



**Determination of Expiration Dating (Shelf life) Protocol for
"Powder, Latex Examination Gloves (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, Latex Examination Gloves (BG)"
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 |
| ASTM D 412-98a (Reapproved 2002)e1 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers- |
| ASTM D 573-04 | Test Method for Rubber- Deterioration in an Air Oven |
| ASTM D 5151-99 | Test Method for Detection of Holes in Medical Gloves |
| ASTM D 3578-05 | 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 :2009 (E) | Medical glove for single use-Part2 : Requirements and testing for Physical properties. |
| EN455-3 :2006 (E) | 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, Latex Examination Gloves (BG)" will be sampling as this;

| No. | Jan07 | Feb07 | Mar07 | Apr07 | May07 | Jun07 | Jul07 | Aug07 | Sep07 | Oct07 | Nov07 | Dec07 |
|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Lot 1 | | | | | | | | | | | | |
| Lot 2 | | | | | | | | | | | | |
| Lot 3 | | | | | | | | | | | | |

5. Established: Tasnee Hasalem Senior Assistant Lab Manager

This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated. Downloaded by SUDARAT KETSIRIKUN on date 01 Apr 2021



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)

The date of manufacture will refer to packing date.

In each lot would be sampling as this table;

Table 1: Number of sampling.

| Glove Sampling condition | "Powder, Latex Examination Gloves (BG)" |
|-----------------------------|---|
| 0) Time zero | 2 Dispensers |
| 1) Accelerated aging | |
| 1) 70 ± 2 °C, 166 ± 2 hour | 2 Dispensers |
| 2) 50 ± 2 °C, 90 ± 1 days | 2 Dispensers |
| 2) Real time aging | 10 Dispensers |

Note: 1 Dispenser contains 100 gloves

Refer to LA.SO.GE.10.037/a051206 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 ± 2 °C, 166 ± 2 h and 50 ± 2 °C, 90 ± 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 ASTM D 573 and EN455-2.

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 ASTM D 3578-05 and 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 | - | 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 | EN455-1 |
| 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. Powder Amount on glove | - | - | 2 | - | 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 | - | 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 | EN455-1 |

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 ASTM 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 | - | 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 | EN455-1 |

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.
- Testing per EN standard are information only.



9. Acceptance Criteria

9 Real time-aged glove must meet the requirements of the appropriate ASTM D 3578-05 EN455-2 and EN455-1. with respect to water leak testing and "before aging" physical properties.

9.2 Oven-aged samples must meet the requirements of the appropriate ASTM D 3578-05 EN455-2 and EN455-1. with respect to water leak testing and "after aging" physical properties.

9 If a 25% or greater change in physical properties 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.10.006 |
| 2. Physical Properties EN | LA.FO.GE.10.006 |
| 3. Water Leak Test ASTM | PR.WI.GE.09.001 |
| 4. Water Leak Test EN | PR.WI.GE.09.001 |
| 5. Dimension | LA.FO.GE.10.010 |
| 6. Protein Content ASTM | LA.FO.GE.10.004 |
| 7. Protein Content EN | LA.FO.GE.10.004 |
| 8. Powder amount on glove | LA.FO.GE.10.017 |
| 9. Summary Report | Accelerated aging Report Real Time aging Report |

11. Established by:

Tasnee Hasalem

27/03/2007

Tasnee Hasalem
Senior-Asst. LAB Manager

Date

12. Approve by:

Sureerat

27/03/2007

Sureerat Choosri
LAB Manager

Date

This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated. Downloaded by: SUDARAT KETSIRIKUN on date 01 Apr 2021



**Accelerated aging Report to Determination of Expiration Dating (Shelf life) for
"Powder, Latex Examination Gloves (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, Latex Examination Gloves (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 |
| ASTM D 412-98a (Reapproved 2002)e1 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers- |
| ASTM D 573-04 | Test Method for Rubber- Deterioration in an Air Oven |
| ASTM D 5151-99 | Test Method for Detection of Holes in Medical Gloves |
| ASTM D3578-05 | 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 :2009 (E) | Medical glove for single use-Part2 : Requirements and testing for Physical properties. |
| EN455-3 :2006 (E) | 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: **27/03/2007**

5. Established:

Tasnee Hasalem Senior 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, Latex Examination Gloves (BG)"*

Sample Identification:

Lot no. **15 MM 260307 B (006043057)** Surface: **Smooth**
MMLXS0101240BG Size: **M**

7. Aging conditions:

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

Disposition: Pass

This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated. Downloaded by SUBARAT KETSIRIKUN on 27 Apr 2024



This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.

8. Test Result:

8.1 Initial (Time zero) Testing:

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578-05 and 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 | 25.31 MPa |
| - Tensile Strength AF aging | | | | | | 14 Min | 21.82 MPa |
| - Elongation BF aging | | | | | | 650 Min | 862 % |
| - Elongation AF aging | | | | | | 500 Min | 808 % |
| - Number of defect | | | | | | 3 Max | 0 defect |
| 2. Physical Properties EN | - | - | 13 | - | EN 455-2 | | |
| - Force at break BF aging | | | | | | 6 Med | 6.90 N |
| - Force at break AF aging | | | | | | 6 Med | 6.87 N |
| - Tensile Strength BF aging | | | | | | 18 Min | 23.89 MPa |
| - Tensile Strength AF aging | | | | | | 14 Min | 24.62 MPa |
| - Elongation BF aging | | | | | | 650 Min | 848 % |
| - Elongation AF aging | | | | | | 500 Min | 828 % |
| 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 | EN 455-1 | 7 Max | 1 defect |
| 5. Dimension - Length | | | | | | 240 Min | 243 mm |
| - Width | | | | | | 95 +/- 10 | 94 mm |
| - Finger | | | | | | 0.16 Min | 0.250 mm |
| - Palm | | | | | | 0.16 Min | 0.220 mm |
| - Cuff | | | | | | - | 0.160 mm |
| - Number of defect | S-2 | 4.0 | 13 | 1/2 | ASTM D3578 | 1 Max | 0 defect |
| 6. Protein Content ASTM | - | - | 3 | - | ASTM D5712 | 200 Max | 43 µg/g |
| 7. Protein Content EN | - | - | 8 | - | EN 455-3 | 200 Max | 130 µg/g |
| 8. Powder Amount on Glove | - | - | 5 | - | ASTM D6124 | 10 Max | 8 mg/dm ² |

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 | S-3 | 4.0 | 32* | 3/4 | ASTM D412, D573 | | |
| - Tensile Strength | | | | | | 14 Min | 28.19 MPa |
| - Elongation | | | | | | 500 Min | 824 % |
| - Number of defect | | | | | | 3 Max | 0 defect |
| 2. Physical Properties EN | - | - | 13 | - | EN 455-2 | | |
| - Force at break | | | | | | 6 Med | 7.73 N |
| - Tensile Strength (EN) | | | | | | 14 Min | 26.41 MPa |
| - Elongation (EN) | | | | | | 500 Min | 840 % |
| 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 | 0 defect |

Disposition: Pass

Downloaded by SUDARAT KEITSIRIKUN on date 01 Apr 2021



8.3 Accelerated aging result at $50 \pm 2 \text{ }^\circ\text{C}$, 90 ± 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 | 14 Min 500 Min 3 Max | 26.88 MPa 798 % 0 defect |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | - | - | 13 | - | EN 455-2 | 6 Med 14 Min 500 Max | 7.50 N 27.64 MPa 816 % |
| 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 | 0 defect |

