

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### STUDY TITLE

Quantitative UV Light Surface Time-Kill Analysis

### Study Identification Number

GLP1038

### Protocol Number

P1042

### Device

U-Pang UV Sterilizer

Model UP101-P

Blue Care Co., Ltd.

10F Woo-Ree Venture-Town, 684-2 Deungchon-Dong,  
Gangseo-Gu, Seoul, Korea (157-030)

### Test Microorganisms

*Escherichia coli* ATCC 11229

### Data Requirements

21 CFR Part 58

### Author

Ashley Rex, B.S.

Study Director

### Study Completion Date

18 MAY 2010

### Testing Facility

Antimicrobial Test Laboratories

3000 Joe DiMaggio Blvd., Suite 32

Round Rock, Texas 78665

### Study Sponsor

Grace Kim

J.S. Chem. International Co. (on behalf of Blue Care Co., Ltd.)

#506 Youngchang B/D, 242-31 Nonhyun-Dong,

Gangnam-Gu, Seoul, Korea (135-010)

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

If the section below is signed by the Study Sponsor, then no claim of confidentiality is made for any information contained in this study. If the following section is not signed by Sponsor, then Antimicrobial Test Laboratories will treat the study as commercially confidential but respect FDA authority regarding GLP study auditing and disclosure rules.

Company: J.S. Chem International Co.

Agent/Submitter: GRACE KIM

Title: Authorized representative for Blue Care Co., Ltd.

Date: 05-28-2010

Signature: Grace Kim

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study meets U.S. Food and Drug Administration's Good Laboratory Practice Standards and requirements for 21 CFR § 58 with the following exception:

- Records concerning test substance characteristics (i.e. composition, purity, stability, strength, solubility) are maintained by the Study Sponsor, or by Study Sponsor's provider of the device used for the study.

#### Study Director

Company: Antimicrobial Test Laboratories

Name: Ashley Rex, B.S.

Title: Study Director

Signature: Ashley Rex

Study Completion Date: 18 MAY 2010

#### Study Sponsor

Company: J.S. Chem. International Co. (on behalf of Blue Care Co., Ltd.)

Name: Grace Kim

Title: Chief Executive Officer

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

#### Submitter (Only Applicable if study will be submitted to Regulatory Agency)

Company:

Name:

Title:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### QUALITY ASSURANCE STATEMENT

Study Title: Quantitative UV Light Surface Time Kill Analysis

Study ID: GLP1038

The following quality assurance audits were conducted in accordance with Good Laboratory Practice Standards outlined in 21 CFR § 58 and reported to management and the Study Director:

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
In Phase	04 MAY 2010	04 MAY 2010	04 MAY 2010
Final Report	18 MAY 2010	18 MAY 2010	18 MAY 2010

Quality Assurance Unit:

Signature: Gina Tanner  
Name: Gina Tanner  
Title: Quality Assurance

Date: 18 MAY 2010



# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### PERSONNEL INVOLVED IN THE STUDY

#### Study Sponsor

Name: Grace Kim

Company: J.S. Chem. International Co. (on behalf of Blue Care Co., Ltd.)

Title: Chief Executive Officer

#### Study Director

Name: Ashley Rex, B.S.

Company: Antimicrobial Test Laboratories

Title: Study Director

#### Assisting Personnel

Name: Benjamin Tanner, Ph.D.

Company: Antimicrobial Test Laboratories

Title: Scientific Director

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### TABLE OF CONTENTS

STUDY TITLE .....	1
STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS .....	2
GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT .....	3
QUALITY ASSURANCE STATEMENT .....	4
PERSONNEL INVOLVED IN THE STUDY.....	5
TABLE OF CONTENTS .....	6
FINAL STUDY REPORT SUMMARY.....	7
FINAL STUDY REPORT .....	8
PROTOCOL CHANGES.....	9
CONTROLS .....	10
STUDY ACCEPTANCE CRITERIA .....	11
CALCULATIONS AND STATISTICAL ANALYSIS .....	12
STUDY RECORD AND TEST SUBSTANCE RETENTION .....	13
RESULTS .....	14
STUDY CONCLUSION .....	20
PROTOCOL.....	20

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### FINAL STUDY REPORT SUMMARY

#### Study Title

Quantitative UV Light Surface Time-Kill Analysis

#### Study Identification Number

GLP1038

#### Protocol Number

P1042

#### Test Microorganisms

*Escherichia coli* ATCC 11229

#### Study Sponsor

Grace Kim

J.S. Chem. International Co. (on behalf of Blue Care Co., Ltd.)

