6.1
7	M	244	0.10	0.12	96	6.1
8	M	240	0.09	0.11	97	6.0
9	M	242	0.09	0.11	96	6.0
10	M	234	0.10	0.11	97	5.9
11	M	243	0.09	0.12	97	5.8
12	M	240	0.10	0.12	97	5.7
13	M	241	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	3

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 80°C @ 5 DAYS:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051313141A:**

Final performance-testing results of samples at conditions of 80°C@ 1 day, 80°C@ 2 days, 80°C@ 3 days, 80°C @ 4 days, 80°C @ 5 days conform to associate standard requirements, and can be used normally.

**IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 80°C:**

Through the accelerated aging performance test at 80°C@ 1 day, 80°C@ 2 days, 80°C @3 days, 80°C @ 4 days, 80°C @ 5 days on 3 lots products (Lot No: 21051309141A, 21051311141A, 21051313141A) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: *Xiao Weili* / QA Director

Date: May 18, 2021

Reviewed by: *Wu Zhigang* / General Manager

Date: May 18, 2021

# SHANXI HONGJIN PLASTIC TECHNOLOGY CO., LTD.

## PERFORMANCE TESTING REPORT @ 70°C FOR 5 TIME POINT

### Purpose:

As per EN455-4, carry out accelerated aging property test at 70°C for 5-time point (namely 1 day, 3 days, 7 days, 8 days, and 10 days) to verify and determine the shelf-life of Nitrile Examination Gloves, Black.

**Date Tested:** 2021.05.13-23

### Samples Tested:

Size: M

**Product Name:** Nitrile Examination Gloves, Black

**Product Lot No.:** 21051309141A

21051311141A

21051313141A

### Standards:

EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C OF LOT NO. 21051309141A**

#### **1. Accelerated Aging Condition: 70°C@ 1 day      Conditioning: At least 16 hours**

##### **A. Accelerated aging performance testing ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	245	0.10	0.12	96	6.4
2	M	245	0.10	0.12	97	6.3
3	M	244	0.09	0.11	97	6.3
4	M	235	0.09	0.11	97	6.2
5	M	244	0.10	0.12	96	6.2
6	M	242	0.10	0.12	96	6.1
7	M	240	0.10	0.12	97	6.1
8	M	230	0.09	0.11	97	6.0
9	M	240	0.10	0.12	97	5.9
10	M	241	0.09	0.11	97	5.8

11	M	232	0.09	0.11	96	5.8
12	M	241	0.09	0.12	97	5.7
13	M	243	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **2. Accelerated Aging Condition: 70°C @ 3 days      Conditioning: At least 16 hours**

#### A. Accelerated aging performance testing ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 20°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	238	0.09	0.12	96	6.4
2	M	243	0.10	0.12	97	6.4
3	M	248	0.10	0.12	97	6.3
4	M	230	0.09	0.11	97	6.2
5	M	240	0.10	0.12	97	6.2
6	M	245	0.10	0.12	96	6.2
7	M	245	0.10	0.12	97	6.1
8	M	245	0.09	0.11	97	6.0
9	M	233	0.10	0.12	97	5.9
10	M	242	0.09	0.11	96	5.8
11	M	240	0.09	0.11	97	5.7
12	M	234	0.09	0.12	97	5.7
13	M	242	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 3 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 70°C @ 7 days      Conditioning: At least 16 hours**

**A. Accelerated aging performance testing ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	97	6.4
2	M	235	0.09	0.12	97	6.3
3	M	240	0.10	0.12	96	6.2
4	M	241	0.09	0.11	97	6.2
5	M	245	0.10	0.12	97	6.1
6	M	250	0.10	0.12	96	6.1
7	M	245	0.10	0.12	96	6.1
8	M	240	0.09	0.11	96	6.0
9	M	243	0.10	0.12	96	5.9
10	M	235	0.09	0.11	97	5.7
11	M	245	0.09	0.11	97	5.7
12	M	240	0.09	0.12	96	5.7
13	M	236	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break ≥6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 7 days:**

Final performance-testing results of samples conform to associate standard requirements, and can

be used normally.

**4. Accelerated Aging Condition: 70°C @ 8 days      Conditioning: At least 16 hours**

**A. Accelerated aging performance testing ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.4
2	M	230	0.10	0.12	96	6.3
3	M	245	0.09	0.12	97	6.3
4	M	240	0.09	0.11	97	6.2
5	M	236	0.10	0.12	96	6.2
6	M	242	0.10	0.12	96	6.1
7	M	242	0.10	0.12	97	6.0
8	M	245	0.09	0.11	96	6.0
9	M	235	0.10	0.12	96	5.9
10	M	246	0.09	0.11	97	5.8
11	M	240	0.09	0.11	96	5.8
12	M	240	0.10	0.12	97	5.7
13	M	245	0.09	0.11	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 8 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 70°C @ 10 days      Conditioning: At least 16 hours**

**A. Accelerated aging performance testing ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length	Thickness (mm)	Palm	Force at
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		(mm)	Test Piece	Middle Fingertip	Width (mm)	Break (N)
1	M	243	0.10	0.12	97	6.4
2	M	241	0.10	0.12	96	6.3
3	M	247	0.10	0.12	96	6.3
4	M	245	0.09	0.11	97	6.2
5	M	245	0.10	0.12	97	6.2
6	M	235	0.10	0.12	96	6.1
7	M	242	0.10	0.12	97	6.1
8	M	248	0.09	0.11	96	6.0
9	M	237	0.10	0.12	97	5.9
10	M	242	0.10	0.11	97	5.8
11	M	251	0.09	0.11	97	5.8
12	M	230	0.09	0.12	97	5.7
13	M	240	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	0

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 10 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051309141A :**

Final performance-testing results of samples at conditions of 70°C@ 1 day, 70°C@ 3 days, 70°C@ 7 days, 70°C@ 8 days, 70°C@ 10 days conform to associate standard requirements, and can be used normally.