Disposition: **Pass**

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

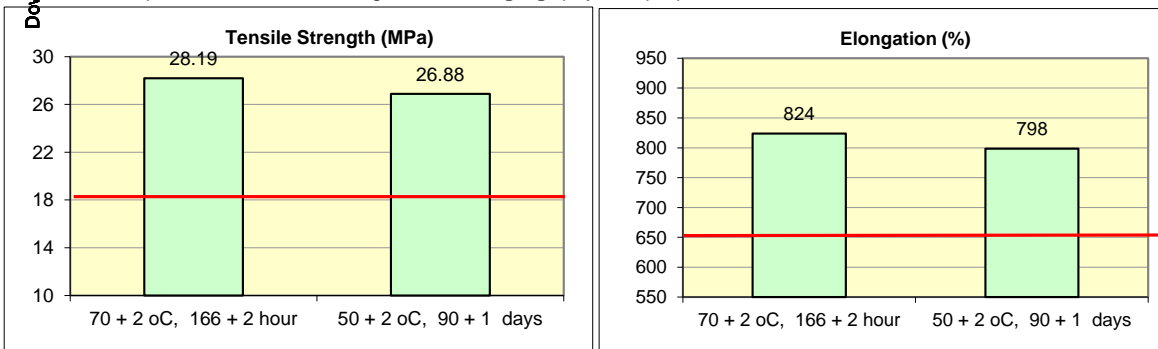
| Testing | % Difference from initial value | |
|---|--|---|
| | $70 \pm 2 \text{ }^\circ\text{C}$, 166 ± 2 hour | $50 \pm 2 \text{ }^\circ\text{C}$, 90 ± 1 days |
| 1. Physical Properties ASTM - Tensile Strength - Elongation | 11.38% 4.45% | 6.20% 7.42% |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | 12.03% 7.27% 0.94% | 8.70% 12.27% 3.77% |

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**

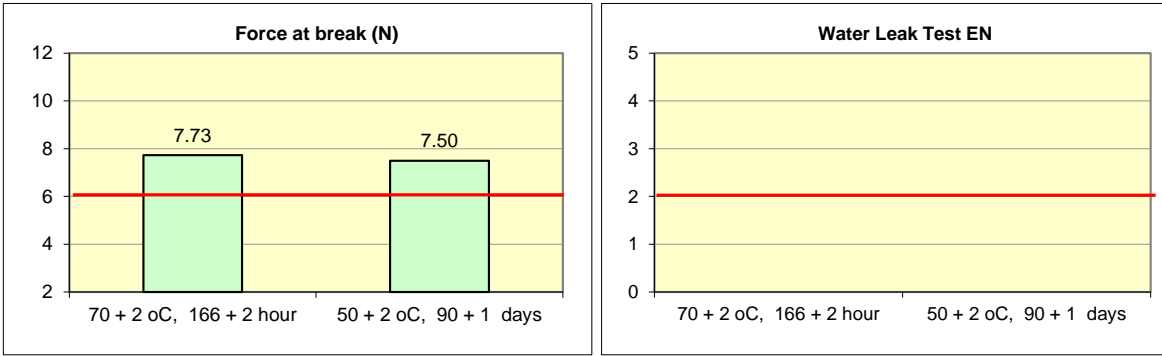
9. Conclusion:

1. Oven-aged samples meet the requirements of the appropriate ASTM D3578-05 and EN455-2 with respect to water leak testing and "after aging" physical properties.

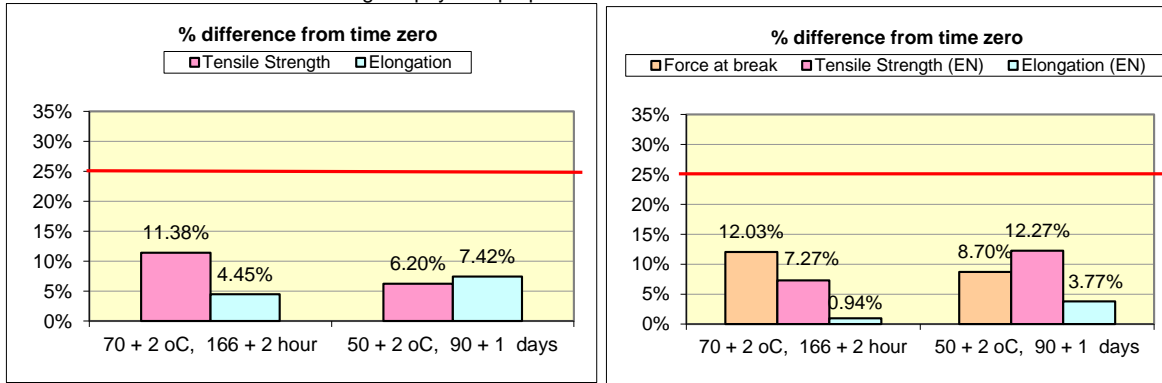




This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated



9 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, Latex Examination Gloves (BG): 1st Lot"

11. Established by:

Tasnee Hasalem
Tasnee Hasalem
Senior-Asst. LAB Manager

10/07/2007

Date

12. Approve by:

Sureerat
Sureerat Choosri
LAB Manager

10/07/2007

Date

Downloaded by SUDARAT KETSIRIKUN on date 01 Apr 2021



**Accelerated aging Report to Determination of Expiration Dating (Shelf life) for
"Powder, Latex Examination Gloves (BG): 2 nd 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, Latex Examination Gloves (BG): 2 nd 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 |
| ASTM D 412-98a (Reapproved 2002)e1 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers- |
| ASTM D 573-04 | Test Method for Rubber- Deterioration in an Air Oven |
| ASTM D 5151-99 | Test Method for Detection of Holes in Medical Gloves |
| ASTM D3578-05 | 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 :2009 (E) | Medical glove for single use-Part2 : Requirements and testing for Physical properties. |
| EN455-3 :2006 (E) | 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: **17/07/2007**

5. Established: Tasnee Hasalem Senior 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, Latex Examination Gloves (BG)"*

Sample Identification:

Lot no. **25 M 160707 B (006171862)** Surface: **Smooth**
MMLXS0101240BG Size: **M**

7. Aging conditions:

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

Disposition: Pass



This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.

8. Test Result:

8.1 Initial (Time zero) Testing:

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578-05 and 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 | 26.67 MPa 23.18 MPa 835 % 826 % 0 defect |
| 2. Physical Properties EN - Force at break BF aging - Force at break AF aging - Tensile Strength BF aging - Tensile Strength AF aging - Elongation BF aging - Elongation AF aging | - | - | 13 | - | EN 455-2 | 6 Med 6 Med 18 Min 14 Min 650 Min 500 Min | 7.25 N 8.09 N 24.12 MPa 28.49 MPa 864 % 864 % |
| 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 | EN 455-1 | 7 Max | 1 defect |
| 5. Dimension - Length - Width - Finger - Palm - Cuff - Number of defect | S-2 | 4.0 | 13 | 1/2 | ASTM D3578 | 240 Min 95 +/- 10 0.16 Min 0.16 Min - | 242 mm 95 mm 0.270 mm 0.220 mm 0.150 mm 0 defect |
| 6. Protein Content ASTM | - | - | 3 | - | ASTM D5712 | 200 Max | 89 µg/g |
| 7. Protein Content EN | - | - | 8 | - | EN 455-3 | 200 Max | 51 µg/g |
| 8. Powder Amount on Glove | - | - | 5 | - | ASTM D6124 | 10 Max | 7 mg/dm ² |

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 | 14 Min 500 Min 3 Max | 30.75 MPa 870 % 0 defect |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | - | - | 13 | - | EN 455-2 | 6 Med 14 Min 500 Min | 7.23 N 26.88 MPa 851 % |
| 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 | 0 defect |

Disposition: Pass

Downloaded by SUDARAT KEITSIRIKUN on date 01 Apr 2021



8.3 Accelerated aging result at $50 \pm 2 \text{ }^\circ\text{C}$, 90 ± 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 | 14 Min 500 Min 3 Max | 27.29 MPa 820 % 0 defect |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | - | - | 13 | - | EN 455-2 | 6 Med 14 Min 500 Max | 7.38 N 26.58 MPa 828 % |
| 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 | 1 defect |