#506 Youngchang B/D, 242-31 Nonhyun-Dong,

Gangnam-Gu, Seoul, Korea (135-010)

#### Testing Facility

Antimicrobial Test Laboratories  
3000 Joe DiMaggio Blvd., Suite 32  
Round Rock, Texas 78665

#### Study Director

Ashley Rex, B.S.

#### Study Completion Date

18 MAY 2010

#### Study Objective

To evaluate sanitization efficacy of the U-Pang UV sterilizer against standard infant bottles contaminated with *Escherichia coli* ATCC 11229 on both the inside of the nipple and bottom of the bottle treated.

#### Study Conclusion

The U-Pang UV Sterilizer demonstrated  $\geq 99.9\%$  reductions for *Escherichia coli* ATCC 11229 with respect to the inside bottom of the bottle and inside of the nipple.

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### FINAL STUDY REPORT

#### Important Dates

Study Initiation Date: 26 April 2010  
Experimental Start Date: 04 May 2010  
Experimental End Date: 06 May 2010

#### Test Device Information

Name: U-Pang UV Sterilizer  
Manufacturer: Blue Care Co., Ltd.  
10F Woo-Ree Venture-Town, 682-2 Deungchon-Dong,  
Gangseo-Gu, Seoul, Korea (157-030)  
Model: UP101-P1004  
Date Received: 23 April 2010  
Storage Conditions: Room Temperature

#### Test Parameters

Microorganism(s): *Escherichia coli* ATCC 11229  
Subculture Number: 1  
Number of Test Bottles: 2 bottles (1 treatment and 1 control)  
Bottle Type: Evenflow Classic without BPA 4oz. Bottle  
UV Exposure Time: 10 minutes  
Organic Soil Load: N/A  
Culture Volume: 10ml  
Volume "Soil" Added: N/A  
Volume Culture/Bottle: 0.020ml per nipple and inside bottom of bottle  
Carrier Dry Time: 1 Hour  
Carrier Dry Temperature: 23°C  
Incubation Time: 46 hours and 25 minutes  
Incubation Temperature: 35.0°C to 35.6°C

#### Test Method

The test was conducted according to the attached protocol.



# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### PROTOCOL CHANGES

#### Protocol Amendments

None.

#### Protocol Deviations

The inoculated bottles and nipples were dried for 1 hour rather than the  $40 \pm 2$  minutes as indicated in the approved protocol P1042. The inoculated bottles and nipples were not dry after 40 minutes; therefore they were allowed extra time to sufficiently dry. It took a full hour for the inoculated bottles and nipples to dry.

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### CONTROLS

#### Media Growth and Viability Controls

Each test microorganism was streaked to TSA to confirm viability and purity.

#### Media Sterility Controls

One TSA plate and a 1ml sample of neutralization media were incubated alongside other plates to verify media sterility.

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### STUDY ACCEPTANCE CRITERIA

**The experimental success (controls) criteria follow:**

1. Control samples must demonstrate a viable count between  $1 \times 10^4$  and  $1 \times 10^6$  CFU/ml.
2. All sterility controls must test negative for growth.
3. All positive controls must test positive for growth.

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### **CALCULATIONS AND STATISTICAL ANALYSIS**

#### **Sample Enumeration**

$$[\text{Plate Count 1} + \text{Plate Count 2}] / 2 \times \text{Dilution Factor} = \text{Colony Forming Unit (CFU)/Sample}$$



# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### STUDY RECORD AND TEST SUBSTANCE RETENTION

#### Study Record Retention

The study report and corresponding data sheets will be held in the archives of Antimicrobial Test Laboratories for at least 2 years after the date of the final report and then destroyed, or if used by the Study Sponsor in support of a label claim, documentation may be returned to the Study Sponsor for archiving at Sponsor's expense.

#### Test Substance Retention

The test device may be returned to the Study Sponsor at Sponsor's request and expense within 30 days of study completion. If the Study Sponsor does not request return of the device, it may be destroyed >30 days after study completion.

# Antimicrobial Test Laboratories

Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

## RESULTS

### Control Results

Control results are in compliance with the aforementioned study acceptance criteria.

