



KIMTECH PURE^{*}
G3 Sterile Latex
Gloves 12"
Hand Specific



DATA PACK



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G3 Sterile Latex[†] Glove, 12" Hand Specific

Codes: 56843, 56844, 56845, 56846, 56847, 56848, 56849, 56842

Product Information

Code	Affiliate #	Size	Palm Width*(mm)	Length* (mm)	Quantity
56843	HC1360S	6.0	77	290	20 pairs/bag; 10 bags/case
56844	HC1365S	6.5	83	305	20 pairs/bag; 10 bags/case
56845	HC1370S	7.0	89	305	20 pairs/bag; 10 bags/case
56846	HC1375S	7.5	95	305	20 pairs/bag; 10 bags/case
56847	HC1380S	8.0	102	305	20 pairs/bag; 10 bags/case
56848	HC1385S	8.5	108	305	20 pairs/bag; 10 bags/case
56849	HC1390S	9.0	114	305	20 pairs/bag; 10 bags/case
56842	HC1310S	10.0	130	305	20 pairs/bag; 10 bags/case

*As measured by ASTM D 3577; 2.5 AQL¹



Property	Description
General Description	Natural rubber latex, powder free, hand specific gloves, textured palm and palm side of fingers, beaded cuff, double chlorination, DI washed, silicone free.

Physical Property	Unit	Upper Limit	Test Method
Watertightness	NA	Pass	ASTM D 5151; 1.5 AQL
Particulate Level ≥0.5 microns	#/cm ²	1500	IEST-RP-CC005; 1.5 AQL
Sterility	SAL	10 ⁻⁶	ANSI/AAMI/ISO 11137

Extractable Ions	Upper Limit	Upper Limit	Test Method (2.5 AQL)
Calcium	20 µg/g	0.14 µg/cm ²	IEST-RP-CC005
Chloride	100 µg/g	0.80 µg/cm ²	IEST-RP-CC005
Magnesium	<5 µg/g	<0.04 µg/cm ²	IEST-RP-CC005
Nitrate	15 µg/g	0.12 µg/cm ²	IEST-RP-CC005
Potassium	<5 µg/g	<0.04 µg/cm ²	IEST-RP-CC005
Sodium	25 µg/g	0.20 µg/cm ²	IEST-RP-CC005
Sulfate	25 µg/g	0.20 µg/cm ²	IEST-RP-CC005
Zinc	90 µg/g	0.72 µg/cm ²	IEST-RP-CC005
Ammonium	10 µg/g	0.08 µg/cm ²	IEST-RP-CC005

Thickness	Target	Target	Test Method (2.5 AQL)
Middle Finger	8.66 mil	0.22 mm	ASTM D 3577
Palm	7.87 mil	0.20 mm	ASTM D 3577
Cuff	5.51 mil	0.14 mm	ASTM D 3577

Property	Tensile Strength	Ultimate Elongation	Median Force at Break
Before Aging	28 Mpa	880%	17 Newtons
After Aging	27 Mpa	900%	17 Newtons
Test Method (2.5 AQL)	ASTM D 412 ASTM D 573	ASTM D 412 ASTM D 573	EN 455-2

¹ AQL levels defined according to ISO 2859-1 (current edition) Sampling Procedures for Inspection by Attributes.

[†] This product contains natural rubber latex, which may cause allergic reactions. Safe use of this glove by or on latex sensitive individuals has not been established. This product should not be worn, or exposed to, individuals allergic to natural rubber latex.

Workmanship Requirement: Gloves shall be made in accordance with reasonable industry practice with respect to defects, dirt and contamination. Gloves should be packaged as specified having described size and color in the appropriate quantity as listed. Shipping Case and inner packaging shall be labeled with product name, size, lot/batch and catalog number. For additional information: 1-800-255-6401 or kimtech@kcc.com

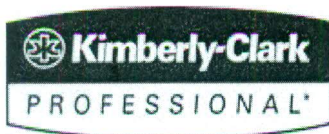
Kimberly-Clark warrants that its products (1) comply with K-C's standard specifications as of the delivery date to K-C's authorized distributors/direct purchasers and are warranted for the following periods from end user's date of purchase (verified by valid sales receipt) (a) five years for Balder Technology auto darkening filters; (b) two years for all other auto darkening filters; and (c) one year for powered air purifying respirators; (2) comply with all K-C labeling representations; and (3) are manufactured in compliance with all applicable federal, state, and local laws in effect at the time and place of manufacture of the products. THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. K-C is not liable for any kind of special, incidental, or consequential damages. K-C's liability for breach of contract, tort or other cause of action shall not exceed the product purchase price. Purchasers and users are deemed to have accepted the above warranty and limitation of liability, and cannot change the terms by verbal agreement or by any writing not signed by K-C. To the extent required by applicable law, K-C does not limit its liability for death/injury resulting from K-C's negligence.

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**Exceptional
Workplaces[®]**

Rev: June 2014



Kimberly-Clark Professional*1400 Holcomb Bridge Rd. Roswell, GA 30076 USA

CERTIFICATE OF ANALYSIS

Product Description : KIMTECH PURE* G3 Sterile Latex Gloves, Hand Specific, 12" , pair-packed

Catalog Numbers : HC 1360S, HC 1365S, HC 1370S, HC 1375S, HC 1380S, HC 1385S, HC 1390S, HC 1310S

K-C Code : 56843, 56844, 56845, 56846, 56847, 56848, 56849, 56842

Lot # : 420214

Total Cases per Lot : 4260

Batches : SM40322XX to SM40592XX

Date of Manufacture : Feb-14

SM40322VX to SM40592VX

Expiration Date : 2019-01

Physical Test Data**

	Watertight	Dimensions	Visual Defects		Elongation (%)	Tensile (MPa)
			Minor	Major	Pre Aging	Pre Aging
Sample Size :	2395	980	2395	2395	100	100
AQL Level :	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL :	58	49	136	92	5	5
Failures :	3	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept
Averages:					835	28.80

Test Methods : Watertight ASTM D 5151, Elongation and Tensile ASTM D 412

Particle Test Data**

Particle Size (µm)	Min	Max	Standard Deviation	Average Particles/cm ²
0.5 - 1.0	233	700	100	550
1.0 - 2.0	28	82	15	59
2.0 - 5.0	8	37	7	20
5.0 - 10.0	1	9	2	5
10.0 - 20.0	0	2	0	1
>20	0	0	0	0
Total per Sample	270	817	117	636

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data**

	Anions Results						Sulfate SO ₄ ⁻²
	Fluoride F ⁻	Chloride Cl ⁻	Nitrite NO ₂ ⁻	Bromide Br ⁻	Nitrate NO ₃ ⁻	Phosphate PO ₄ ⁻³	
µg/g glove	0.509	36.847	1.526	1.526	3.147	2.543	4.503
µg/cm ²	0.004	0.298	0.013	0.013	0.026	0.021	0.036
	Cations Results				Trace Element Results		
	Sodium Na ⁺	Ammonium NH ₄ ⁺	Potassium K ⁺	Magnesium Mg ⁺²	Calcium Ca ⁺²	Zinc Zn	
µg/g glove	1.181	1.063	1.323	1.018	2.831	50.12	
µg/cm ²	0.010	0.009	0.011	0.008	0.023	0.41	

Test Method : IEST-RP-CC005.4

Endotoxin Data**

Test Result:	0.400	Endotoxin Units/ device
Specification:	≤ 20	Endotoxin Units/ device

Test Method : Limulus Amebocyte Lysate (LAL) Test: Kinetic Turbidimetric Technique

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**Testing performed at final quality inspection gate prior to sterilization.

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Review By :

QK 17-MAR-2014
(QA Manager - SSMT)

www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 20-Feb-2014

MY03S11114714-1-1

This is to certify that Synergy Sterilisation (M) Sdn. Bhd. has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 Sterilisation of Health Care Products

EN ISO 9001:2008 Quality Management System

EN ISO 13485:2012 Quality System - Medical Devices

Safeskin Medical & Scientific (Thailand) Ltd
200 MOO 8, KANJANAVANICH ROAD
TAMBOL PRIK, AMPHUR SADAO
SONGKHLA

THAILAND

Order Information

Account Number:	101195
Synergy Health Sales Part Reference:	1024136
Customer Reference Number:	4027005367
Product Description:	KIMTECH Pure* G3, Sterile Latex Gloves, Hand Specific 12" Pair Packed
Validation Reference:	0.0472
Quantity Received:	576
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	50.0
Customer Unit Lot/Batch Number:	SEE BELOW



www.synergyhealthplc.com

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Safeskin Medical & Scientific (Thailand) Ltd
 200 MOO 8, KANJANAVANICH ROAD
 TAMBOL PRIK, AMPHUR SADA O
 SONGKHLA

THAILAND

Other Process Details:

Catalog Number	Batch No/Lot No.	Quantity
HC1370S	420114/SM40272XX	10
HC1370S	420114/SM40312XX	26
HC1370S	420114/SM40312XX	4
HC1370S	420214/SM40322XX	32
HC1370S	420214/SM40322XX	36
HC1370S	420214/SM40322XX	36
HC1370S	420214/SM40322XX	22
HC1370S	420214/SM40332XX	14
HC1370S	420214/SM40352XX	36
HC1370S	420214/SM40352XX	36
HC1375S	420114/SM40312XX	36
HC1375S	420114/SM40312XX	36
HC1375S	420114/SM40312XX	23
HC1375S	420214/SM40322XX	13
HC1375S	420214/SM40332XX	36
HC1385S	420214/SM40322XX	36
HC1385S	420214/SM40322XX	33
HC1385S	420214/SM40352XX	3
HC1385S	420214/SM40352XX	36
HC1385S	420214/SM40352XX	36
HC1385S	420214/SM40352XX	36

Irradiation Data

Date and Time of Irradiation:	19-Feb-2014 11:35
Reference Dose Range kGy:	30.6 - 32.3
Calculated Minimum Dose kGy:	26.0
Calculated Maximum Dose kGy:	37.2



www.synergyhealthplc.com

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TAMBOL PRIK, AMPHUR SADAO
SONGKHLA

THAILAND

1/20/02/2014
NORAZI ZAKARIA
QA Executive/Senior Chemist
Synergy Sterilisation (M) Sdn. Bhd.
+60(0)44152111

Irradiation Release Authorised By Synergy Health plc

Registered Office: Suite 18.01 18th Floor, MWE Plaza, 8, Lebuh Farquhar, 10200, Penang, MALAYSIA

VAT Number:

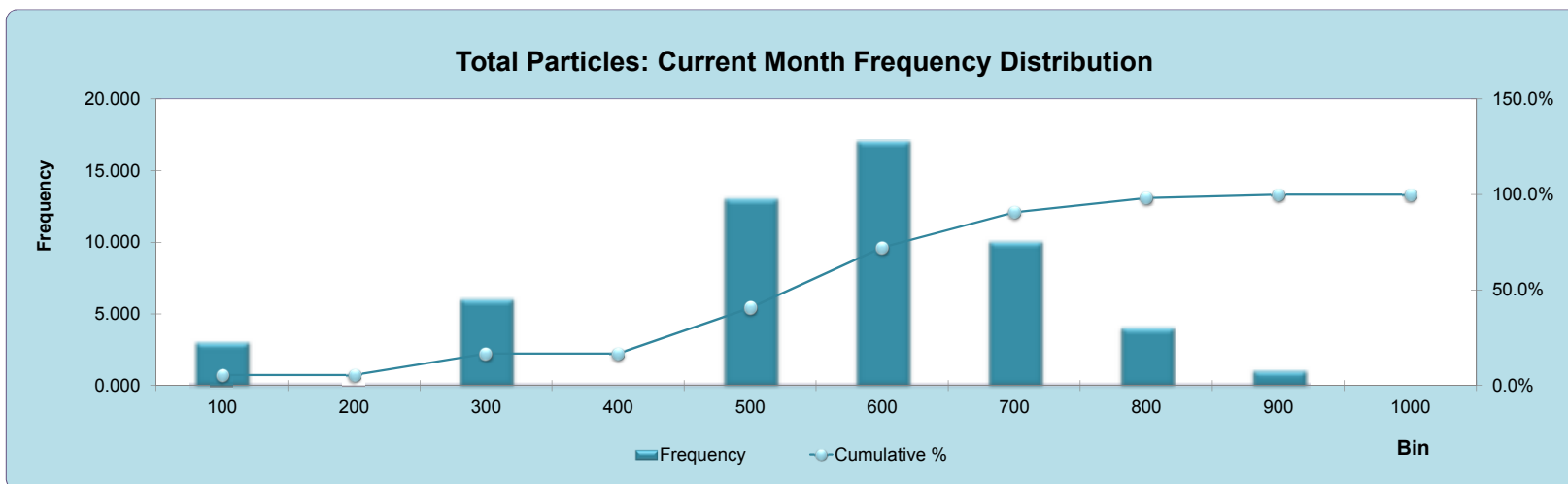
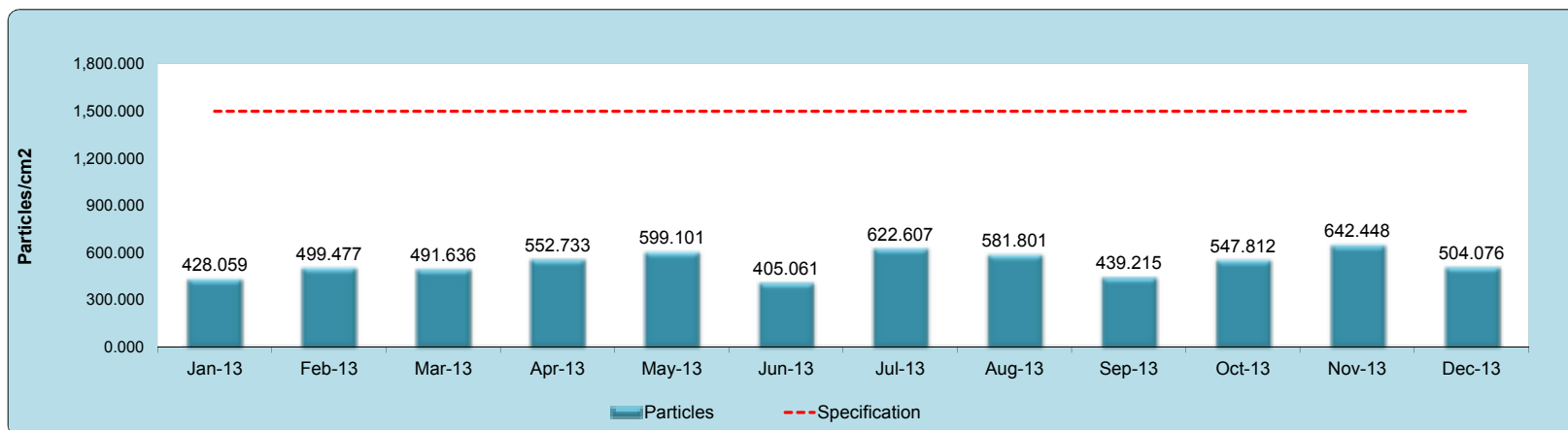
Page 3 of 3

Kimtech Pure G3 Sterile Latex Gloves, Hand Specific, 12", pair-packed (Product Code 42)

