


Laboratory Testing of Zebra's Z-Band[®] Direct Thermal Wristbands with Antimicrobial Coating



TECHNICAL SPECIFICATIONS





Introduction

This document details the laboratory testing completed on Zebra® Z-Band direct thermal wristbands, featuring Zebra's patent-pending antimicrobial coating. Independent laboratories and the Zebra Technologies Supplies research and development team tested the wristbands to ensure they meet Zebra's high standards for image durability, scannability and comfort. The tests evaluated the following:

- Antimicrobial activity
- Durability
- Potential to cause skin irritation

Since bar coded wristbands provide a convenient way to comply with The Joint Commission's National Patient Safety Goal to "improve the accuracy of patient identification," it is important for wristbands to be readable and scannable during the patient's stay. As you will see, Zebra's antimicrobial-coated Z-Band wristbands were shown to be readable on the first scan. They also proved to be non-irritating and able to prevent microorganisms from growing or surviving on them.

The following facilities conducted the testing:

- Antimicrobial: Northland Laboratories, 1818 Skokie Blvd, Northbrook, IL 60062—Report Date: November, 2006 and January, 2008
- Image Durability and Peel Adhesion: Zebra's Supplies R&D Laboratory—Testing Completed: December, 2006
- Tensile Strength: Zebra's Supplies research and development team utilized Northwestern University's Central Facilities supported by the MRSEC program of the National Science Foundation (DMR-0520513)
- Skin Irritability: Toxikon Corporation, 15 Wiggins Ave. Bedford, MA 01730—Report Date: May, 2006

The next section details the tests' procedures and results.

Materials, Methods, and Results

1. Antimicrobial Activity Testing

Zebra's Z-Band direct thermal wristbands feature inorganic ionic silver as an antimicrobial, which the following tests demonstrate kills certain microorganisms that come into contact with it. As the silver ions are taken into the microorganisms, they react and bond to the cellular enzyme. This inhibits the microorganisms' enzyme activity and multiplication, thus killing them.

Zebra contracted with an independent laboratory to test the ability of three microorganisms—*S. aureus*, *P. aeruginosa*, and *E. coli*, the three leading causes of hospital infections in the United States—to grow and survive on Zebra's Z-Band antimicrobial-coated direct thermal wristband, as well as three competing wristbands and technologies (including PDC's ScanBand, LaserBand's Original LaserBand and Hollister's Ident-A-Band with insert cards) that did not have an antimicrobial coating.

Test articles of the Zebra wristband and three competitive wristbands were tested to the following standard methodologies:

- FDA BAM Chapter 3, total plate count
- ASTM E2180: JIS Z 2801: Antimicrobial products-testing for antimicrobial activity and efficacy

Also referencing:

- FDA BAM, Food and Drug Administration Bacteriological Analytical Manual
- ASTM E2180, American Society for Testing and Materials Standards
- JIS Z 2801, Japanese Industrial Standard

All four of the wristband test articles were individually inoculated with *Staphylococcus aureus*, *Escherichia coli* and *Pseudomonas aeruginosa*. The 0hr wristband test articles for each microorganism were serially diluted and plated out right away to determine initial bacterial concentration levels. The 24hr wristband test articles for each microorganism were incubated under high-humidity conditions for 24 hours and plated thereafter to determine the bacterial concentration levels after 24 hours. As shown in the pictures of the samples, none of the three microorganisms tested were able to grow or survive on the Zebra Z-Band wristband during the 24-hour test period. See Figures 1-3. The activity of the microorganisms is represented graphically in Figure 4.

Figure 1. *Staphylococcus aureus* at 0 HR and at 24 HR.



