

# Protecting Patient Safety with Laboratory Bar Code Labeling



A ZEBRA WHITE PAPER





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## Executive Summary

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Both hospital and independent laboratories are important checkpoints for detecting and preventing errors that threaten patient safety. Marking and tracking lab samples and specimens with bar codes is a highly effective method for preventing errors in the first place. Using bar coding for lab sample management prevents mistakes, improves patient safety and adds efficiency to laboratory operations. This white paper illustrates the benefits of automated sample labeling and tracking and provides guidance for implementing labeling systems that provide safe, accurate sample identification.

### Opportunity for Improvement

Patient identification errors occur on about 1 percent of laboratory samples,<sup>1</sup> and approximately one in 18 sample identification errors leads directly to an adverse event.<sup>2</sup> Each year, there are 160,900 adverse events in U.S. hospitals each year because of sample identification errors.<sup>3</sup> In addition, a recent study found that 5.8 percent of phlebotomy samples are mislabeled, resulting in misdiagnosis, unnecessary treatment and wasteful tests.<sup>4</sup> Errors can also occur in the laboratory during sample receipt, testing and result reporting processes. For example, one study found a 0.46 percent error rate in the transcription of patient data,<sup>5</sup> which translates to approximately one transcription error per every 217 tests. The most common sources of error in the pre-analytic phase of the testing process are inappropriate test requests, order entry errors, patient or specimen identification errors, and mistakes in evaluating specimen adequacy.<sup>6</sup>

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<sup>1</sup> Paul N. Valenstein, RL Sirota “Identification errors in pathology and laboratory medicine,” *Archives of Pathology and Laboratory Medicine*, Vol. 129, No. 10, pp. 1228-1233.


<sup>2</sup> Paul N. Valenstein, MD, Stephen S. Raab, MD, Molly K. Walsh, PhD “Identification Errors Involving Clinical Laboratories: A College of American Pathologists Q-Probes Study of Patient and Specimen Identification Errors at 120 Institutions,” *Archives of Pathology and Laboratory Medicine*: Vol. 130, No. 8, pp. 1106-1113.

<sup>3</sup> Ibid.

<sup>4</sup> Giuseppe Lippi, Gian Luca Salvagno, Martina Montagnana, Massimo Franchini, Gian Cesare Guidi, “Phlebotomy Issues and Quality Improvement in Results of Laboratory Testing,” *Clin. Lab.* 5+6/2006.

<sup>5</sup> Laura Sciacovelli, Paolo Carraro, Mario Plebani “Errors in Laboratory Medicine: Transcription Errors and Interpretative Comments in Report,” *Institute for Quality in Laboratory Medicine Conference*, April 28, 2005.

<sup>6</sup> Plebani M. Errors in clinical laboratories or errors in laboratory medicine? *Clin Chem Lab Med.* 2006; 44:750-759.



Sample identification and results reporting errors can lead to misdiagnosis and inappropriate treatment with deadly consequences. A 2006 *Wall Street Journal* article reported that while malpractice claims for pathology errors are relatively low, they are the second-most costly.<sup>7</sup> In addition to creating a serious risk to patient safety, sample misidentification has a significant financial impact, with redraws, retesting and additional treatment resulting from sample errors costing the healthcare industry an estimated \$200 to \$400 million per year.<sup>8</sup> As of October 1, 2008, the Centers for Medicare & Medicaid Services will no longer reimburse hospitals for the treatment of certain preventable errors, including blood transfusion errors.<sup>9</sup>

## Preventive Processes

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Accurate sample labeling is the best defense against misidentification errors and their consequences. Labeling samples at the time they are drawn is a proven method to reduce errors. The accuracy and error prevention benefits can be extended into laboratory operations by using bar codes to identify samples and by scanning them to record transfers and support test result entry. Automated data entry is highly accurate, which improves patient safety by eliminating errors. As a side benefit, bar code sample identification and data entry also saves time, enabling lab staff to spend more time on clinical rather than clerical activities.

