



**Determination of Expiration Dating (Shelf life) Protocol for  
"Powder Free Online Chorination, Latex Examination Gloves (LOF\_BG) "**

**1. Purpose:**

To determine the appropriate shelf life of glove and confidence that glove has consistency of quality through real time and control condition.

**2. Scope:**

Valid for : "Powder Including Accelerated Stability Test.  
Including Accelerated Stability Test and Real Time Stability Studies

**3. Normative Reference:**

ASTM D 7160-05	Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D 7161-05	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
EN455-4 :2009	Medical gloves for single use-Part4 : Requirements and testing for Shelf life determination
ASTM D 412-06a <sup>e2</sup>	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension Elastomers-Tension
ASTM D 573-04(Reapproved 2010)	Test Method for Rubber- Deterioration in an Air Oven
ASTM D 5151-06	Test Method for Detection of Holes in Medical Gloves
ASTM3578-05(Reapproved 2010)	Standard Specification for Rubber Examination Gloves
EN455-1 : 2000	Medical glove for single use-Part1 : Requirements and testing for freedom from hole
EN455-2 :2009	Medical glove for single use-Part2 : Requirements and testing for Physical properties.
EN455-3 :2006	Medical glove for single use-Part3 : Requirements and testing for Biological evaluation.
ISO 2859-1:1999	Sampling procedure for inspection by attributes

**4. Action Plan:**

Three Discrete finished product of "Powder Free Online Chorination, Latex Examination Gloves (LOF\_BG) " will be sampling as this;

No.	Oct'13	Nov'13	Dec'13	Jan'14
Lot 1				
Lot 2				
Lot 3				

Randomly selected glove samples from the packing area as plan on action plan. The glove samples should be fresh produced. (the date of packing are closed to date of production)

**5. Established:** Supattra Tangrakwaraskul Assistant Lab Manager

**6. Preparation and Sampling:** In each lot would be sampling as this table;

Table 1: Number of sampling.

Glove Sampling condition	"Powder Free Online Chlorination, Latex Examination Gloves (LOF_BG) "
<b>0) Time zero</b>	2 Dispensers
<b>1) Accelerated aging</b>	
1) $70 \pm 2$ °C, $166 \pm 2$ hour	2 Dispensers
2) $50 \pm 2$ °C, $90 \pm 1$ days	2 Dispensers
<b>2) Real time aging</b>	10 Dispensers

**Note:** 1 Dispenser contains 100 gloves

Refer to LA.SO.GE.10.018 PRODUCT TEST: SHELF LIFE (STABILITY STUDY), (Table 1 )

**7. Aging conditions:**

7.1 Accelerated aging;

1. A sufficient number of samples shall be incubated at  $70 \pm 2$  °C,  $166 \pm 2$  h and  $50 \pm 2$  °C,  $90 \pm 1$  days  
Temperature and humidity of the aging chamber should be monitored and recorded at least daily

**Note:** Humidity record for information only.

2. At the end of the incubation periods, Test the gloves per section 8. The measurement of physical properties should be performed no earlier than 16 h and no later than 96 h from the time of removal from the oven in accordance with Test Method D 573

7 Real Time aging;

1. Real time studies of gloves sampled from same three lots should be initiated at the same time as the accelerated studies.
2. Sufficient samples shall be stored in the warehouse area or under conditions that are representative of actual storage conditions.  
Temperature and humidity should be monitored and recorded at least daily

**Note:** Humidity record for information only.

## 8. Test Program for Accelerated and Real Time Aging

### 8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578, EN455-1, EN455-2 at time zero

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573
2. Physical Properties EN	-	-	13	Med	EN 455-2
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151
4. Water Leak Test EN	G-1	1.5	200	7/8	EN 455-1
5. Dimension	S-2	4.0	13	1/2	ASTM D3578
6. Protein Content ASTM	-	-	3	-	ASTM D5712
7. Protein Content EN	-	-	8	-	EN 455-3
8. Residual Powder on glove	-	-	5	-	ASTM D6124

### 8.2 Accelerated aging;

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573
2. Physical Properties EN	-	-	13	Med	EN 455-2
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151
4. Water Leak Test EN	G-1	1.5	200	7/8	EN 455-1

Testing should begin within 96 h. And also, measurement of physical properties should be performed no earlier

than 16 h and no later than 96 h from the time of removal from the oven in accordance with Test Method D 573

### 8.3 Real Time aging;

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573
2. Physical Properties EN	-	-	13	Med	EN 455-2
3. Water Leak Test ASTM	S-3	2.5	32*	3/4	ASTM D5151
4. Water Leak Test EN	G-1	1.5	200	7/8	EN 455-1
5. Dimension	S-2	4.0	13	1/2	ASTM D 3578
6. Protein Content ASTM	-	-	3	-	ASTM D5712
7. Protein Content EN	-	-	8	-	EN 455-3
8. Residual Powder on glove	-	-	5	-	ASTM D6124

Testing shall be performed no sooner than 24 h from date of manufacturing at the initiation of the study and, at a

minimum, at yearly intervals up to five years.

**Note:** - "32\*" means sample size as 32, although sample size per that inspection level are less than 32, but for testing will

not less than 32 gloves according Table 2 in ASTM D7160-05 and Table 1 in ASTM D7161-05



Sample size per ISO 2859, Lot size as 1,600 gloves.

- The physical properties result should be compare with initial ( time zero) test result.

9. Acceptance Criteria

9.1 Real time-aged glove must meet the requirements of the appropriate ASTM D3578 with respect to water leak testing and "before aging" physical properties.

9.2 Oven-aged samples must meet the requirements of the appropriate ASTM D3578 with respect to water leaktesting and "after aging" physical properties.

9.3 If a 25% or greater change in physical prepreties from the initial value is observed, an investigation should be initiated to determine if the change is an indication of an increased rate of degradation.

10. Addition form for data collection

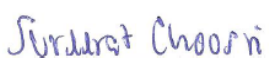
Data Description	Record
1. Physical Properties ASTM	LA.FO.GE.10.033
2. Physical Properties EN	LA.FO.GE.10.033
3. Water Leak Test	QA.FO.GE.08.001
4. Dimension	LA.FO.GE.10.001
5. Protein Content ASTM	LA.FO.GE.10.002
6. Protein Content EN	LA.FO.GE.10.002
7. Residual Powder on glove	LA.FO.GE.10.003
8. Summary Report	Accelerated aging Report Real Time aging Report

11. Established by:

  
Asst. LAB Manager

19/11/2013  
Date

12. Approve by:

  
QA& LAB Manager

19/11/2013  
Date

**Accelerated aging Report to Determination of Expiration Dating (Shelf life) for  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 1st Lot"**

**1. Purpose:**

To determine the appropriate shelf life of glove and confidence that glove has consistency of quality through real time and control condition.

**2. Scope:**

Valid for : **"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 1st Lot"**  
Including Accelerated Stability Test.

**3. Normative Reference:**

ASTM D 7160-05	Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D 7161-05	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
EN455-4 :2009	Medical gloves for single use-Part4 : Requirements and testing for Shelf life determination
ASTM D 412-06ae2	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension Elastomers-Tension
ASTM D 573-04(Reapproved 2010)	Test Method for Rubber- Deterioration in an Air Oven
ASTM D 5151-06	Test Method for Detection of Holes in Medical Gloves
ASTM3578-05(Reapproved 2010)	Standard Specification for Rubber Examination Gloves
EN455-1 : 2000	Medical glove for single use-Part1 : Requirements and testing for freedom from hole
EN455-2 :2009	Medical glove for single use-Part2 : Requirements and testing for Physical properties.
EN455-3 :2006	Medical glove for single use-Part3 : Requirements and testing for Biological evaluation.
ISO 2859-1:1999	Sampling procedure for inspection by attributes

**4. Study Date:**

Date of Manufacture: **19/11/2013**

**5. Established:** **Supattra Tangrakwaraskul** Assistant Lab Manager**6. Preparation and Sampling:**

Randomly selected glove samples from the packing area as plan on action plan. The glove samples should be fresh produced. (the date of packing are closed to date of production)

(Refer to: Determination of Expiration Dating (Shelf life) Protocol for

**"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG) "**

**Sample Identification:**

**Lot no. 12BXSLOF0401240BG 19/11/2013 C**

**Surface: Textured at finger tip**

**XSLOF0401240BG (400304675)**

**Size: XS**

**7. Aging conditions:**

Accerlerated conditions as,  $70 \pm 2$  °C,  $166 \pm 2$  h and  $50 \pm 2$  °C,  $90 \pm 1$  days. In that periods, temperature are meet that specified as record on "Attachemnt 1 Record of Accelerated Conditions"

**Disposition: PASS**

**8. Test Result:**

## 8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578,EN455-1, EN455-2 at time zero

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med/Ave)
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573		
- Tensile Strength BF aging						18 Min	27.94 MPa
- Tensile Strength AF aging						14 Min	25.54 MPa
- Elongation BF aging						650 Min	817 %
- Elongation AF aging						500 Min	810 %
- Number of defect						3 Max	0 defect
2. Physical Properties EN	-	-	13	Med	EN455-2		
- Force at break BF aging						6.5 Min	7.66 N
- Force at break AF aging						6.0 Min	7.01 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	0 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	3 defect
5. Dimension - Length						240 Med	240 mm
- Width						70+/-10	76 mm
- Finger						0.16 Min	0.25 mm
- Palm						0.16 Min	0.22 mm
- Cuff						-	0.15 mm
- Number of defect	S-2	4.0	13	1/2	ASTM D3578	1 Max	1 defect
6. Protein Content ASTM	-	-	3	-	ASTM D5712	50 Max	45.97 ug/g
7. Protein Content EN	-	-	8	-	EN 455-3	50 Max	24.76 ug/g
8. Residual Powder on Glove	-	-	5	-	ASTM D6124	2 Max	0.12 mg/glove

Disposition: **PASS**8.2 Accelerated aging result at  $70 \pm 2^{\circ}\text{C}$ ,  $166 \pm 2$  hour

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med)
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573		
- Tensile Strength						16 Min	25.54 MPa
- Elongation						500 Min	810 %
- Number of defect						3 Max	0 defect
2. Physical Properties EN	-	-	13	Med	EN455-2		
- Force at break						6 Min	7.01 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	1 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	5 defect

Disposition: **PASS**



8.3 Accelerated aging result at  $50 \pm 2^\circ\text{C}$ ,  $90 \pm 1$  days

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med)
1. Physical Properties ASTM - Tensile Strength - Elongation - Number of defect	S-3	4.0	32*	3/4	ASTM D412, D573	16 Min 500 Min 3 Max	23.02 MPa 853 % 0 defect
2. Physical Properties EN - Force at break	-	-	13	Med	EN455-2	6 Min	6.6 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	0 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	4 defect

Disposition: **PASS**

8.4 Comparison between initial (Time zero) result with after accelerated aging results for physical properties.

Testing	% Difference from initial value	
	$70 \pm 2^\circ\text{C}$ , $166 \pm 2$ hour	$50 \pm 2^\circ\text{C}$ , $90 \pm 1$ days
1. Physical Properties ASTM - Tensile Strength - Elongation	8.6% 0.9%	17.6% 4.4%
2. Physical Properties EN - Force at break	8.5%	13.8%