**II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C OF LOT NO. 21051311141A**

**1. Accelerated Aging Condition: 70°C @ 1 day      Conditioning: At least 16 hours**

**A. Accelerated aging performance testing---Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		

1	M	242	0.09	0.12	97	6.4
2	M	244	0.10	0.12	97	6.3
3	M	241	0.10	0.12	96	6.2
4	M	241	0.09	0.11	97	6.2
5	M	243	0.10	0.12	97	6.1
6	M	234	0.10	0.12	96	6.1
7	M	246	0.10	0.12	97	6.0
8	M	240	0.09	0.11	97	6.0
9	M	240	0.10	0.12	97	5.9
10	M	242	0.09	0.11	97	5.8
11	M	231	0.09	0.11	96	5.8
12	M	242	0.10	0.12	97	5.7
13	M	235	0.09	0.11	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 2. Accelerated Aging Condition: 70°C @ 3 days      Conditioning: At least 16 hours

#### A. Accelerated aging performance testing ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli      Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	237	0.10	0.12	97	6.4
2	M	245	0.10	0.12	97	6.3
3	M	235	0.10	0.12	96	6.2
4	M	241	0.09	0.11	96	6.2
5	M	230	0.10	0.12	97	6.1
6	M	241	0.10	0.12	97	6.1
7	M	245	0.10	0.12	97	6.1
8	M	243	0.09	0.11	97	6.0

9	M	255	0.10	0.12	97	5.9
10	M	245	0.09	0.11	97	5.8
11	M	246	0.09	0.11	97	5.8
12	M	240	0.09	0.12	97	5.7
13	M	236	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C@ 3 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **3. Accelerated Aging Condition: 70°C @ 7 days      Conditioning: At least 16 hours**

### A. Accelerated aging performance testing ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli      Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	245	0.10	0.12	97	6.4
2	M	240	0.09	0.12	97	6.3
3	M	241	0.10	0.12	97	6.3
4	M	237	0.09	0.11	96	6.2
5	M	242	0.10	0.12	97	6.2
6	M	242	0.10	0.12	97	6.1
7	M	241	0.10	0.12	96	6.0
8	M	245	0.09	0.11	97	6.0
9	M	241	0.10	0.12	97	5.9
10	M	240	0.09	0.11	97	5.8
11	M	240	0.09	0.11	96	5.8
12	M	243	0.09	0.12	97	5.7
13	M	230	0.10	0.12	97	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the

specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	3

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 7 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 70°C @ 8 days      Conditioning: At least 16 hours**

**A. Accelerated aging performance testing ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	245	0.10	0.12	97	6.3
2	M	240	0.10	0.12	97	6.3
3	M	242	0.10	0.12	97	6.2
4	M	237	0.09	0.11	96	6.2
5	M	240	0.10	0.12	97	6.1
6	M	232	0.10	0.12	97	6.1
7	M	240	0.10	0.12	96	6.0
8	M	240	0.09	0.11	97	6.0
9	M	242	0.10	0.12	97	5.9
10	M	235	0.10	0.12	96	5.8
11	M	240	0.09	0.11	97	5.8
12	M	239	0.09	0.12	97	5.7
13	M	242	0.09	0.11	97	5.5
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 8 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 70°C @ 10 days      Conditioning: At least 16 hours**

**A. Accelerated aging performance testing ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	245	0.10	0.12	96	6.3
2	M	235	0.10	0.12	96	6.3
3	M	242	0.10	0.12	97	6.3
4	M	240	0.09	0.11	97	6.2
5	M	240	0.10	0.12	97	6.2
6	M	240	0.10	0.12	97	6.1
7	M	242	0.10	0.12	96	6.1
8	M	242	0.09	0.11	97	6.0
9	M	231	0.10	0.12	97	5.9
10	M	241	0.09	0.11	97	5.8
11	M	245	0.09	0.11	97	5.8
12	M	235	0.10	0.12	97	5.7
13	M	236	0.10	0.12	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break ≥6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 10 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051311141A :**

Final performance-testing results of samples at conditions of 70°C@ 1 day, 70°C@3 days, 70°C@ 7 days, 70°C@ 8 days, 70°C@ 10 days conform to associate standard requirements, and can be used normally.