Test Microorganism	Media Growth Control	Media Sterility Control
<i>Escherichia coli</i> ATCC 11229	Growth	No Growth

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

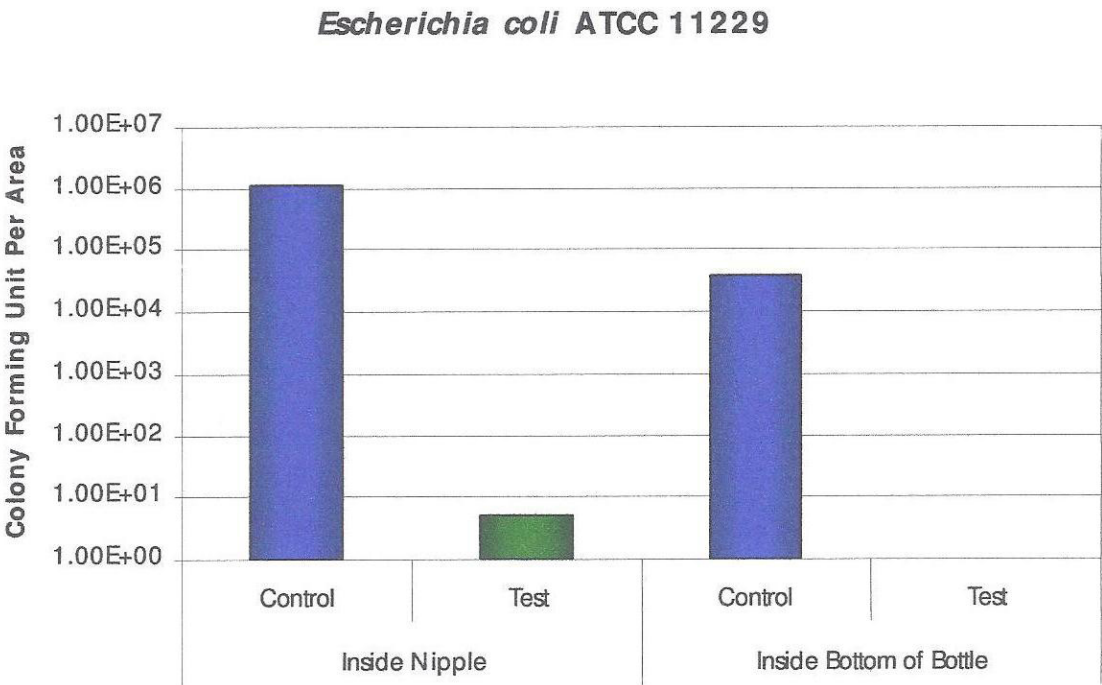
### RESULTS

#### Test Results

Test Microorganism	Carrier Description		Colony Forming Units Per Area	Percent Reduction
	Area of Bottle	Control or Test		
<i>Escherichia coli</i> ATCC 11229	Inside Nipple	Control	1.15E+06	99.9 %
		Test	5.00E+00	
	Inside Bottom of Bottle	Control	3.95E+04	>99.9 %
		Test	<5	

RESULTS

Graph of Results



Note: Non-detectable Colony Forming Units of < 5 are presented as zero on the chart.



# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

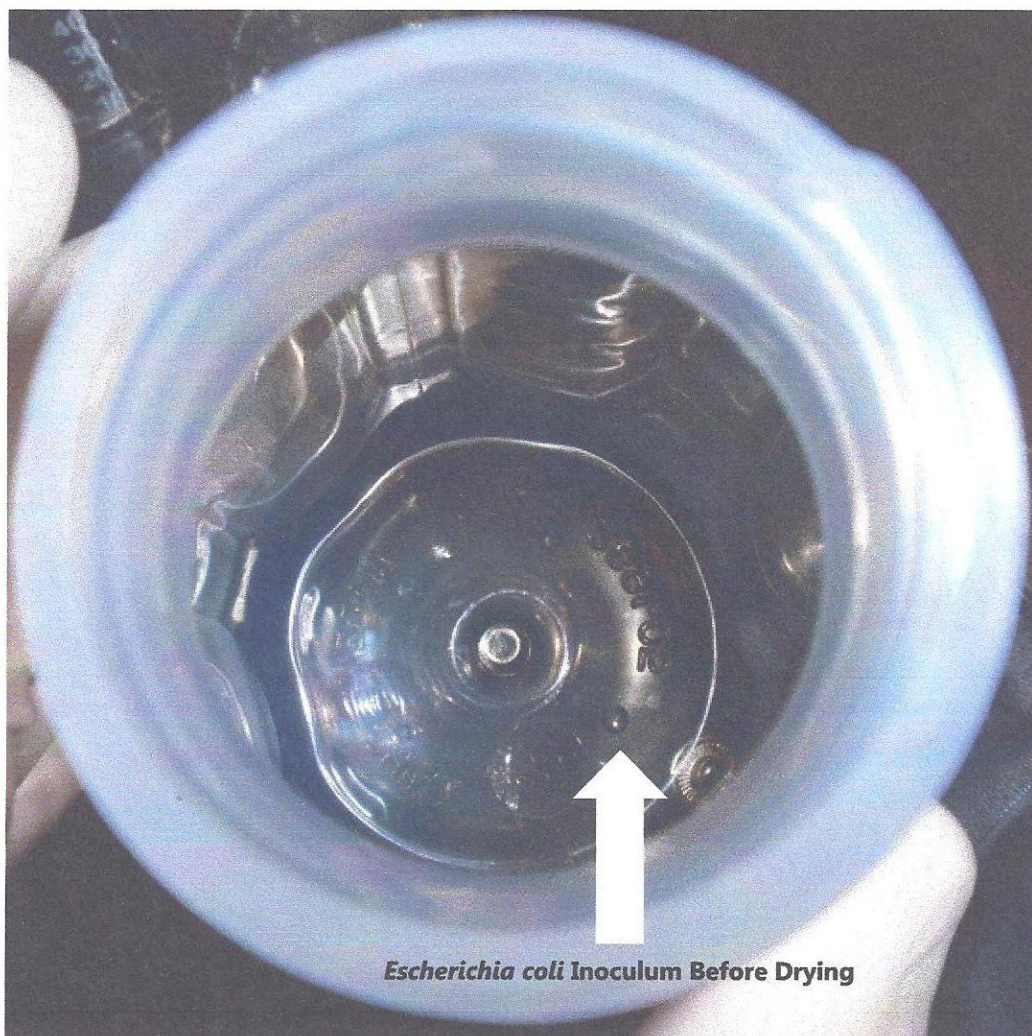
Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### RESULTS