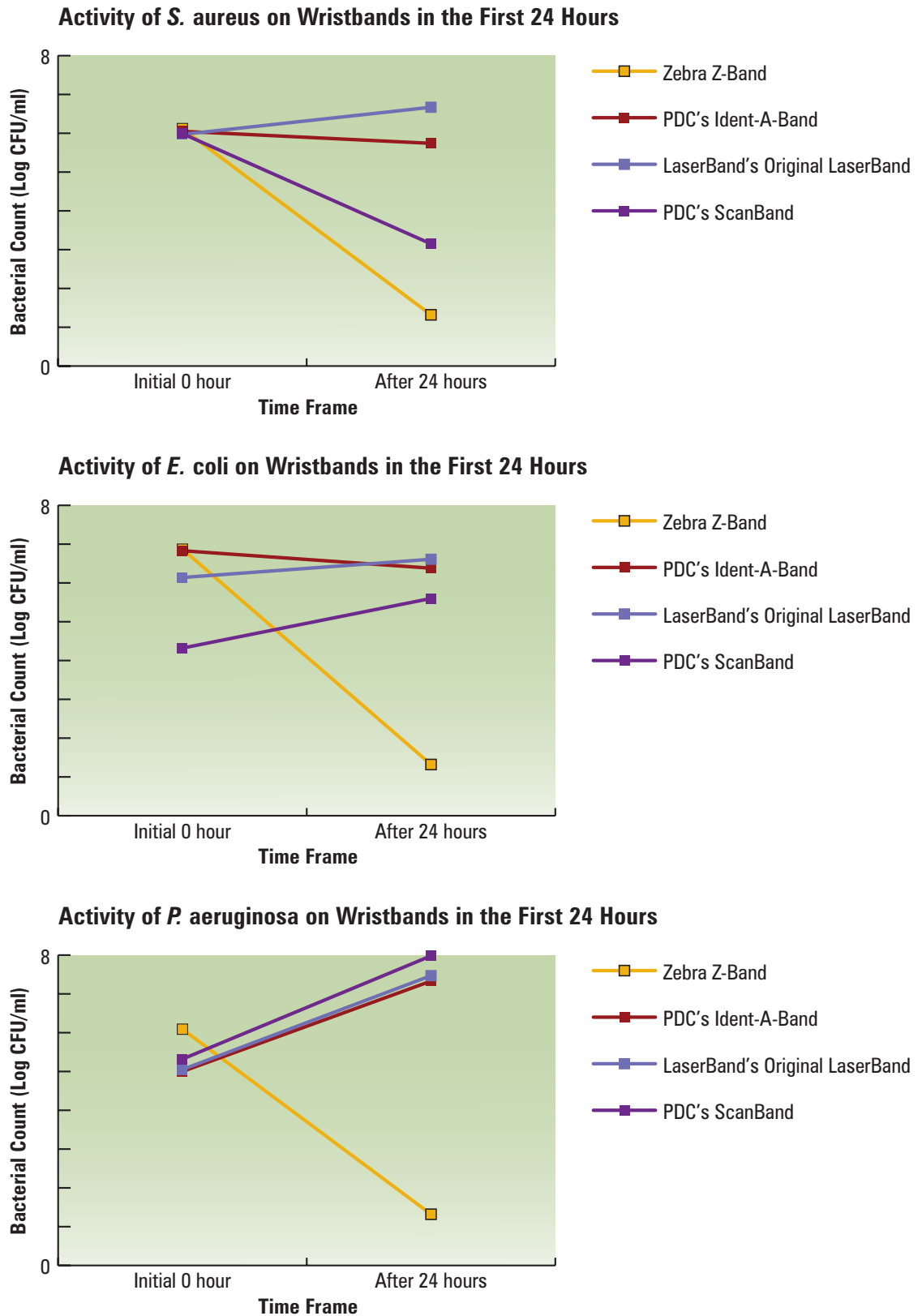
**Figure 2. Escherichia coli
at 0 HR and at 24 HR**




**Figure 3. Pseudomonas aeruginosa
at 0 HR and at 24 HR**



Figure 4. Activity of microorganisms within the 24 hour test period.