Catalog Numbers HC 1360S, HC 1365S, HC 1370S, HC 1375S, HC 1380S, HC 1385S, HC 1390S, HC 1310S

K-C Code 56843, 56844, 56845, 56846, 56847, 56848, 56849, 56842

Monthly Particles January 2013 to December 2013



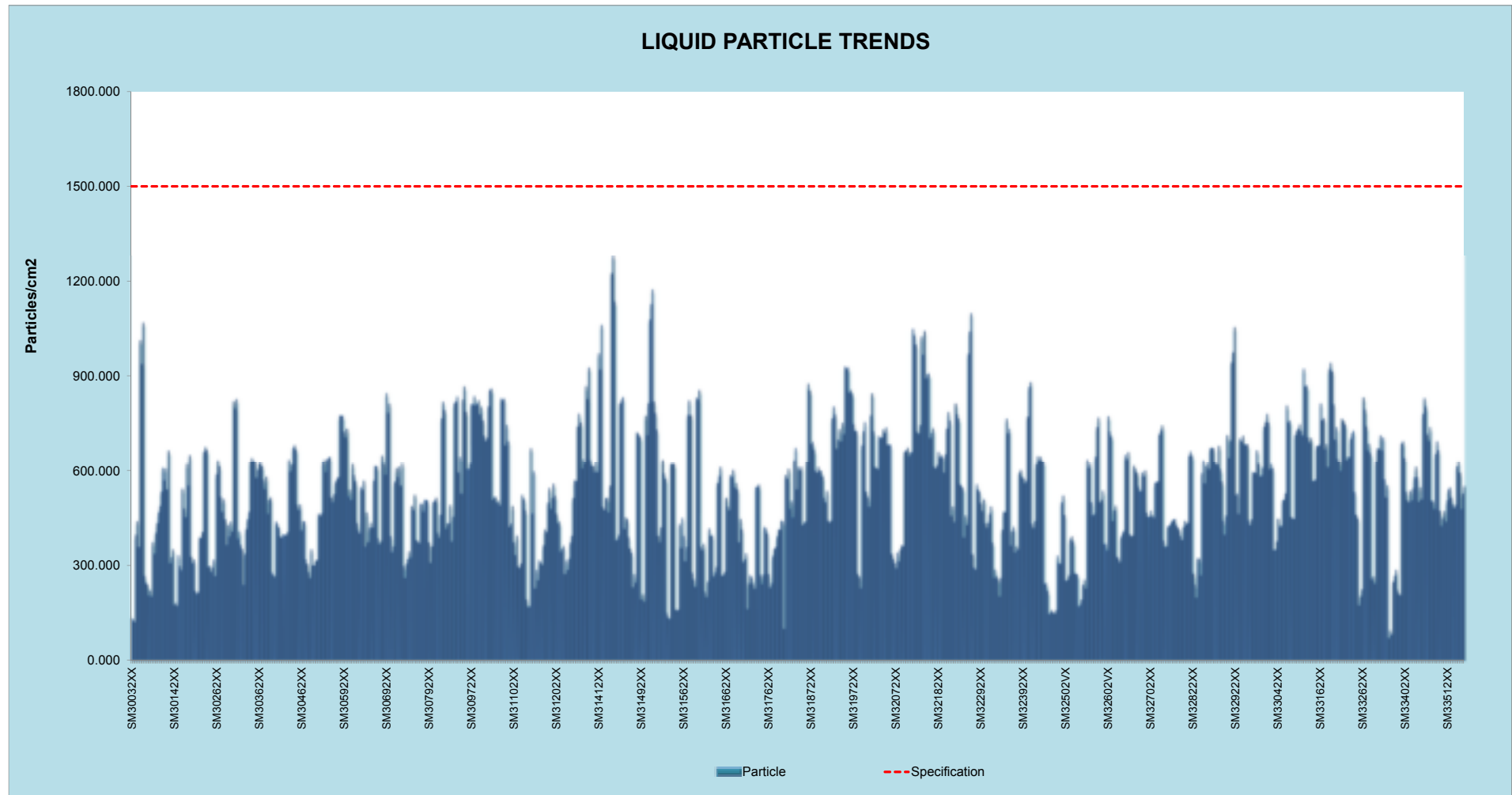
PARTICLE COUNT STATISTICS	AVERAGE	STD. DEV.	MAX	MIN	N
Current Month (Dec,13)	504.076	174.647	825.576	67.987	54.000
LAST Month (Nov,13)	642.448	168.432	937.445	171.190	75.000

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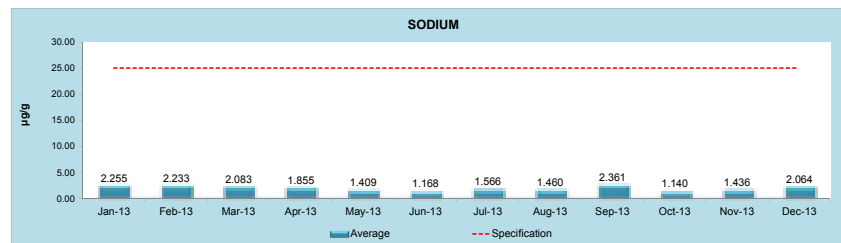
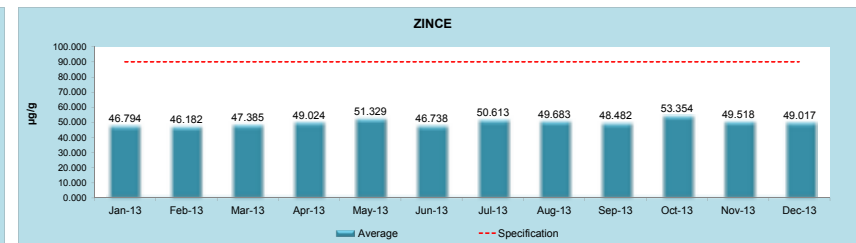
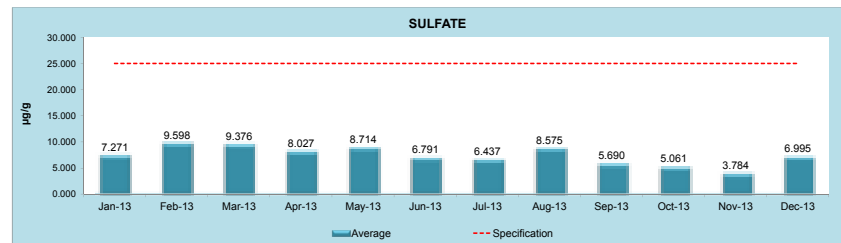
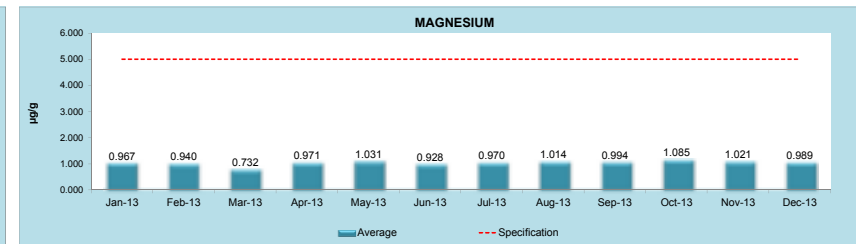
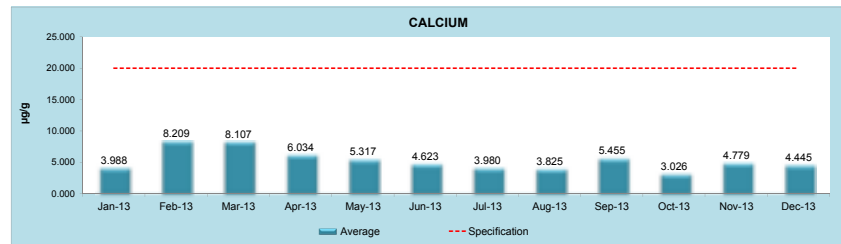
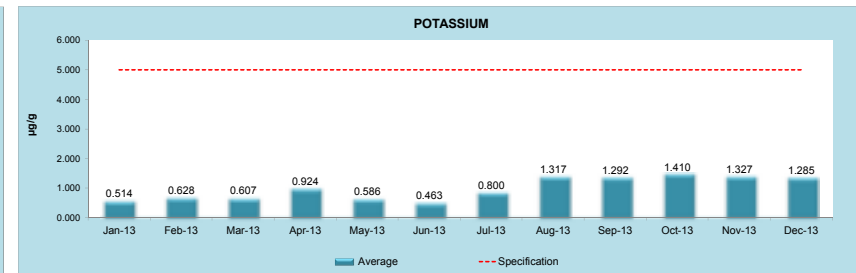
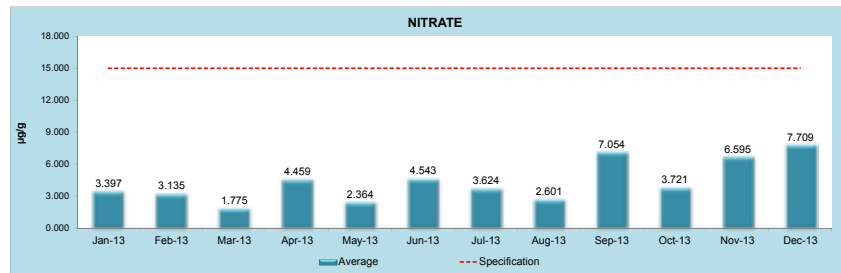
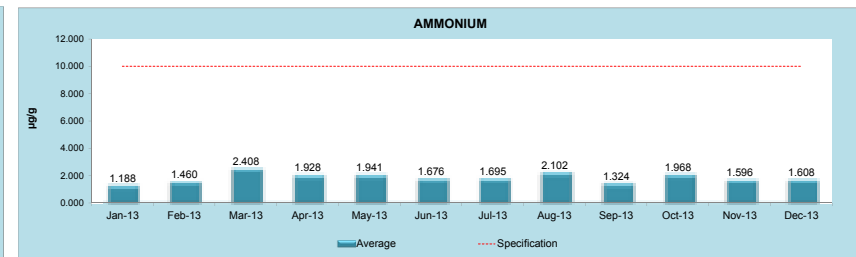
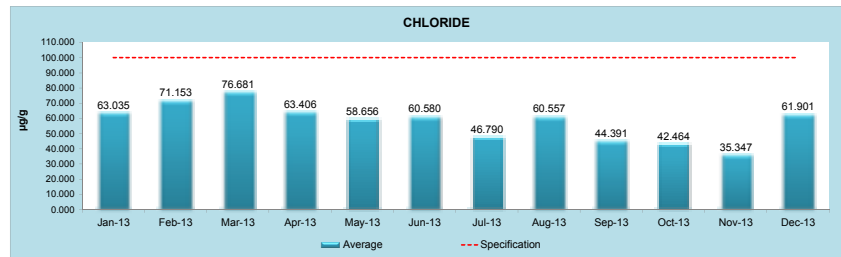


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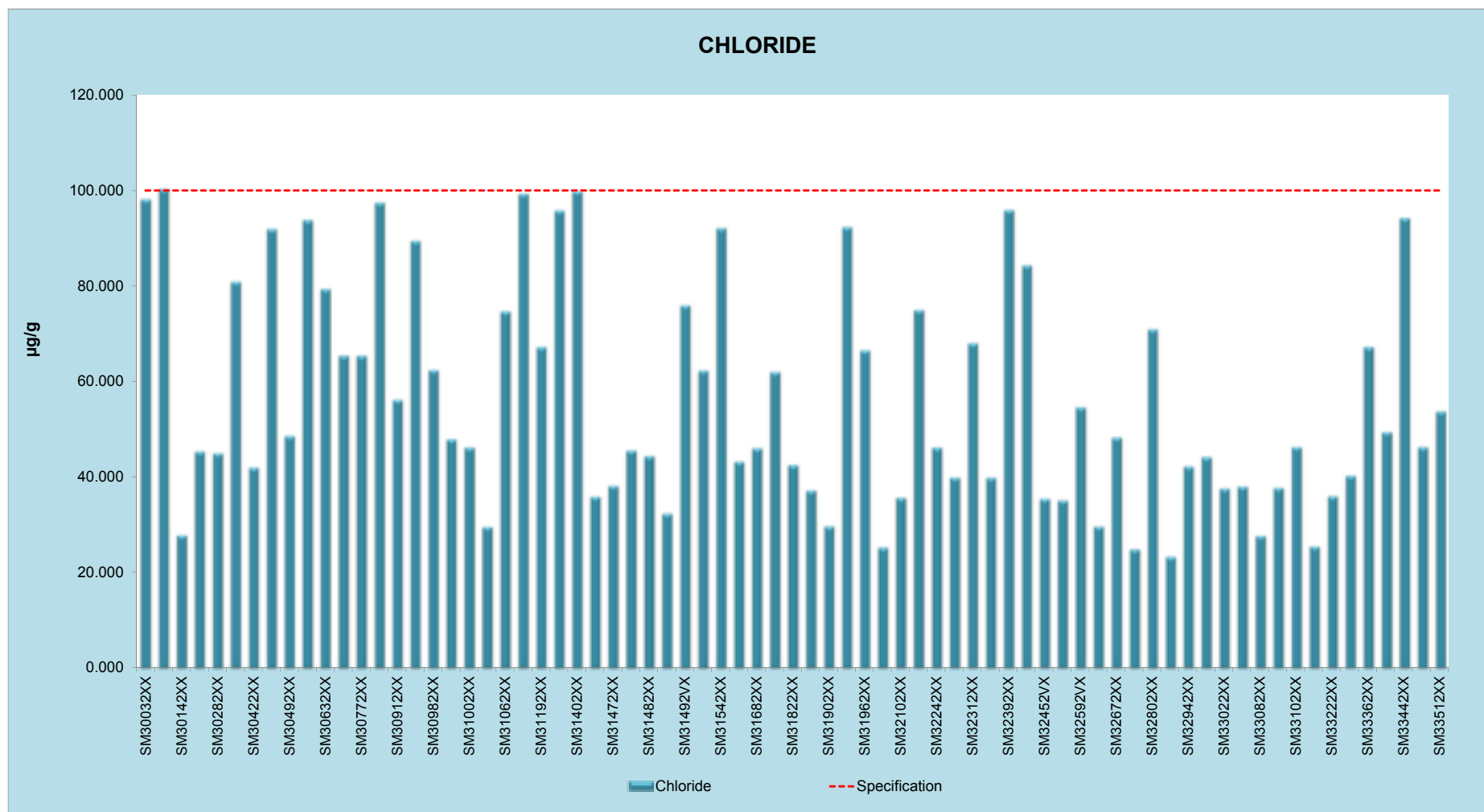