### III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C OF LOT NO. 21051313141A

**1. Accelerated Aging Condition: 70°C @ 1 day      Conditioning: At least 16 hours**

#### A. Accelerated aging performance testing ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	234	0.10	0.12	97	6.4
2	M	241	0.10	0.12	97	6.3
3	M	240	0.10	0.12	96	6.3
4	M	244	0.09	0.11	97	6.2
5	M	240	0.10	0.12	96	6.2
6	M	232	0.10	0.12	97	6.1
7	M	240	0.10	0.12	97	6.0
8	M	234	0.09	0.11	97	6.0
9	M	242	0.10	0.12	97	5.9
10	M	240	0.09	0.11	96	5.8
11	M	240	0.09	0.11	97	5.8
12	M	238	0.09	0.12	97	5.7
13	M	240	0.09	0.11	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 70°C @ 1 DAY:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**2. Accelerated Aging Condition: 70°C @ 3 days      Conditioning: At least 16 hours**

#### A. Accelerated aging performance testing ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 20°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.3
2	M	240	0.09	0.11	97	6.3
3	M	241	0.10	0.12	97	6.2
4	M	235	0.09	0.11	96	6.2
5	M	241	0.10	0.12	96	6.2
6	M	240	0.10	0.12	97	6.1
7	M	243	0.10	0.12	97	6.0
8	M	242	0.09	0.11	97	6.0
9	M	234	0.10	0.12	97	5.9
10	M	241	0.09	0.11	97	5.8
11	M	239	0.09	0.11	96	5.7
12	M	240	0.09	0.12	97	5.7
13	M	244	0.09	0.11	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 70°C @ 3 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 70°C @ 7 days      Conditioning: At least 16 hours**

**A. Accelerated aging performance testing ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.10	0.12	97	6.3
2	M	240	0.10	0.12	96	6.3
3	M	237	0.10	0.12	96	6.3
4	M	242	0.09	0.11	97	6.2

5	M	244	0.10	0.12	97	6.2
6	M	240	0.10	0.12	96	6.1
7	M	240	0.10	0.12	97	6.1
8	M	241	0.09	0.11	97	6.0
9	M	243	0.10	0.12	97	5.9
10	M	237	0.09	0.11	97	5.8
11	M	242	0.09	0.11	96	5.8
12	M	240	0.09	0.12	97	5.7
13	M	242	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 7 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **4. Accelerated Aging Condition: 70°C @ 8 days      Conditioning: At least 16 hours**

#### A. Accelerated aging performance testing ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli      Test Condition: 22°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.09	0.11	97	6.4
2	M	240	0.10	0.12	97	6.3
3	M	244	0.10	0.12	97	6.2
4	M	240	0.10	0.12	96	6.2
5	M	240	0.09	0.11	97	6.2
6	M	240	0.10	0.12	96	6.1
7	M	240	0.10	0.12	97	6.0
8	M	237	0.10	0.12	97	6.0
9	M	240	0.09	0.11	97	5.9
10	M	235	0.10	0.12	97	5.8
11	M	240	0.09	0.11	97	5.8
12	M	239	0.09	0.11	97	5.7

13	M	240	0.09	0.12	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	3

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 8 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## **5. Accelerated Aging Condition: 70°C @ 10 days      Conditioning: At least 16 hours**

### A. Accelerated aging performance testing ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli      Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.09	0.11	97	6.4
2	M	235	0.10	0.12	96	6.3
3	M	240	0.10	0.12	97	6.3
4	M	241	0.10	0.12	97	6.2
5	M	240	0.10	0.12	96	6.2
6	M	244	0.09	0.11	97	6.1
7	M	240	0.10	0.12	97	6.1
8	M	241	0.10	0.12	96	6.0
9	M	242	0.10	0.12	97	5.9
10	M	239	0.10	0.13	97	5.8
11	M	240	0.10	0.12	97	5.8
12	M	235	0.09	0.11	96	5.7
13	M	242	0.10	0.12	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 70°C @ 10 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 6. FINAL RESULTS of LOT NO. 21051313141A:

Final performance-testing results of samples at conditions of 70°C@ 1 day, 70°C@ 3 days, 70°C@ 7 days, 70°C @ 8 days, 70°C @ 10 days conform to associate standard requirements, and can be used normally.

### IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 70°C:

Through the accelerated aging performance test at 70°C@ 1 day, 70°C@ 3 days, 70°C @7 days, 70°C @ 8 days, 70°C @ 10 days on 3 lots products (Lot No: 21051309141A, 21051311141A, 21051313141A) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: *Xiao Weili* / QA Director

Date: May 24, 2021

Reviewed by: *Wu Zhigang* / General Manager

Date: May 24, 2021

# SHANXI HONGJIN PLASTIC TECHNOLOGY CO., LTD.

## PERFORMANCE TESTING REPORT @ 60°C FOR 5 TIME POINT

### Purpose:

As per EN455-4, carry out accelerated aging property test at 60°C for 5-time point (namely 5 days, 15 days, 22 days, 35 days, and 42 days) to verify and determine the shelf-life of Nitrile Examination Gloves, Black.

**Date Tested:** 2021.05.13-06.24

### **Samples Tested:**

Size: M

**Product Name:** Nitrile Examination Gloves, Black

**Product Lot No.:** 21051309141A

21051311141A

21051313141A

### **Standards:**

EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C OF LOT NO.**

#### **21051309141A**

**1. Accelerated Aging Condition: 60°C@ 5 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.10	0.12	97	6.3
2	M	240	0.09	0.11	97	6.3
3	M	236	0.10	0.12	97	6.2
4	M	240	0.10	0.11	97	6.2
5	M	230	0.09	0.12	97	6.1
6	M	244	0.09	0.11	96	6.1
7	M	242	0.10	0.12	97	6.1
8	M	241	0.09	0.12	96	6.0
9	M	235	0.09	0.11	97	6.0
10	M	240	0.10	0.11	96	5.9
11	M	245	0.09	0.12	97	5.8

