StainerShield

Effective On-Demand Pre-Stainer Slide Labeling
And Identification For Laboratory Medicines

Product White Paper

Strategic Partnership

TimeMed®

GeneralData

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All label and label material constructions are sold with the understanding that the purchaser has independently determined the suitability of each product for the application for which it is purchased. The seller disclaims any implied warranty of fitness of a product for a particular purpose. All materials should be tested thoroughly by the purchaser under end-use conditions to ensure they meet the requirements of a specific application.

Executive Summary

Medical errors affect every facet of healthcare, and improving the accuracy and efficiency of the healthcare system is a priority for healthcare providers. In laboratory medicine, errors most often occur in the pre-analytical phase, and can be attributable to factors such as misidentified specimens and incomplete patient data.

In an effort to reduce errors, improve accuracy and productivity, and enhance patient safety, many labs are adopting barcode-based identification and tracking systems and technologies into their processes. However, labs have thus far experienced significant problems with barcode identification of tissue and specimen slides.

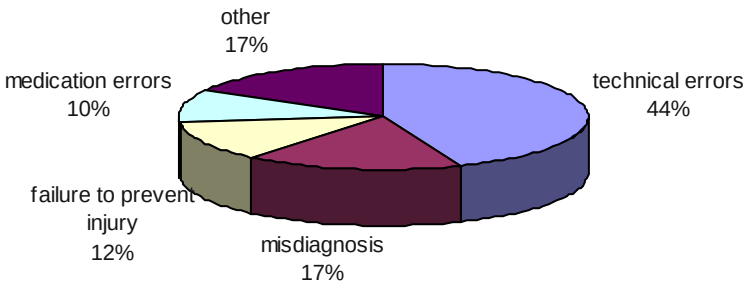
StainerShield™, a new labeling solution from General Data, enables laboratories to successfully utilize barcode identification for their tissue and specimen slides. This white paper will:

- Provide an overview of the ways medical errors affect healthcare generally and laboratory medicine specifically;
- Detail the problems laboratories face with the issues of tissue and specimen slide labeling;
- Explain how StainerShield can help laboratories reduce errors, improve productivity, and enhance patient safety;
- Explore StainerShield product features and benefits, and compare them to other laboratory pre-stainer slide identification solutions currently on the market;
- Provide test data and results of StainerShield labels exposed to various chemicals, stains, and other environmental agents.

Introduction

Improving the quality and efficiency of the healthcare delivery system is a priority both in the United States and abroad. Recent reports have uncovered that between 44,000 to 98,000 people die in hospitals each year from preventable medical errors. This mortality rate exceeds attributable deaths to motor-vehicle accidents, breast cancer, and AIDS[1]. All phases of healthcare, from diagnosis to testing to treatment, experience different types of errors.

Fig 1: Study Of Medical Error Types That Occur In Healthcare Settings



Source: Institute of Medicine (IOM), "To Err Is Human: Building A Safer Health System", 2000, online

Laboratory medicine includes such specialties as clinical chemistry, hematology, microbiology, genetics, anatomic pathology, and transfusion medicine. Each year, over 7 billion laboratory tests are performed in the U.S., influencing an estimated 70% of medical decisions.[2] Errors in laboratory testing most often occur in the pre-analytical phase[3], and are usually attributable to factors such as misidentification of specimens, illegible handwriting, and incomplete or inaccurate patient data. Professional organizations such as the American Society of Cytopathology have studied the issue of reducing medical error in the laboratory and have proposed a range of corrective actions, including the recommendation of the use of barcode identification from the time of patient registration through the laboratory process[4].

The attempt to use barcodes to identify tissue and specimen samples in the laboratory has been difficult and has met with mixed results. Tissue and specimen slides are subjected to various chemicals, stains, solvents, reagents and heat as part of the laboratory's analytical processes. Traditional pressure-sensitive labels, including those that are formulated to be chemical resistant, have not been able to withstand a laboratory's slide staining and preparation processes. The harsh chemicals, solvents, and stains of an

[1] *Institute of Medicine (IOM), "To Err Is Human: Building a Safer Health System", 2000, online.*

[2] *Marc D. Silverstein, MD "An Approach to Medical Errors and Patient Safety in Laboratory Services", 2003, online*

[3] *Pierangelo Bonini, Mario Plebani, Ferruccio Ceriotti, Francesca Rubboli "Errors in Laboratory Medicine" 2002, Clinical Chemistry 48:5 691-698*

[4] *"The American Society of Cytopathology's Role in Reducing Medical Error and Improving Patient Safety", American Society of Cytopathology Position Statement, 2002, online*

automated stainer or hand staining protocol will render the printed information on the label illegible, or remove the label from the slide entirely. As a result, many labs are forced to wait until after the staining process to apply identification labels to specimen slides. This inability to identify specimen slides at the beginning of the lab's process often results in errors attributed to either misidentified samples or greatly reduced laboratory efficiency and productivity.