Zebra additionally contracted with an independent laboratory to test the ability for the following strains of MRSA (Methicillin-resistant Staphylococcus aureus) to grow and survive on Zebra’s Z-Band antimicrobial wristbands:

- MRSA Type II – ATCC #BAA-41
- MRSA Type III –ATCC #BAA-39
- MRSA Type IV – ATCC #BAA-42

The test articles were tested to the following standard methodologies:

- FDA BAM, Federal Food and Drug Administration Bacteriological Analytical Manual
- ASTM E2180, American Society for Testing and Medical Standards
- JIS Z2801, Japanese Industrial Standard

The wristband test articles were inoculated with MRSA Type II, MRSA Type III, and MRS Type IV. The 0hr wristband test articles for each microorganism were serially diluted and plated out right away to determine the initial bacterial concentration levels. The 0hr measurements showed that the antimicrobial immediately affected each type of MRSA types. The 24hr wristband test articles for each type of MRSA were incubated under high-humidity conditions for 24 hours and plated thereafter to determine the bacterial concentration levels after 24 hours. After 24 hours, none of the three MRSA types tested were able to grow or survive on the Zebra Z-Band antimicrobial wristband during the 24 hour test period.

2. Durability Testing

Optimum scanning performance and image durability are important, especially regarding the narrow 5 mil 128 Subset C bar codes that are printed on today’s hospital wristbands. A bar code that fails to scan or requires repeated attempts to scan, can both jeopardize patient safety and staff productivity. Zebra’s Supplies research and development team tested the image durability of Z-Band direct thermal wristbands to insure optimum image durability and scanning performance.

The image durability of a 5 mil narrow-bar 16 digit Code 128 C bar code printed on a Z-Band wristband at Zebra’s recommended darkness and print speed settings was measured by scanning with a MS1690 Focus Area Imaging Bar Code Scanner after exposure to solvents, abrasion and water. For each test performed, a “Pass” or “Fail” designation was noted. Following are definitions of the designations:

- **Pass** = Immediate scan of bar code without repeated attempts
- **Fail** = Failure of bar code to scan or required repeated attempts to scan

Solvents

The following solvents were tested using an AATCC Crockmeter, using a crocking cloth and a Crockmeter heavy arm:

91% Isopropyl Alcohol

50X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.
All Zebra Wristbands: **Pass**



70% Ethyl Rubbing Alcohol

50X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Betadine

100X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Purell

50X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Abrasion

An abrasion test was conducted using an AATCC Crockmeter, using a crocking cloth and a Crockmeter heavy arm.

1000X rubs with a dry crocking cloth on a 5 mill narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Water Resistance

The water resistance was tested using a Cimarec Stirring Hot Plate.

The 5 mil narrow-bar 16 digit Code 128 C bar code was immersed in 105° F/40° C water, at stir setting 3.

All Zebra Wristbands: **Pass**. Up to 6 hours.

Tensile Strength

The tensile strength was tested using a MTS Sintech 20/G Materials Testing Workstation, at a speed of 1 inch/minute. This test simulates pulling the wristband off a wrist.

All Zebra Wristbands: Withstand up to 45 pounds of force.

Peel Adhesion

The peel adhesion was tested using an IMASS SP-2000 Slip/Peel Tester at a speed of 12 inches per minute and a peel angle of 180 degrees. This test simulates peeling the wristband apart at the adhesive tab.

All Zebra Wristbands: Withstand up to 55 ounces of force.



3. Skin Irritation Testing

Zebra's Z-Band wristbands were tested for the potential to produce a primary dermal irritation after a single exposure to the skin.

Z-Band wristbands were tested to FDA 21CFR, Part 58, referencing:

- ISO 10993-10, 2002, Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
- ISO 10993-12, 2002, Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

The test articles received a topical 4-hour application of the USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the Z-Band materials. After 72 hours, there were no signs of erythema or edema. Therefore, Z-Band wristbands are not likely to cause dermal irritation and are considered a negligible irritant, according to Toxikon Corporation.

C o n c l u s i o n

Zebra is committed to providing hospitals with wristbands that meet our high standards for image durability, scannability and comfort. Zebra's Z-Band direct thermal wristbands:

- Feature an antimicrobial coating that prevents *S. aureus*, *P. aeruginosa*, and *E. coli*—the three leading causes of hospital infections in the United States—as well as MRSA Types II, III, and IV, from growing or surviving on them.
- Are scannable after repeated exposure to water and common solvents found in hospitals, as well as abrasion.
- Show no signs of erythema or edema when testing for primary skin irritation.

Ihr zuständiger Fachhändler in Deutschland:

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