12	M	237	0.10	0.12	97	5.7
13	M	242	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 5 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **2. Accelerated Aging Condition: 60°C @ 15 days      Conditioning: At least 16 hours**

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 50%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	231	0.10	0.12	96	6.3
2	M	240	0.09	0.11	97	6.3
3	M	245	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	238	0.09	0.12	96	6.1
6	M	244	0.09	0.11	97	6.1
7	M	242	0.10	0.12	97	6.1
8	M	238	0.09	0.12	97	6.1
9	M	245	0.09	0.11	96	6.0
10	M	242	0.10	0.11	97	5.9
11	M	245	0.09	0.12	97	5.8
12	M	245	0.10	0.12	97	5.7
13	M	236	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 15 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 60°C @ 22 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	232	0.10	0.12	97	6.3
2	M	240	0.09	0.11	97	6.3
3	M	242	0.10	0.12	96	6.2
4	M	231	0.10	0.11	96	6.2
5	M	245	0.09	0.12	97	6.2
6	M	240	0.09	0.11	97	6.1
7	M	240	0.10	0.12	97	6.1
8	M	244	0.09	0.12	97	6.0
9	M	240	0.09	0.11	96	6.0
10	M	241	0.10	0.11	97	5.8
11	M	242	0.09	0.12	97	5.8
12	M	240	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break ≥6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 22 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 60°C @ 35 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	97	6.5
2	M	240	0.09	0.11	97	6.3
3	M	242	0.10	0.12	96	6.2
4	M	241	0.10	0.11	96	6.2
5	M	240	0.09	0.12	97	6.1
6	M	240	0.09	0.11	97	6.1
7	M	240	0.10	0.12	97	6.0
8	M	234	0.09	0.12	97	6.0
9	M	239	0.09	0.11	96	6.0
10	M	240	0.10	0.11	96	5.9
11	M	242	0.09	0.12	97	5.8
12	M	237	0.10	0.12	97	5.7
13	M	240	0.09	0.11	97	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 35 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 60°C @ 42 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length	Thickness (mm)	Palm	Force at
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		(mm)	Test Piece	Middle Fingertip	Width (mm)	Break (N)
1	M	245	0.10	0.12	96	6.4
2	M	250	0.09	0.11	97	6.3
3	M	245	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	245	0.09	0.12	96	6.1
6	M	242	0.09	0.11	97	6.1
7	M	235	0.10	0.12	97	6.1
8	M	252	0.09	0.12	96	6.0
9	M	233	0.09	0.11	97	6.0
10	M	245	0.10	0.11	97	5.9
11	M	230	0.09	0.12	97	5.8
12	M	242	0.10	0.12	96	5.7
13	M	240	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	3

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 42 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051309141A:**

Final performance-testing results of samples at conditions of 60°C@ 5 days, 60°C@ 15 days, 60°C@ 22 days, 60°C@ 35 days, 60°C@ 42 days conform to associate standard requirements, and can be used normally.

**II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C OF LOT NO. 21051311141A**

**1. Accelerated Aging Condition: 60°C @ 5 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 21.5°C, 50%

Serial No.	Size	Length	Thickness (mm)	Palm	Force at
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		(mm)	Test Piece	Middle Fingertip	Width (mm)	Break (N)
1	M	244	0.10	0.12	97	6.3
2	M	230	0.09	0.11	97	6.3
3	M	234	0.10	0.12	96	6.2
4	M	245	0.10	0.11	97	6.2
5	M	236	0.09	0.12	97	6.1
6	M	240	0.09	0.11	97	6.1
7	M	248	0.10	0.12	97	6.1
8	M	240	0.09	0.12	96	6.0
9	M	242	0.09	0.11	97	6.0
10	M	241	0.10	0.11	96	5.9
11	M	242	0.09	0.12	97	5.8
12	M	250	0.10	0.12	97	5.7
13	M	242	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 5 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 2. Accelerated Aging Condition: 60°C @ 15 days Conditioning: At least 16 hours

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	238	0.10	0.12	97	6.3
2	M	240	0.09	0.11	97	6.3
3	M	240	0.10	0.12	97	6.3
4	M	230	0.10	0.11	96	6.2
5	M	240	0.09	0.12	96	6.1
6	M	246	0.09	0.11	97	6.1

7	M	233	0.10	0.12	97	6.1
8	M	247	0.09	0.12	97	6.1
9	M	250	0.10	0.12	97	6.0
10	M	242	0.10	0.11	96	5.9
11	M	243	0.09	0.12	97	5.8
12	M	238	0.10	0.12	97	5.7
13	M	242	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C@ 15 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **3. Accelerated Aging Condition: 60°C @ 22 days      Conditioning: At least 16 hours**

#### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.3
2	M	235	0.09	0.11	97	6.3
3	M	237	0.10	0.12	96	6.2
4	M	245	0.10	0.11	97	6.2
5	M	245	0.09	0.12	97	6.1
6	M	242	0.09	0.11	96	6.1
7	M	245	0.10	0.12	97	6.1
8	M	241	0.09	0.12	97	6.0
9	M	245	0.09	0.11	97	6.0
10	M	243	0.10	0.11	97	5.9
11	M	242	0.09	0.12	96	5.8
12	M	230	0.10	0.12	97	5.7
13	M	239	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the

specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 22 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 60°C @ 35 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.11	97	6.4
2	M	243	0.09	0.11	97	6.4
3	M	245	0.10	0.12	96	6.2
4	M	248	0.10	0.11	97	6.2
5	M	245	0.09	0.12	96	6.1
6	M	243	0.09	0.11	96	6.1
7	M	245	0.10	0.12	97	6.0
8	M	246	0.09	0.12	97	6.0
9	M	241	0.09	0.11	96	6.0
10	M	242	0.10	0.11	97	5.9
11	M	243	0.09	0.12	97	5.8
12	M	242	0.10	0.12	97	5.7
13	M	241	0.09	0.11	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 35 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 60°C @ 42 days      Conditioning: At least 16 hours**