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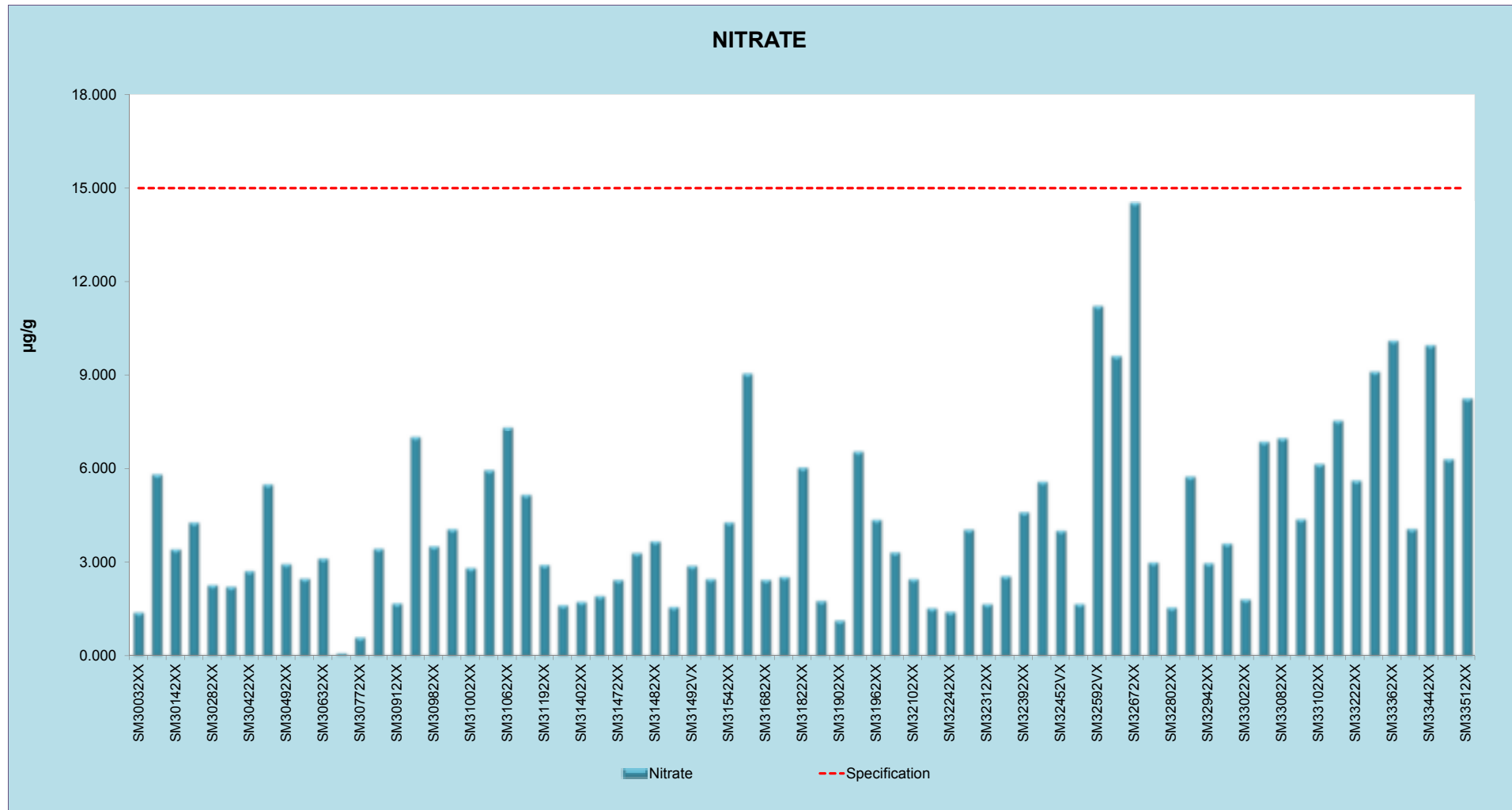


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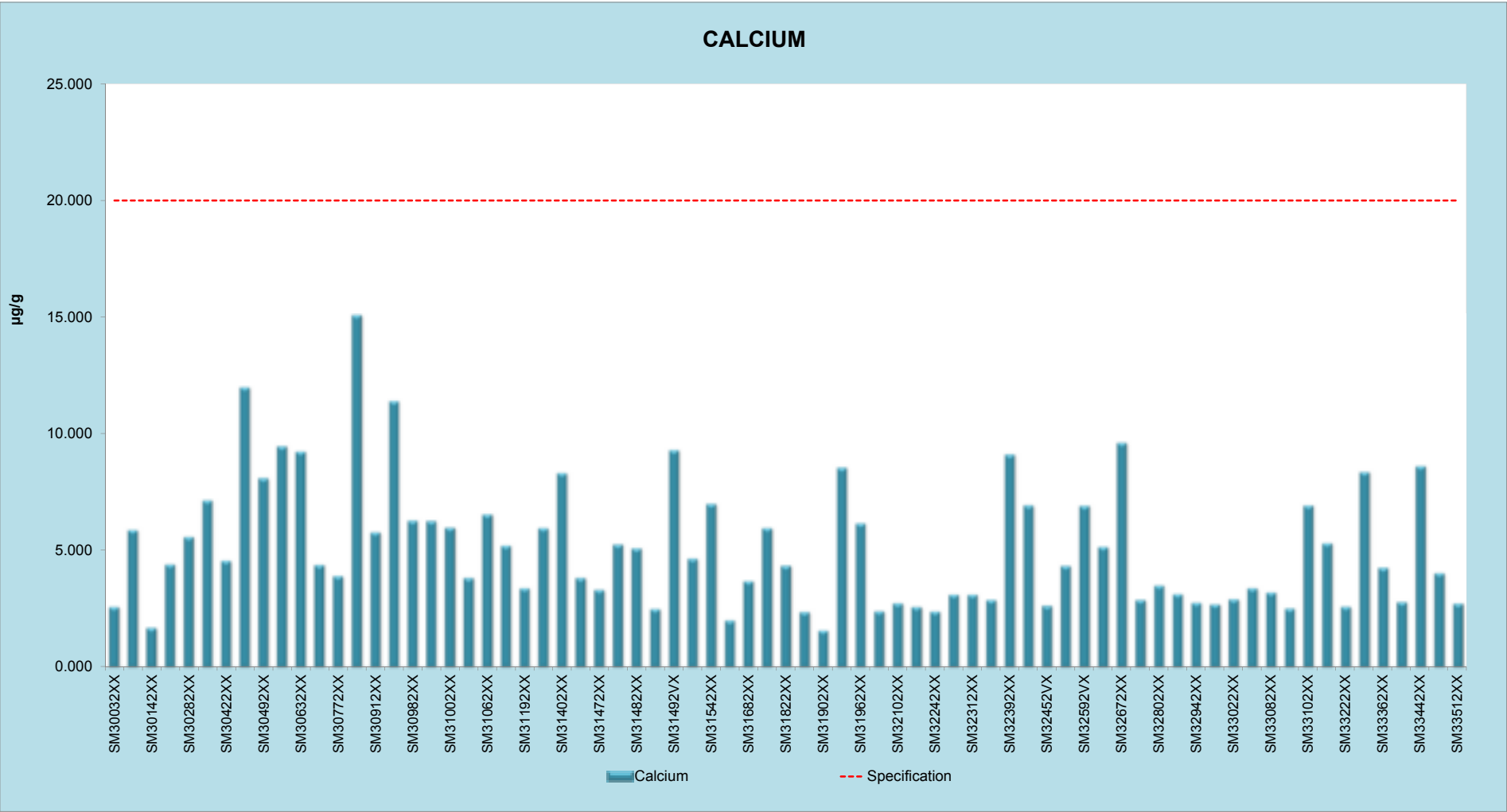


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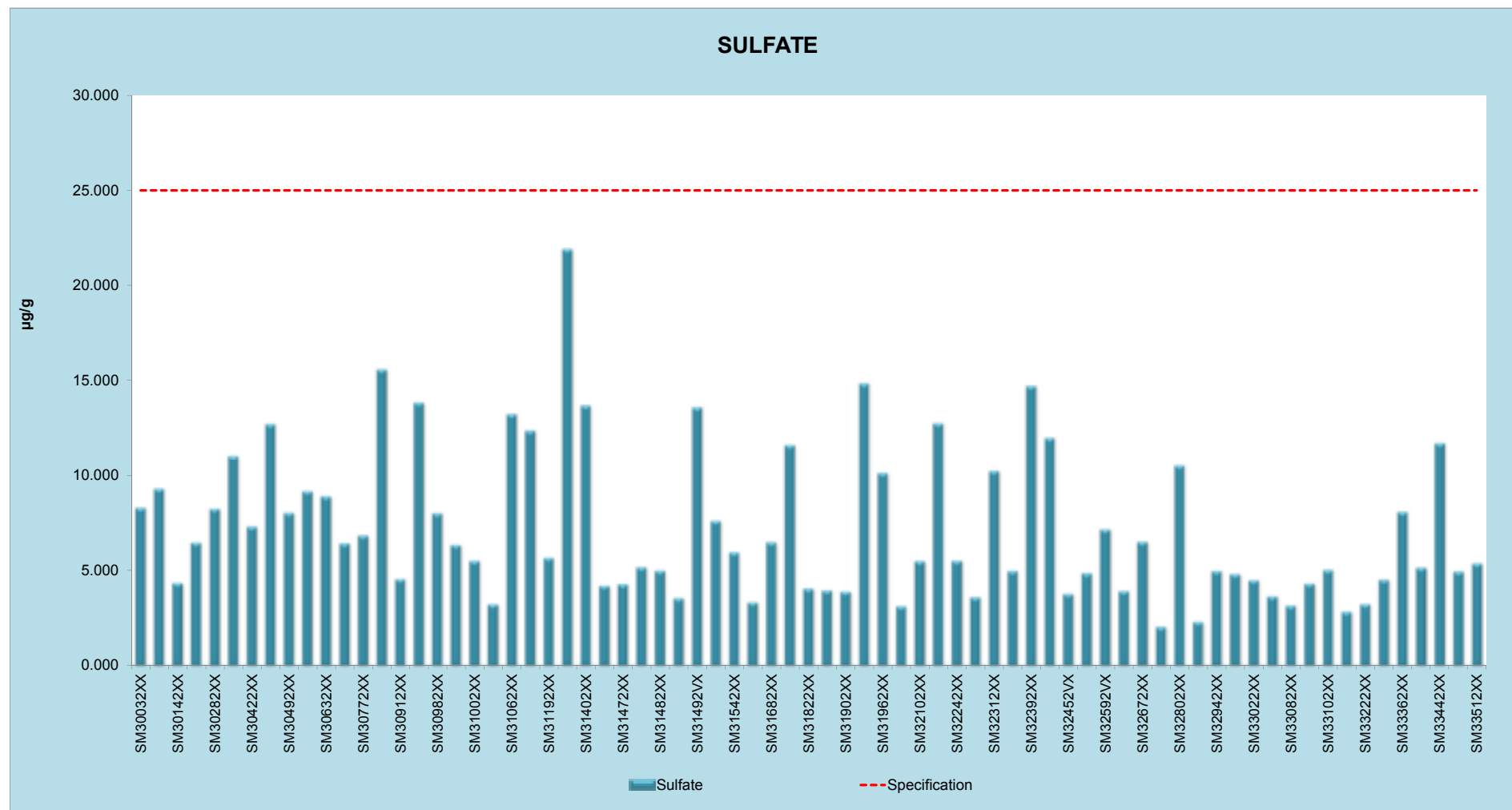


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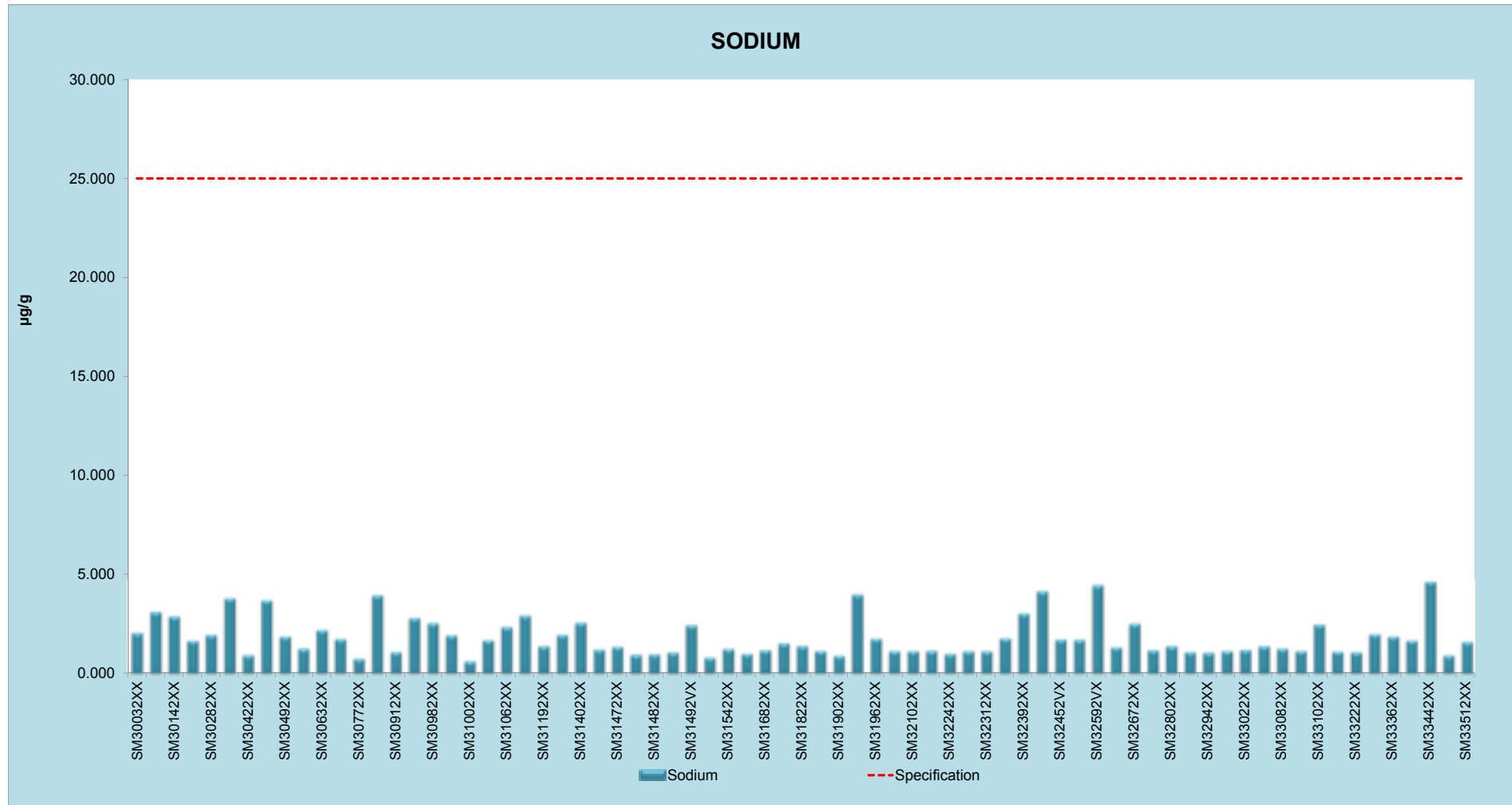