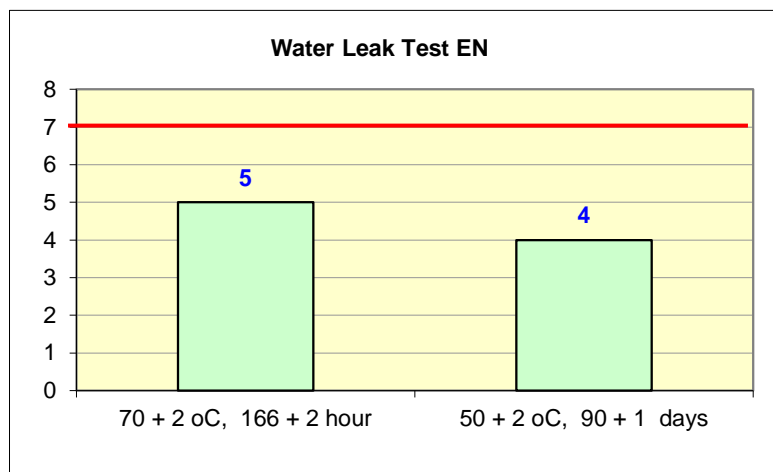
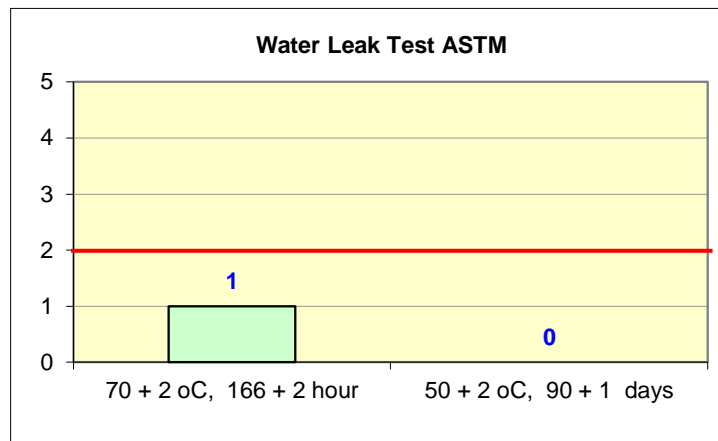
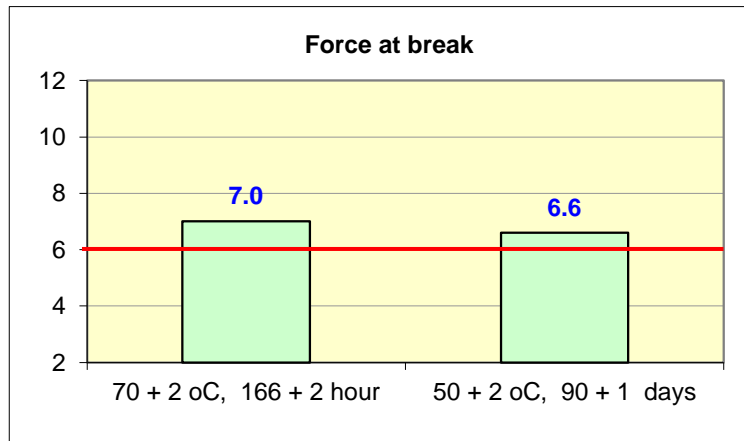
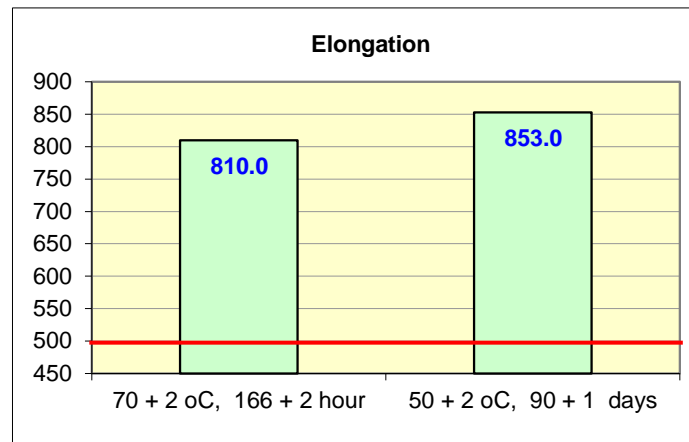
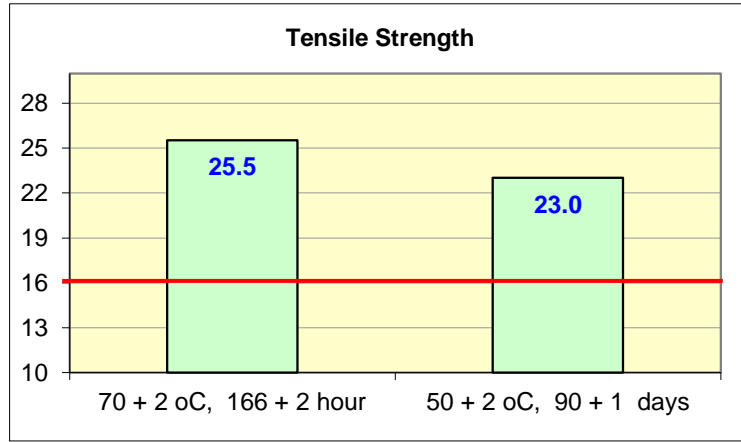
**Note:** - "32\*" means sample size as 32, although sample size per that inspection level are less than 32, but for testing will not less than 32 gloves according Table 2 in ASTM D7160-05  
- Sample size per ISO 2859, Lot size as 1,600 gloves.

Disposition: **PASS**

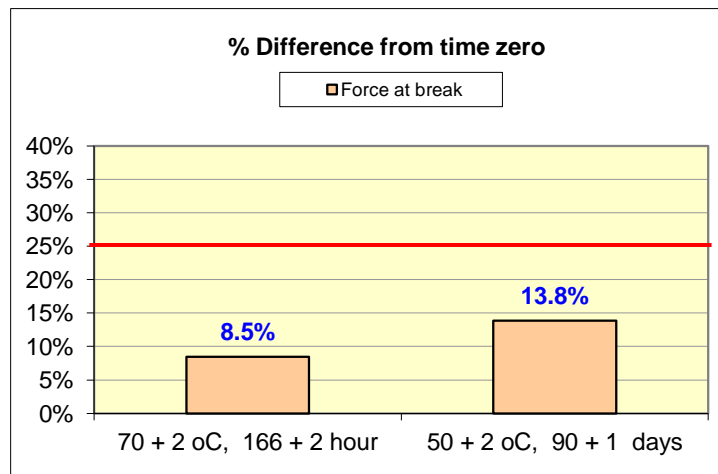
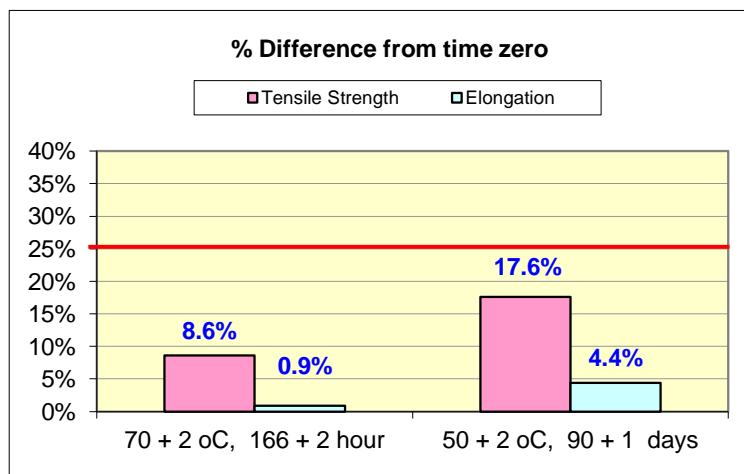


9. Conclusion:

9.1 Oven-aged samples meet the requirements of the appropriate ASTM D3578,EN455-1 ,EN455-2 with respect to water leak testing and "after aging" physical properties.



9.2 There are less than 25% change in physical properties from the initial value is observed.







10. Expiration Date Determination

Base on these accelerated aging result, shall be assigned shelf life of three (3) years for "Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 1st Lot"

11. Established by:

สุวิภา ทังอุกมัจฉาสกุล

Asst. LAB Manager

20/03/2014

Date

12. Approve by:

วิวัฒน์ วัฒนศิริ

LAB Manager

23/03/2014

Date

**Accelerated aging Report to Determination of Expiration Dating (Shelf life) for  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 2nd Lot"**

**1. Purpose:**

To determine the appropriate shelf life of glove and confidence that glove has consistency of quality through real time and control condition.

**2. Scope:**

Valid for: **"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 2nd Lot"**  
Including Accelerated Stability Test.

**3. Normative Reference:**

ASTM D 7160-05	Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D 7161-05	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
EN455-4 :2009	Medical gloves for single use-Part4 : Requirements and testing for Shelf life determination
ASTM D 412-06ae2	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension Elastomers-Tension
ASTM D 573-04(Reapproved 2010)	Test Method for Rubber- Deterioration in an Air Oven
ASTM D 5151-06	Test Method for Detection of Holes in Medical Gloves
ASTM3578-05(Reapproved 2010)	Standard Specification for Rubber Examination Gloves
EN455-1 : 2000	Medical glove for single use-Part1 : Requirements and testing for freedom from hole
EN455-2 :2009	Medical glove for single use-Part2 : Requirements and testing for Physical properties.
EN455-3 :2006	Medical glove for single use-Part3 : Requirements and testing for Biological evaluation.
ISO 2859-1:1999	Sampling procedure for inspection by attributes

**4. Study Date:**

Date of Manufacture: 19/11/2013

**5. Established:** Supattra Tangrakwaraskul Assistant Lab Manager**6. Preparation and Sampling:**

Randomly selected glove samples from the packing area as plan on action plan. The glove samples should be fresh produced. (the date of packing are closed to date of production)

(Refer to: Determination of Expiration Dating (Shelf life) Protocol for

**"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG) "**

**Sample Identification:**

Lot no. **11SSLOF0401240BG 19/11/2013 C**

Surface: **Textured at finger tip**

**SSLOF0401240BG (400304628)**

Size: **SS**

**7. Aging conditions:**

Accelerated conditions as,  $70 \pm 2$  °C,  $166 \pm 2$  h and  $50 \pm 2$  °C,  $90 \pm 1$  days. In that periods, temperature are meet that specified as record on "Attachemnt 1 Record of Accelerated Conditions"

Disposition: PASS



8. Test Result:

8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578,EN455-1, EN455-2 at time zero