StainerShield™ is a patent-pending pressure-sensitive label that is designed specifically for pre-stainer labeling of tissue and specimen slides. It has been uniquely formulated to withstand the harsh chemicals, solvents, reagents and stains of a laboratory's slide staining and preparation process. StainerShield labels can be placed on specimen slides before they go through the staining process, and will survive repeated exposure to the chemicals and stains of laboratory staining protocols.

StainerShield labels can be imaged on-demand, using a standard desktop thermal barcode label printer. This enables the lab to print patient and sample-specific data and barcodes on the label using data from their information systems, in a format that works best for their lab.

Barcode labeling of tissue and specimen slides pre-stainer, at the beginning of the laboratory's process, enables labs to fully utilize the advantages of barcode identification and tracking technologies. Using StainerShield labels, labs can identify their slides on-demand with patient and specimen data at the time the specimen slide is produced – greatly reducing the risk of error by misidentification or missing/incomplete specimen or patient data.

StainerShield Product Features and Benefits

StainerShield labels feature a unique combination of qualities that make them a superior solution for pre-stainer slide labeling in the laboratory. These features include: direct thermal printable; on-demand printing capability; solvent and stain resistance; and image longevity.

Direct Thermal Printable

Barcode label printing is typically performed using a thermal printer. This printing technology utilizes a printhead that uses heat to image the surface of a label. There are two types of thermal printing methods: *thermal transfer*, in which heat from the printhead activates ink on a printer ribbon carrier and transfers the image to the surface of the label, and *direct thermal*, in which heat from the printhead activates a special chemical layer formulated in the label. No ink from a ribbon carrier is required.

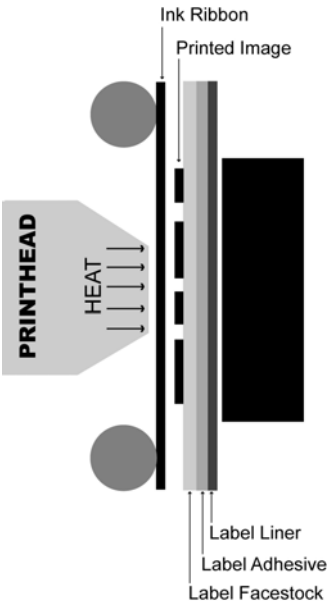


Fig 2: Thermal Transfer Printing

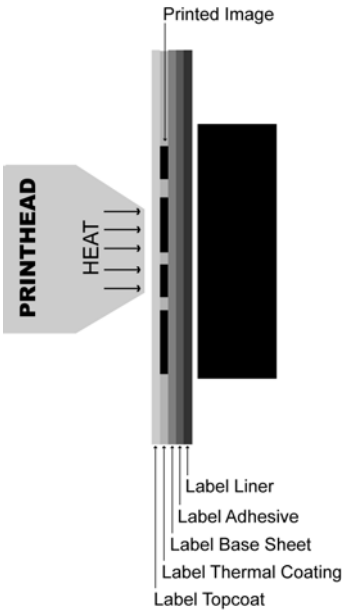


Fig 3: Direct Thermal Printing

StainerShield labels are formulated for direct thermal printing. The advantages of this method of imaging over thermal transfer imaging are numerous, and include:

- *No ink ribbon required.* The printing process is much simpler, and does not require an expensive printing, laminating, or etching system. In addition, since no printer ribbon is required, the laboratory does not have to worry about the handling and disposal of used printer ink ribbons and the patient data recorded on them by the printing process;

- *Printed image protected behind chemical and solvent-resistant topcoat.* Thermal transfer printing places the printed image on the surface of the label, where it can be subjected to smudging, abrasion, or degradation by chemicals and solvents. StainerShield's direct thermal technology protects the printed image behind a special topcoat that is highly resistant to the chemicals, solvents and stains typically used in a laboratory slide preparation process;

- *Superior image resolution.* StainerShield labels produce extremely clear, crisp images, even at high resolutions and small font sizes.

On-Demand Printing Capability

Using StainerShield labels with a direct thermal barcode label printer enables laboratories to have patient and specimen-specific data and barcodes clearly identified on the slide. Unlike pre-printed labels that show a simple control number, StainerShield labels can be variably imaged using data from the hospital or laboratory information system. They can be printed as they are needed, right at the cutting station as individual slides are being

prepared for staining. This greatly reduces the chance for errors due to misidentification of samples.

Solvent and Stain Resistance

In order for a laboratory to utilize a slide identification label at the beginning of their process – ideally affixed to the slide at the tissue-cutting station – the label must be able to withstand the solvents, stains, and other chemicals that are part of the laboratory staining procedures. The label must survive either automated or hand-staining protocols without significant discoloration, image degradation or separation from the slide. This is referred to as "pre-stainer labeling."

StainerShield's unique construction gives it superior resistance to many of the chemicals and stains used in laboratory staining procedures. The glove-friendly adhesive is formulated for high initial tack and aggressive adhesion to a slide's surface. It resists softening and erosion by exposure to chemicals and solvents. StainerShield's topcoat provides a protective barrier for the printed image against the solvents, chemicals and stains of a laboratory slide staining process.