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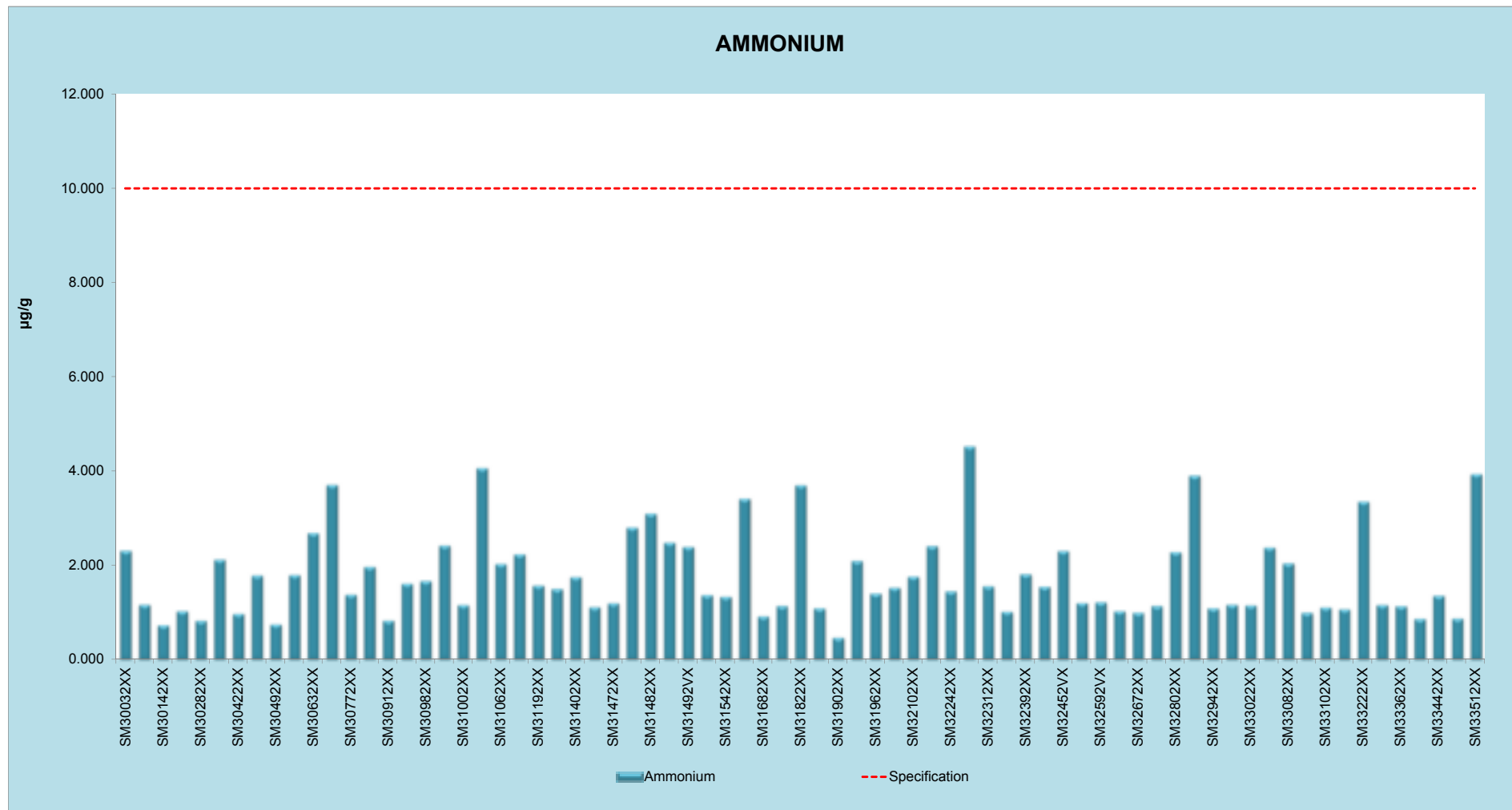


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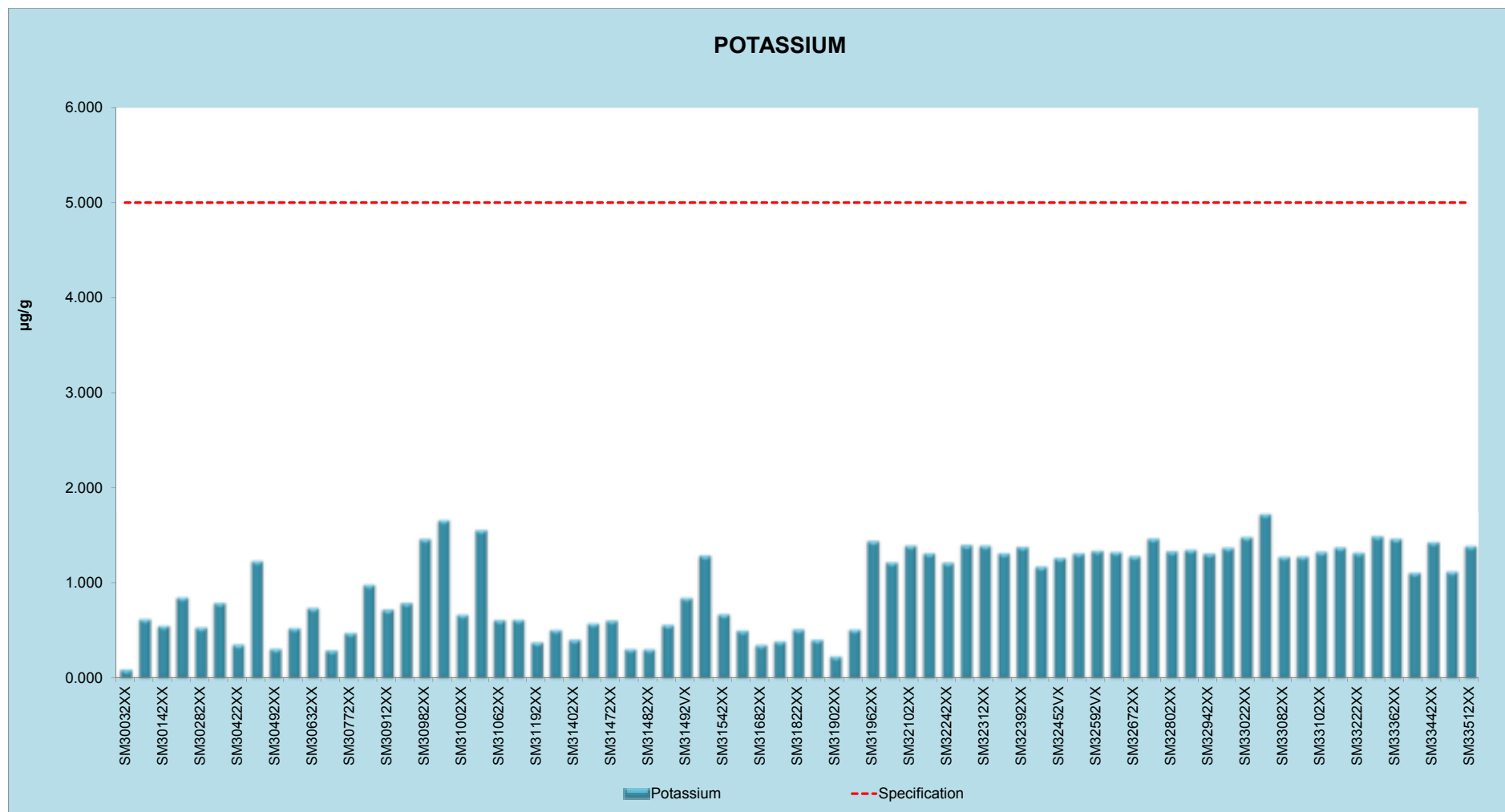


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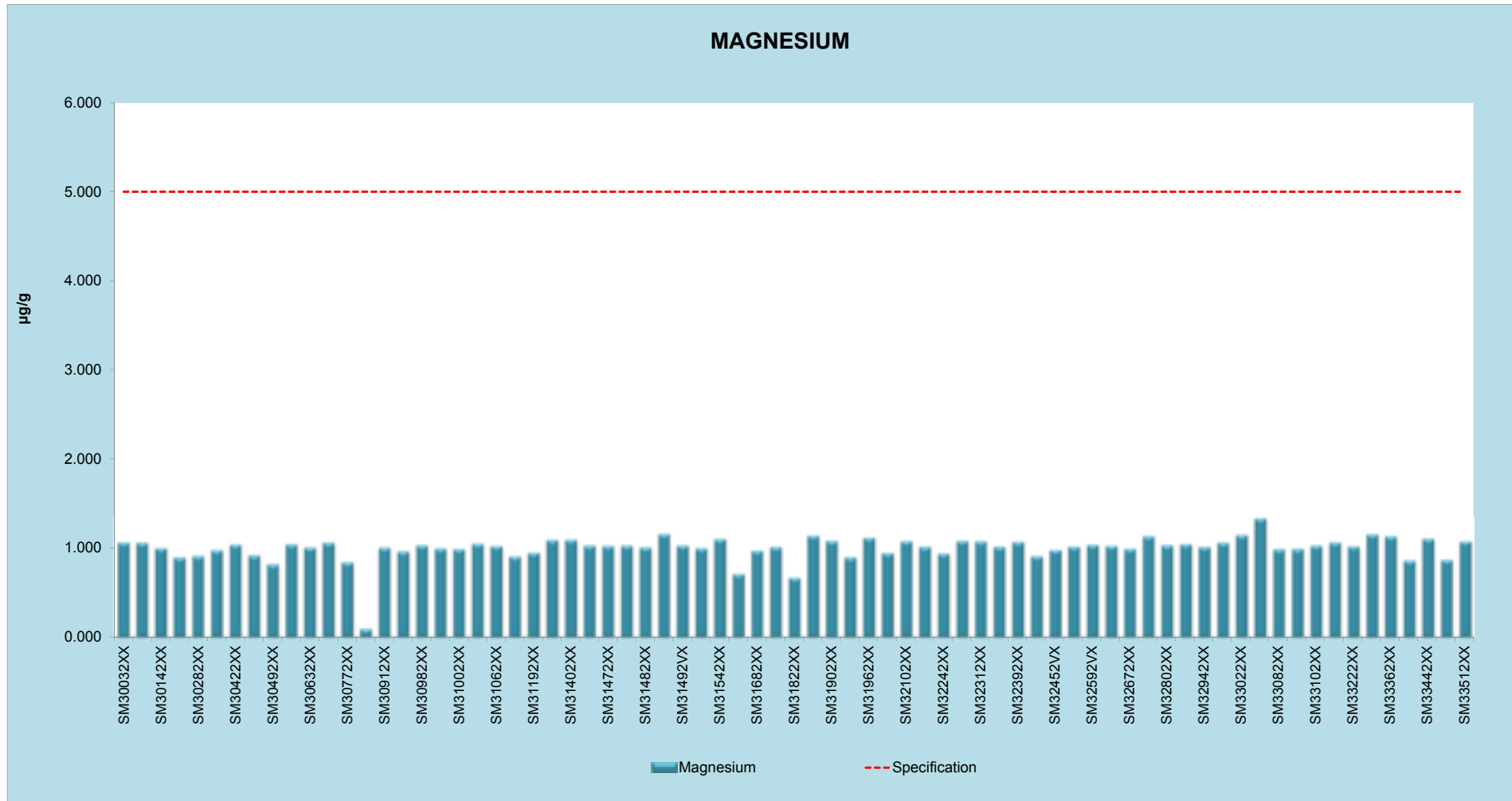


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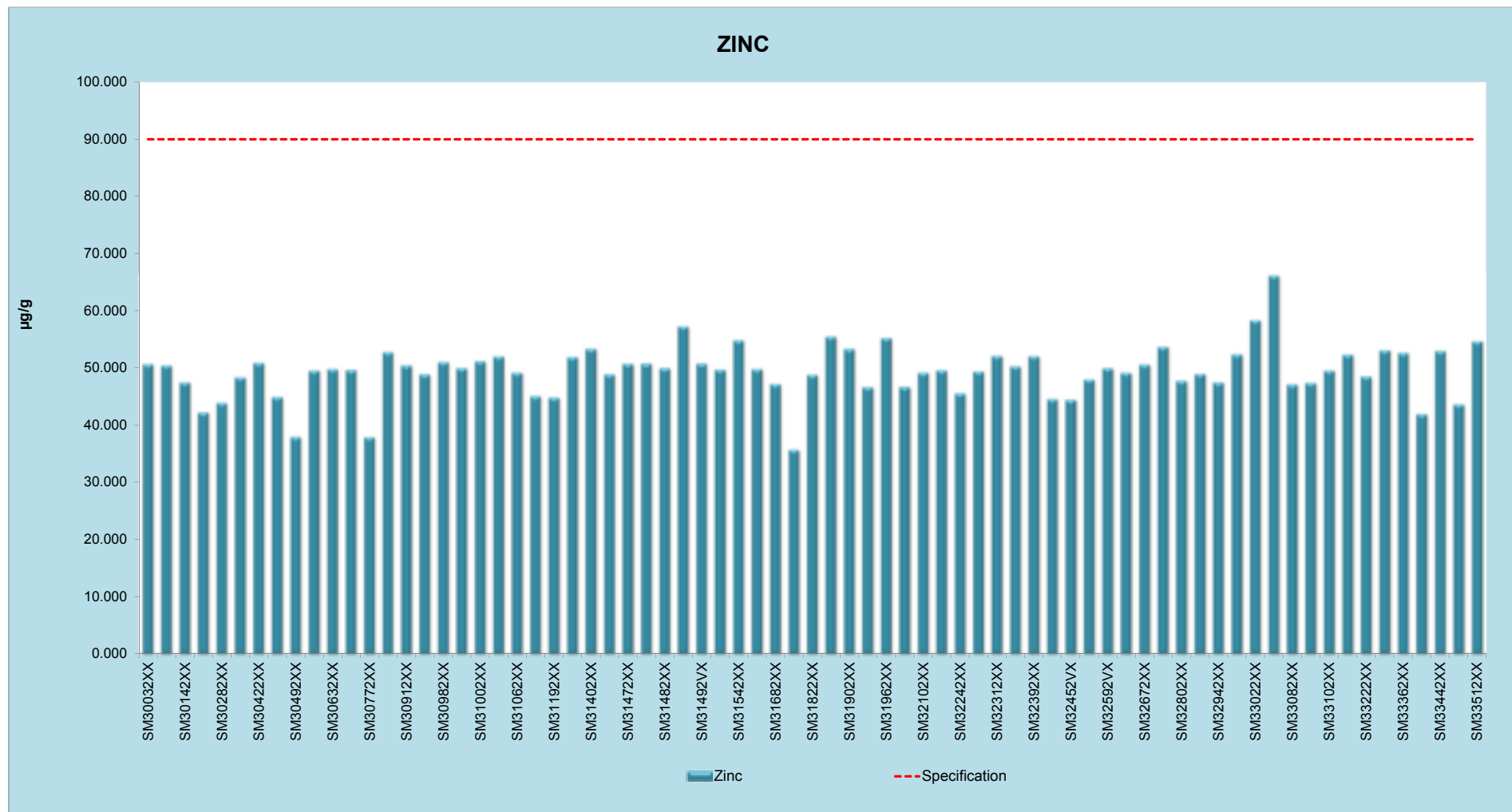