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med/Ave)
1. Physical Properties ASTM - Tensile Strength BF aging - Tensile Strength AF aging - Elongation BF aging - Elongation AF aging - Number of defect	S-3	4.0	32*	3/4	ASTM D412, D573	18 Min 14 Min 650 Min 500 Min 3 Max	26.7 MPa 24.3 MPa 833 % 824 % 0 defect
2. Physical Properties EN - Force at break BF aging - Force at break AF aging	-	-	13	Med	EN455-2	6.5 Min 6.0 Min	7.65 N 7.16 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	0 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	5 defect
5. Dimension - Length - Width - Finger - Palm - Cuff - Number of defect	- - - - - S-2	- - - - - 4.0	- - - - - 13	- - - - - 1/2	- - - - - ASTM D3578	240 Med 80+/-10 0.16 Min 0.16 Min - 1 Max	240 mm 82 mm 0.25 mm 0.21 mm 0.16 mm 0 defect
6. Protein Content ASTM	-	-	3	-	ASTM D5712	50 Max	35.62 ug/g
7. Protein Content EN	-	-	8	-	EN 455-3	50 Max	20.85 ug/g
8. Residual Powder on Glove	-	-	5	-	ASTM D6124	2 Max	0.12 mg/glove

Disposition: **PASS**

8.2 Accelerated aging result at 70 ± 2 °C, 166 ± 2 hour

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med)
1. Physical Properties ASTM - Tensile Strength - Elongation - Number of defect	S-3	4.0	32*	3/4	ASTM D412, D573	16 Min 500 Min 3 Max	24.3 MPa 824 % 0 defect
2. Physical Properties EN - Force at break	-	-	13	Med	EN455-2	6 Min	7.16 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	2 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	4 defect

Disposition: **PASS**



8.3 Accelerated aging result at  $50 \pm 2 \text{ }^\circ\text{C}$ ,  $90 \pm 1$  days

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med)
1. Physical Properties ASTM - Tensile Strength - Elongation - Number of defect	S-3	4.0	32*	3/4	ASTM D412, D573	16 Min 500 Min 3 Max	24.88 MPa 823 % 0 defect
2. Physical Properties EN - Force at break	-	-	13	Med	EN455-2	6 Min	6.57 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	1 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	5 defect

Disposition: **PASS**

8.4 Comparison between initial (Time zero) result with after accelerated aging results for physical properties.

Testing	% Difference from initial value	
	$70 \pm 2 \text{ }^\circ\text{C}$ , $166 \pm 2$ hour	$50 \pm 2 \text{ }^\circ\text{C}$ , $90 \pm 1$ days
1. Physical Properties ASTM - Tensile Strength - Elongation	9.1% 1.1%	6.9% 1.2%
2. Physical Properties EN - Force at break	6.4%	14.1%

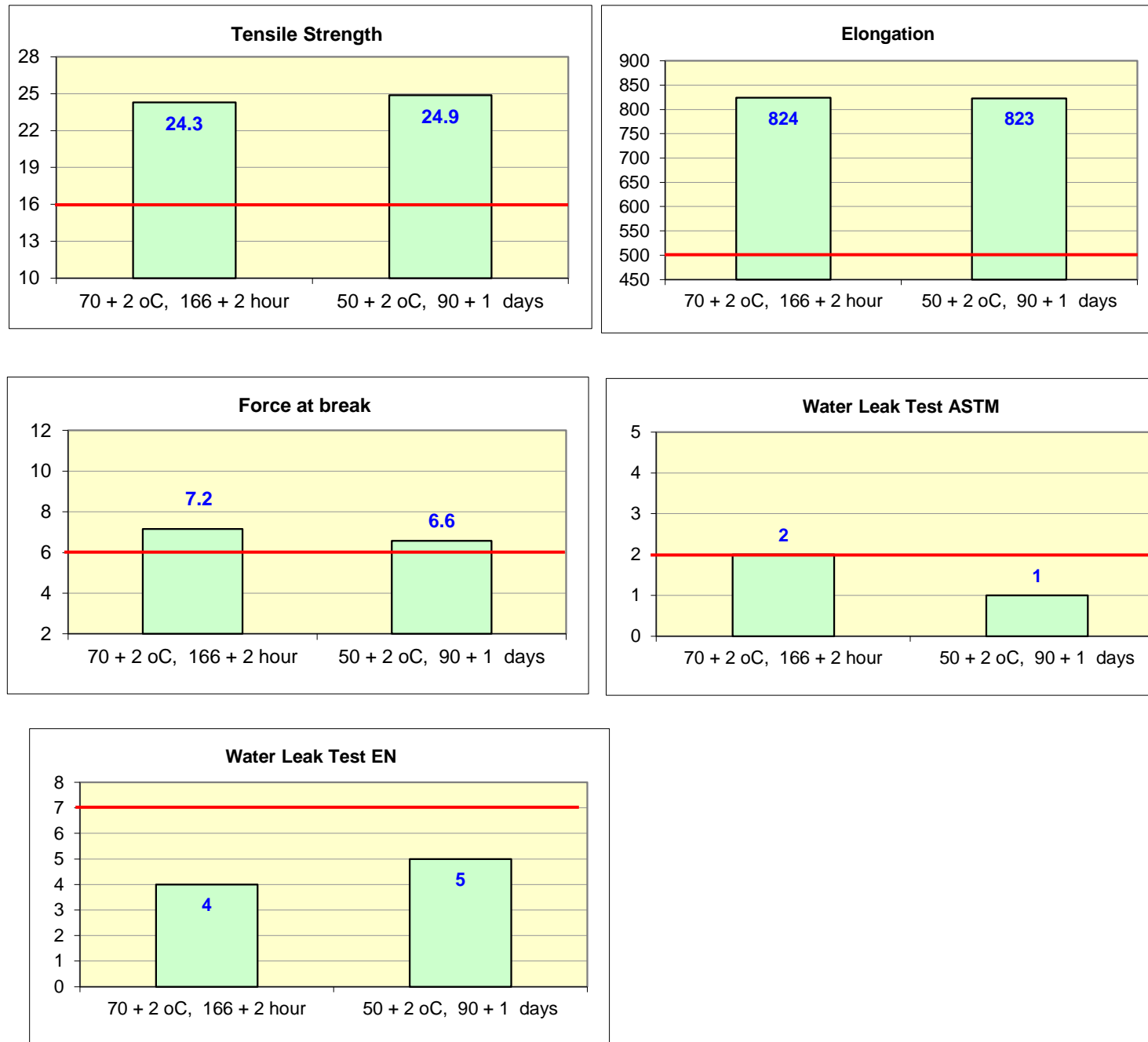
**Note:** - "32\*" means sample size as 32, although sample size per that inspection level are less than 32, but for testing will not less than 32 gloves according Table 2 in ASTM D7160-05  
- Sample size per ISO 2859, Lot size as 1,600 gloves.

Disposition: **PASS**

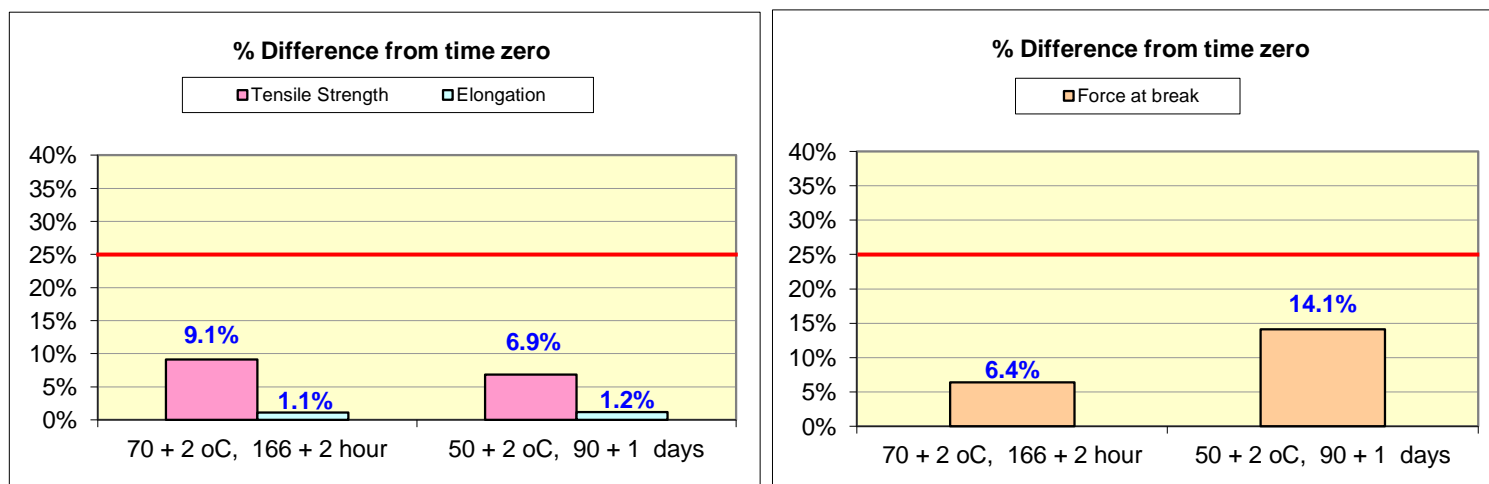


9. Conclusion:

9.1 Oven-aged samples meet the requirements of the appropriate ASTM D3578, EN455-1, EN455-2 with respect to water leak testing and "after aging" physical properties.



9.2 There are less than 25% change in physical properties from the initial value is observed.





10. Expiration Date Determination

Base on these accelerated aging result, shall be assigned shelf life of three (3) years for  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 2nd Lot"

11. Established by:

สัทททา ตั้งอุดมวิมลกุล

Asst. LAB Manager

20/03/2014

Date

12. Approve by:

วิวัฒน์ วิวัฒน์

LAB Manager

23/03/2014

Date

**Accelerated aging Report to Determination of Expiration Dating (Shelf life) for  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 3rd lot"**

**1. Purpose:**

To determine the appropriate shelf life of glove and confidence that glove has consistency of quality through real time and control condition.

**2. Scope:**

Valid for: **"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 3rd lot"**  
Including Accelerated Stability Test.