For example, Hamilton Medical Center in Dalton, Ga., reported that turnaround times for lab test results were reduced between 3 percent and 59 percent per procedure after bedside specimen labeling and bar code sample tracking were implemented.<sup>10</sup> The hospital attributed the improvement to time saved in re-labeling and elimination of manual entry of test results.

Two case studies available on [www.zebra.com](http://www.zebra.com) also illustrate the safety and efficiency benefits of using bar codes to support laboratory operations. Northeast Medical Center, an acute-care hospital in North Carolina, began labeling specimens at the patient bedside using mobile thermal printers and label material developed for use on test tubes. Labels are bar coded for identification and color coded to provide an extra visual indicator of what tests should be performed. Producing sample labels on demand instead of applying preprinted labels has led to a significant reduction of mislabeling errors, and thermal printing has also proven to be more reliable and accurate than the previous method. Another Zebra customer, NHS Argyll & Clyde, a Scottish healthcare provider that is part of the U.K.'s National Health Service, increased its sample identification accuracy from 85 percent to 100 percent with an on-demand printing system. The bar codes on sample labels are used in lab operations, greatly reducing the need for manual data entry and saving hours per week.


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<sup>7</sup> Wall Street Journal "Hospitals Move to Cut Dangerous Lab Errors" June 20, 2006.

<sup>8</sup> Bologna L, Hardy G, Mutter M. Reducing specimen and medication error with handheld technology. Presented at 2001 Annual Conference and Exhibition. Healthcare Information and Management Society, Feb 4-8, 2001, Chicago, IL, cited by Margaret Herrin in "A Pledge of Safety: How one laboratory automated its specimen collection process to increase productivity, streamline workflow and improve patient care." ADVANCE for Administrators of the Laboratory, October 2006.

<sup>9</sup> Centers for Medicare & Medicaid Services, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Final Rule.

<sup>10</sup> Margaret Herrin, Kenneth Lowery, Larry Early and John Forrester, Hamilton Medical Center; Sandra Trakowski, Mary Wojcik, Care Fusion Inc. "Hamilton Medical Center Finds That Deployment of a Positive Patient Identification (PPID) Specimen Collection Solution Improves Both Patient Safety and Work Flow Processes."



The accuracy of bar code data entry has been widely estimated at one error per 3 million characters, which is much more accurate than typing or other forms of manual data entry. To ensure proper sample identification, it is important that the bar code be produced correctly and remain affixed to the collection container throughout the life of the sample. Labeling operations are thus essential to the success of bar code-based patient safety and laboratory automation initiatives.

## Lab Labeling Considerations

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Engineered specifically to produce the exact bars and spaces and durable images that bar coding requires, thermal bar code label printers are typically the printer of choice for laboratory labeling applications. Thermal printers are especially effective for laboratory labeling because they require minimal space, excel at generating small labels and are easy to load and use. Factors impacting the success of bar coded label printing in laboratories include:

- Location of label application
- Label material

## Labeling Location Options

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Ideally, sample labels will be produced and applied at the time the sample is drawn. This practice virtually eliminates the possibility of applying the wrong label to the wrong sample. The Valley Hospital in Ridgewood, N.J., analyzed specimen identification errors and found that carrying multiple labels into a patient room was the leading cause of specimen mislabeling. Labeling away from the bedside was the second leading cause.

Bedside sample labeling with bar codes is also an effective method to help comply with the Joint Commission's 2008 National Patient Safety Goal (NPSG) to establish processes to maintain sample identities throughout pre-analytical, analytical and post-analytical stages and to use at least two patient identifiers whenever collecting lab samples.


Hospitals that have adopted bedside labeling report dramatic reductions in erroneous and misidentified samples. For example, Columbus, Ohio-based OhioHealth collects approximately 19,000 draws per month and has experienced only two labeling errors since implementation of a bedside labeling system in mid-2007. Point-of-care labeling also eliminates the need to re-label in the lab, saving time for laboratory staff. For in-depth information about bedside specimen labeling, including additional case studies, documented results and statistics, plus discussion of relevant Joint Commission and HIPAA requirements, see Zebra's white paper "Benefiting from Bedside Specimen Labeling" (available at [www.zebra.com](http://www.zebra.com)).