Disposition: **Pass**

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

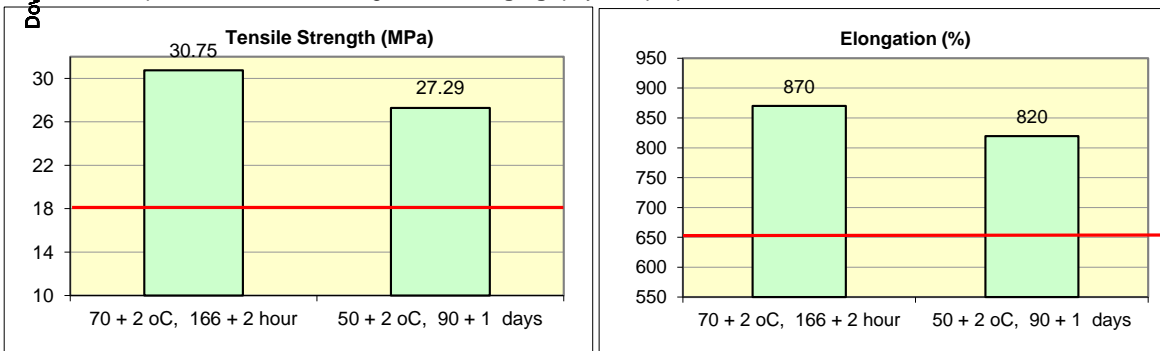
| Testing | % Difference from initial value | |
|---|--|---|
| | $70 \pm 2 \text{ }^\circ\text{C}$, 166 ± 2 hour | $50 \pm 2 \text{ }^\circ\text{C}$, 90 ± 1 days |
| 1. Physical Properties ASTM - Tensile Strength - Elongation | 15.30% 4.17% | 2.32% 1.87% |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | 0.28% 5.65% 1.48% | 1.79% 6.70% 4.17% |

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**

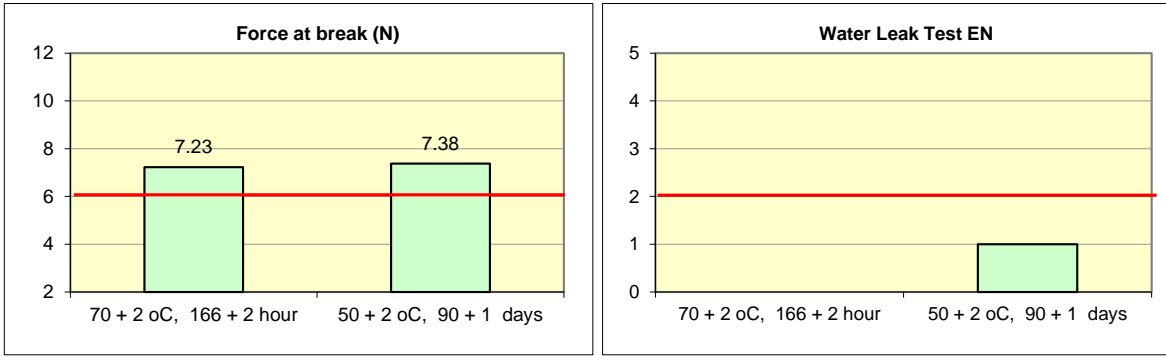
9. Conclusion:

9.1 Oven-aged samples meet the requirements of the appropriate ASTM D3578-05 and EN455-2 with respect to water leak testing and "after aging" physical properties.

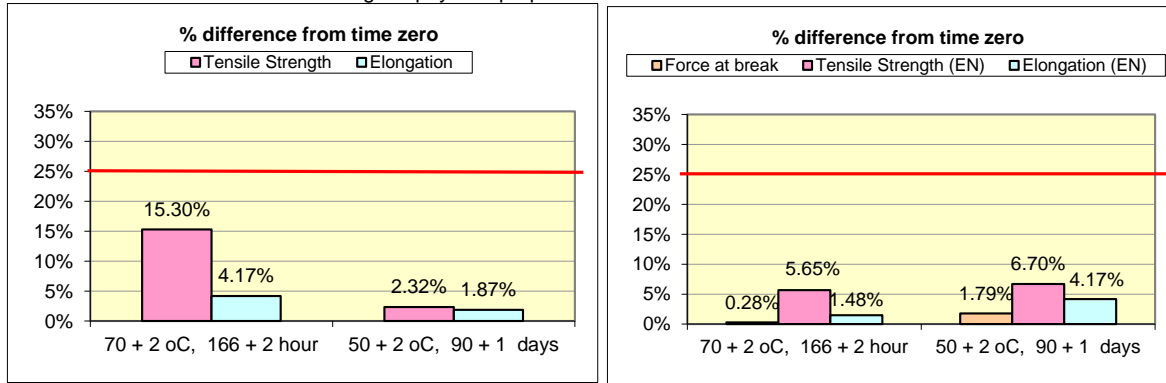




This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated. Downloaded by: SUDARAT KETSIRIKUN on date 01 Apr 2021



9 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, Latex Examination Gloves (BG): 2 nd Lot"

11. Established by:

Tasnee Hasalem
 Tasnee Hasalem
 Senior-Asst. LAB Manager

24/10/2007

Date

12. Approve by:

Sureerat
 Sureerat Choosri
 LAB Manager

24/10/2007

Date



**Accelerated aging Report to Determination of Expiration Dating (Shelf life) for
"Powder, Latex Examination Gloves (BG): 3 rd 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, Latex Examination Gloves (BG): 3 rd 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 |
| ASTM D 412-98a (Reapproved 2002)e1 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers- |
| ASTM D 573-04 | Test Method for Rubber- Deterioration in an Air Oven |
| ASTM D 5151-99 | Test Method for Detection of Holes in Medical Gloves |
| ASTM D3578-05 | 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 :2009 (E) | Medical glove for single use-Part2 : Requirements and testing for Physical properties. |
| EN455-3 :2006 (E) | 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: **13/11/2007**

5. **Established:** Tasnee Hasalem Senior 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, Latex Examination Gloves (BG)"*

6. **Sample Identification:**

Lot no. **25 M 121107 B(006371917)** Surface: **Smooth**
MMLXF0101240BG Size: **M**

7. **Aging conditions:**

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

Disposition: Pass

This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.
Downloaded by SUBARAT KEITSIRIKUN on 04 Apr 2024



This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.

8. Test Result:

8.1 Initial (Time zero) Testing:

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578-05 and 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 | 25.19 MPa 23.70 MPa 842 % 862 % 0 defect |
| 2. Physical Properties EN - Force at break BF aging - Force at break AF aging - Tensile Strength BF aging - Tensile Strength AF aging - Elongation BF aging - Elongation AF aging | - | - | 13 | - | EN 455-2 | 6 Med 6 Med 18 Min 14 Min 650 Min 500 Min | 6.25 N 6.54 N 24.66 MPa 27.64 MPa 860 % 820 % |
| 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 | EN 455-1 | 7 Max | 1 defect |
| 5. Dimension - Length - Width - Finger - Palm - Cuff - Number of defect | S-2 | 4.0 | 13 | 1/2 | ASTM D3578 | 240 Min 95 +/- 10 0.16 Min 0.16 Min - | 242 mm 95 mm 0.270 mm 0.210 mm 0.150 mm 0 defect |
| 6. Protein Content ASTM | - | - | 3 | - | ASTM D5712 | 200 Max | 48 µg/g |
| 7. Protein Content EN | - | - | 8 | - | EN 455-3 | 200 Max | 121 µg/g |
| 8. Powder Amount on Glove | - | - | 5 | - | ASTM D6124 | 10 Max | 9 mg/dm ² |

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 | 14 Min 500 Min 3 Max | 27.47 MPa 838 % 0 defect |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | - | - | 13 | - | EN 455-2 | 6 Med 14 Min 500 Min | 6.77 N 27.50 MPa 861 % |
| 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 | 0 defect |

Disposition: Pass

Downloaded by SUDARAT KEITSIRIKUN on date 01 Apr 2021



8.3 Accelerated aging result at $50 \pm 2 \text{ }^\circ\text{C}$, 90 ± 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 | 14 Min 500 Min 3 Max | 26.36 MPa 830 % 0 defect |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | - | - | 13 | - | EN 455-2 | 6 Med 14 Min 500 Max | 6.91 N 28.15 MPa 867 % |
| 3. Water Leak Test ASTM | G-1 | 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 | 1 defect |