**3. Normative Reference:**

ASTM D 7160-05	Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D 7161-05	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
EN455-4 :2009	Medical gloves for single use-Part4 : Requirements and testing for Shelf life determination
ASTM D 412-06ae2	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension Elastomers-Tension
ASTM D 573-04(Reapproved 2010)	Test Method for Rubber- Deterioration in an Air Oven
ASTM D 5151-06	Test Method for Detection of Holes in Medical Gloves
ASTM3578-05(Reapproved 2010)	Standard Specification for Rubber Examination Gloves
EN455-1 : 2000	Medical glove for single use-Part1 : Requirements and testing for freedom from hole
EN455-2 :2009	Medical glove for single use-Part2 : Requirements and testing for Physical properties.
EN455-3 :2006	Medical glove for single use-Part3 : Requirements and testing for Biological evaluation.
ISO 2859-1:1999	Sampling procedure for inspection by attributes

**4. Study Date:**

Date of Manufacture: **21/11/2013**

**5. Established:** **Supattra Tangrakwaraskul** Assistant Lab Manager**6. Preparation and Sampling:**

Randomly selected glove samples from the packing area as plan on action plan. The glove samples should be fresh produced. (the date of packing are closed to date of production)

(Refer to: Determination of Expiration Dating (Shelf life) Protocol for

**"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG) "**

**Sample Identification:**

Lot no. **09MMLOF0401240BG 21/11/2013 A**

Surface: **Textured at finger tip**

**MMLOF0401240BG (400304261)**

Size: **MM**

**7. Aging conditions:**

Accelerated conditions as,  $70 \pm 2$  °C,  $166 \pm 2$  h and  $50 \pm 2$  °C,  $90 \pm 1$  days. In that periods, temperature are meet that specified as record on "Attachemnt 1 Record of Accelerated Conditions"

Disposition: **PASS**



8. Test Result:

8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578,EN455-1, EN455-2 at time zero

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med/ Ave)
1. Physical Properties ASTM - Tensile Strength BF aging - Tensile Strength AF aging - Elongation BF aging - Elongation AF aging - Number of defect	S-3	4.0	32*	3/4	ASTM D412, D573	18 Min 14 Min 650 Min 500 Min 3 Max	28.00 MPa 25.74 MPa 810 % 815 % 0 defect
2. Physical Properties EN - Force at break BF aging - Force at break AF aging	-	-	13	Med	EN455-2	6.5 Min 6.0 Min	7.66 N 7.48 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	0 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	4 defect
5. Dimension - Length - Width - Finger - Palm - Cuff - Number of defect	S-2	4.0	13	1/2	ASTM D3578	240 Med 95+/-10 0.16 Min 0.16 Min -	241 mm 93.5 mm 0.26 mm 0.21 mm 0.16 mm 1 defect
6. Protein Content ASTM	-	-	3	-	ASTM D5712	50 Max	32.01 ug/g
7. Protein Content EN	-	-	8	-	EN 455-3	50 Max	8.12 ug/g
8. Residual Powder on Glove	-	-	5	-	ASTM D6124	2 Max	0.18 mg/glove

Disposition: **PASS**

8.2 Accelerated aging result at 70 ± 2 °C, 166 ± 2 hour

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med)
1. Physical Properties ASTM - Tensile Strength - Elongation - Number of defect	S-3	4.0	32*	3/4	ASTM D412, D573	16 Min 500 Min 3 Max	25.7 MPa 815 % 0 defect
2. Physical Properties EN - Force at break	-	-	13	Med	EN455-2	6 Min	7.48 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	2 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	6 defect

Disposition: **PASS**





8.3 Accelerated aging result at  $50 \pm 2 \text{ }^\circ\text{C}$ ,  $90 \pm 1$  days

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med)
1. Physical Properties ASTM - Tensile Strength - Elongation - Number of defect	S-3	4.0	32*	3/4	ASTM D412, D573	16 Min 500 Min 3 Max	25.19 MPa 812 % 0 defect
2. Physical Properties EN - Force at break	-	-	13	Med	EN455-2	6 Min	7.75 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	1 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	4 defect

Disposition: **PASS**

8.4 Comparison between initial (Time zero) result with after accelerated aging results for physical properties.

Testing	% Difference from initial value	
	$70 \pm 2 \text{ }^\circ\text{C}$ , $166 \pm 2$ hour	$50 \pm 2 \text{ }^\circ\text{C}$ , $90 \pm 1$ days
1. Physical Properties ASTM - Tensile Strength - Elongation	8.1% 0.6%	10.0% 0.2%
2. Physical Properties EN - Force at break	2.3%	1.2%

**Note:** - "32\*" means sample size as 32, although sample size per that inspection level are less than 32, but for testing will not less than 32 gloves according Table 2 in ASTM D7160-05

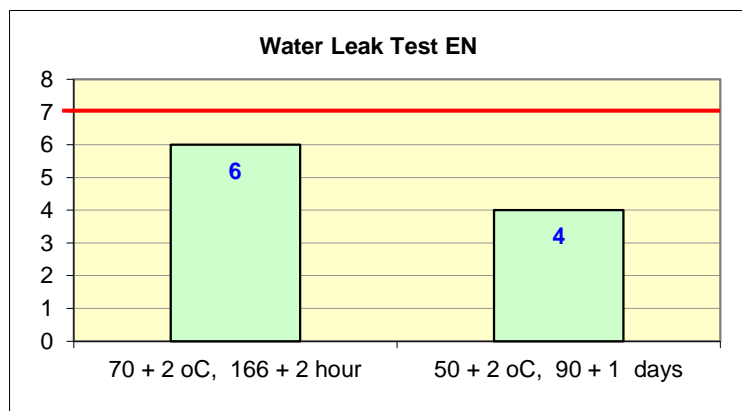
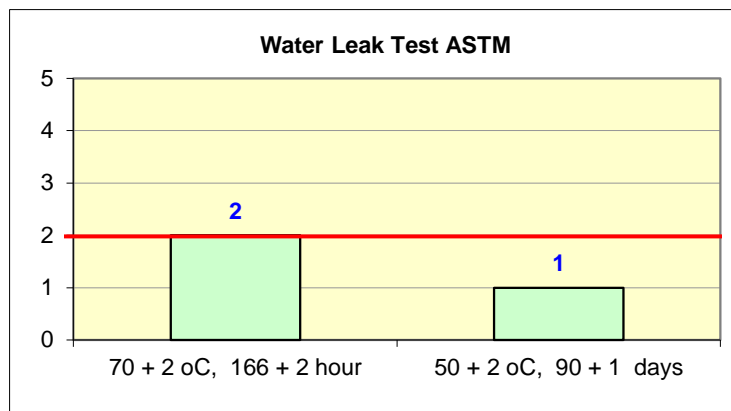
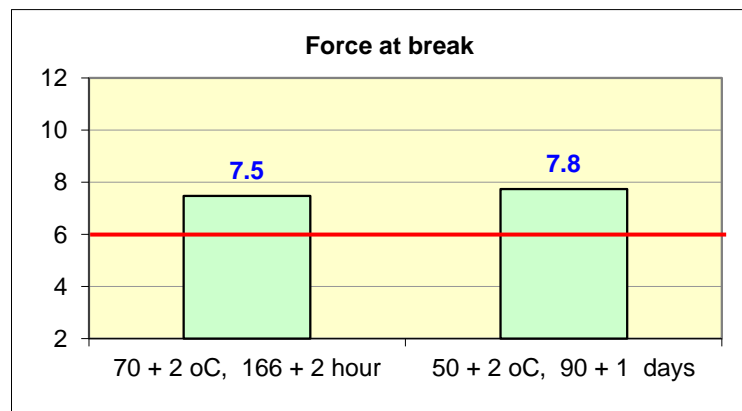
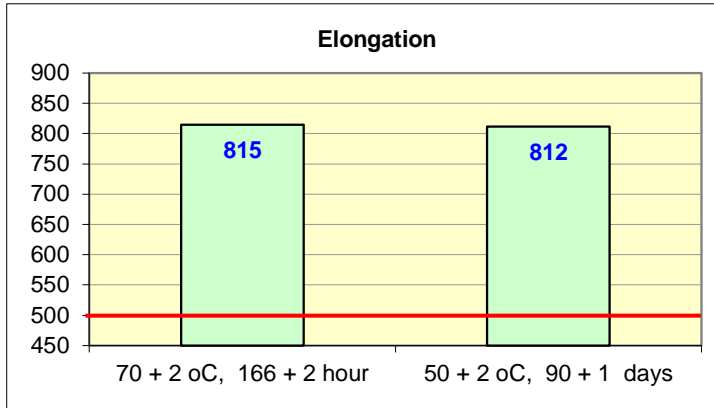
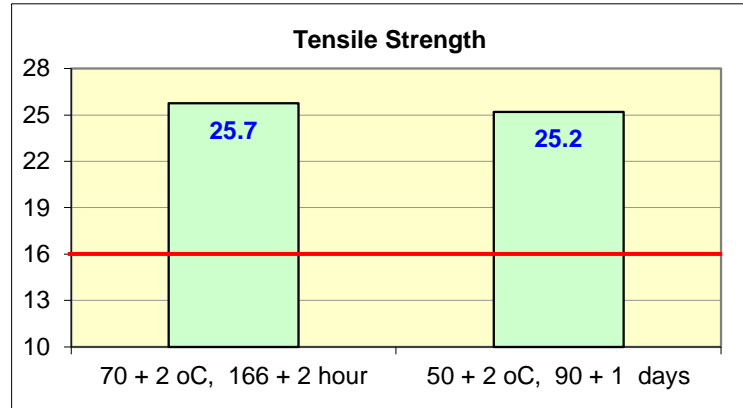
- Sample size per ISO 2859, Lot size as 1,600 gloves.

Disposition: **PASS**

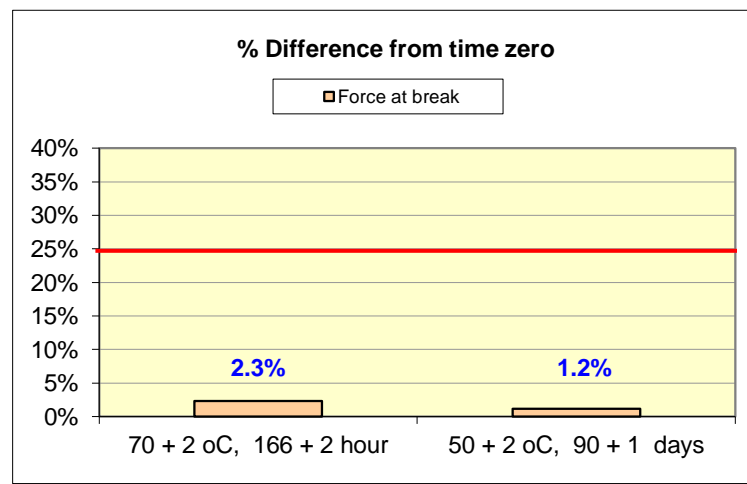
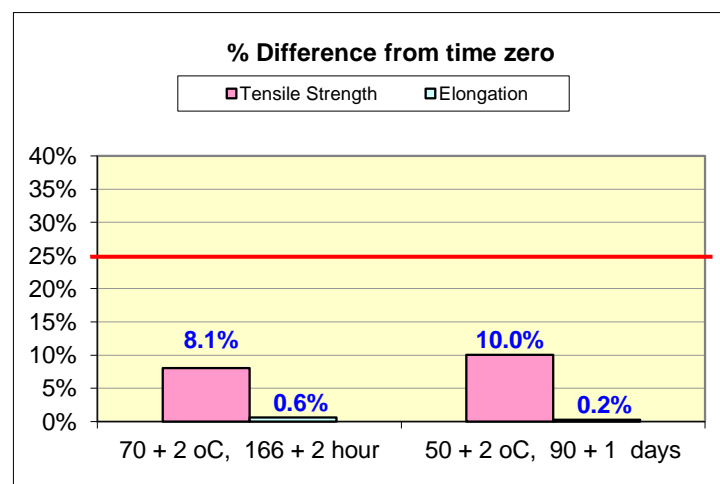


9. Conclusion:

9.1 Oven-aged samples meet the requirements of the appropriate ASTM D3578, EN455-1, EN455-2 with respect to water leak testing and "after aging" physical properties.