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<sup>11</sup> Lawrence J. Bologna, MBA, MS, FACHE, Michael Mutter, MS, RPH "Life After Phlebotomy Deployment: Reducing Major Patient and Specimen Identification Errors," *Journal of Healthcare Information Management*. Winter 2002 - Volume 16, Issue 1.

<sup>12</sup> Cristina De Martini "Going Mobile at the Bedside for Improved Patient Safety," *Insight 2008 Annual Conference*, September 24-27, Grapevine, TX.





Point-of-care labeling is not a prerequisite for realizing the benefits of bar coding in the laboratory. There are no major technology, integration or cost hurdles to setting up bar code label printing systems in labs. Even in cases where bedside labeling is used, laboratory staff will want on-demand label printing capability so aliquot samples can be accurately labeled and tracked with bar codes. Files, forms and even test equipment can also be bar coded to support efficient, automated operations.

## The Importance of Supplies

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The label provides the critical link between the physical specimen and all of the information in software systems associated with it. The range of label sizes and materials available for thermal printers helps automated sample management systems run accurately and effectively, and also helps keep operating costs down. Since thermal printers can quickly and easily be loaded with a variety of media, they make it convenient to carefully match specific labels with items to be identified, (test tubes, slides, etc.) and the environments where they'll be used (e.g., frozen storage, warming, chemical agents). In addition, the cost-effectiveness and compact size of thermal printers (most are about the size of an office phone) means multiple printers can be installed throughout the lab, enhancing staff productivity and improving workflow.

Supplies and printers work together as a system. Thermal printers are compatible with a wide range of paper and synthetic label material that can stand up to the demands of laboratory testing and storage processes. This includes exposure to extreme temperatures and chemical immersions, as well as testing in autoclaves, centrifuges and other laboratory equipment. The durable coatings found on most labels help ensure that bar codes remain sharp and readable throughout the life of the sample.

For top quality and durability, label supplies should be matched for use not only for specific testing and storage needs, but also with the specific make and model of the printer used. Adhesives and protective coatings that work perfectly well for labeling one type of container or test may not be ideal for other applications. For example, pathology labs require the ability to store specimens for up to 20 years. And, in areas such as blood banking and cellular therapies, products are often cryopreserved and then stored for an extended period before eventual transplantation into a patient. In addition, blood labels must be compliant with the ISBT 128 standard. For more information about label selection, see Zebra's guide "The Do's and Don'ts of Selecting Hospital Bar Code Labels and Wristbands" and for information on blood banking labeling requirements, refer to "Introduction to Blood Banking: The Role of Bar Coding in Improving Transfusion Safety," both of which are available at [www.zebra.com](http://www.zebra.com).

Although the conditions to which individual samples are exposed can vary significantly, many labs try to consolidate on only one or a few types of label materials because of the time and hassle associated with loading media. This results in expensive materials designed to withstand exposure to temperature extremes, chemicals and solutions being used on samples that could be labeled with less expensive media.

Here are some examples of labels offered by Zebra Technologies that show the breadth and capabilities of thermal supplies for laboratory use.