A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	96	6.3
2	M	243	0.09	0.11	96	6.3
3	M	237	0.10	0.12	97	6.2
4	M	235	0.10	0.11	95	6.2
5	M	243	0.09	0.12	96	6.1
6	M	242	0.09	0.11	97	6.1
7	M	245	0.10	0.12	95	6.1
8	M	243	0.09	0.12	96	6.1
9	M	235	0.09	0.11	97	6.0
10	M	243	0.10	0.11	96	5.9
11	M	243	0.09	0.12	97	5.8
12	M	240	0.10	0.12	96	5.7
13	M	230	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break ≥6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 42 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051311141A:**

Final performance-testing results of samples at conditions of 60°C@ 5 days, 60°C@15 days, 60°C@ 22 days, 60°C@ 35 days, 60°C@ 42 days conform to associate standard requirements, and can be used normally.

### III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C OF LOT NO. 21051313141A

#### 1. Accelerated Aging Condition: 60°C @ 5 days      Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.4
2	M	240	0.09	0.11	97	6.3
3	M	237	0.10	0.12	96	6.2
4	M	240	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	233	0.09	0.11	97	6.1
7	M	240	0.10	0.12	96	6.0
8	M	241	0.09	0.12	97	6.0
9	M	240	0.09	0.11	97	6.0
10	M	242	0.10	0.11	97	5.9
11	M	240	0.09	0.12	96	5.8
12	M	236	0.10	0.12	97	5.7
13	M	240	0.10	0.12	97	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 60°C @ 5 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 2. Accelerated Aging Condition: 60°C @ 15 days      Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.10	0.12	97	6.3
2	M	240	0.09	0.11	97	6.3
3	M	236	0.10	0.12	97	6.3
4	M	240	0.10	0.11	97	6.2
5	M	240	0.09	0.12	96	6.1
6	M	235	0.10	0.11	97	6.1
7	M	240	0.10	0.12	97	6.1
8	M	244	0.09	0.12	97	6.1
9	M	242	0.09	0.11	97	6.0
10	M	241	0.10	0.12	97	5.9
11	M	241	0.09	0.12	97	5.8
12	M	238	0.10	0.12	96	5.7
13	M	240	0.09	0.11	97	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 15 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 60°C @ 22 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.3
2	M	237	0.09	0.11	97	6.3
3	M	240	0.10	0.12	97	6.2
4	M	240	0.10	0.11	97	6.2

5	M	239	0.09	0.12	96	6.1
6	M	241	0.09	0.11	96	6.1
7	M	240	0.10	0.12	96	6.1
8	M	242	0.09	0.11	96	6.0
9	M	240	0.09	0.11	97	6.0
10	M	237	0.10	0.11	96	5.9
11	M	241	0.09	0.12	96	5.9
12	M	240	0.10	0.12	97	5.7
13	M	241	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **4. Accelerated Aging Condition: 60°C @ 35 days      Conditioning: At least 16 hours**

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 21°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.11	97	6.3
2	M	241	0.09	0.11	97	6.3
3	M	242	0.10	0.12	97	6.2
4	M	241	0.10	0.11	98	6.2
5	M	240	0.09	0.12	97	6.1
6	M	235	0.09	0.11	97	6.1
7	M	243	0.10	0.12	97	6.0
8	M	242	0.09	0.12	97	6.0
9	M	241	0.09	0.11	96	6.0
10	M	243	0.10	0.11	97	5.9
11	M	239	0.09	0.12	96	5.8
12	M	242	0.10	0.12	96	5.7

13	M	240	0.09	0.11	97	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 60°C @ 35 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### **5. Accelerated Aging Condition: 60°C @ 42 days      Conditioning: At least 16 hours**

#### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.09	0.12	95	6.3
2	M	240	0.09	0.11	96	6.3
3	M	242	0.10	0.12	96	6.2
4	M	243	0.10	0.11	95	6.2
5	M	240	0.09	0.12	96	6.1
6	M	241	0.09	0.11	95	6.1
7	M	240	0.10	0.12	95	6.1
8	M	242	0.09	0.11	96	6.0
9	M	240	0.09	0.11	95	6.0
10	M	242	0.10	0.11	96	5.9
11	M	243	0.09	0.12	95	5.8
12	M	240	0.10	0.12	95	5.7
13	M	237	0.09	0.11	97	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 60°C @ 42 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051313141A:**

Final performance-testing results of samples at conditions of 60°C@ 5 days, 60°C@ 15 days, 60°C@ 22 days, 60°C @ 35 days, 60°C @ 42 days conform to associate standard requirements, and can be used normally.

**IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 60°C:**

Through the accelerated aging performance test at 60°C@ 5 days, 60°C@ 15 days, 60°C @22 days, 60°C @ 35 days, 60°C @ 42 days on 3 lots of products (Lot No: 21051309141A, 21051311141A, 21051313141A) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: *Xiao Weili* / QA Director

Date: June 24, 2021

Reviewed by: *Wu Zhigang* / General Manager

Date: June 24, 2021

# SHANXI HONGJIN PLASTIC TECHNOLOGY CO., LTD.

## PERFORMANCE TESTING REPORT @ 50°C FOR 5 TIME POINT

### Purpose:

As per EN455-4, carry out accelerated aging property test at 50°C for 5-time point (namely 22 days, 35 days, 55 days, 90 days, and 120 days) to verify and determine the shelf-life of Nitrile Examination Gloves, Black

**Date Tested:** 2021.05.13-09.10

### Samples Tested:

Size: M

**Product Name:** Nitrile Examination Gloves, Black

**Product Lot No.:** 21051309141A

21051311141A

21051313141A

### Standards:

EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

**The detailed testing results of the samples above-mentioned are as follows:**

### **I. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C OF LOT NO.**

#### **21051309141A**

**I. Accelerated Aging Condition: 50°C@ 22 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	97	6.3
2	M	240	0.09	0.11	96	6.3
3	M	244	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	244	0.09	0.11	97	6.1
7	M	232	0.10	0.12	97	6.1
8	M	243	0.09	0.12	96	6.0
9	M	235	0.09	0.11	97	6.0
10	M	240	0.10	0.11	97	5.9
11	M	231	0.09	0.12	97	5.8

12	M	242	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **2. Accelerated Aging Condition: 50°C @ 35 days      Conditioning: At least 16 hours**

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	97	6.3
2	M	240	0.09	0.11	96	6.3
3	M	244	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.1
5	M	240	0.09	0.12	96	6.1
6	M	244	0.09	0.11	97	6.1
7	M	242	0.10	0.12	97	6.1
8	M	243	0.09	0.12	96	6.0
9	M	244	0.09	0.11	96	6.0
10	M	240	0.10	0.11	97	5.9
11	M	240	0.09	0.12	96	5.8
12	M	234	0.10	0.12	97	5.7
13	M	238	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	3

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 35 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 50°C @ 55 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.4
2	M	240	0.09	0.11	97	6.3
3	M	244	0.10	0.12	96	6.2
4	M	241	0.10	0.11	96	6.2
5	M	240	0.09	0.12	97	6.1
6	M	244	0.09	0.11	97	6.1
7	M	240	0.10	0.12	97	6.0
8	M	243	0.09	0.12	96	6.0
9	M	237	0.09	0.11	97	6.0
10	M	240	0.10	0.11	96	5.9
11	M	241	0.09	0.12	97	5.8
12	M	240	0.10	0.12	97	5.7
13	M	241	0.09	0.11	97	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break ≥6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 55 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 50°C @ 90 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.10	0.12	97	6.3
2	M	240	0.09	0.11	98	6.3
3	M	244	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	244	0.09	0.11	97	6.1
7	M	236	0.10	0.12	97	6.0
8	M	243	0.09	0.12	96	6.0
9	M	235	0.09	0.11	97	6.0
10	M	240	0.10	0.11	97	5.9
11	M	237	0.09	0.12	97	5.7
12	M	241	0.10	0.12	97	5.7
13	M	240	0.09	0.11	97	5.7
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 90 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 50°C @ 120 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length	Thickness (mm)	Palm	Force at
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		(mm)	Test Piece	Middle Fingertip	Width (mm)	Break (N)
1	M	238	0.10	0.12	97	6.3
2	M	240	0.09	0.11	96	6.3
3	M	244	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	243	0.09	0.12	97	6.1
6	M	244	0.09	0.11	97	6.1
7	M	242	0.10	0.12	97	6.1
8	M	235	0.09	0.12	96	6.0
9	M	245	0.09	0.11	97	6.0
10	M	240	0.10	0.12	97	5.9
11	M	241	0.09	0.12	96	5.8
12	M	239	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 120 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051309141A:**

Final performance-testing results of samples at conditions of 50°C@ 22 days, 50°C@ 35 days, 50°C@ 55 days, 50°C@ 90 days, 50°C@ 120 days conform to associate standard requirements, and can be used normally.

**II. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C OF LOT NO. 21051311141A**

**1. Accelerated Aging Condition: 50°C @ 22 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 50%

Serial No.	Size	Length	Thickness (mm)	Palm	Force at
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		(mm)	Test Piece	Middle Fingertip	Width (mm)	Break (N)
1	M	242	0.10	0.12	97	6.3
2	M	240	0.09	0.11	96	6.3
3	M	234	0.10	0.12	97	6.2
4	M	241	0.10	0.12	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	246	0.09	0.11	97	6.1
7	M	239	0.10	0.12	97	6.0
8	M	243	0.09	0.12	96	6.0
9	M	245	0.09	0.11	97	6.0
10	M	240	0.10	0.12	97	5.9
11	M	241	0.09	0.12	97	5.8
12	M	242	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.5
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **2. Accelerated Aging Condition: 50°C @ 35 days      Conditioning: At least 16 hours**

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	97	6.4
2	M	240	0.09	0.11	98	6.3
3	M	235	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	240	0.09	0.12	96	6.1
6	M	244	0.09	0.11	97	6.1

7	M	239	0.10	0.12	97	6.1
8	M	243	0.09	0.12	96	6.0
9	M	245	0.09	0.11	97	6.0
10	M	240	0.10	0.11	97	5.8
11	M	241	0.09	0.12	97	5.8
12	M	237	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C@ 35 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