9.2 There are less than 25% change in physical properties from the initial value is observed.





10. Expiration Date Determination

Base on these accelerated aging result, shall be assigned shelf life of three (3) years for "Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 3rd lot"

11. Established by:

สุวิภา หังอุกรณ์จิราสกุล

Asst. LAB Manager

20/03/2014

Date

12. Approve by:

วิ.ส.วิเศษ ว.ส.วิเศษ

LAB Manager

23/03/2014

Date

**Real-time aging Report to Determination of Expiration Dating (Shelf life) for  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 1st Lot"**

**1. Purpose:**

The purpose of this document is to report a real-time aging result for appropriate shelf life of glove;  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 1st Lot"

**2. Scope:**

Valid for: **"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 1st Lot"**

**3. Normative Reference:**

ASTM D 7160-05	Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D 7161-05	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
EN455-4 : 2009	Medical gloves for single use-Part4 : Requirements and testing for Shelf life determination
ASTM D 412-16	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension Elastomers-Tension
ASTM D 573-04 (Reapproved 2015)	Test Method for Rubber- Deterioration in an Air Oven
ASTM D 5151-06 (Reapproved 2015)	Test Method for Detection of Holes in Medical Gloves
ASTM D3578-05 (Reapproved 2015)	Standard Specification for Rubber Examination Gloves
ASTM D6319-10 (Reapproved 2015)	Standard Specification for Nitrile Examination Gloves for Medical Application
EN455-1 : 2000	Medical glove for single use-Part1 : Requirements and testing for freedom from hole
EN455-2 : 2015	Medical glove for single use-Part2 : Requirements and testing for Physical properties.
EN455-3 : 2015	Medical glove for single use-Part3 : Requirements and testing for Biological evaluation.
ISO 2859-1:1999	Sampling procedure for inspection by attributes

**4. Study Date:**

Date of Manufacture: **19/11/2013**

**5. Established:** **Preechaya Insuwan** Assistant Lab Manager

**6. Preparation and Sampling:**

Randomly selected glove samples from the packing area as plan on action plan. The glove samples should be fresh produced. (the date of packing are closed to date of production)

(Refer to: Determination of Expiration Dating (Shelf life) Protocol for

**"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG) "**

**Sample Identification:**

Lot no. **12BXSLOF0401240BG 19/11/2013 C**  
**XSLOF0401240BG (400304675)**

Surface: **Textured at finger tip**  
Size: **XS**



7. Aging conditions:

Storage warehouse is uncontrolled.

8. Test Result:

8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578,EN455-1,EN455-2 at time zero

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med/ Ave)
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573		
- Tensile Strength BF aging						18 Min	27.94 MPa
- Tensile Strength AF aging						14 Min	25.54 MPa
- Elongation BF aging						650 Min	817 %
- Elongation AF aging						500 Min	810 %
- Number of defect						3 Max	0 defect
2. Physical Properties EN	-	-	13	Med	EN455-2		
- Force at break BF aging						6.5 Min	7.66 N
- Force at break AF aging						6.0 Min	7.01 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	0 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	3 defect
5. Dimension - Length						240 Med	240 mm
- Width						70+/-10	76 mm
- Finger						0.16 Min	0.25 mm
- Palm						0.16 Min	0.22 mm
- Cuff						-	0.15 mm
- Number of defect	S-2	4.0	13	1/2	ASTM D3578	1 Max	1 defect
6. Protein Content ASTM	-	-	3	-	ASTM D5712	50 Max	45.97 ug/g
7. Protein Content EN	-	-	8	-	EN 455-3	50 Max	24.76 ug/g
8. Residual Powder on Glove	-	-	5	-	ASTM D6124	2 Max	0.12 mg/glove

Disposition: Pass

8.2 Real-time aging results

Yrs.	1. Physical Properties ASTM (S-3 AQL 4.0: n=32* Ac/Re=3/4) Test Method: ASTM D412				2. Physical Properties EN (n=13) Test Method: EN 455-2						
	Before Aging				Before Aging			After Aging			Disposition
	Tensile (MPa)	Elongation (%)	No. of defect	Disposition	Force (N)	Tensile (MPa)	Elongation (%)	Force (N)	Tensile (MPa)	Elongation (%)	
	18 min	650 min	3 max		6.5 min	-	-	6 min	-	-	
0	27.94	817	0	Pass	7.66	29.49	836	7.01	26.73	801	Pass
1	28.80	840	0	Pass	8.26	27.83	802	7.79	26.83	789	Pass
2	28.66	786	0	Pass	7.62	29.69	822	7.43	29.01	833	Pass
3	29.81	791	0	Pass	8.34	31.30	793	7.65	28.72	823	Pass
4	30.14	757	0	Pass	8.61	33.76	758	7.99	30.44	763	Pass
5	28.78	769	0	Pass	7.71	28.88	777	7.19	27.25	811	Pass



yrs.	3. Water Leak Test (S-3 AQL 2.5: n=32 Ac/Re=2/3) Test Method: ASTM D5151		4.. Water Leak Test (G-I AQL 1.5: n=200 Ac/Re=7/8) Test Method: EN455-1	
	No.of defect	Disposition	No.of defect	Disposition
	2 Max		7 Max	
0	0	Pass	3	Pass
1	0	Pass	0	Pass
2	0	Pass	1	Pass
3	0	Pass	2	Pass
4	0	Pass	4	Pass
5	0	Pass	1	Pass

yrs.	Dimension					Disposition
	Length (mm)	Width (mm)	Thickness(mm)			
			Finger	Palm	Cuff	
			0.16	0.16	-	
0	240	76	0.25	0.22	0.15	Pass
1	240	75	0.26	0.21	0.16	Pass
2	240	75	0.26	0.21	0.16	Pass
3	240	75	0.25	0.21	0.15	Pass
4	240	75	0.24	0.19	0.13	Pass
5	240	75	0.23	0.19	0.13	Pass

yrs.	Residual powder		Protein ASTM		Protein EN	
	< 2 mg/glove	Disposition	50 ug/g	Disposition	50 ug/g	Disposition
0	0.12	Pass	45.97	Pass	24.76	Pass
1	0.18	Pass	17.51	Pass	8.72	Pass
2	0.12	Pass	25.92	Pass	18.60	Pass
3	0.12	Pass	29.37	Pass	18.64	Pass
4	0.24	Pass	35.28	Pass	19.61	Pass
5	0.24	Pass	19.55	Pass	9.62	Pass

8.3 Comparison between initial (Time zero) result with after accelerated aging results for physical properties.

yrs.	1. Physical Properties ASTM			2. Physical Properties EN	
	Tensile (MPa)	Elongation (%)	Disposition	Force (N)	Disposition
1	3.08	2.82	Pass	7.83	Pass
2	2.58	3.79	Pass	0.52	Pass
3	6.69	3.18	Pass	8.88	Pass
4	7.86	7.29	Pass	12.40	Pass
5	3.02	5.88	Pass	0.65	Pass

**Note:** - "32\*" means sample size as 32, although sample size per that inspection level are less than 32, but for testing will not less than 32 gloves according Table 1 in ASTM D7161-05.

Sample size per ISO 2859, Lot size as 1,600 gloves.

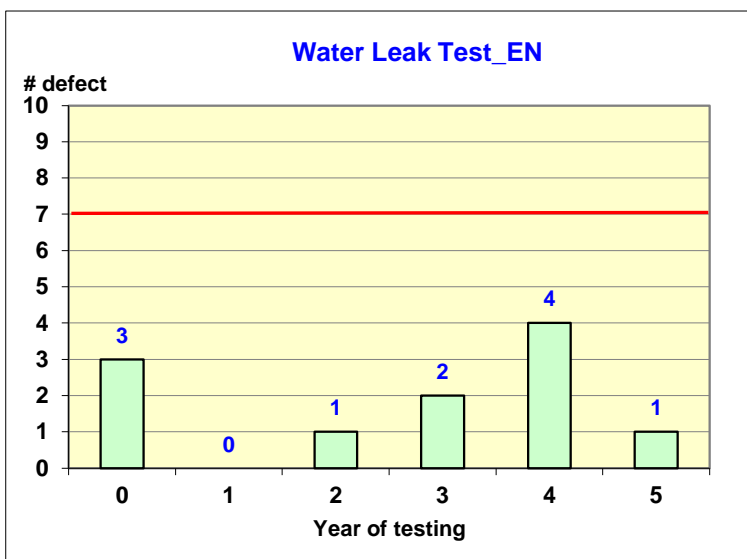
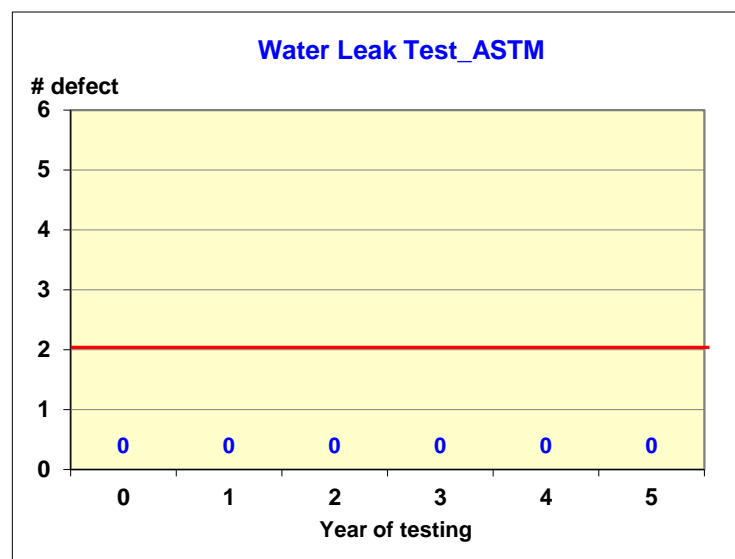
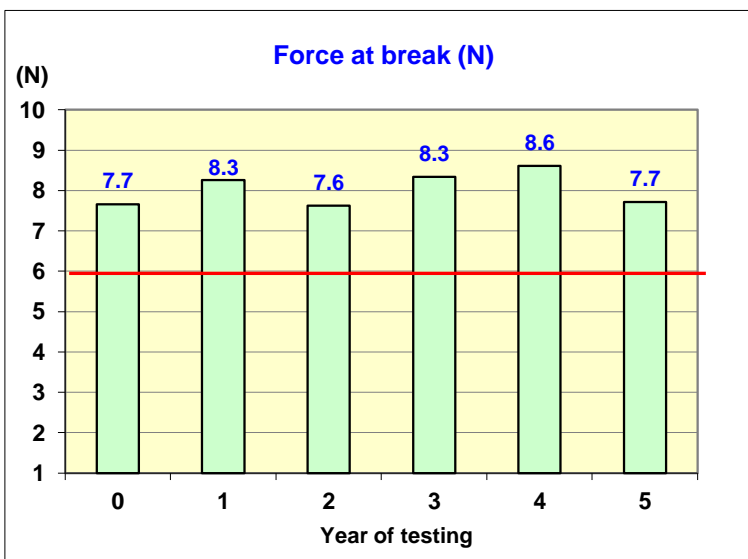
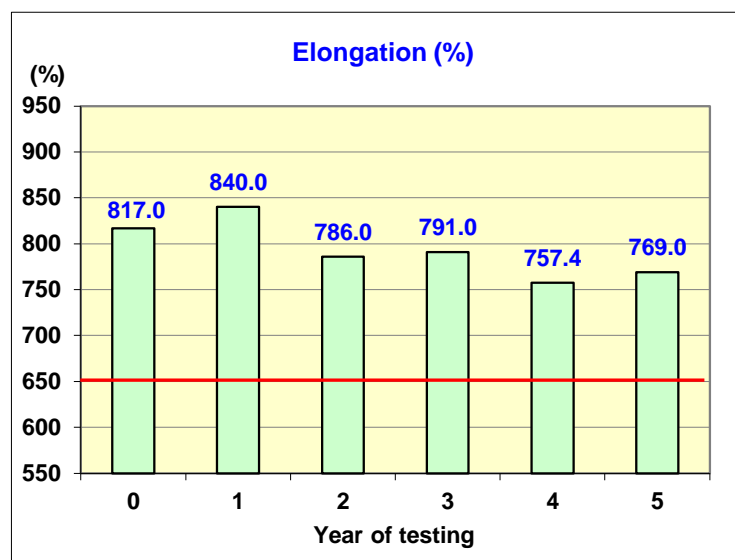
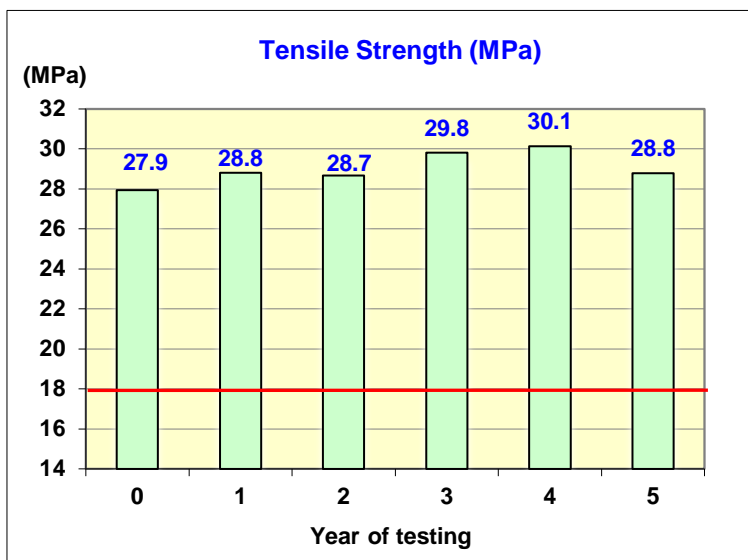
- At year 0 as before aging result of initial testing.
- Testing per EN standard are information only.



