Introduction

In this century of biology and scientific advances has come an increase in the amount of lab samples being created and stored. Each day laboratories face the challenges of labeling thousands upon thousands of samples correctly—for identification, tracking and reporting reasons— necessitating the need for minimizing mislabeling and scrutinizing workflow processes.

In the study associated with this original white paper, it was found that of the 350 scientists surveyed, nearly 60% reported that from time to time, samples were lost due to label failure with almost half of the respondents reporting losses impacting greater than 2% of their samples.

Revolutionary changes in our ability to diagnose, treat and cure disease will continue and with that the increased possibility of label failure. How can the world stay ahead of the trends and how will scientists and clinicians smoothly make the necessary transition to more sophisticated, standardized sample-labeling methods?

The Real Cost of Sample Loss

Loss can have far-reaching consequences ranging from minor to devastating and affect many types of lab environments including clinical, industrial, academic, drug development and patient care to name just a few. For instance, should a pathological sample be a loss in a clinical lab, the impact would be severe due to the inability to replace the sample.

In 2005, one calculation pinpointed the cost of one lost patient sample in a clinical setting at $7,123 not including extended costs related to such things as patient anxiety, diagnosis delays, lawsuits and fatalities. Even though inroads have been made to improve identification and labeling, mislabeling continues mostly due to manual methods; as of 2010 more than 13,000 diagnostic labs (around 85%) still relied on manual methods like Excel spreadsheets and Sharpies to identify and log samples.

The problem is worldwide and touches multiple overlapping arenas. For instance, as research into cancer and genomics accelerates, the potential for error, e.g., sample storage and indexing, sample-tracking and data storage increases.

In 2011, estimates showed that nearly 600M biospecimens were stored in the U.S. with growth expected at an annual growth rate of about 7% or 20M specimens. Other costs attributed to mistakes, such as in the pharmaceutical arena, can result in repeat studies for quality control, data integrity, or drug safety; possible intellectual property losses; and approval delays.

Errors have prompted some institutions and companies to create information systems, such as one adopted by Medizinisches Proteom Center at Ruhr-Universiteat Bochum, Germany who started the Laboratory Information Management System (LIMS) as a way to organize and store the vast amounts of their associated data and sample production.

Most large companies have rigorous structures like LIMS, however, its estimated that 27% of clinical labs and 74% of academic labs are still manual. Aside from the scientific and medical value that samples represent, the costs to maintain high volumes is also a huge factor and pushes expenses up into the millions.

An Increased Scrutiny of Sample Handling

As might be expected, regulators, funders and accrediting agencies have worked arduously to mitigate sample losses within their realms of responsibility. In 2004, The College of American Pathologists (CAP) cited 1.3% of clinical labs for quality management issues prompting CAP and others to find solutions. As a result, clinical labs were to have adopted AUTO 12-A by April 29, 2014, a standard barcode specimen labeling method developed by the Clinical and Laboratory Standards Institute (CLIA) resulting in noticeable and significant improvement in specimen tracking.

Regulatory bodies like The Joint Commission, College of American Pathologists, Clinical and Laboratory Standards Institute, (CLIA) and Centers for Disease Control (CDC) have sample-handling policies and regulations specific to their areas of expertise. For instance, the Centers for Disease Control (CDC) oversees laboratory medicine best practices including use of barcode systems, point-of-care-testing barcode systems and dedicated phlebotomy teams. (See the original white paper for detailed responsibilities of all associated regulatory bodies)

The importance of mechanized sample reading and patient privacy will most likely be the drivers for additional implementations of barcode identifications systems in the future, as well as, the increase in widespread sample sharing and sample-handling practices. Expectations are that clinical labs with automated LIMS systems will be fully implemented in the next five years.

Isolating the Weak Spots in the Sample Handling Workflow

While scientific communities work on agreeing on new best practices for labeling, workflow process weaknesses have also come under scrutiny. Most occur in the pre-analysis phase when samples are identified and labeled and include errors such as specimen/requisition mismatch, unlabeled specimens and mislabeled specimens. Post-analysis problems, such as label adhesion capabilities, also occur. Nearly a quarter of the respondents surveyed reported having a label fall off of a sample container during post-analysis processing.

In a research performed by the University of California at Los Angles (ULA) Medical Center, upon reviewing more than 120 institutions and more than 16,000 potential specimen errors, more than 50% of the errors were due to mislabeled specimens with patient identification and specimen handling occurring mostly in patient settings and outside the walls of the laboratory.

Central Maine Medical Center curbs sample misidentification by enforcing proper labeling, i.e., labels must be created in the presence of the patient and include their full legal name, two unique identifiers such as date of birth and a medical record number, and the sample source or site. Samples are rejected if they have no label, have exceeded their preservation time, been collected in an inappropriate manner or container, or the sample container is broken or leaking.

In Pursuit of a Better Workflow

Labs have common points of label failure and most errors could be eliminated by adding two key improvements: 1) Reduce labeling errors by establishing a standardized barcoding system upon sample receipt; and 2) Reduce label failure by using durable labels designed for temperature extremes.

A variety of situations can prompt institutions to make improvements to their processes, e.g., following Hurricane Katrina the Louisiana Cancer Research Consortium (LCRC) implemented many changes including adopting an integrated system with customized data entry, automated label design and

printing, electronic tracking, as well as, instituting the use of durable synthetic labels and a standardizable form.

Conclusion

Analysis by labs of their processes and weak points can lead to possible improvements like adopting standardized labeling methods, barcoding, and applying labels designed to withstand extremes in the lab environment. With minor changes, many labs can dramatically reduce the risk of failure in their sample workflow, protecting not just their samples, but also the potential value that each sample represents for future studies and discovery.

Recommendations

- Use machine-printed labels. Removing the variable of handwriting can eliminate one of the biggest known risks in sample identification.

- Use labels tested for the environment. With many samples going into extreme environments during processing and storage, it is key to use a label material shown to withstand these environments.

- Test all labels before use. Even with performance data from the label manufacturer, good practice calls for testing new materials through the entire sample-handling workflow.

- Move to automated tracking. Best practice calls for applying a sample identification code before the sample is processed, which can be easily achieved with a simple automated system.