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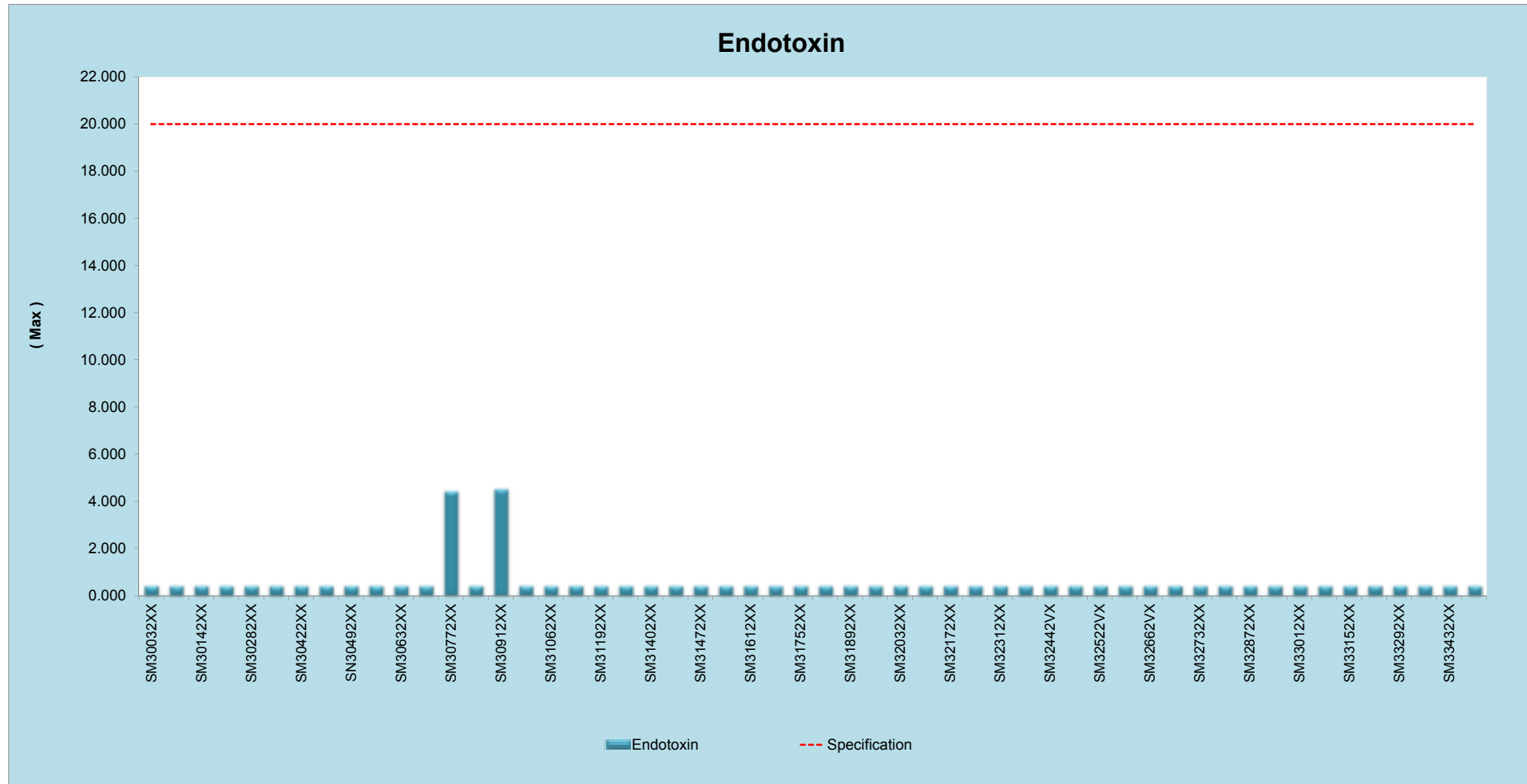


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Monthly Particles January 2013 to December 2013





Case

G3

 **9.0**

(EN) Sterile Latex Gloves (FR) Gants stériles en latex
(ES) Guantes estériles de látex (DE) Sterile Latex-Handschuhe
(NL) Steriele latex handschoenen (IT) Guanti sterili in lattice
(RU) Стерильные перчатки из натурального латекса
(PT) Luvas estéreis em látex (KO) 멸균 라텍스 장갑
(JA) 滅菌ラテックス手袋

Code #

(EU)

HC1390S

(US)

56849 07

Batch #

Lot

Family

LOT

製造番号

420214

SM40322XX

製造




02-2014

Дата производства

使用期限

2019-01

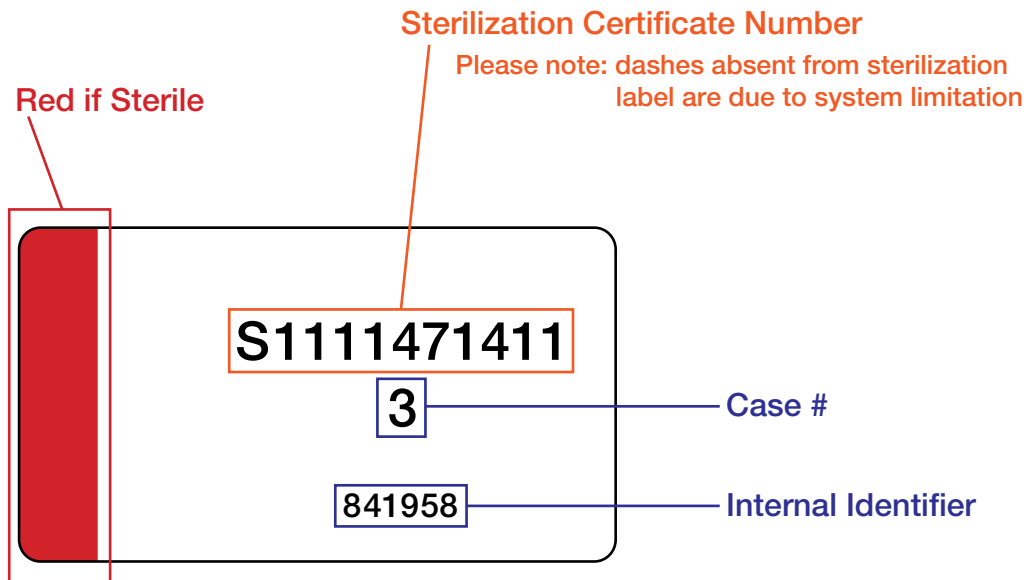


12"(30,5cm)
20   x 10  = 200



01 3 06 80651 56849 7

Case Label



Sterilization Label

ISOTRON MALAYSIA SDN BHD
(Company No.: 512058-V)



MS ISO/IEC 17025
TESTING
SAMM NO : 309



ISO 9001 : 2008
CERT NO : FS60510



ISO 13485 : 2003
CERT NO : MD 75461

Customer: SAFESKIN MEDICAL & SCIENTIFIC
200 Moo 8, Kanchanavanich Road
Tombol Prik, Amphur Sadao, Songkhla
90120 Thailand.

**PRODUCT STERILITY TEST
CERTIFICATE OF ANALYSIS**

Certificate No.: 803
Purchase Order No.: 4561072439
Isotron sample Log No.: 1234
Isotron Batch No.: M210121009
Date Processed: 08/12/10 & 10/12/10
Product Name: Kimtech Pure* G3 Sterile Latex, Gloves Hand Specific, 12" Pairs Packed (HC1300S)
Product Lot No.: SM02932XX
No. of Samples: 100 pairs
Date Samples Received: 22/11/10
Date Tested: 15/12/10
Date Incubation Completed: 29/12/10

Results:

Item Description	Test Results	Reference Standard
Product Sterility Test in Tryptone Soya Broth	All Negative	ISO 11737-2

Incubation condition: 30 ± 2°C

Comments: Volume of media used: 400ml

Certified By: _____

Date: 30/12/10

JAYANTHIMALA . A
QA Manager
Isotron (Malaysia) Sdn. Bhd.

FM-127 Rev.4; 2nd March 2007

LABORATORY TESTING

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**SAFESKIN
Medical & Scientific (Thailand) Ltd.**

STERILITY TEST REPORT

KIMTECH PURE* G3 STERILE LATEX

**GLOVES HAND SPECIFIC ,12” PAIRS PACKED
(HC1300S)**

TEST REPORT NO. 1012654

NOVEMBER - DECEMBER 2010

Report Prepared By: 20/10/10 Microbiologist

Report Approved By: 30/10/10 QA Manager

JAYANTHIMALA . A
QA Manager
Isotron (Malaysia) Sdn. Bhd.



CONTENTS

- Introduction
- Sterility testing
- Test of sterility test form
- Media formulae
- Environmental Monitoring data sheets
- Certificate of irradiation
- Validation report for the application of verification doses



INTRODUCTION

Sterility is an absolute term, but the assurance that any given item is sterile is a probability function. The sterility assurance level (SAL) is defined as the probability of any given unit being non-sterile after exposure to a validated sterilization process.

The bioburden estimation of the products was done following method 1 by Safeskin Medical & Scientific (Thailand) and the dose verification was advised by customer as 6.3 kGy +/- 10 %.

Dose was delivered as follows:

Min 5.9 kGy

Max 6.3 kGy

100 samples were irradiated and test of sterility was performed on all 100 samples.



STERILITY TESTING

Sample

Kimtech Pure*G3 Sterile Latex Gloves Hand Specific, 12" Pairs Packed (HC1300S)
Product Lot No: SM02932XX

Method

References: USP 33 <71>, 2010

- : ISO 11137 – 2:2006 Sterilization of Healthcare Products –Radiation Part 2 – 2006 Establishing the Sterilization Dose**
- : ISO 11737- 2: 2009 Sterilization of medical devices – Microbiological Methods Part 2: Tests of sterility performed in the validation of a Sterilization process.**

All sterility testing was carried out under the protection of laminar flow in a clean room operated in accordance with LWI 51 (Test Of Sterility – Gamma Processing) and monitored in accordance with LWI 20 (Cleaning and Environmental Monitoring of Clean Room) supplemented by the placement of settle plates and contact plates.

The whole of the sample were aseptically transferred into a bottle containing 400 ml of Tryptone Soya Broth to completely immerse the sample. The samples were incubated at 30°C +/-2°C for 14 days. The samples are inspected daily for signs of microbial growth.

Results

Please see Test of Sterility Result Forms.

Zero positive results were noted after a full incubation period of 14 days.

**TEST FOR STERILITY RESULT FORM**

Customer Name: Safeskin Medical & Scientific (Thailand) Ltd.
200 Moo 8, Kanchanavanich Road, Tambol Prik,
Amphur Sadao, Songkhla 90120, Thailand

Test Number: 803

Test Product: Kimtech Pure*G3 Sterile Latex Gloves Hand
Specific, 12" Pairs Packed (HC1300S)

Product Lot Number: SM02932XX

Date Samples Received : 22.11.2010

Date Test Carried Out: 15.12.2010

Date Test Complete: 29.12.2010

Signature: *Leathage 29/12/10*

100 samples were tested for sterility.

Growth Promotion : Test media meets the USP 33 <71>

Tryptone Soy Broth (2616TSB02/01/11 & 2617TSB 02/01/11)	
Test Organism	Result
<i>Bacillus spizizenii</i> ATCC 6633	Growth
<i>Candida albicans</i> ATCC 10231	Growth
<i>Aspergillus brasiliensis</i> ATCC 16404	Growth
Negative Control	No Growth

TSB Mfr. Batch No: VM187059

TSB Batch No: 2616TSB02/01/11 & 2617TSB 02/01/11

Negative control: All clear

Positive control: Growth: *S.aureus*, *B.spizizenii*, *Ps aeruginosa*,
C.albican, *A.brasiliensi*

14 days at 28 °C - 32 °C

Daily check on 100 items
Result: All clear

TEST PASSED ☒ **FAILED** ☐
Signature: *Leathage 29/12/10*

Day	Number Negative	Number Positive	Date	Initials
1	100	Nil	16.12.10	<i>Leathage 29/12/10</i>
2	100	Nil	17.12.10	<i>Leathage 29/12/10</i>
3	100	Nil	18.12.10	<i>Leathage 29/12/10</i>
4	100	Nil	19.12.10	<i>Leathage 29/12/10</i>
5	100	Nil	20.12.10	<i>Leathage 29/12/10</i>
6	100	Nil	21.12.10	<i>Leathage 29/12/10</i>
7	100	Nil	22.12.10	<i>Leathage 29/12/10</i>
8	100	Nil	23.12.10	<i>Leathage 29/12/10</i>
9	100	Nil	24.12.10	<i>Leathage 29/12/10</i>
10	100	Nil	25.12.10	<i>Leathage 29/12/10</i>
11	100	Nil	26.12.10	<i>Leathage 29/12/10</i>
12	100	Nil	27.12.10	<i>Leathage 29/12/10</i>
13	100	Nil	28.12.10	<i>Leathage 29/12/10</i>
14	100	Nil	29.12.10	<i>Leathage 29/12/10</i>



MEDIA FORMULAE

Tryptone Soya Agar (Merck)	gm/L
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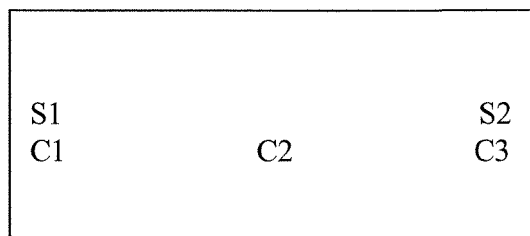
Tryptone Soya Agar pH 7.3 +/- 0.2	40
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Tryptone Soya Broth (Merck)	gm/L
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Tryptone Soya Broth pH 7.3 +/- 0.2	30
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ENVIRONMENTAL MONITORING DATA SHEET



LAMINAR FLOW CABINET

Key :

S = settle plates

C = contact plates

Date exposed : 15.12.2010

Date read : 22.12.2010

Total : 0 CFU

	TOTAL CFU
Date	22.12.2010
S1	0
S2	0

	TOTAL CFU
	22.12.2010
C1	0
C2	0
C3	0

Analyst : *Quadrage 29/12/10*

CERTIFICATE OF IRRADIATION

Number: **MA** 0030999 00

SAF005

Page 1

SAFESKIN MEDICAL & SCIENTIFIC
(THAILAND) LTD
ATTN: FON @ SAIYUD. THANMAJARD
200 MOO 8, KANJANAVANICH ROAD
TAMBOL PRIK, AMPHUR SADAD
SONGKHLA- THAILAND



ISOTRON MALAYSIA Sdn Bhd
Company No 512058-V
Kuala Ketil Industrial Estate
09300 Kuala Ketil, Kedah


Tel: 60 (0) 4 415 1111
Fax: 60 (0) 4 415 1110
<http://www.isotron.com>

Cust. Ref: PD 4561072439
Date Rec'd: 15/12/10
Date: 15/12/10

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
M1SAF0051001	SAMPLE IRRADIATION @ 0.1 - 15.0 kGy	1	ISOTRON BATCH NO: M210121009 DESCRIPTION: KIMTECH PURE*63 STERILE LATEX GLOVES HAND SPECIFIC, 12" PAIRS PACKED (HC1300S) LOT NO: SM02932XX IRRADIATION DATE: 08/12/2010 & 10/12/2010 DOSE REQUIRED: 6.3 kGy +/-10% (5.7 - 6.9 kGy) ACTUAL DOSE RECEIVED: MIN: 5.9 kGy MAX: 6.3 kGy
Total		1	Last Page 1 of 1

STERILITY TEST REPORT 1012654

This is to certify that the above items have been irradiated as specified above


TAI ENG THING
 Authorised Signature: QA Officer
 Isotron (Malaysia) Sdn Bhd
 For and on behalf of **ISOTRON MALAYSIA** Sdn Bhd

Page 8 of 13

**APPLICATION OF VERIFICATION DOSES**

Reported by: _____

Tai Eng Thing
QA Officer

Approved by: _____

Jayanthimala A
QAM

Report number : 10-245-VD

Sample batch number : M210121009

Customer name : Safeskin Medical & Scientific (Thailand) Ltd.