9. Conclusion:

Glove samples at naturally aging for 5 years meet the requirement of ASTM D3578,EN455-1,EN455-2 Specification with respect to water leak testing and physical properties.

- 9.1 For Physical properties of Tensile, %Elongation were more than the control limit so that, this glove had the high flexible and resistance for naturally aging condition.
  - 9.2 The real-time aged glove sample are accept at AQL 2.5. The amount of defect in these gloves according to Sampling level S-3 AQL2.5 (ASTM D 5151) as chart display on chart below.
- Trend of result as these charts.





10. Expiration Date Determination

Based on these real-time aging results of "Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 1st Lot" expiration date may be up to a maximum of five (5) yeares. This type of glove will be labeled for 5 years expiration date.

11. Established by:

ปวีณา อินทวิวัฒน์  
Asst. LAB Manager

20/12/2018  
Date

12. Approve by:

วิวัฒน์ วัฒนวิวัฒน์  
LAB Manager

20/12/2018  
Date

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**Real-time aging Report to Determination of Expiration Dating (Shelf life) for  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 2nd Lot"**

**1. Purpose:**

The purpose of this document is to report a real-time aging result for appropriate shelf life of  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 2nd Lot"

**2. Scope:**

Valid for: "Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 2nd Lot"

**3. Normative Reference:**

ASTM D 7160-05	Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D 7161-05	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
EN455-4 : 2009	Medical gloves for single use-Part4 : Requirements and testing for Shelf life determination
ASTM D 412-16	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension Elastomers-Tension
ASTM D 573-04 (Reapproved 2015)	Test Method for Rubber- Deterioration in an Air Oven
ASTM D 5151-06 (Reapproved 2015)	Test Method for Detection of Holes in Medical Gloves
ASTM D3578-05 (Reapproved 2015)	Standard Specification for Rubber Examination Gloves
ASTM D6319-10 (Reapproved 2015)	Standard Specification for Nitrile Examination Gloves for Medical Application
EN455-1 : 2000	Medical glove for single use-Part1 : Requirements and testing for freedom from hole
EN455-2 : 2015	Medical glove for single use-Part2 : Requirements and testing for Physical properties.
EN455-3 : 2015	Medical glove for single use-Part3 : Requirements and testing for Biological evaluation.
ISO 2859-1:1999	Sampling procedure for inspection by attributes

**4. Study Date:**

Date of Manufacture: 19/11/2013

**5. Established:** Preechaya Insuwan Assistant Lab Manager

**6. Preparation and Sampling:**

Randomly selected glove samples from the packing area as plan on action plan. The glove samples should be fresh produced. (the date of packing are closed to date of production)

(Refer to: Determination of Expiration Dating (Shelf life) Protocol for

**"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG) "**

**Sample Identification:**

Lot no. **11SSLOF0401240BG 19/11/2013 C**  
**SSLOF0401240BG (400304628)**

**Surface: Textured at finger tip**  
**Size: SS**



7. Aging conditions:

Storage warehouse is uncontrolled.

8. Test Result:

8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578,EN455-1,EN455-2 at time zero

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med/ Ave)
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573		
- Tensile Strength BF aging						18 Min	26.7 MPa
- Tensile Strength AF aging						14 Min	24.3 MPa
- Elongation BF aging						650 Min	833 %
- Elongation AF aging						500 Min	824 %
- Number of defect						3 Max	0 defect
2. Physical Properties EN	-	-	13	Med	EN455-2		
- Force at break BF aging						6.5 Min	7.65 N
- Force at break AF aging						6.0 Min	7.16 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	0 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	5 defect
5. Dimension - Length						240 Med	240 mm
- Width						80+/-10	82 mm
- Finger						0.16 Min	0.25 mm
- Palm						0.16 Min	0.21 mm
- Cuff						-	0.16 mm
- Number of defect	S-2	4.0	13	1/2	ASTM D3578	1 Max	0 defect
6. Protein Content ASTM	-	-	3	-	ASTM D5712	50 Max	35.62 ug/g
7. Protein Content EN	-	-	8	-	EN 455-3	50 Max	20.85 ug/g
8. Residual Powder on Glove	-	-	5	-	ASTM D6124	2 Max	0.12 mg/glove

Disposition: Pass

8.2 Real-time aging results

yrs.	1. Physical Properties ASTM (S-3 AQL 4.0: n=32* Ac/Re=3/4) Test Method: ASTM D412				2. Physical Properties EN (n=13) Test Method: EN 455-2						Disposition
	Before Aging				Before Aging			After Aging			
	Tensile (MPa)	Elongation (%)	No. of defect	Disposition	Force (N)	Tensile (MPa)	Elongation (%)	Force (N)	Tensile (MPa)	Elongation (%)	
	18 min	650 min	3 max		6.5 min	-	-	6 min	-	-	
0	26.71	833	0	Pass	7.65	28.96	842	7.16	26.62	801	Pass
1	28.77	814	0	Pass	7.39	25.25	754	7.41	26.98	739	Pass
2	24.02	805	0	Pass	7.62	28.90	805	7.13	27.10	810	Pass
3	27.76	803	0	Pass	7.91	30.58	824	7.97	30.94	801	Pass
4	28.42	779	0	Pass	8.56	33.91	785	7.92	30.70	779	Pass
5	28.78	759	0	Pass	7.76	30.43	772	6.99	26.86	796	Pass



yrs.	3. Water Leak Test (S-3 AQL 2.5: n=32 Ac/Re=2/3) Test Method: ASTM D5151		4.. Water Leak Test (G-I AQL 1.5: n=200 Ac/Re=7/8) Test Method: EN455-1	
	No.of defect	Disposition	No.of defect	Disposition
	2 Max		7 Max	
0	0	Pass	5	Pass
1	1	Pass	3	Pass
2	1	Pass	1	Pass
3	1	Pass	7	Pass
4	0	Pass	6	Pass
5	2	Pass	0	Pass

yrs.	Dimension					Disposition
	Length (mm)	Width (mm)	Thickness(mm)			
			Finger	Palm	Cuff	
0.16			0.16	-		
0	240	82	0.25	0.21	0.16	Pass
1	241	83	0.26	0.21	0.15	Pass
2	241	83	0.26	0.22	0.16	Pass
3	240	82	0.25	0.21	0.15	Pass
4	240	82	0.24	0.19	0.13	Pass
5	242	82	0.23	0.19	0.13	Pass

yrs.	Residual powder		Protein ASTM		Protein EN	
	< 2 mg/glove	Disposition	50 ug/g	Disposition	50 ug/g	Disposition
0	0.12	Pass	35.62	Pass	20.85	Pass
1	0.14	Pass	14.50	Pass	7.66	Pass
2	0.14	Pass	26.51	Pass	15.45	Pass
3	0.16	Pass	28.19	Pass	15.05	Pass
4	0.22	Pass	26.15	Pass	17.67	Pass
5	0.26	Pass	17.87	Pass	9.76	Pass

8.3 Comparison between initial (Time zero) result with after accelerated aging results for physical properties.

yrs.	1. Physical Properties ASTM			2. Physical Properties EN	
	Tensile (MPa)	Elongation (%)	Disposition	Force (N)	Disposition
1	7.71	2.28	Pass	3.40	Pass
2	10.07	3.36	Pass	0.39	Pass
3	3.93	3.60	Pass	3.40	Pass
4	6.42	6.42	Pass	11.90	Pass
5	7.73	8.92	Pass	1.38	Pass

**Note:** - "32\*" means sample size as 32, although sample size per that inspection level are less than 32, but for testing will not less than 32 gloves according Table 1 in ASTM D7161-05.

Sample size per ISO 2859, Lot size as 1,600 gloves.

- At year 0 as before aging result of initial testing.
- Testing per EN standard are information only.