Disposition: **Pass**

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

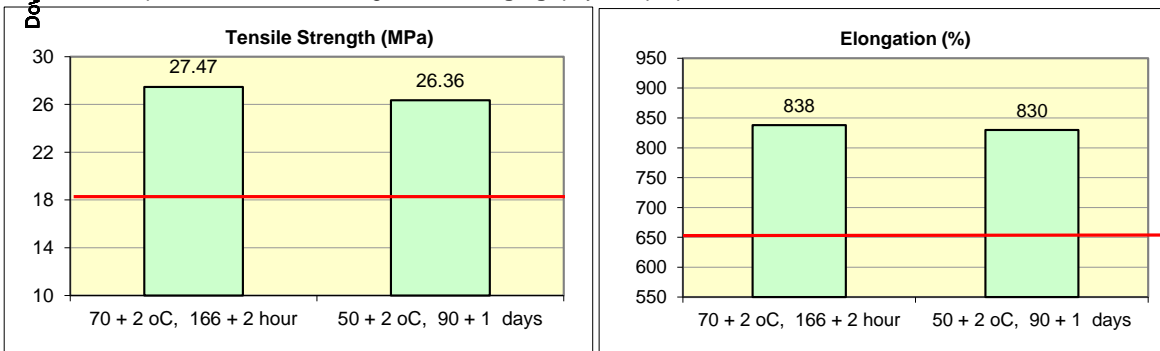
| Testing | % Difference from initial value | |
|---|--|---|
| | $70 \pm 2 \text{ }^\circ\text{C}$, 166 ± 2 hour | $50 \pm 2 \text{ }^\circ\text{C}$, 90 ± 1 days |
| 1. Physical Properties ASTM - Tensile Strength - Elongation | 9.05% 0.48% | 4.64% 1.43% |
| 2. Physical Properties EN - Force at break - Tensile Strength (EN) - Elongation (EN) | 8.32% 0.51% 0.09% | 10.56% 1.85% 0.81% |

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**

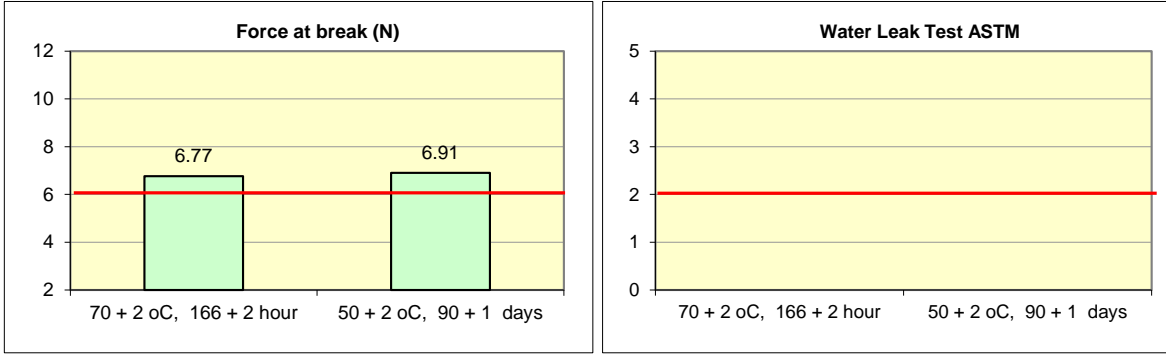
9. Conclusion:

1. Oven-aged samples meet the requirements of the appropriate ASTM D3578-05 and EN455-2 with respect to water leak testing and "after aging" physical properties.

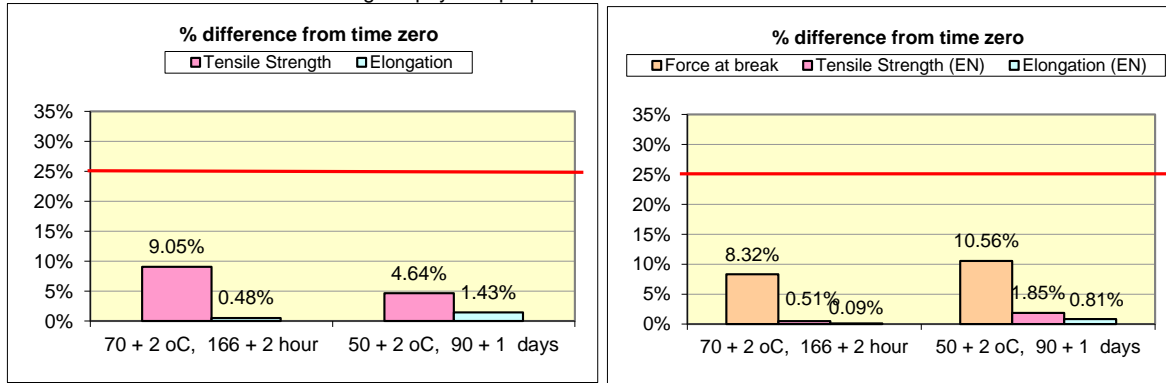




This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated



9 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, Latex Examination Gloves (BG): 3 rd Lot"

11. Established by:

Tasnee Hasalem
 Tasnee Hasalem
 Senior-Asst. LAB Manager

26/03/2008

Date

12. Approve by:

Sureerat
 Sureerat Choosri
 LAB Manager

26/03/2008

Date

Downloaded by : SUDARAT KETSIRIKUN on date 01 Apr 2021

Real-time aging Report to Determination of Expiration Dating (Shelf life) for
"Powder, Latex Examination Gloves (BG): 1st Lot"

1. Purpose:

The purpose of this document is to report a real-time aging result for appropriate shelf life of
"Powder, Latex Examination Gloves (BG): 1st Lot" according to Realtime aging Protocol.

2. Scope:

Valid for: "Powder, Latex Examination Gloves (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 |
| ASTM D 412-98a (Reapproved 2002)e1 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension |
| ASTM D 573-04 | Test Method for Rubber- Deterioration in an Air Oven |
| ASTM D 5151-99 | Test Method for Detection of Holes in Medical Gloves |
| ASTM D3578-05 | 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 :2009 (E) | Medical glove for single use-Part2 : Requirements and testing for Physical properties. |
| EN455-3 :2006 (E) | 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: 27/03/2007

5. Established:

Rosna Yensuk 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, Latex Examination Gloves (BG)"*

Sample Identification:

Lot no. 15 MM 260307 B (006043057)
MMLXS0101240BG

Surface: Smooth
Size: M

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 D3578-05 and 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 | 25.31 MPa |
| - Tensile Strength AF aging | | | | | | 14 Min | 21.82 MPa |
| - Elongation BF aging | | | | | | 650 Min | 862 % |
| - Elongation AF aging | | | | | | 500 Min | 808 % |
| - Number of defect | | | | | | 3 Max | 0 defect |
| 2. Physical Properties EN | - | - | 13 | - | EN 455-2 | | |
| - Force at break BF aging | | | | | | 6 Med | 6.90 N |
| - Force at break AF aging | | | | | | 6 Med | 6.87 N |
| - Tensile Strength BF aging | | | | | | 18 Min | 23.89 MPa |
| - Tensile Strength AF aging | | | | | | 14 Min | 24.62 MPa |
| - Elongation BF aging | | | | | | 650 Min | 848 % |
| - Elongation AF aging | | | | | | 500 Min | 828 % |
| 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 | EN 455-1 | 7 Max | 1 defect |
| 5. Dimension - Length | | | | | | 240 Med. | 243 mm |
| - Width | | | | | | 95 +/- 10 | 94 mm |
| - Finger | | | | | | 0.16 Min | 0.250 mm |
| - Palm | | | | | | 0.16 Min | 0.220 mm |
| - Cuff | | | | | | - | 0.160 mm |
| - Number of defect | S-2 | 4.0 | 13 | 1/2 | ASTM D3578 | 1 Max | 0 defect |
| 6. Protein Content ASTM | - | - | 3 | - | ASTM D5712 | 200 Max | 43 µg/g |
| 7. Protein Content EN | - | - | 8 | - | EN 455-3 | 200 Max | 130 µg/g |
| 8. Residual Powder on glove | - | - | 5 | - | ASTM D6124 | 10 Max | 8 mg/dm ² |