## 3. Accelerated Aging Condition: 50°C @ 55 days Conditioning: At least 16 hours

### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.3
2	M	240	0.09	0.11	96	6.3
3	M	236	0.10	0.12	97	6.3
4	M	241	0.10	0.12	97	6.2
5	M	241	0.09	0.12	97	6.1
6	M	240	0.09	0.11	97	6.1
7	M	232	0.10	0.12	97	6.1
8	M	243	0.09	0.12	96	6.1
9	M	245	0.09	0.11	97	6.0
10	M	240	0.10	0.11	97	5.9
11	M	241	0.09	0.12	97	5.9
12	M	236	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.6

Median Value	6.1
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It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 55 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**4. Accelerated Aging Condition: 50°C @ 90 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	244	0.10	0.12	97	6.3
2	M	237	0.09	0.11	97	6.2
3	M	241	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	244	0.09	0.11	98	6.1
7	M	242	0.10	0.12	97	6.0
8	M	243	0.09	0.12	96	6.0
9	M	241	0.09	0.11	97	6.0
10	M	236	0.10	0.11	97	5.9
11	M	240	0.09	0.12	97	5.8
12	M	242	0.10	0.12	97	5.7
13	M	235	0.09	0.11	96	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 90 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**5. Accelerated Aging Condition: 50°C @ 120 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING----**Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.10	0.12	97	6.4
2	M	240	0.09	0.11	96	6.3
3	M	244	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	242	0.09	0.12	97	6.1
6	M	238	0.09	0.11	97	6.1
7	M	242	0.10	0.12	97	6.1
8	M	243	0.09	0.12	96	6.1
9	M	245	0.09	0.11	97	6.0
10	M	235	0.10	0.11	97	5.8
11	M	241	0.09	0.12	97	5.8
12	M	239	0.10	0.12	97	5.7
13	M	241	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break ≥6N).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 120 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051311141A:**

Final performance-testing results of samples at conditions of 50°C@ 22 days, 50°C@35 days, 50°C@ 55 days, 50°C@ 90 days, 50°C@ 120 days conform to associate standard requirements, and can be used normally.

### III. ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C OF LOT NO. 21051313141A

#### 1. Accelerated Aging Condition: 50°C @ 22 days      Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 53%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	236	0.10	0.12	97	6.3
2	M	240	0.09	0.11	96	6.3
3	M	244	0.10	0.12	97	6.3
4	M	237	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	239	0.09	0.11	96	6.1
7	M	242	0.10	0.12	97	6.1
8	M	236	0.09	0.12	97	6.0
9	M	235	0.09	0.11	96	6.0
10	M	241	0.10	0.11	97	5.9
11	M	241	0.09	0.12	97	5.8
12	M	239	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.7
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

#### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

#### C. TESTING RESULTS AT 50°C @ 22 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### 2. Accelerated Aging Condition: 50°C @ 35 days      Conditioning: At least 16 hours

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	240	0.10	0.12	97	6.4
2	M	240	0.09	0.11	98	6.3
3	M	244	0.10	0.12	97	6.2
4	M	237	0.10	0.12	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	241	0.09	0.11	98	6.1
7	M	242	0.10	0.12	97	6.1
8	M	243	0.09	0.12	96	6.1
9	M	236	0.09	0.11	97	6.0
10	M	240	0.10	0.12	97	5.9
11	M	241	0.09	0.12	97	5.8
12	M	237	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

**B. Samples Pinhole Testing**

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 35 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**3. Accelerated Aging Condition: 50°C @ 55 days      Conditioning: At least 16 hours**

**A. ACCELERATED AGING PERFORMANCE TESTING ----Dimensions and Physical Properties**

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	243	0.10	0.12	97	6.3

2	M	240	0.09	0.11	96	6.3
3	M	244	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	241	0.09	0.12	96	6.1
6	M	244	0.09	0.11	97	6.1
7	M	242	0.10	0.12	97	6.0
8	M	243	0.09	0.12	96	6.0
9	M	242	0.09	0.11	97	6.0
10	M	240	0.10	0.11	97	5.9
11	M	241	0.09	0.12	96	5.8
12	M	242	0.10	0.12	97	5.7
13	M	241	0.09	0.11	96	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping

200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	1

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 55 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

### 4. Accelerated Aging Condition: 50°C @ 90 days      Conditioning: At least 16 hours

#### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.10	0.12	97	6.4
2	M	240	0.09	0.11	98	6.3
3	M	244	0.10	0.12	97	6.2
4	M	241	0.10	0.12	97	6.2
5	M	240	0.09	0.11	97	6.1
6	M	244	0.09	0.11	97	6.1
7	M	235	0.10	0.12	97	6.1
8	M	243	0.09	0.12	96	6.0
9	M	245	0.09	0.11	97	6.0

10	M	240	0.10	0.11	97	5.9
11	M	241	0.09	0.11	97	5.8
12	M	242	0.10	0.12	97	5.7
13	M	235	0.09	0.11	96	5.6
Median Value						6.1

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	2

It is showed from the above data that pinholes conform to requirements.