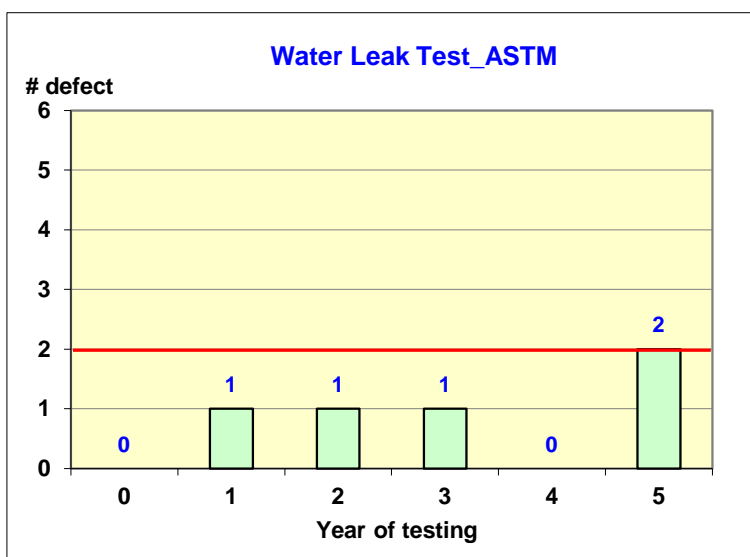
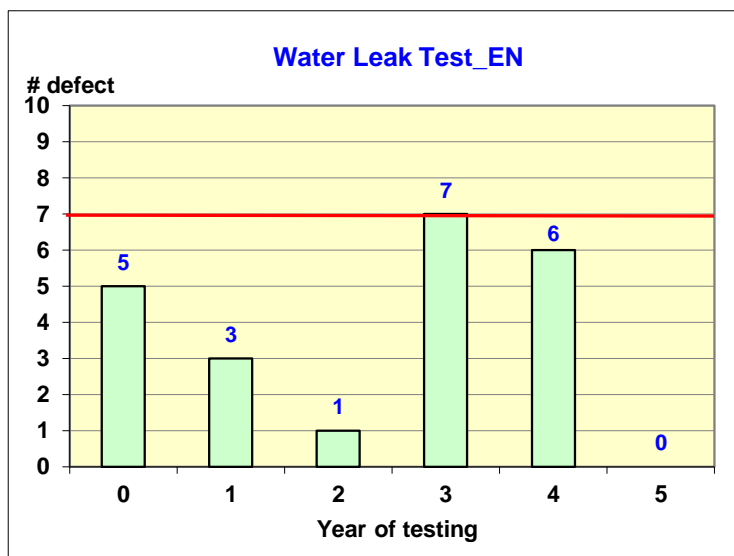
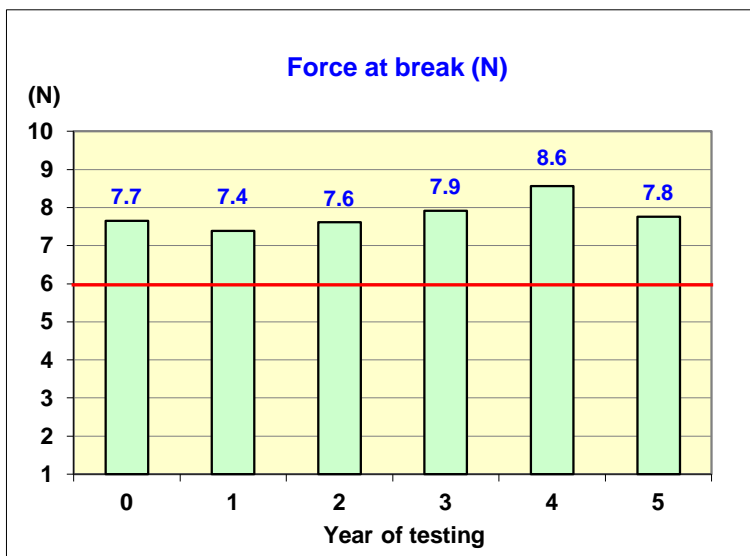
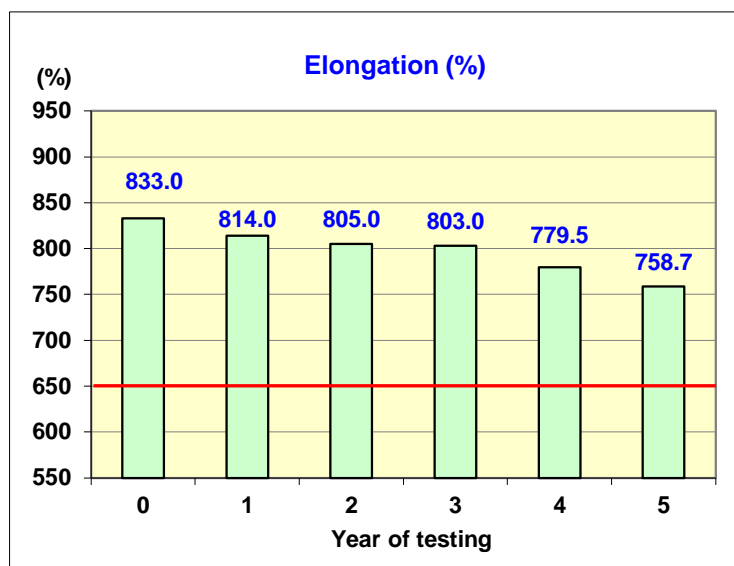
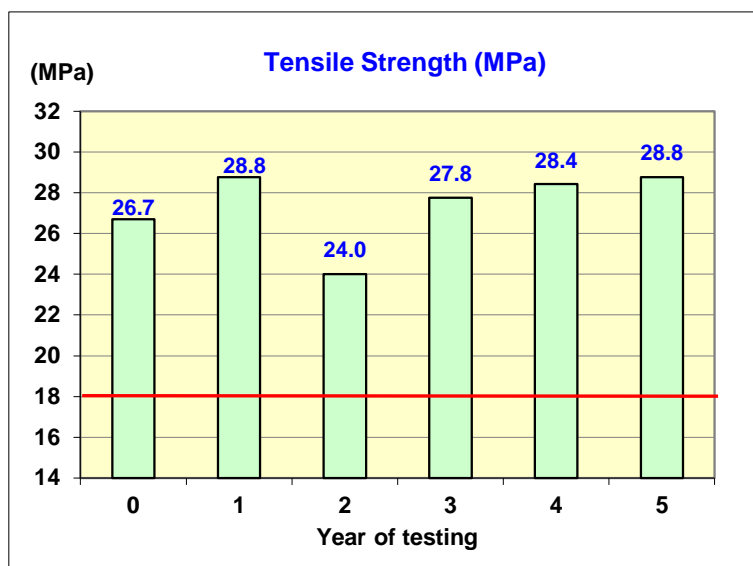
9. Conclusion:

Glove samples at naturally aging for 5 years meet the requirement of ASTM D3578,EN455-1,EN455-2

Specification with respect to water leak testing and physical properties.

- 9.1 For Physical properties of Tensile, %Elongation were more than the control limit so that, this glove had the high flexible and resistance for naturally aging condition.
- 9.2 The real-time aged glove sample are accept at AQL 2.5. The amount of defect in these gloves according to Sampling level S-3 AQL2.5 (ASTM D 5151) as chart display on chart below.

Trend of result as these charts.





10. Expiration Date Determination

Based on these real-time aging results of "Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 2nd Lot" expiration date may be up to a maximum of five (5) yeares. This type of glove will be labeled for 5 years expiration date.

11. Established by:

ชัชฎา อินทวิสุวณ

Asst. LAB Manager

20/12/2018

Date

12. Approve by:

วิภาณี วิเศษ

LAB Manager

20/12/2018

Date

**Real-time aging Report to Determination of Expiration Dating (Shelf life) for  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 3rd lot"**

**1. Purpose:**

The purpose of this document is to report a real-time aging result for appropriate shelf life of  
"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 3rd lot"

**2. Scope:**

Valid for: "Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG): 3rd lot"

**3. Normative Reference:**

ASTM D 7160-05	Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D 7161-05	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
EN455-4 : 2009	Medical gloves for single use-Part4 : Requirements and testing for Shelf life determination
ASTM D 412-16	Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension Elastomers-Tension
ASTM D 573-04 (Reapproved 2015)	Test Method for Rubber- Deterioration in an Air Oven
ASTM D 5151-06 (Reapproved 2015)	Test Method for Detection of Holes in Medical Gloves
ASTM D3578-05 (Reapproved 2015)	Standard Specification for Rubber Examination Gloves
ASTM D6319-10 (Reapproved 2015)	Standard Specification for Nitrile Examination Gloves for Medical Application
EN455-1 : 2000	Medical glove for single use-Part1 : Requirements and testing for freedom from hole
EN455-2 : 2015	Medical glove for single use-Part2 : Requirements and testing for Physical properties.
EN455-3 : 2015	Medical glove for single use-Part3 : Requirements and testing for Biological evaluation.
ISO 2859-1:1999	Sampling procedure for inspection by attributes

**4. Study Date:**

Date of Manufacture: 21/11/2013

**5. Established:** Preechaya Insuwan Assistant Lab Manager

**6. Preparation and Sampling:**

Randomly selected glove samples from the packing area as plan on action plan. The glove samples should be fresh produced. (the date of packing are closed to date of production)  
(Refer to: Determination of Expiration Dating (Shelf life) Protocol for

**"Powder Free Online Chlorination, Latex Examination Gloves (LOF\_BG) "**

**Sample Identification:**

Lot no. **09MMLOF0401240BG 21/11/2013 A**  
**MMLOF0401240BG (400304261)**

**Surface: Textured at finger tip**  
**Size: MM**



7. Aging conditions:

Storage warehouse is uncontrolled.

8. Test Result:

8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578,EN455-1,EN455-2 at time zero

Testing	Inspection level	AQL	Sample size	Ac/Re	Test Method	Specification	Test Result (Med/ Ave)
1. Physical Properties ASTM	S-3	4.0	32*	3/4	ASTM D412, D573		
- Tensile Strength BF aging						18 Min	28.00 MPa
- Tensile Strength AF aging						14 Min	25.74 MPa
- Elongation BF aging						650 Min	810 %
- Elongation AF aging						500 Min	815 %
- Number of defect						3 Max	0 defect
2. Physical Properties EN	-	-	13	Med	EN455-2		
- Force at break BF aging						6.5 Min	7.66 N
- Force at break AF aging						6.0 Min	7.48 N
3. Water Leak Test ASTM	S-3	2.5	32*	2/3	ASTM D5151	2 Max	0 defect
4. Water Leak Test EN	G-1	1.5	200	7/8	EN455-1	7 Max	4 defect
5. Dimension - Length						240 Med	241 mm
- Width						95+/-10	93.5 mm
- Finger						0.16 Min	0.26 mm
- Palm						0.16 Min	0.21 mm
- Cuff						-	0.16 mm
- Number of defect	S-2	4.0	13	1/2	ASTM D3578	1 Max	1 defect
6. Protein Content ASTM	-	-	3	-	ASTM D5712	50 Max	32.01 ug/g
7. Protein Content EN	-	-	8	-	EN 455-3	50 Max	8.12 ug/g
8. Residual Powder on Glove	-	-	5	-	ASTM D6124	2 Max	0.18 mg/glove