A/C number : SAF002

Sample description : Kimtech Pure*G3 Sterile Latex Gloves, Hand Specific, 12" Pairs Packed
(HC1300S)
Lot no.: SM02932XX

Microbiological dose setting methods described in ISO11137-2: 2006 require the irradiation of samples at a given dose within a range of $\pm 10\%$.

This exercise is to confirm that the doses applied to all samples throughout the package are within the specified range of $6.3 \text{ kGy} \pm 10\%$.

Dose values are obtained by reading calibrated **Amber Perspex** dosimeters placed among the samples as described in attachment 1. Dosimeters are distributed throughout the package to ensure that the positions of maximum and minimum doses are identified and that the absorbed doses in these positions can be recorded.

Samples are processed with key parameters of both the product and the total exposure time being recorded. After irradiation, dosimeters are recovered and the absorbed doses from each position from the samples are calculated and recorded. Detail results are recorded in attachment 2.

SUMMARY

The one carton sample were irradiated within the required dose range of 5.7 kGy to 6.9 kGy ($6.3 \text{ kGy} \pm 10\%$) and actual dose received were 5.9 kGy to 6.3 kGy.

**LOAD DESCRIPTION**

Type of carton : Corrugated inner box

Carton dimension (mm) L X W X H : 345 X 265 X 370

Weight of 1 carton (kg) : 7.80

Density (g/cm³) : 0.23

PROCESSING INFORMATION

Average dose rate : 1.9 kGy / h

Verification dose requested : 6.3 kGy \pm 10%

Minimum dose less 10% tolerance : 5.7 kGy
(rounded off to the upper 0.1 kGy)

Minimum exposure time (hh:mm) : 3 hours

Maximum dose plus 10% tolerance : 6.9 kGy
(rounded off to the lower 0.1 kGy)

Maximum exposure time : 3 hours 38 minutes

Exposure started on / at : 08 / 12 / 10 at 21:50 and
10 / 12 / 10 at 09:50

Exposure was interrupted for : 0 minute

Exposure finished on / at : 08 / 12 / 10 at 22:52 and
10 / 12 / 10 at 12:40

Actual exposure time : 3 hours 9 minutes

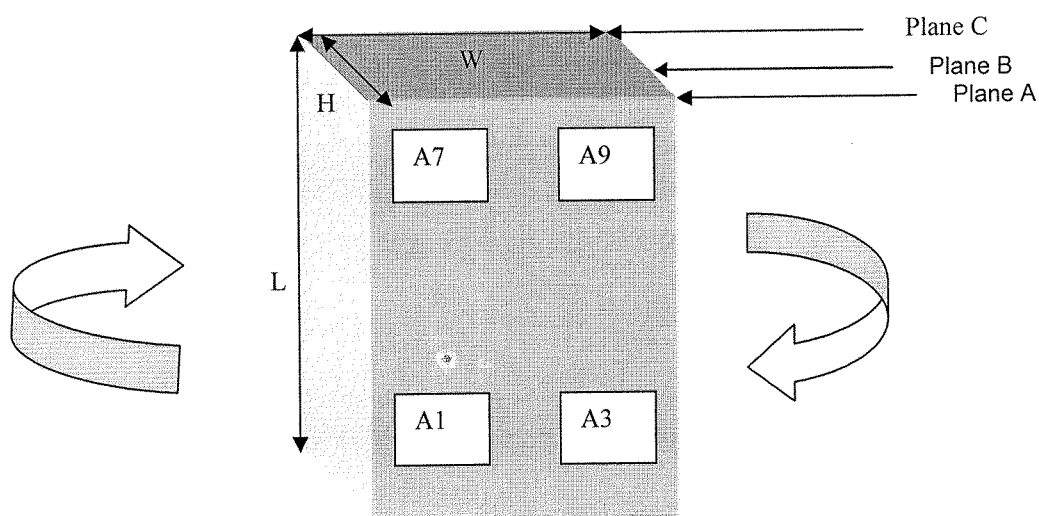
DOSIMETRY RESULTS SUMMARY


	Minimum dose	Maximum dose
Dose requested (kGy)	5.7	6.9
Actual dose received (kGy)	5.9	6.3

Reference : Attach detailed dosimetry report.

EXPOSURE TO RADIATION

For irradiation, a carton is placed on a hanging cage. The rotation of the carton aims at obtaining doses within the narrowest possible range. The exposure time is calculated from the times when the cage start touching at the end unit of the TEKSI.

CARTON LOADING DIAGRAM ON TEKSI

 Represents dosimeter location at each plane



VALIDATION DOSIMETRY

ISOTRON Malaysia Site

R&D dosimetry using Amber Perspex dosimeters Batch No.: 3042V
N.P.L. Certificate Number: 2009060186-1
Thermo Unicam UV1 Spectrophotometer serial number: 90903

Date: 09/12/2010
Customer Name: SAFESKIN
Product description:
Reference: 4561072439
Plant Batch Number and Date: M210121009

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine
A1	148	311	0.476	1.8	
A3	146	316	0.462	1.8	
A7	156	298	0.523	2.0	
A9	155	295	0.525	2.0	
B1	141	301	0.468	1.8	
B3	149	314	0.475	1.8	
B7	153	293	0.522	2.0	
B9	155	299	0.518	2.0	

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine

Signed: RP Dated: 09/12/10



VALIDATION DOSIMETRY

ISOTRON Malaysia Site

R&D dosimetry using Amber Perspex dosimeters Batch No.: 3042V

N.P.L. Certificate Number: 2009060186-1

Thermo Unicam UV1 Spectrophotometer serial number: 90903

Date: 10/12/10

Customer Name: SAFESKIN

Product description:

Reference: 4561072439

Plant Batch Number and Date: M210121009

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine
A1	295	276	1.069	4.1	
A3	323	298	1.084	4.2	
A7	294	261	1.126	4.3	
A9	326	290	1.124	4.3	
B1	310	293	1.058	4.1	
B3	315	298	1.057	4.1	
B7	362	323	1.121	4.3	
B9	326	291	1.120	4.3	

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine

Signed: _____

Dated: _____

10/12/10



Isotron (Malaysia) Sdn Bhd

Company No. 512058-V

(formerly known as Isotron Sterilisation Malaysia Sdn. Bhd.)

Plot 203, Kuala Ketil Industrial Estate

09300 Kuala Ketil

Kedah, Malaysia

Tel : 60 (0)4 415 1111

Fax : 60 (0)4 415 1110

Website : www.isotron.com

Dear Ms. Supat,

Please find enclosed with our compliments, the completed process validation for KIMTECH Pure* G3 Sterile Latex Gloves, 12" Hand Specific Pairs, in accordance with ISO 11137. Please note the validation reference number is 0.0348 Rev. 1 and we would appreciate you quoting this number on your PO for all future inputs of KIMTECH Pure* G3 Sterile Latex Gloves, 12" Hand Specific Pairs, this will aid in identifying your products prior to processing.

Yours sincerely,

A handwritten signature in black ink, appearing to be "Jayanthimala A.", with the date "03/01/2011" written below it.

Jayanthimala A.
QAM



**DOSE MAPPING REPORT
SAFESKIN MEDICAL & SCIENTIFIC
(THAILAND) LTD.
FOR**

**KIMTECH Pure* G3, Sterile Latex Gloves
-12" Hand Specific Pairs**

Validation Report Number : 0.0348 Rev. 1

Validation Ref: 0.0348

Performance Qualification Isotron Malaysia

Rev 01



Summary of Performance Qualification:

Customer Name: Safeskin Medical & Scientific (Thai) Ltd.

Report Ref.: 0.0348

Issue Date: 31.12.2010

Expiry Date: 31.12.2015

Product Description: KIMTECH Pure* G3, Sterile Latex Gloves -
12" Hand Specific Pairs

Type of package: Corugated Carton

No of Packages/Irradiation Container: 16

Dimensions of Package (mm): 345 x 265 x 370

Method : ASTM E 2303-03

Reference Standard : ISO 11137

Dose Specification:

Minimum dose (kGy): 25.0

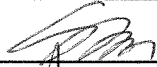

Maximum dose (kGy): 50.0

Requirement	Minimum specification	Maximum specification
Dose at DRef	31.1	48.3
Dwell time(s)	160	239
Number of Xs	37	55

Conclusion

The delivered dose in the product presentation illustrated on page 7 achieves the requested dose specification of 25.0 kGy minimum dose and 50.0 kGy maximum dose. In order to meet this specification during routine processing the recorded dose at D_{ref} must be between 31.1 kGy and 48.3 kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
QA Officer		31/12/10
QAM		03/01/2011

Note:

It is the responsibility of the customer to routinely provide product in the presentation and orientation outlined in this report.

This performance qualification validates the delivery of radiation doses only. Validation of the sterilisation effect and radiation induced material effects, if any, are not addressed by this qualification.



Product description: KIMTECH Pure* G3 Sterile Latex Gloves - 12" Hand Specific Pairs

Qualification data is obtained by placing red dosimeters in a defined pattern throughout an Isotron tote loaded with product.

The performance qualification is conducted in triplicate with the dosimeters placed throughout the product to assess both the dose distribution and determine the variability of the absorbed dose measurements, when processed under the same processing conditions.

Following processing the relationship between $\overline{D_{ref}} / \overline{D_{min}}$ and $\overline{D_{ref}} / \overline{D_{max}}$ are calculated to determine an acceptable D_{Ref} processing range.

D_{Ref} processing range is calculated by multiplying the R_{min} by the Customer minimum specification and the R_{max} by the Customer maximum specification. During routine processing if the D_{Ref} value falls within this range then processing is deemed as meeting the required specification:

D_{Ref} Minimum = Expected value of R_{min} x Minimum Dose Required

D_{Ref} Maximum = Expected value of R_{max} x Maximum Dose Required

Uncertainty

The specification for D_{Ref} incorporates an estimation of the uncertainty associated with the measurement system. Uncertainty has been calculated using the method outlined in ASTM E 2303-03. This method provides a confidence level of 95%.

Definitions

- D_{Ref} - Reference Dose
- D_{Min} - Minimum Dose
- D_{Max} - Maximum Dose
- R_{min} - D_{Ref}/D_{Min} ratio
- R_{max} - D_{Ref}/D_{Max} ratio
- CV% - Coefficient of Variance
- Co60 - Cobalt 60



Product description: KIMTECH Pure* G3 Sterile Latex Gloves

- 12" Hand Specific Pairs - Low Density

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
A11	34.1	33.9	33.5	33.8	0.31	0.92	
A21	33.4	33.0	32.8	33.1	0.31	0.94	0.19
A31	31.7	31.5	31.1	31.4	0.31	0.99	0.19
A41	31.6	31.9	32.0	31.8	0.21	0.66	0.09
A51	32.7	32.8	32.8	32.8	0.06	0.18	0.01
A15	33.4	32.7	32.9	33.0	0.36	1.09	0.26
A25	31.8	32.1	31.6	31.8	0.25	0.79	0.13
A35	30.4	30.5	30.1	30.3	0.21	0.69	0.09
A45	30.5	30.7	30.6	30.6	0.10	0.33	0.02
A55	31.8	32.0	31.5	31.8	0.25	0.79	0.13
A19	34.0	33.1	34.5	33.9	0.71	2.09	1.01
A29	34.3	34.0	33.1	33.8	0.62	1.83	0.78
A39	30.7	34.4	34.5	33.2	2.17	6.54	9.38
A49	30.9	33.7	33.5	32.7	1.56	4.77	4.88
A59	32.1	34.0	33.6	33.2	1.00	3.01	2.01
B11	29.5	29.3	28.3	29.0	0.64	2.21	0.83
B21	28.4	28.9	28.3	28.5	0.32	1.12	0.21
B31	27.0	27.4	27.3	27.2	0.21	0.77	0.09
B41	27.6	28.2	28.0	27.9	0.31	1.11	0.19
B51	28.3	28.0	28.8	28.4	0.40	1.41	0.33
B15	28.4	29.0	28.1	28.5	0.46	1.61	0.42
B25	28.4	28.8	27.4	28.2	0.72	2.55	1.04
B35	27.2	27.4	27.4	27.3	0.12	0.44	0.03
B45	27.5	27.4	27.9	27.6	0.26	0.94	0.14
B55	28.7	28.5	27.4	28.2	0.70	2.48	0.98
B19	30.2	31.0	32.4	31.2	1.11	3.56	2.48
B29	31.3	31.7	31.6	31.5	0.21	0.67	0.09
B39	27.6	29.2	31.3	29.4	1.86	6.33	6.89
B49	27.4	29.7	30.2	29.1	1.49	5.12	4.46
B59	29.1	30	30.5	29.9	0.71	2.37	1.01

Pooled variance (s2overall)

0.66

Minimum detectable difference (5)

1.11

Mean Minimum dose (DMin)

27.2 (B31)

Mean Maximum dose (DMax)

33.9 (A19)

Expected value of Rmin

1.244

Expected value of Rmax

0.996

Isotron Ratio

1/Rmin	0.804
1/Rmax	1.004

Customer Spec Min 25.0 Max 50.0

Dref Minimum 31.1

Dref Maximum 49.8



Product description: KIMTECH Pure* G3 Sterile Latex Gloves
- 12" Hand Specific Pairs - High Density