#### Photographs from the Study





# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

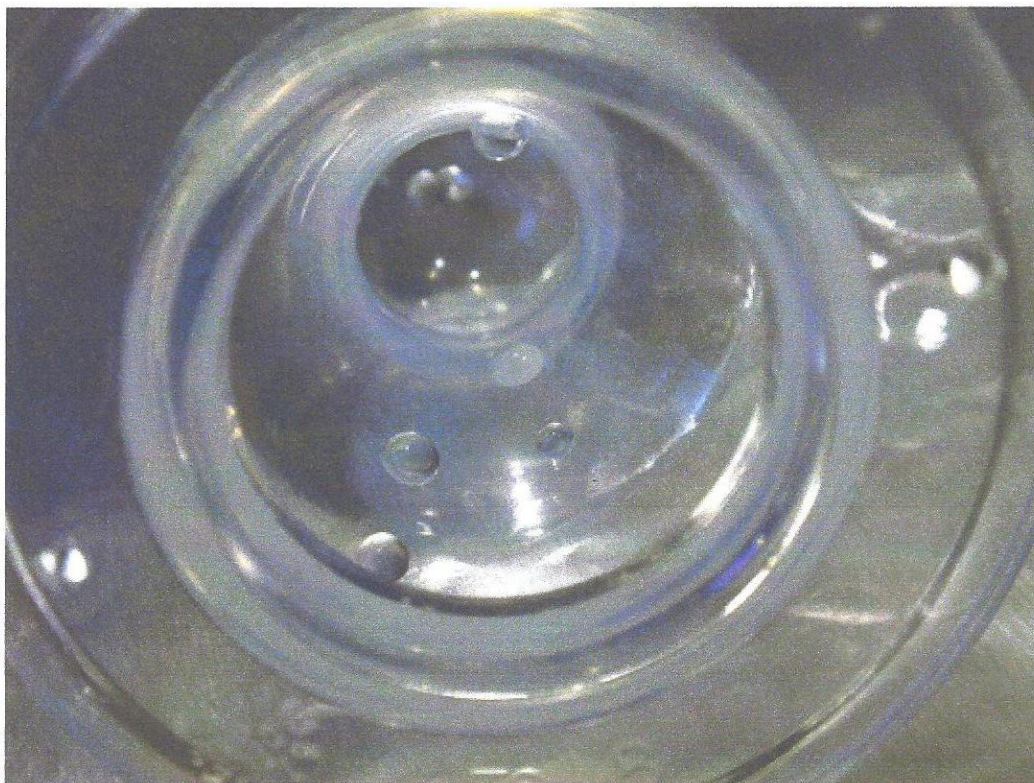
Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### RESULTS

#### Photographs from the Study



Inoculated Nipple

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

### RESULTS

#### Photographs from the Study



Bottle and Nipple inside the Device while being exposed to U.V.



# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### STUDY CONCLUSION

For Study Identification Number GLP1038, the U-Pang UV Sterilizer demonstrated remarkable efficacy with respect to the inside bottom of each bottle and inside nipple resulting in percent reductions >99.9% for *Escherichia coli*.



# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

---

Study ID: GLP1038

Study Sponsor: J.S. Chem. International Co.

Protocol Number: P1042

---

### PROTOCOL