Disposition: Pass

8.2 Real-time aging results

Yrs.	1. Physical Properties ASTM (S-3 AQL 4.0: n=32* Ac/Re=3/4) Test Method: ASTM D412				2. Physical Properties EN (n=13) Test Method: EN 455-2						
	Before Aging				Before Aging			After Aging			Disposition
	Tensile (MPa)	Elongation (%)	No. of defect	Disposition	Force (N)	Tensile (MPa)	Elongation (%)	Force (N)	Tensile (MPa)	Elongation (%)	
	18 min	650 min	3 max		6.5 min	-	-	6 min	-	-	
0	28.00	810	0	Pass	7.66	29.45	819	7.48	28.34	826	Pass
1	27.84	823	0	Pass	8.50	28.93	826	8.46	26.96	777	Pass
2	29.91	824	0	Pass	8.03	30.50	819	7.43	28.61	820	Pass
3	29.76	799	0	Pass	8.66	31.93	801	8.10	29.33	791	Pass
4	30.35	762	0	Pass	8.48	33.98	762	8.68	33.48	779	Pass
5	29.01	781	0	Pass	8.27	31.25	793	8.01	30.02	791	Pass



yrs.	3. Water Leak Test (S-3 AQL 2.5: n=32 Ac/Re=2/3) Test Method: ASTM D5151		4.. Water Leak Test (G-I AQL 1.5: n=200 Ac/Re=7/8) Test Method: EN455-1	
	No.of defect	Disposition	No.of defect	Disposition
	3 Max		7 Max	
0	0	Pass	4	Pass
1	0	Pass	6	Pass
2	0	Pass	1	Pass
3	0	Pass	3	Pass
4	0	Pass	5	Pass
5	2	Pass	1	Pass

yrs.	Dimension					Disposition
	Length (mm)	Width (mm)	Thickness(mm)			
			Finger	Palm	Cuff	
			0.16	0.16	-	
0	241	94	0.26	0.21	0.16	Pass
1	240	94	0.26	0.21	0.16	Pass
2	240	94	0.26	0.21	0.16	Pass
3	241	94	0.25	0.21	0.15	Pass
4	240	95	0.24	0.19	0.13	Pass
5	240	93	0.23	0.19	0.14	Pass

yrs.	Residual powder		Protein ASTM		Protein EN	
	< 2 mg/glove	Disposition	50 ug/g	Disposition	50 ug/g	Disposition
0	0.18	Pass	32.01	Pass	8.12	Pass
1	0.20	Pass	8.63	Pass	5.25	Pass
2	0.16	Pass	37.50	Pass	14.64	Pass
3	0.14	Pass	24.26	Pass	14.76	Pass
4	0.18	Pass	13.03	Pass	15.25	Pass
5	0.24	Pass	12.72	Pass	5.88	Pass

8.3 Comparison between initial (Time zero) result with after accelerated aging results for physical properties.

yrs.	1. Physical Properties ASTM			2. Physical Properties EN	
	Tensile (MPa)	Elongation (%)	Disposition	Force (N)	Disposition
1	0.57	1.60	Pass	10.97	Pass
2	6.82	1.73	Pass	4.83	Pass
3	6.29	1.36	Pass	13.05	Pass
4	8.40	5.94	Pass	10.70	Pass
5	3.60	3.61	Pass	8.02	Pass

**Note:** - "32\*" means sample size as 32, although sample size per that inspection level are less than 32, but for testing will not less than 32 gloves according Table 1 in ASTM D7161-05.  
Sample size per ISO 2859, Lot size as 1,600 gloves.  
- At year 0 as before aging result of initial testing.  
- Testing per EN standard are information only.

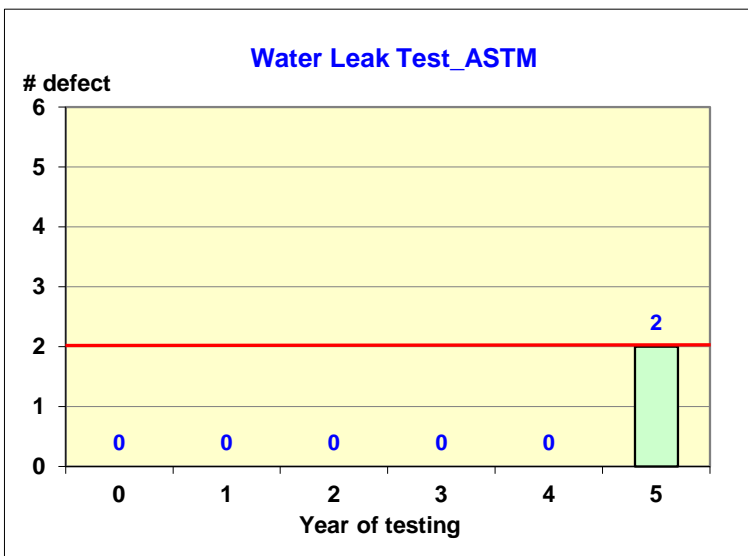
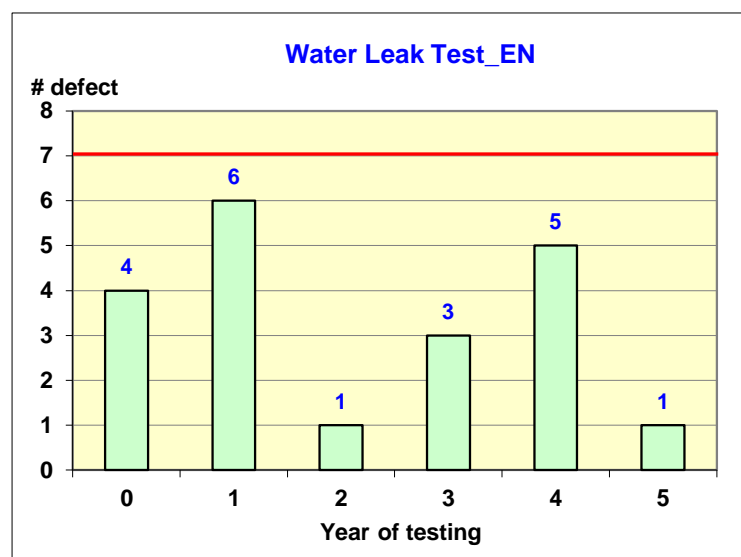
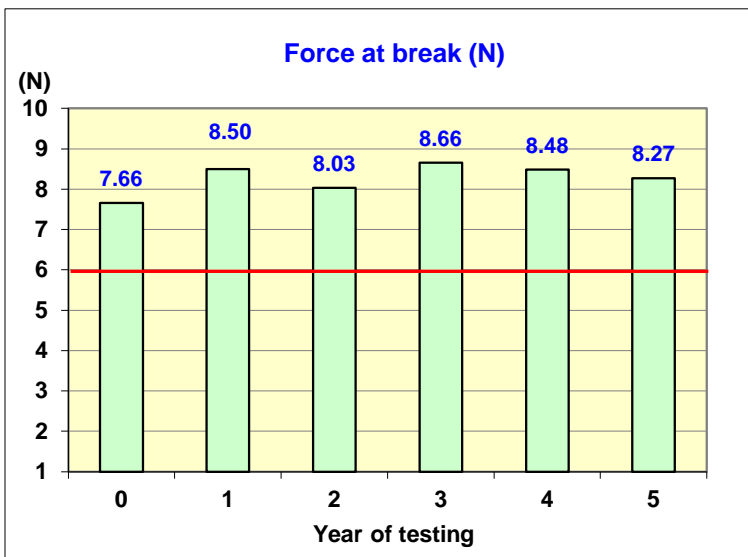
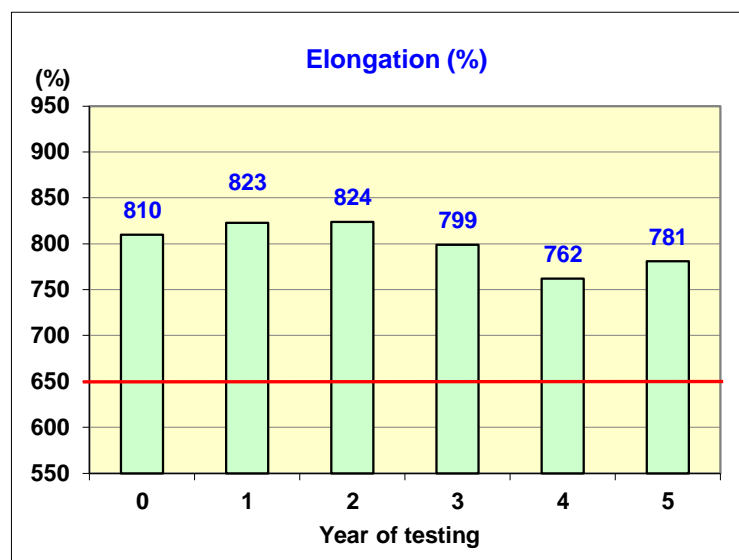
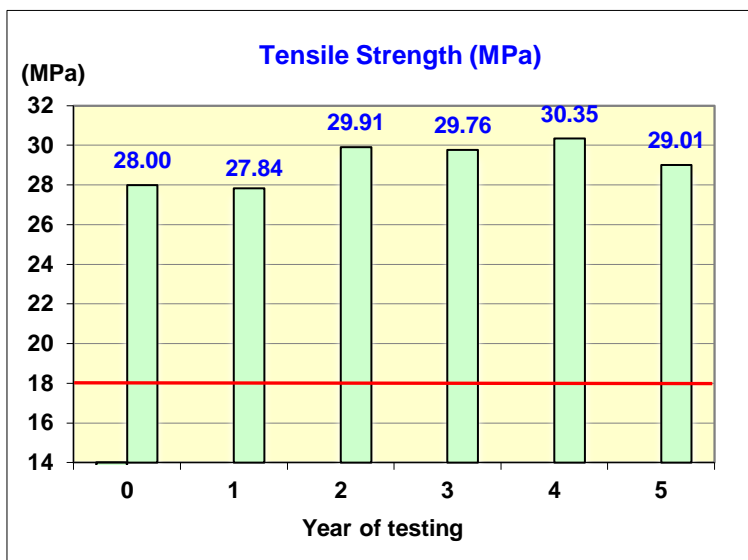




9. Conclusion:

Glove samples at naturally aging for 5 years meet the requirement of ASTM D3578,EN455-1,EN455-2 Specification with respect to water leak testing and physical properties.

- 9.1 For Physical properties of Tensile, %Elongation were more than the control limit so that, this glove had the high flexible and resistance for naturally aging condition.
  - 9.2 The real-time aged glove sample are accept at AQL 2.5. The amount of defect in these gloves according to Sampling level S-3 AQL2.5 (ASTM D 5151) as chart display on chart below.
- Trend of result as these charts.





10. Expiration Date Determination

Based on these real-time aging results of Real-time aging Report to Determination of Expiration Dating (Shelf life) for expiration date may be up to a maximum of five (5) yeares. This type of glove will be labeled for 5 years expiration date.

11. Established by:

ปวีณา อินทสุวรรณ  
Asst. LAB Manager

20/12/2018  
Date

12. Approve by:

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LAB Manager

20/12/2018  
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