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 Med | - | - | |
| 0 | 23.51 | 862 | 0 | Pass | 6.90 | 23.89 | 848 | - | - | - | Pass |
| 1 | 28.46 | 852 | 0 | Pass | 7.78 | 28.85 | 848 | - | - | - | Pass |
| 2 | 25.73 | 798 | 0 | Pass | 6.95 | 25.51 | 784 | - | - | - | Pass |
| 3 | - | - | - | - | 7.72 | 28.39 | 765 | - | - | - | Pass |
| 4 | - | - | - | - | 7.64 | 28.54 | 776 | 7.22 | 27.88 | 765 | Pass |
| 5 | - | - | - | - | 8.00 | 29.31 | 796 | 7.58 | 27.04 | 780 | 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 EN455-1 Letter L G-1 Multiple ,Normal sampling 5 round (1 round = 50 pcs) Test Method: EN455-1 | |
|------|--|-------------|--|-------------|
| | No.of defect | Disposition | No.of defect | Disposition |
| | 3 Max | | 7 Max | |
| 0 | 1 | Pass | - | - |
| 1 | 0 | Pass | - | - |
| 2 | 0 | Pass | - | - |
| 3 | 0 | Pass | 0 | Pass |
| 4 | - | - | 0 | Pass |
| 5 | - | - | 0 | Pass |

| yrs. | Dimension (Avg) | | | | | Disposition |
|------|-----------------|------------|---------------|-------|-------|-------------|
| | Length (mm) | Width (mm) | Thickness(mm) | | | |
| | | | Finger | Palm | Cuff | |
| 0 | 243 | 94 | 0.250 | 0.220 | 0.160 | Pass |
| 1 | - | - | - | - | - | - |
| 2 | - | - | - | - | - | - |
| 3 | 243 | 96 | 0.237 | 0.193 | 0.150 | Pass |
| 4 | 240 | 93 | 0.250 | 0.208 | 0.161 | Pass |
| 5 | 240 | 93 | 0.269 | 0.210 | 0.167 | Pass |

| yrs. | Residual powder | | Protein ASTM | | Protein EN | |
|------|-----------------|-------------|--------------|-------------|--------------|-------------|
| | 6-15 mg/dm2 | Disposition | 200 ug/g Max | Disposition | 200 ug/g Max | Disposition |
| 0 | 8 | Pass | 43 | Pass | 130 | Pass |
| 1 | - | - | - | - | - | - |
| 2 | - | - | - | - | - | - |
| 3 | 7 | Pass | 20 | Pass | 59 | Pass |
| 4 | 8 | Pass | - | - | 52 | Pass |
| 5 | 6 | Pass | - | - | 62 | Pass |

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) | Tensile (MPa) | Elongation (%) | Disposition |
| 1 | 21.05% | 1.21% | Pass | 12.75% | 20.76% | 0.00% | Pass |
| 2 | 9.44% | 7.47% | Pass | 0.72% | 6.78% | 7.55% | Pass |
| 3 | - | - | - | 11.88% | 18.84% | 9.79% | Pass |
| 4 | - | - | - | 10.72% | 19.46% | 8.49% | Pass |
| 5 | - | - | - | 15.94% | 22.69% | 6.13% | 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.



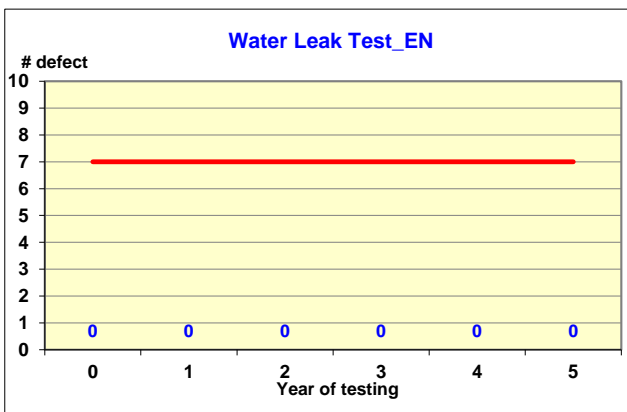
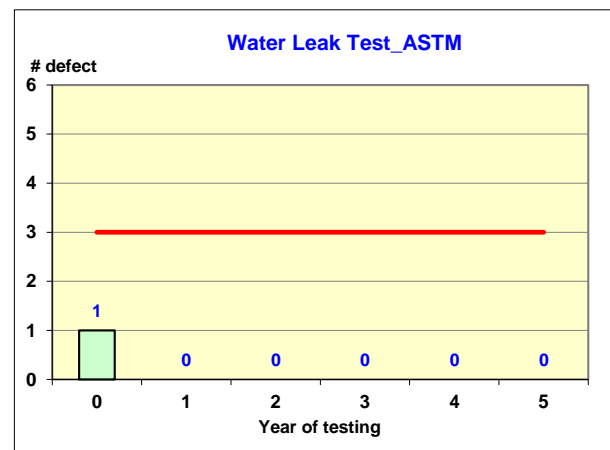
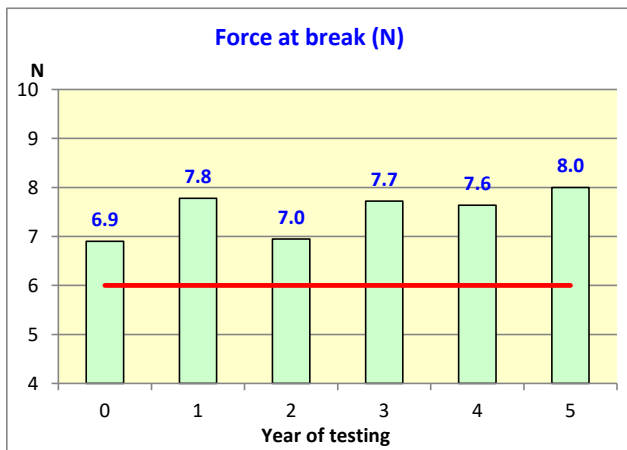
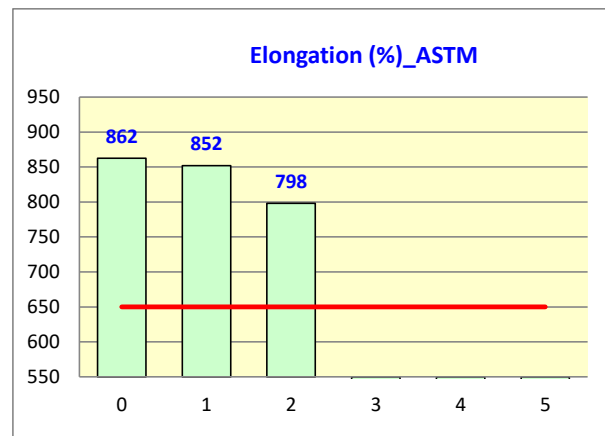
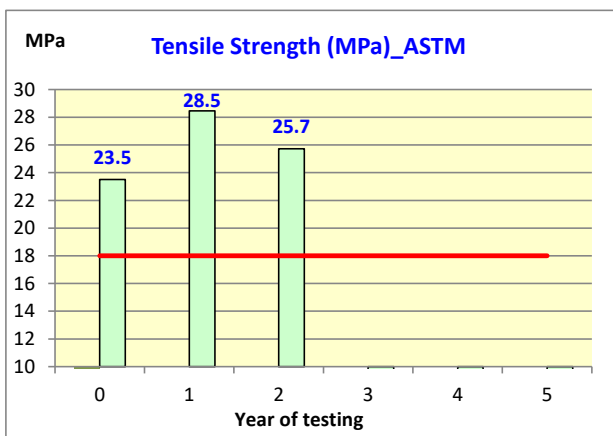
9. Conclusion:

Glove samples at naturally aging for 5 years meet the requirement of ASTM D3578-05 and 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 ASTM D3578-05 and EN455-2 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 (ASTM D 5151) and GI (EN 455-1) as chart display on chart below.

Trend of result as these charts.



SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

Registration number 0107562000106

Headquarter: No. 110, Kanjanavanit Road, Pathong,
Hat Yai, Songkhla 90230 Thailand
Tel: (66) 74-471-471
Fax: (66) 74-291-650

Office: No. 10 Soi 10, Phetkasem Road, Hat Yai,
Hat Yai, Songkhla 90110 Thailand
Tel: (66) 74-344-663
Fax: (66) 74-344-677, 74-237-423, 74-237-832

บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)

ทะเบียนเลขที่ 0107562000106

สำนักงานใหญ่: เลขที่ 110 ถนนกาญจนาภิเษก ตำบลพะวง อำเภอหาดใหญ่
จังหวัดสงขลา 90230 ประเทศไทย
เบอร์โทรศัพท์: 074-471-471
เบอร์โทรฟัคซ์: 074-291-650

สำนักงาน: เลขที่ 10 ซอย 10 ถนนเพชรเกษม ตำบลหาดใหญ่
อำเภอหาดใหญ่ จังหวัดสงขลา 90110 ประเทศไทย
เบอร์โทรศัพท์: 074-344-663
เบอร์โทรฟัคซ์: 074-344-667, 074-237-423, 074-237-832



10. Expiration Date Determination

"Powder, Latex Examination Gloves (BG): 1st Lot are labeled for 5 years expiration date.

11. Established and Approved by:

Rosna Yensuk
LAB Manager

01/05/2012

Date

Real-time aging Report to Determination of Expiration Dating (Shelf life) for
"Powder, Latex Examination Gloves (BG): 2nd Lot"

1. Purpose:

The purpose of this document is to report a real-time aging result for appropriate shelf life of
"Powder, Latex Examination Gloves (BG): 2nd Lot" according to Realtime aging Protocol.

2. Scope:

Valid for: "Powder, Latex Examination Gloves (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 |
| ASTM D 412-98a (Reapproved 2002)e1 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension |
| ASTM D 573-04 | Test Method for Rubber- Deterioration in an Air Oven |
| ASTM D 5151-99 | Test Method for Detection of Holes in Medical Gloves |
| ASTM D3578-05 | 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 :2009 (E) | Medical glove for single use-Part2 : Requirements and testing for Physical properties. |
| EN455-3 :2006 (E) | 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: 17/07/2007

5. Established: Rosna Yensuk 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, Latex Examination Gloves (BG)"*

Sample Identification:

Lot no. 25 M 160707 B (006171862)
MMLXS0101240BG

Surface: Smooth
Size: M

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 D3578-05 and 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 | 26.67 MPa 23.18 MPa 835 % 826 % 0 defect |
| 2. Physical Properties EN - Force at break BF aging - Force at break AF aging - Tensile Strength BF aging - Tensile Strength AF aging - Elongation BF aging - Elongation AF aging | - | - | 13 | - | EN 455-2 | 6 Med 6 Med 18 Min 14 Min 650 Min 500 Min | 7.25 N 8.09 N 24.12 MPa 28.49 MPa 864 % 864 % |
| 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 | EN 455-1 | 7 Max | 1 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 - | 242 mm 95 mm 0.270 mm 0.220 mm 0.150 mm 0 defect |
| 6. Protein Content ASTM | - | - | 3 | - | ASTM D5712 | 200 Max | 89 µg/g |
| 7. Protein Content EN | - | - | 8 | - | EN 455-3 | 200 Max | 51 µg/g |
| 8. Residual Powder on glove | - | - | 5 | - | ASTM D6124 | 10 Max | 7 mg/dm ² |

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) 18 min | Elongation (%) 650 min | No. of defect 3 max | Disposition | Force (N) | Tensile (MPa) | Elongation (%) | Force (N) | Tensile(MPa) a) | Elongation (%) | | |
| 0 | 26.67 | 835 | 0 | Pass | 9.67 | 24.12 | 864 | - | - | - | Pass | |
| 1 | 27.44 | 826 | 0 | Pass | 9.24 | 33.69 | 892 | - | - | - | Pass | |
| 2 | 31.59 | 804 | 0 | Pass | 8.69 | 31.58 | 807 | - | - | - | Pass | |
| 3 | - | - | - | - | 7.94 | 31.52 | 784 | 7.74 | 29.73 | 779 | Pass | |
| 4 | - | - | - | - | 8.13 | 29.90 | 778 | 8.29 | 29.09 | 765 | Pass | |
| 5 | - | - | - | - | 8.32 | 30.77 | 805 | 7.20 | 26.15 | 769 | Pass | |

This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated. Downloaded by SUDARAT KETSIRIKUN on date 01 Apr 2021



| yrs. | 3. Water Leak Test (S-3 AQL 2.5: n=32 Ac/Re=2/3) Test Method: ASTM D5151 | | 4. Water Leak Test EN455-1 Letter L G-1 Multiple ,Normal sampling 5 round (1 round = 50 pcs) Test Method: EN455-1 | |
|------|--|-------------|--|-------------|
| | No.of defect | Disposition | No.of defect | Disposition |
| | 3 Max | | 7 Max | |
| 0 | 0 | Pass | - | - |
| 1 | 0 | Pass | - | - |
| 2 | 1 | Pass | - | - |
| 3 | - | Pass | 0 | Pass |
| 4 | - | - | 0 | Pass |
| 5 | - | - | 0 | Pass |

| yrs. | Dimension (Avg) | | | | | Disposition |
|------|-----------------|------------|---------------|-------|-------|-------------|
| | Length (mm) | Width (mm) | Thickness(mm) | | | |
| | | | Finger | Palm | Cuff | |
| 0 | 242 | 95 | 0.270 | 0.220 | 0.150 | Pass |
| 1 | - | - | - | - | - | - |
| 2 | - | - | - | - | - | - |
| 3 | 240 | 94 | 0.261 | 0.213 | 0.144 | Pass |
| 4 | 240 | 94 | 0.266 | 0.220 | 0.147 | Pass |
| 5 | 240 | 94.1 | 0.271 | 0.219 | 0.151 | Pass |

| yrs. | Residual powder | | Protein ASTM | | Protein EN | |
|------|-----------------|-------------|--------------|-------------|--------------|-------------|
| | 6-15 mg/dm2 | Disposition | 200 ug/g Max | Disposition | 200 ug/g Max | Disposition |
| 0 | 7 | Pass | 51 | Pass | 89 | Pass |
| 1 | - | - | - | - | - | - |
| 2 | - | - | - | - | - | - |
| 3 | 6 | Pass | - | - | 64 | Pass |
| 4 | 7 | Pass | - | - | 82 | Pass |
| 5 | 6 | Pass | - | - | 59 | Pass |

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) | Tensile (MPa) | Elongation (%) | Disposition |
| 1 | 2.89% | 1.10% | Pass | 4.45% | 39.68% | 3.24% | Pass |
| 2 | 18.45% | 3.78% | Pass | 10.13% | 30.93% | 6.60% | Pass |
| 3 | - | - | - | 17.89% | 30.68% | 9.26% | Pass |
| 4 | - | - | - | 15.93% | 23.96% | 9.95% | Pass |
| 5 | - | - | - | 13.96% | 27.57% | 6.83% | 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.