### C. TESTING RESULTS AT 50°C @ 90 days:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

#### **5. Accelerated Aging Condition: 50°C @ 120 days      Conditioning: At least 16 hours**

##### A. ACCELERATED AGING PERFORMANCE TESTING----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 6N.

Tested by: Wang Xiaoli      Test Condition: 22°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.09	0.11	97	6.4
2	M	240	0.09	0.11	96	6.3
3	M	236	0.10	0.12	97	6.2
4	M	241	0.10	0.11	97	6.2
5	M	240	0.09	0.12	97	6.1
6	M	244	0.09	0.11	96	6.1
7	M	238	0.10	0.12	97	6.0
8	M	243	0.09	0.12	96	6.0
9	M	235	0.10	0.12	97	6.0
10	M	240	0.10	0.11	97	5.9
11	M	245	0.09	0.12	97	5.8
12	M	237	0.10	0.12	97	5.7
13	M	240	0.09	0.11	96	5.6
Median Value						6.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break  $\geq 6N$ ).

### B. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Wang Xiaoli, Cao Liping 200pcs (Ac=7, Re=8)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	200	3

It is showed from the above data that pinholes conform to requirements.

**C. TESTING RESULTS AT 50°C @ 120 days:**

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

**6. FINAL RESULTS of LOT NO. 21051313141A:**

Final performance-testing results of samples at conditions of 50°C@ 22 days, 50°C@ 35 days, 50°C@ 55 days, 50°C @ 90 days, 50°C @ 120 days conform to associate standard requirements, and can be used normally.

**IV. FINAL RESULT FOR ACCELERATED AGING PERFORMANCE TESTING RESULT AT 50°C:**

Through the accelerated aging performance test at 50°C@ 22 days, 50°C@ 35 days, 50°C @55 days, 50°C @ 90 days, 50°C @ 120 days on 3 lots products (Lot No: 21051309141A, 21051311141A, 21051313141A) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by: *Xiao Weili* / QA Director

Date: September 11, 2021

Reviewed by: *Wu Zhigang* / General Manager

Date: September 11, 2021

# SHANXI HONGJIN PLASTIC TECHNOLOGY CO., LTD.

## Summary for Accelerated Aging Shelf Life Testing

### 1.0 Purpose:

Conduct accelerated aging shelf life determination for Nitrile Examination Gloves, Black as per EN455-4, so as to determine its shelf life.

### 2.0 Standard:

2.1 EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

2.2 EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

2.3 EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

### 3.0 Samples Information:

**Size:** M

**Product Name:** Nitrile Examination Gloves, Black

**Product Lot No.:** 21051309141A

21051311141A

21051313141A

### 4.0 Instruction of Sampling Testing:

According to EN455-1 and EN455-2, sample gloves individually from three production lots and conduct the following testing and record the testing data under the condition of time zero and accelerated aging for shelf life determination.

Item		Criteria	Quantity and Acceptance Criteria
Length (mm)		$\geq 240\text{mm}$	13 pieces, median
Width (mm)		$95 \pm 10\text{mm}$	13 pieces, median
Thickness (mm)	Middle Fingertip $t_f$	$t_f/t_x \geq 0.9$	13 pieces
	Test piece $t_x$		
Force at Break (N)		$\geq 6\text{N}$	13 pieces, median
Watertightness		---	G-I, AQL1.5, sampling 200 pieces (Ac7, Re 7)
Notes: 1. Condition of sampling testing: Temperature: $23 \pm 2^\circ\text{C}$ , Humidity: $50 \pm 5\%$ 2. Samples shall be conditioned at least 16 hours before testing.			

If all the testing results comply with the criteria requirements, then the lot of products will be accepted. On the contrary, it will be rejected.

### 5.0 Summary for Accelerated Aging Shelf Life Determination Study:

#### 5.1 Time Zero Testing:

5.1.1 Time zero testing were conducted from May 13, 2021. Based on the performance test results, it is showed that the samples meet associate standard requirements, and can be used normally and

accelerated aging shelf life determination study and real time study were started subsequently.

**5.2 Accelerated Aging Shelf Life Testing:**

5.2.1 As per Annex B in EN 455-4, 4 different temperatures and 5-time point at each temperature are used for accelerated aging shelf life testing, and the testing is continued at least 110 days. The selected temperature and days are as follows:

# \ Temp	80°C	70°C	60°C	50°C
1	1 Day	1 Day	5 Days	22 Days
2	2 Days	3 Days	15 Days	35 Days
3	3 Days	7 Days	22 Days	55 Days
4	4 Days	8 Days	35 Days	90 Days
5	5 Days	10 Days	42 Days	120 Days

5.2.2 As per the arrangements in the above table, the actual schedules for each testing are as follows:

Temp \ Testing Period	80°C	70°C	60°C	50°C
	2021.05.13-18	2021.05.13-23	2021.05.13-06.24	2021.05.13-09.10

5.2.3 The accelerated aging testing was performed as per the above condition and schedule, and based on the accelerated aging performance testing results; it is showed that the samples meet associated standard requirements.

Details for accelerated aging testing for each condition refer to corresponding testing report.

**5.3 Conclusion for accelerated aging performance testing:**

Through the time zero and accelerated aging performance test according to the condition listed in section 5.1 and 5.2 on 3 lots products (namely Lot No: 21051309141A, 21051311141A, 21051313141A as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and the maximum shelf life of Nitrile Examination Gloves, Black determined by accelerated aging testing is 3 years.

Prepared by: *Xiao Weili* / QA Director

Date: September 11, 2021

Reviewed by: *Wu Zhigang* / General Manager

Date: September 11, 2021