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
A11	32.0	33.0	33.3	32.8	0.68	2.07	
A21	32.0	32.0	31.8	31.9	0.12	0.38	0.03
A31	29.9	28.8	30.1	29.6	0.70	2.36	0.98
A41	31.0	30.6	31.1	30.9	0.26	0.84	0.14
A51	31.9	32.3	31.8	32.0	0.26	0.81	0.14
A15	32.9	32.1	32.0	32.3	0.49	1.52	0.49
A25	33.0	30.5	30.4	31.3	1.47	4.70	4.34
A35	33.2	28.9	29.4	30.5	2.35	7.70	11.06
A45	29.6	29.8	30.0	29.8	0.20	0.67	0.08
A55	30.3	30.5	31.1	30.6	0.42	1.37	0.35
A19	32.9	30.8	32.3	32.0	1.08	3.38	2.34
A29	34.0	32.7	33.6	33.4	0.67	2.01	0.89
A39	33.1	34.1	34.4	33.9	0.68	2.01	0.93
A49	33.2	33.0	30.1	32.1	1.73	5.39	6.02
A59	34.7	32.7	30.4	32.6	2.15	6.60	9.26
B11	27.2	27.4	26.9	27.2	0.25	0.92	0.13
B21	27.4	27.3	25.9	26.9	0.84	3.12	1.41
B31	26.9	26.0	29.4	27.4	1.76	6.42	6.21
B41	26.0	26.1	27.8	26.6	1.01	3.80	2.05
B51	26.8	26.6	27.0	26.8	0.20	0.75	0.08
B15	31.8	26.3	26.9	28.3	3.02	10.67	18.21
B25	30.3	26.8	28.9	28.7	1.76	6.13	6.21
B35	30.1	26.5	26.7	27.8	2.02	7.27	8.19
B45	27.7	26.4	26.5	26.9	0.72	2.68	1.05
B55	27.5	26.5	26.7	26.9	0.53	1.97	0.56
B19	28.6	29.9	28.5	29.0	0.78	2.69	1.22
B29	28.9	31.6	29.8	30.1	1.37	4.55	3.78
B39	31.9	29.9	32.6	31.5	1.40	4.44	3.93
B49	31.8	29.3	28.4	29.8	1.76	5.91	6.21
B59	32.9	28.6	28.7	30.1	2.45	8.14	12.05

Pooled variance (s^2_{overall})

1.87

Minimum detectable difference (\bar{d})

1.87

Mean Minimum dose (D_{Min})

26.6 (B41)

Mean Maximum dose (D_{Max})

33.9 (A39)

Expected value of R_{min}

1.236

Expected value of R_{max}

0.966

Isotron Ratio	
1/Rmin	0.809
1/Rmax	1.035

Customer Spec Min **25.0** Max **50.0**

Dref Minimum **30.9**

Dref Maximum **48.3**

**Product Detail**Customer Name: **Safeskin Medical & Scientific (Thai) Ltd**A/C No: **SAF002**Report Ref.: **0.0348**Issue Date: **31.12.2010**Expiry Date: **31.12.2015**

Product Description: **KIMTECH Pure* G3, Sterile Latex Gloves - 12" Hand Specific Pairs**
- Low density

Product weight : **8.03 kg**Carton dimension : **345 (L) x 265 (W) x 370 (H)**Density : **0.24 g/cm³**Plant Batch No: **M210120328**Current Cobalt Loading (Mc_i): **3968516**Standard Plant Dwell Time (sec): **166** Dwell Time (sec): **166**Number of Xs: **37.99** Value of X: **4.37**Dose Range Specification (kGy): **25.0** Min. **50.0** Max.

Minimum dwell time to achieve	Minimum dose	Maximum dose
First tote	154	242
Second tote	151	241
Third tote	152	241

Product Description: **KIMTECH Pure* G3, Sterile Latex Gloves - 12" Hand Specific Pairs**
- High density

Product weight : **9.82 kg**Carton dimension : **345 (L) x 265 (W) x 370 (H)**Density : **0.29 g/cm³**Plant Batch No: **M210120329**Current Cobalt Loading (Mc_i): **3968516**Standard Plant Dwell Time (sec): **166** Dwell Time (sec): **166**Number of Xs: **37.99** Value of X: **4.37**Dose Range Specification (kGy): **25.0** Min. **50.0** Max.

Minimum dwell time to achieve	Minimum dose	Maximum dose
First tote	160	239
Second tote	160	243
Third tote	160	241

Validation Ref: 0.0348

Performance Qualification Isotron Malaysia

Rev 01



Customer Name: Safeskin Medical & Scientific (Thai) Ltd.

Type of Package: Corugated Carton

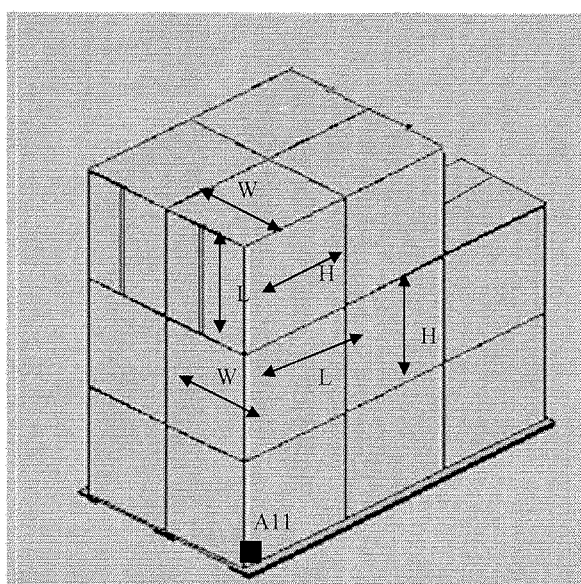
Product Description: KIMTECH Pure* G3, Sterile Latex Gloves - 12" Hand Specific Pairs


Fit Per Tub: 16

Issue Date: 31.12.2010

Expiry Date: 31.12.2015

This performance qualification relates only to the above product loaded in the configuration outlined below.



Authorised By:	Signature	Date
QA Manager		03/01/2011

Validation Ref: 0.0348

Performance Qualification Isotron Malaysia

Rev 01



Customer Name: Safeskin Medical & Scientific (Thai) Ltd.

Type of Package: Corugated Carton

Product Description: KIMTECH Pure* G3, Sterile Latex Gloves - 12" Hand Specific Pairs

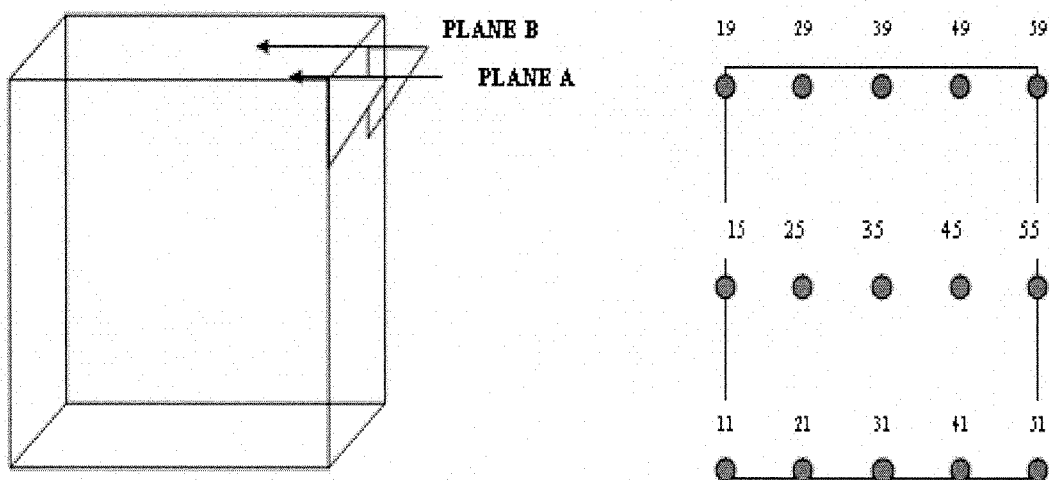
Fit Per Tub: 16

Issue Date: 31.12.2010

Expiry Date: 31.12.2015

This performance qualification relates only to the above product loaded in the configuration outlined below.

LOCATION OF DOSIMETERS



As per our Operational Qualification Report, Source Loading 20th replenished on 22nd Sept 2010, the dose distribution in the front plane (plane A) is the same as in the back plane.

Authorised By:	Signature	Date
QA Manager		03/01/2011

Test Method for Analyzing Liquid Particle Counts

This test method is used to analyze the mobile particle contaminants from cleanroom gloves.

1. Scope

- 1.1. The test method covers the average particulate contamination found on gloves designated for cleanroom applicability.
- 1.2. The average contaminant concentration will be reported in particles per cm^2 in two ways:
 - 1.2.1. By size grouping, 0.5 to 1.0 microns, 1.0 to 2.0 microns, 2.0 to 5.0 microns, 5.0 to 10.0 microns, 10.0 to 20.0 microns, greater than 20.0 microns, and a total particle count greater than 0.5 microns.
 - 1.2.2. Statistical analysis of each grouping consisting of Minimum Value, Maximum Value, Standard Deviation, and Average Value, for each group of individual gloves.
- 1.3. The safe and proper use of gloves is beyond the scope of this test method.
- 1.4. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

- 2.1. IEST-RP-CC005.3 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
- 2.2. Work Instruction

3. Apparatus

- 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
- 3.2. Particle Measuring Systems CLS-900 Liquid Particle Counting System
- 3.3. 2000 mL glass beaker or 1000mL glass conical flask
- 3.4. Stainless Steel Forceps, 10" length
- 3.5. 250 ml Volumetric Flask
- 3.6. 500 ml Volumetric Flask
- 3.7. High Purity Deionized Water System, capable of producing 18.2 MOhm quality water
- 3.8. Point of Use Filter, 0.2 micron size
- 3.9. Orbital Shaker, $\frac{3}{4}$ " orbit, capable of 200 rpm
- 3.10. Circular Die, 1.5 inch diameter, calibrated

4. Procedure

- 4.1. Test Preparation
 - 4.1.1. Prior to extraction, all Erlenmeyer flasks will be cleaned no less than five times with high purity deionized water filtered to 0.2 microns at point of use.
 - 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity deionized water prior to use.
- 4.2. Extraction
 - 4.2.1. Randomly pull a glove from the package.
 - 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
 - 4.2.3. Empty into the inside of the glove 500 ml high purity filtered deionized water.
 - 4.2.4. Allow the glove to settle into the Erlenmeyer flask.
 - 4.2.5. Place an additional 250 ml high purity filtered deionized water over the glove within the Erlenmeyer flask.
 - 4.2.6. Allow the Erlenmeyer flask with glove to agitate on the shaker for 10 minutes \pm 10 seconds at a rate of 150 rpm \pm 10 rpm.
 - 4.2.7. Using clean tongs, immediately remove the glove from the container. Drain any trapped liquid into the beaker by manipulating the fingers on the glove, with the tongs
 - 4.2.8. Dispose of the glove.
 - 4.2.9. Repeat the extraction two additional times to complete the set.
 - 4.2.10. Prepare a process blank, using all the steps in section 4.2, without placing the glove in the Erlenmeyer flask.

4.3. Measurement

4.3.1. Follow the Work Instruction for the Liquid Particle Counter for analyzing the solutions.

4.4. Glove Surface Area

4.4.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.

4.4.2. Record as A.

4.4.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cut-out sections.

4.4.4. Weight the six cut-out sections. Record this as B.

4.4.5. Calculate the surface area of the glove using the following equation :

$$\frac{A \times 5 \times 5 \times 4}{B}$$

5. Calculations

5.1. Calculate counts/cm² by channel size using the following equation:

$$\frac{(\text{Sample (counts/mL)} - \text{Blank (Counts/mL)}) \times \text{Extraction volume (mL)} \times \text{DF}}{\text{Surface area (in cm}^2\text{)}}$$

5.2. Total Counts/cm² : = $\sum AllChannelSizes$

6. Reporting

6.1. The final report should include the Lot Number, Batch number, Product Description, Part Number, and any other pertinent information about the sample, as well as the final calculated counts/cm² by channel size and a total counts/cm² greater than 0.5 microns.

6.2. Statistics will be calculated and reported on sample sizes greater than three.

Test Method for Analyzing Extractables

This test method is used to analyze the soluble ionic extractable contaminants from cleanroom gloves.

1. Scope

- 1.1. The test method covers the average ionic contamination found on gloves designated for cleanroom applicability.
- 1.2. The average contaminant concentration will be reported in one of two ways:
 - 1.2.1. Micrograms of ionic contaminant per gram of glove weight (ug/g), also described as ppm.
 - 1.2.2. Micrograms of ionic contaminant per square centimeter of glove area (ug/cm²)
- 1.3. This test method does not cover contaminants that are insoluble in water, or organic macromolecules.
- 1.4. The safe and proper use of gloves is beyond the scope of this test method.
- 1.5. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

- 2.1. IEST-RP-CC005.2 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments.
- 2.2. Work Instruction WI 10-05-26, Work Instruction for Performing Ion Chromatography Analysis of Gloves

3. Apparatus

- 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
- 3.2. Ion Chromatograph
- 3.3. Extraction Containers, 1 liter capacity, HDPE with screw type lids
- 3.4. Stainless Steel Forceps, 10" length
- 3.5. 500 ml Volumetric Flask
- 3.6. High Purity Deionized Water System, capable of producing 18.0 MOhm quality water
- 3.7. Point of Use Filter, 0.1 micron size
- 3.8. Circular Die, 1.5 inch diameter, calibrated

4. Procedure

4.1. Test Preparation

- 4.1.1. Prior to extraction, all extraction containers will be cleaned using high purity deionized water high purity deionized water filtered to 0.2 microns at point of use.
- 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity de-ionized water prior to use.

4.2. Extraction

- 4.2.1. Randomly pull a glove from the package.
- 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
- 4.3. Empty into the inside of the glove approximately 250 ml high purity filtered deionized water.
- 4.4. Allow the glove to settle into the extraction container.
- 4.5. Pour remaining 250 ml high purity filtered deionized water over the glove within the extraction container.
- 4.6. Place the lid upon the container and seal tightly.
- 4.7. Gently swirl the container to ensure that all surfaces of the glove are wetted.
- 4.8. Allow the glove to extract in the deionized water for at least 10 minutes, but no longer than 11 minutes.
- 4.9. Remove the glove by the fingers, allowing most of the water trapped in the fingers to drain back in to the extraction container.
- 4.10. Dispose of the glove.
- 4.11. Repeat extraction two additional times to complete the set.
- 4.12. Prepare a sample blank, using all the steps in section 2, without placing the glove in the extraction container.

4.13. Measurement

4.13.1. Follow the guidelines for the Ion Chromatograph for analyzing aqueous solutions.

4.14. Glove weight and surface area

4.14.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.

4.14.2. Record as A.

4.14.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cut-out sections.

4.14.4. Weight the six cut-out sections. Record this as B.

4.14.5. Calculate the surface area of the glove using the following equation :

$$\text{Surface area} = \frac{A \times 5 \times 5 \times 4}{B}$$

5. Calculations

5.1. Once the data output from the Chromatograph has been reviewed for errors, calculate the following:

$$5.1.1. \text{ ug/g (ppm) contamination: } = \frac{(\text{Analyte Conc.}) * (500\text{ml})}{\text{Glove Weight}}$$

$$5.1.2. \text{ ug/cm}^2 \text{ contamination: } = \frac{(\text{Analyte Conc.}) * (500\text{ml})}{\text{Surface Area}}$$

6. Reporting

6.1. The final report should include the Lot number, Batch number, Product description, Part number, and any other pertinent information about the sample, as well as the final calculated contaminant concentration in ug/g and ug/cm².

Test Method for Analyzing Bacterial Endotoxins

This test method is used to detect or quantify endotoxins in sterile medical and cleanroom gloves

1. Scope

- 1.1 The test method is a kinetic turbidimetric method used to detect or quantify Gram-negative bacteria using Limulus Amoebocyte Lysate (LAL) from horseshoe crab (*Limulus polyphemus* or *Tachypleus tridentatus*).
- 1.2 The average contaminant concentration will be reported in endotoxin units per device (pair)
- 1.3 This procedure is an overview of the Kimberly-Clark Internal procedure
- 1.4 The safe and proper use of gloves is beyond the scope of this test method
- 1.5 This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2 Referenced Documents

- 2.1 U.S. Pharmacopoeia USP 24 NF 19, Second Supplement, Bacterial Endotoxin Test.
- 2.2 ASTM D7102-10 Standard Guide for Determination of Endotoxin on Sterile Medical Gloves.