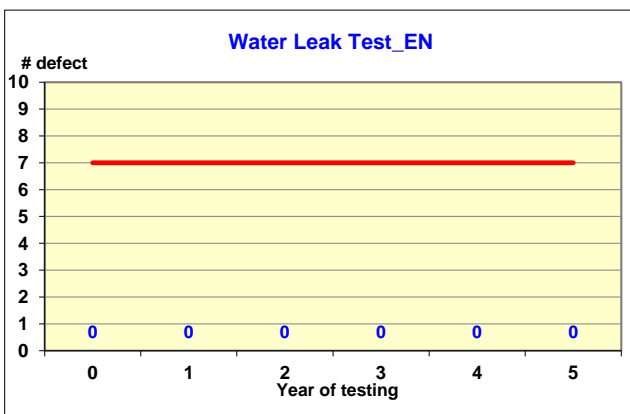
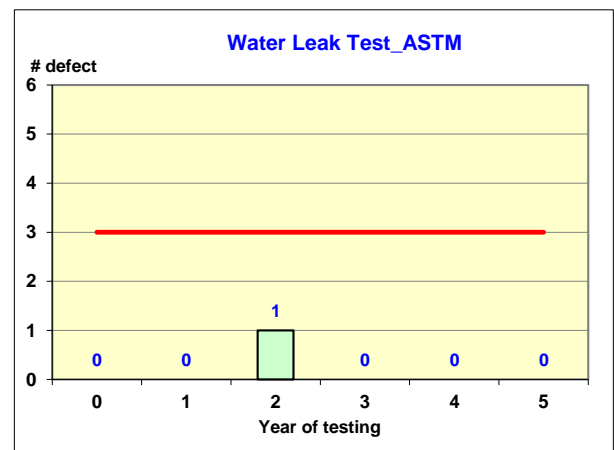
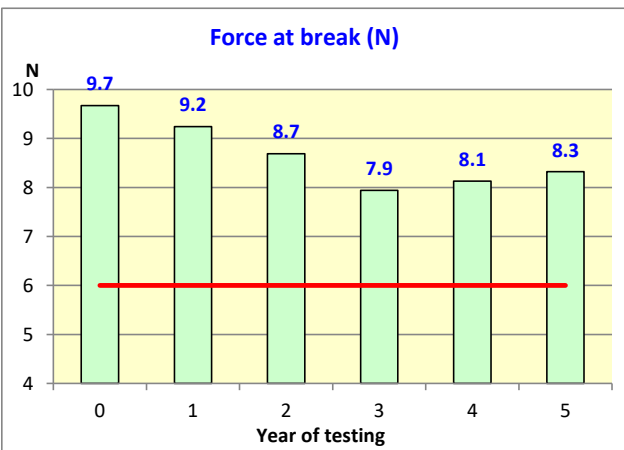
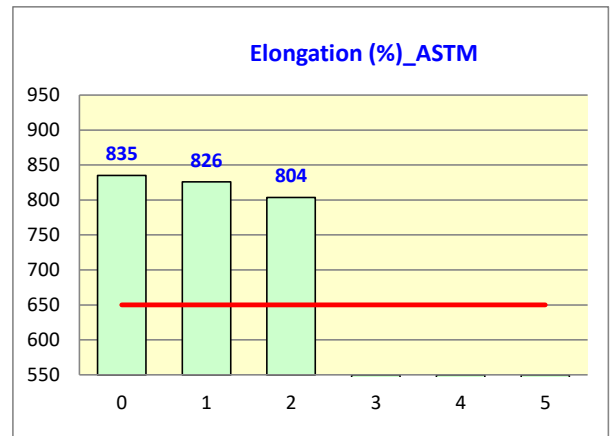
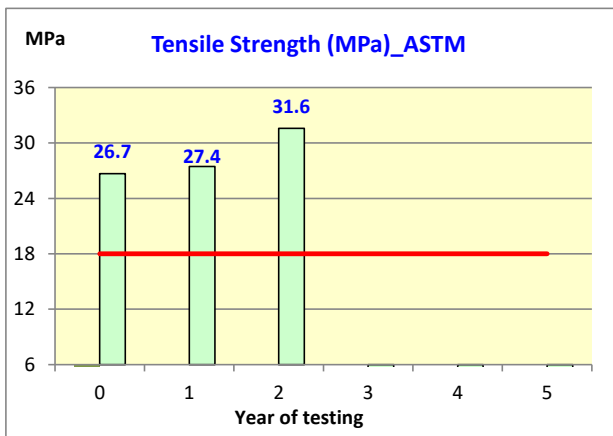


This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.

9. Conclusion:

Glove samples at naturally aging for 5 years meet the requirement of ASTM D3578-05 and 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 ASTM D3578-05 and EN455-2 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 (ASTM D 5151) and GI (EN 455-1) as chart display on chart below. Trend of result as these charts.



Downloaded by , SUDARAT KETSIRIKUN on date 01 Apr 2021



10. Expiration Date Determination

"Powder, Latex Examination Gloves (BG): 2nd Lo are labeled for 5 years expiration date.

11. Established and Approved by:

Rosna Yensuk
LAB Manager

06/08/2012

Date



**Real-time aging Report to Determination of Expiration Dating (Shelf life) for
"Powder, Latex Examination Gloves (BG): 3rd Lot"**

1. **Purpose:**

The purpose of this document is to report a real-time aging result for appropriate shelf life of
"Powder, Latex Examination Gloves (BG): 3rd Lot" according to Realtime aging Protocol.

2. **Scope:**

Valid for: "Powder, Latex Examination Gloves (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 |
| ASTM D 412-98a (Reapproved 2002)e1 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension |
| ASTM D 573-04 | Test Method for Rubber- Deterioration in an Air Oven |
| ASTM D 5151-99 | Test Method for Detection of Holes in Medical Gloves |
| ASTM D3578-05 | 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 :2009 (E) | Medical glove for single use-Part2 : Requirements and testing for Physical properties. |
| EN455-3 :2006 (E) | 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: **13/11/2007**

5. **Established:** Rosna Yensuk 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, Latex Examination Gloves (BG)"*

Sample Identification:

Lot no. **25 M 121107 B(006371917)**
MMLXF0101240BG

Surface: **Smooth**
Size: **M**

7. **Aging conditions:**

Storage warehouse is uncontrolled.

This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.
Downloaded by: SUDARAT KETSINIKUN on date 01-Apr-2021



8. Test Result:

8.1 Initial (Time zero) Testing;

Before start any aging. Sample glove should be meeting the requirements of ASTM D3578-05 and 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 | 25.19 MPa |
| - Tensile Strength AF aging | | | | | | 14 Min | 23.70 MPa |
| - Elongation BF aging | | | | | | 650 Min | 842 % |
| - Elongation AF aging | | | | | | 500 Min | 862 % |
| - Number of defect | | | | | | 3 Max | 0 defect |
| 2. Physical Properties EN | - | - | 13 | - | EN 455-2 | | |
| - Force at break BF aging | | | | | | 6 Med | 6.25 N |
| - Force at break AF aging | | | | | | 6 Med | 6.54 N |
| - Tensile Strength BF aging | | | | | | 18 Min | 24.66 MPa |
| - Tensile Strength AF aging | | | | | | 14 Min | 27.64 MPa |
| - Elongation BF aging | | | | | | 650 Min | 860 % |
| - Elongation AF aging | | | | | | 500 Min | 820 % |
| 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 | EN 455-1 | 7 Max | 1 defect |
| 5. Dimension - Length | | | | | | 240 Med. | 242 mm |
| - Width | | | | | | 95 +/- 10 | 95 mm |
| - Finger | | | | | | 0.16 Min | 0.270 mm |
| - Palm | | | | | | 0.16 Min | 0.210 mm |
| - Cuff | | | | | | - | 0.150 mm |
| - Number of defect | S-2 | 4.0 | 13 | 1/2 | ASTM D3578 | 1 Max | 0 defect |
| 6. Protein Content ASTM | - | - | 3 | - | ASTM D5712 | 200 Max | 48 µg/g |
| 7. Protein Content EN | - | - | 8 | - | EN 455-3 | 200 Max | 121 µg/g |
| 8. Residual Powder on glove | - | - | 5 | - | ASTM D6124 | 10 Max | 9 mg/dm ² |

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 Med | - | - | |
| 0 | 25.19 | 842 | 0 | Pass | 6.25 | 24.66 | 860 | - | - | - | Pass |
| 1 | 31.40 | 888 | 0 | Pass | 7.46 | 31.26 | 872 | - | - | - | Pass |
| 2 | 28.78 | 807 | 0 | Pass | 8.01 | 29.74 | 824 | - | - | - | Pass |
| 3 | - | - | - | - | 7.49 | 29.29 | 823 | 8.03 | 30.40 | 769 | Pass |
| 4 | - | - | - | - | 7.54 | 28.88 | 783 | 7.26 | 26.06 | 770 | Pass |
| 5 | - | - | - | - | 7.95 | 29.14 | 803 | 6.80 | 28.08 | 780 | 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 EN455-1 Letter L G-1 Multiple ,Normal sampling 5 round (1 round = 50 pcs) Test Method: EN455-1 | |
|------|--|-------------|--|-------------|
| | No.of defect | Disposition | No.of defect | Disposition |
| | 3 Max | | 7 Max | |
| 0 | 0 | Pass | - | - |
| 1 | 0 | Pass | - | - |
| 2 | 0 | Pass | - | - |
| 3 | - | - | 0 | Pass |
| 4 | - | - | 0 | Pass |
| 5 | - | - | 0 | Pass |