<b>Application</b>	<b>Material</b>	<b>Description</b>
<b>Blood Bag Labeling</b>	8000T Primary Blood Bag	Thermal transfer polypropylene label with an all-temp acrylic adhesive. When coupled with suggested Zebra ribbon, provides exceptional chemical resistance, including isopropyl alcohol, blood and instant hand-sanitizers. Meets FDA 175.105 indirect food contact requirements.
<b>Blood Bag Labeling</b>	8000T Blood Bag	Thermal transfer polypropylene label with permanent acrylic adhesive. Meets FDA guidelines for uniform labeling of blood and blood components.
<b>Cryogenic Storage</b>	8000T CryoCool™	Thermal transfer polypropylene label with a cold-temp permanent acrylic adhesive that offers low temperature performance down to -320 degrees F.
<b>General Lab Applications (flat surfaces)</b>	Z-Select™ 4000D	Direct thermal paper label with a glove-compatible permanent acrylic adhesive. Meets FDA 175.105 indirect food contact requirements.
<b>General Lab Applications (flat surfaces)</b>	Z-Select 4000T	Thermal transfer paper label with a glove-compatible permanent acrylic adhesive. Meets FDA 175.105 indirect food contact requirements.
<b>General Lab Applications (flat surfaces)</b>	PolyPro™ 4000D	Direct thermal polypropylene label with an all-temp acrylic adhesive resistant to moisture, alcohol and most solvents. Can be applied to surfaces as cold as -40 degrees F. Meets FDA 175.105 indirect food contact requirements.
<b>General Lab Applications (flat surfaces)</b>	PolyPro 4000T	Thermal transfer Kimdura®, polypropylene material with a permanent acrylic adhesive. Meets FDA 175.105 indirect food contact requirements.
<b>Microscope Slide Labeling</b>	Z-Xtreme™ 5000T	Thermal transfer matte polyester label with a permanent acrylic adhesive. Resistant to staining. When coupled with Zebra's Image Lock™ ribbon, provides exceptionally strong chemical and abrasion resistance, including xylene and acetone.
<b>Vials, Test Tubes, Syringes (curved surfaces)</b>	PolyPro 3000T High-Tack	Thermal transfer polypropylene label with a high-tack permanent acrylic adhesive resistant to moisture, alcohol and most weak to moderate solvents.
<b>Vials, Test Tubes, Syringes (curved surfaces)</b>	8000D Lab	Direct thermal paper label with a glove-compatible permanent acrylic adhesive specifically designed to adhere to small curved surfaces. Meets FDA 175.105 indirect food contact requirements.
<b>Vials, Test Tubes, Syringes (curved surfaces)</b>	8000T Lab	Thermal transfer paper label with a glove-compatible permanent acrylic adhesive specifically designed to adhere to small curved surfaces. Meets FDA 175.105 indirect food contact requirements.

Besides the many specialty materials options, labels for thermal printers are also available in many shapes and sizes for convenient specimen labeling, including very small labels for slides and test tubes. Zebra can also create custom labels that take into consideration the specific chemical immersions, temperatures and tests a sample will be exposed to as well as the type of container the label will be applied to.



## Conclusion

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The laboratory is an important line of defense against patient safety errors because of the role it can play in preventing adverse events related to sample misidentification. By establishing processes to accurately label and identify samples, laboratory staff can significantly reduce the incidence of misidentified, lost or unusable samples, and the related negative consequences, including redraws, misdiagnosis and inappropriate treatment.

Bar code labeling and sample tracking is proven to reduce sample identification and data entry errors. Specimen labeling systems can be implemented in the lab regardless of whether or not bedside specimen labeling is used, and most LIS/LIMS systems support bar code data entry, so bar coding is a convenient complement to legacy processes and technologies. Reliability is essential to successful sample labeling and improved patient safety. Bar codes must be crisp, readable and durable, and label material must be engineered to withstand challenging test and storage conditions. Finding the right printer and supply combinations usually requires expert assistance.

Zebra Technologies is a longstanding leader in providing solutions that protect patient safety and privacy. Zebra and its partners have provided bar code and radio frequency identification (RFID) solutions at the heart of many patient safety initiatives, including laboratory labeling, bedside bar code medication administration, positive patient identification to prevent surgical errors, point-of-care sample identification, automated drug dispensing, blood bag identification and counterfeit drug prevention.

Zebra Technologies Corporation improves customers' business performance through products and solutions that identify, track and manage assets, transactions and people. In more than 100 countries around the world, more than 90 percent of Fortune 500 companies use innovative and reliable Zebra printers, supplies, RFID products and software to increase productivity, improve quality, lower costs, and deliver better customer service. Information about Zebra and Zebra-brand products can be found at [www.zebra.com](http://www.zebra.com).

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