3 Apparatus

- 3.1 Microplate reader
- 3.2 Computer and windows software
- 3.3 Hot air oven capable of 250C
- 3.4 Refrigerator capable of 5C
- 3.5 Freezer capable of -10 to -20C
- 3.6 Vortex mixer
- 3.7 Incubator capable of 180 rpm, 35C
- 3.8 Timer
- 3.9 Micropipettor: single and 8 channel
- 3.10 Laminar flow hood
- 3.11 96 well flat bottom microplate, sterile, non-pyrogenic, individually wrapped
- 3.12 Sterile, non-pyrogenic pipette tips
- 3.13 Aluminum foil
- 3.14 Glass beaker 600 mL, 1000 mL
- 3.15 Glass tube
- 3.16 Pyrogen@-5000 test kit catalog N383 or N384 (BioWhittaker, Inc)
- 3.17 Pyrogenic-free water

4 Test Preparation:

4.1 All glassware used for assay must be depyrogenated in a hot air oven at temperature 250C for 2 hours

4.2 All surface areas must be cleaned with 70% ethyl alcohol solution

4.3 Glove Sample preparation:

4.3.1 Transfer 10 gloves into a 600 or 1000 mL beaker and add 400 mL of pyrogen-free water (only exterior of the gloves are soaked with water)

4.3.2 Cover beaker with pyrogen-free aluminum foil and place in incubator shaker at 180 rpm, for 60 minutes at 35C

4.3.3 After extraction is completed take the beakers out, discard the gloves from the solution.

4.3.4 Store the test solution at 2-8C

4.3.5 Perform dilution of test solution as necessary for testing

4.4 Reagent, standard endotoxin stock and CSE preparation:

4.4.1 LAL reagent (lysate):

4.4.1.1 allow reconstitution buffer to warm to room temperature before use

4.4.1.2 Reconstitute lysate with reconstitution buffer as per test kit instruction

4.4.1.3 Swirl gently to avoid foaming

4.4.2 Standard Endotoxin stock solution:

4.4.2.1 Reconstitute endotoxin with specified volume to pyrogen-free water

4.4.2.2 Shake vigorously for 15 min at high speed on a vortex mixer.

4.4.3 Control standard endotoxin (CSE):

4.4.3.1 Prepare the CSE per manufacturer's instruction.
Prepare serial dilutions (4) as necessary

4.5 LAL Testing

4.5.1 Carefully dispense 100 uL pyrogenic-free water (blank or negative control), positive control, 4 concentrations of CSE and diluted test solution into microtiter wells of microplate. Bubbles must be avoided

4.5.2 Place filler plate into microtiter reader (ensure temperature is at 37C)

4.5.3 When the assay is finished, print standard curve results and calculate results vs. the standard.

Glossary of Terms

Item	Definition
Anion	The ion in an electrolyzed solution that migrates to the anode when voltage is generated; broadly: a negatively charged ion. Typical examples include Chloride (Cl-), Phosphate (PO4-3), Sulfate (SO4-2), Nitrate (NO3-).
AQL	Acceptable Quality Level. Applies to product attributes and defines the allowable number of defects for various sample sizes. For example, AQL 1.5 means that the sample must demonstrate that it exceeds 1.5% defects in order to reject the sample.
ASTM	American Society of Testing and Materials. The ASTM issues testing standards and specifications. The FDA utilizes many of the standards developed by the ASTM to establish medical device requirements.
Average	The sum of individual observations divided by the total number of observations. Average represents the central tendency of a "sample" group. The sample group can be used to make inferences about the entire population.
Bioburden	Bioburden is the population of viable microorganisms on a raw material, component, a finished product and/or a package. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.
Biocompatibility	The property of not causing cytological change when introduced to a biological system or model.
Calcium carbonate	A mold-release agent often used that facilitates the release of latex gloves from their porcelain molds (formers). Calcium carbonate is a non water-soluble crystal. It occurs in nature as oyster shells, chalk and limestone.
Calibration	Comparison of a measurement standard or instrument of unknown accuracy with another standard or instrument of known accuracy to detect, correlate, report, or eliminate by adjustment, any variation in the accuracy of the unknown standard or instrument.
Cation	The ion in an electrolyzed solution that migrates to the cathode when voltage is generated; broadly: a positively charged ion. Typical examples include: Sodium (Na+), Calcium (Ca2+), Magnesium (Mg2+), Potassium (K+).
CE Mark	What is CE Marking? CE Marking is the symbol as shown on the top of this page. The letters "CE" are the abbreviation of French phrase "Conformité Européene" which literaturately means "European Conformity".
Certificate of Analysis (CoA) for cleanroom gloves	An authenticated document issued by the manufacturing plant that certifies the quality and purity of the cleanroom glove products being exported.
Certificate of Irradiation (Col) for cleanroom sterile gloves	An authenticated document issued by the sterilization plant that certifies the sterile cleanroom gloves as having been irradiated. Document includes the manufacturer lot & batch number. Irradiation data, allowable dose range and actual dose.
CFU (colony forming units)	Either one or an aggregate of many microbial cells which, when cultivated on solid media, will develop into a single visual colony. The unit of measure used for reporting bioburden (CFU/product).
Cleanroom	A room in which the concentration of airborne particles is controlled to specified limits. Federal Standard 209E - A document that establishes standard classes of air cleanliness for airborne particulate levels in cleanrooms and clean zones.
Contact sensitizer (other keywords: accelerators, MBT, carbamate, thiurams, mercaptobenzothiazole)	A chemical agent used in the manufacturing process of gloves that may elicit a delayed type allergic reaction (Type IV) after repeatedly exposing the substance to a susceptible individual.
Deionize	To remove ions. Deionization is generally the removal of ions from water by a process called ion exchange. Water is passed over a resin (plastic) exchange bed. The ions in the water have a greater attraction to the exchange bed than to the water.
Do we have sulfur in our gloves?	All latex (both NRL and Nitrile) use native S as a cross link element. Vinyl gloves do not typically have sulfur.
Dose audit	A check to make sure the dose is still correct. The population and sterilization resistance of microorganisms vary with environmental conditions such as temperature and moisture.
Dose mapping	Product dose mapping is conducted to identify the zones of minimum and maximum dose, within the product load with the specified loading pattern, and to assess the reproducibility of the process.
Dose setting	"Dose Setting using Bioburden Information." Determine the number of organisms on the packaged, pre-sterilized gloves.
Dosimeter	A device that measures the amount of radiation which reaches the position where the dosimeter is placed.
Elongation	Measurement in percent of the length a glove material can be stretched before it breaks.
Endotoxin	Pieces off the cell wall of dead bacteria, capable of causing multiple local and systemic pathological problems, including fever, complement activation, cell lysis, tissue inflammation, diarrhea, microthrombi formation (clots) and disseminated intravascula.

Glossary of Terms

Enzyme-Linked Immunosorbent Assay (ELISA)	A highly sensitive immunoassay for specific antibodies or antigens (including allergens) depending on how the test is set up. Results expressed as mg/g or mL; ppm; Au/g or mL.
Gamma Irradiation	The process of product sterilization utilizing gamma wave radiation. It is the most compatible sterilization process for latex gloves.
Good Manufacturing Practices (GMPs)	What are GMPs? Good Manufacturing Practices (GMPs) are regulations that describe the methods, equipment, facilities, and controls required for producing: human and veterinary products (21 CFR 210-211), medical devices (21 CFR 820), processed food.
IENT	Institute of Environmental Standards and Technology. A consortium that develops standards and recommended practices and provides training by industry experts. The standards and recommended practices are developed by committees comprised of scientists.
Ion	An atom or group of atoms that carries a positive or negative electric charge.
ISO	The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. ISO has developed a series of standards relating to Quality Systems known as the ISO 9000 family standards.
ISO 9002	A quality system model for quality assurance in production and installation. I would skip ISO 9003 because it implies like 9002 doesn't cover inspection and testing.
Latex	Commonly, it is a milky, usually whitish fluid obtained from over 1,000 species of trees and plants. Relating to gloves, it is natural rubber latex, the raw material which comes from the Hevea brasiliensis tree.
Leaching	Process applied in the production of gloves by which chemicals or contaminants are dissolved and carried away by water to reduce chemical residual levels. Wet gel leaching occurs right after latex is dipped onto the mold.
Lowry	Determines the concentration of total protein present in a sample. A Modified Lowry assay was developed for use with latex products.
Mean	Represents the "Central Tendency" or average of an entire population. The formula is the same as for the average, except the mean includes the entire population. It is typically impractical to measure every member of any population.
Method 1	Dose setting utilizing the number (bioburden) and resistance of micro-organisms on the products to determine the level of irradiation necessary for sterilization with the desired safety margin (e.g. 10-6).
Micrometer (micron)	A unit of measurement equal to one-millionth of a meter or approximately 0.0003937 inch (e.g. 25 micrometers are approximately 0.001 inch).
Micron	A unit of length equal to one millionth (10-6) of a meter.
Modified Lowry assay	See Lowry.
Modulus	A measurement of the resistance to stretch. A lower modulus represents a glove in which it is easier to move and thus less fatiguing.
Non-pyrogenic	Non-fever causing. Reflects low levels of endotoxins which cause fever, inflammation, endotoxic shock, elicit micro-thrombi formation and numerous other adverse conditions. (See Endotoxin)
NVR (Non-Volatile Residues)	Refers to materials or components that do not evaporate at normal temperature and pressure.
Particle	A solid or liquid object, generally between .001 micron and 1000 microns in size.
Particle Size	The maximum linear dimension of a particle as observed with an optical microscope or the equivalent diameter of a particle detected by an instrument.
Particle Size Distribution	The relative percentage by weight or number of different particle size fractions.
Particulate	A substance that consists of particles (minute quantities of solid or liquid matter).
pH	Hydrogen ion concentration; measurement of how acidic or basic a glove extract is.
Product Dose Mapping	See "Dose Mapping."
Protein content	Regarding latex gloves, protein content is the measurement of total protein regardless of allergenic content. The ASTM D5712 Modified Lowry assay is the method recognized by the government for use with gloves.
Proteins	Any of a class of naturally occurring complex combinations of amino acids (containing carbon, hydrogen, oxygen, nitrogen, usually sulfur, occasionally phosphorus) which are essential constituents of all living cells.
Pyrogen	A fever-producing substance. Endotoxin is a pyrogen.
Pyrogenic	Capable of eliciting a fever.
SAL	See "Sterility Assurance Level."
SAL Dose	The level of radiation delivered to the product to achieve the required SAL (sterility assurance level).
Sampling	A process consisting of the withdrawal or isolation of the fractional part of a whole. In air or gas analysis, the separation of a portion of an ambient atmosphere with or without the simultaneous isolation of selected components.
Silicone [gloves]	Silicone is a synthetic polymer, or macro-molecule, whose backbone is a repeating chain of Si-O molecules, with various organic groups attached to the silicon. The most common silicone is PDMS, poly-dimethylsiloxane [(CH ₃) ₂ Si-O].

Glossary of Terms

Silicone-free gloves	Currently, all our cleanroom nonsterile products are silicone free. We do not make the same claim with our boxed products. Some of them have silicone in them.
SPC (Statistical Process Control)	Statistical process control is the practice of using statistical methods such as control charts and capability analysis to monitor and control a process. The application of statistics to determine non-random changes in a process. Any changes or "shifts" in the process will be reflected as non-random occurrences and can be studied for root cause.
Specification – Design	A concise document defining technical requirements in sufficient detail to form the basis for a product or process. It indicates when appropriate, the procedure that determines whether or not the given requirements are satisfied.
Specification – Performance	A concise document that details the performance requirements for a product. The performance specification includes procedures and/or references for testing and certification of the product.
Standard Deviation	A statistical measurement of variability equal to the square root of the arithmetic average of the squares of the deviations from the mean in a frequency distribution.
Static Decay	The materials ability to dissipate a charge. Normally tested by placing a known charge (5000 volts) on the material (glove). A non-contact meter measures the charge on the material.
Static Dissipative	A property of material having a surface resistivity of at least 105 OHMs per square, but less than 1.0 x 10 ¹² OHMs per square surface resistivity.
Statistical Capability	A process with a Cpk > 1.0 (although this can be defined as > 1.33 as well).
Statistical Control	A process which, when sampled on a regular basis, demonstrates an average that is consistent with the population central tendency and variability. In other words, the sample is statistically from the same population as previous samples.
Sterile	Assurance that a given device is without living organisms.
Sterility Assurance Level (SAL)	The expected probability of an item being non-sterile after exposure to a valid sterilization process. This is a safety factor over and above demonstrating that all microorganisms are killed.
Sterilization	A physical or chemical process that completely destroys or eliminates all forms of microbial life.
Sterilization Dose	Minimum absorbed dose required to achieve the specified sterility assurance level.
Sterilization Label	Label on the outside of every sterile cleanroom glove case showing the certificate number and sterilization batch. The label also provides a sterility indication showing the case has been irradiated/sterilized.
Sterilization Validation	Establishing documented evidence the sterilization process, dose range and dwell time are appropriate for the product being sterilized.
Synthetic rubber	Not of natural origin; produced by chemical synthesis. Synthetic gloves include, but are not limited to, vinyl (PVC), neoprene (chloroprene), nitrile, viton (fluorocarbon rubber), styrene butadiene (SBR), Tactylon (Styrene-Ethylene- Butadiene-Styrene—SE).
Talc	Magnesium silicate, Mg ₃ Si ₄ O ₁₀ (OH) ₂ , used as a solid lubricant. Banned from use on surgical gloves after found to cause granulomas and adhesions in surgical wounds.
Technical Data Sheet	Data sheet summarizing Kimberly-Clark's glove technical claims for our customers.
Tensile strength	Measurement of the amount of stretch or pull required to rupture or break the glove material. Measurement is in Pa's or MPa's.
Validation	Establishing documented evidence that a system does what it purports to do.
Vulcanization	The process of treating crude latex, subjecting it to heat and sulfur to render it non-sticky, increasing its strength and elasticity.
What is a polymer?	Polymers are primarily made of carbon, hydrogen and oxygen. The structure of polymers is like a chain where repeating units (-mers) are connected many (-poly) times.
What is ESD (Electrostatic Discharge)? [cleanroom gloves]	The rapid, spontaneous transfer of electrostatic charge. Usually the charge flows as a spark between two bodies with differing electrostatic potentials (voltages) as they approach one another. (ESD Assoc.)
What is the melting point of latex and nitrile gloves?	Akron Rubber Development Laboratory has determined that the melting point of nitrile is at 283.4 Celsius.
What is the relationship between non-volatile residue testing and particle counting? (gloves)	NVR is determined by weight, and particles definitely have weight, but not enough to be a measurable part of the NVR for most cleanroom consumables. The weight of particles depends on their volume and what their made of.