| yrs. | Dimension (Avg) | | | | | Disposition |
|------|-----------------|------------|---------------|-------|-------|-------------|
| | Length (mm) | Width (mm) | Thickness(mm) | | | |
| | | | Finger | Palm | Cuff | |
| 0 | 242 | 95 | 0.270 | 0.210 | 0.150 | Pass |
| 1 | - | - | - | - | - | - |
| 2 | - | - | - | - | - | - |
| 3 | 240 | 93 | 0.255 | 0.212 | 0.149 | Pass |
| 4 | 240 | 94 | 0.266 | 0.209 | 0.155 | Pass |
| 5 | 240 | 95 | 0.260 | 0.206 | 0.149 | Pass |

| yrs. | Residual powder | | Protein ASTM | | Protein EN | |
|------|-----------------|-------------|--------------|-------------|--------------|-------------|
| | 6-15 mg/dm2 | Disposition | 200 ug/g Max | Disposition | 200 ug/g Max | Disposition |
| 0 | 9 | Pass | 48 | Pass | 121 | Pass |
| 1 | - | - | - | - | - | - |
| 2 | - | - | - | - | - | - |
| 3 | 7 | Pass | - | - | 58 | Pass |
| 4 | 8 | Pass | - | - | 68 | Pass |
| 5 | 7 | Pass | - | - | 58 | Pass |

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) | Tensile (MPa) | Elongation (%) | Disposition |
| 1 | 24.65% | 5.46% | Pass | 19.36% | 26.76% | 1.40% | Pass |
| 2 | 14.25% | 4.10% | Pass | 28.16% | 20.60% | 4.19% | Pass |
| 3 | - | - | - | 19.84% | 18.78% | 4.30% | Pass |
| 4 | - | - | - | 20.64% | 17.11% | 8.95% | Pass |
| 5 | - | - | - | 27.20% | 18.17% | 6.63% | 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.



This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.

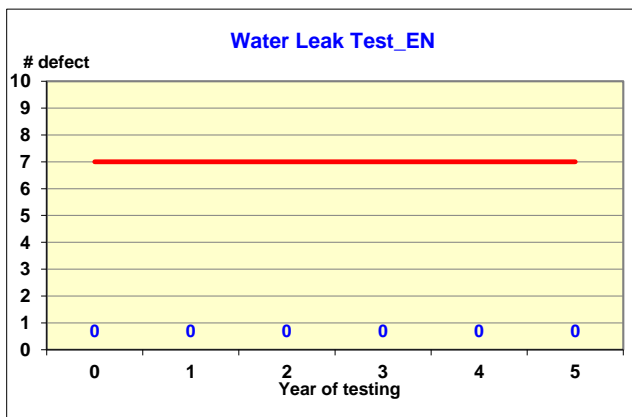
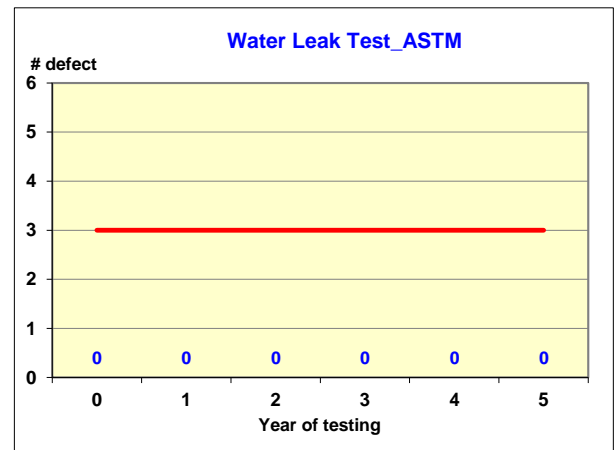
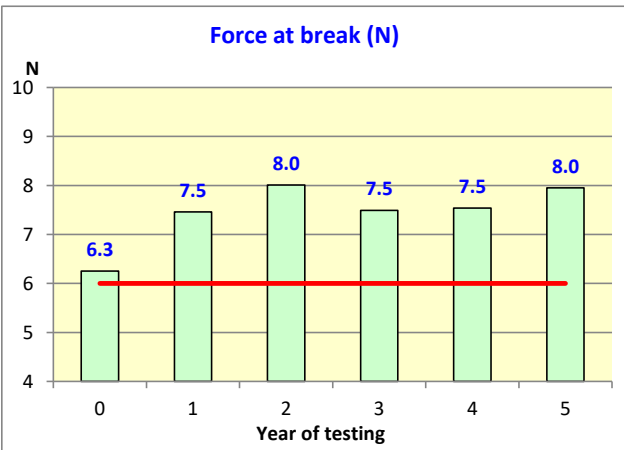
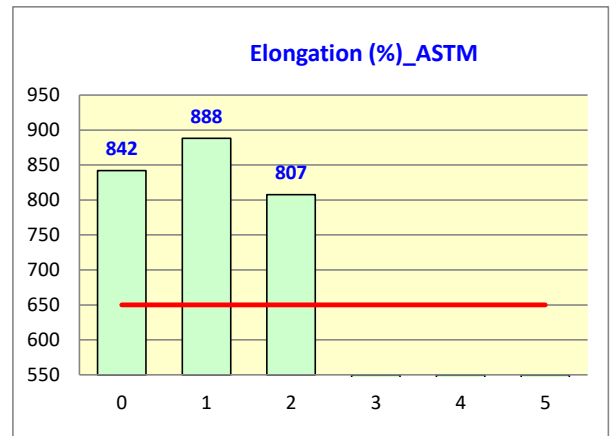
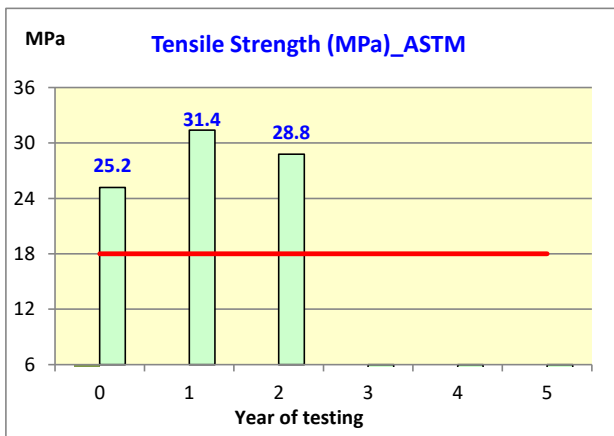
9. Conclusion:

Glove samples at naturally aging for 5 years meet the requirement of ASTM D3578-05 and 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 ASTM D3578-05 and EN455-2 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 (ASTM D 5151) and GI (EN 455-1) as chart display on chart below.

Trend of result as these charts.



Downloaded by , SUDARAT KETSIRIKUN on date 01 Apr 2021

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

Registration number 0107562000106

Headquarter: No. 110, Kanjanevanit Road, Phatong,
Hat Yai, Songkhle 90230 Thailand
Tel: (66) 74-471-471
Fax: (66) 74-291-650

Office: No. 10 Soi 10, Phetkasem Road, Hat Yai,
Hat Yai, Songkhle 90110 Thailand
Tel: (66) 74-344-663
Fax: (66) 74-344-677, 74-237-423, 74-237-832

บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)

ทะเบียนเลขที่ 0107562000106

สำนักงานใหญ่: เลขที่ 110 ถนนกาญจนาภิเษก ตำบลพะตง อำเภอหาดใหญ่
จังหวัดสงขลา 90230 ประเทศไทย
เบอร์โทรศัพท์: 074-471-471
เบอร์โทรฟักซ์: 074-291-650

สำนักงาน: เลขที่ 10 ซอย 10 ถนนเพชรเกษม ตำบลหาดใหญ่
อำเภอหาดใหญ่ จังหวัดสงขลา 90110 ประเทศไทย
เบอร์โทรศัพท์: 074-344-663
เบอร์โทรฟักซ์: 074-344-667, 074-237-423, 074-237-832



This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated

Downloaded by , SUDARAT KETSIRIKUN on date 01 Apr 2021

10. Expiration Date Determination

"Powder, Latex Examination Gloves (BG): 3rd Lot" are labeled for 5 years expiration date.

11. Established and Approved by:

Rosna Yensuk
LAB Manager

11/12/2012

Date