StainerShield's resistance to various chemicals, stains, solvents and heat has been tested and measured in General Data's research, development and testing lab. The testing methodologies and results can be found in the section entitled "Test Results."

Image Longevity

Another concern of laboratories with regard to tissue and specimen slides is the proper archiving and storage of specimen slides once testing and analysis is complete. A barcode-based archive system allows for simplified storage and retrieval of slides, and the ability to easily record and track the location of a slide using any number of identifiers, including patient ID, hospital, test date, and slide location (cabinet/drawer). Placing a barcoded identification label on the slide enables laboratories to fully utilize these barcode-based slide storage and archive systems.

StainerShield labels have been tested for storage and shelf life. Under proper storage and filing conditions – indoor, temperature below 77°F/25°C, relative humidity between 45% - 65%, and stored with compatible materials – barcodes, text and other data imaged on StainerShield labels can be expected to remain fully legible for at least 20 years.

These projections are estimates assuming proper storage conditions and not a guarantee of performance.

Pre-Stainer Slide Identification Product Comparison

IDENTIFICATION METHOD	COST	EASE OF USE	EASE OF PRINTING / IMAGING	CAN INCLUDE ON-DEMAND DATA FROM LAB IS	CAN INCLUDE LINEAR BAR CODES	CAN INCLUDE 2-D BAR CODES	CHEMICAL, SOLVENT, STAIN RESISTANCE	HEAT RESISTANCE	COMMENTS
LABEL – pre-printed and laminated	low	very easy	no printing required	no	yes – pre-printed control number only	no	excellent	excellent	no ability to print patient or lab data and barcodes on label; more opportunities for errors
LABEL – thermal transfer with "xylene-resistant" label and ribbon	mod-erate	easy	requires thermal transfer printer and special ribbon	yes	yes	yes	fair	excellent	printed image will smudge or smear when handled
LABEL - thermal transfer with adhesive-backed laminate "flap"	high	Requires additional step of securing flap to label	requires thermal transfer printer and ribbon	yes	yes	yes	fair	excellent	solvents will leach under flap; can not use in print/apply
Direct laser etching of Slides	very high	difficult	expensive to use and maintain	yes	yes	no	superior	superior	very slow; high start-up costs; requires use of expensive slides
LABEL – StainerShield direct thermal imaging	mod-erate	very easy	simple direct thermal printing	yes	yes	yes	excellent	good	not recommended when slide must be heated above 95°C

Test Results

Introduction

Samples of StainerShield labels have been tested for resistance to a number of common laboratory chemicals and stains. Testing was also performed to determine the thermal activation level when the label was exposed to various heat temperatures and durations.

The concern was to determine the effects that different chemicals, stains and heat would have on StainerShield labels in typical laboratory slide staining protocols. This would give users a clear understanding of StainerShield's capabilities and limitations, and provide an overview of what effects to expect in different circumstances.

All testing was performed by qualified technicians in General Data's research, development and testing facilities.

These test results are to be used as guidelines and are not intended to be guarantees of performance. All users should test the product thoroughly under their end-use conditions to ensure it meets the requirements of their specific application. Testing samples are available from General Data.

Testing Procedures

Chemical and Stain Testing
This set of tests were run on labels affixed to clear, non-frosted glass slides to determine the effects various chemicals and stains have on the label's performance and legibility. For each test, a set of 12 slides were prepared. A StainerShield label was imaged with text, barcodes, and a control number using a SATO M84Pro thermal printer. After imaging, the labels were applied by hand to each of the slides. The slides were then placed in a laboratory oven at 60°C for 30 minutes to simulate the procedure of setting tissue samples in paraffin.

For each test, the set of 12 slides were immersed in a bath of the chemical or stain. A slide was removed at 5-minute intervals for evaluation.

Each sample was evaluated for two main label characteristics: the effect on the label construction itself; and the effect on the label's printed information. For each characteristic, the effect was categorized as follows:

Label Construction

Value	Description
A	discoloration
B	infiltration into label at edges
C	infiltration into adhesive at edges

Printed Image

Value	Description
A	fade
B	smear/smudge
C	breakup

The effect was rated on a scale of 0 to 4, zero being no effect and 4 being complete failure:

Effects Rating For Label Construction And Printed Image

Value	Description
0	no effect
1	slight
2	moderate
3	severe
4	complete failure

Ratings measured in the slight to moderate range had no measurable effect on the label's overall performance, including adhesion and scannability.

Heat Resistance Testing

This set of tests were run on labels affixed to clear, non-frosted glass slides to determine the effect of various temperatures for specific time durations. For each temperature point, a set of 12 slides were prepared. A StainerShield label was imaged with text, barcodes, and a control number using a SATO M84Pro thermal printer. After imaging, the labels were applied by hand to each of the slides.

For each test, a set of 12 slides were placed in a laboratory oven at a controlled temperature setting. A slide was removed at 5-minute intervals for evaluation.

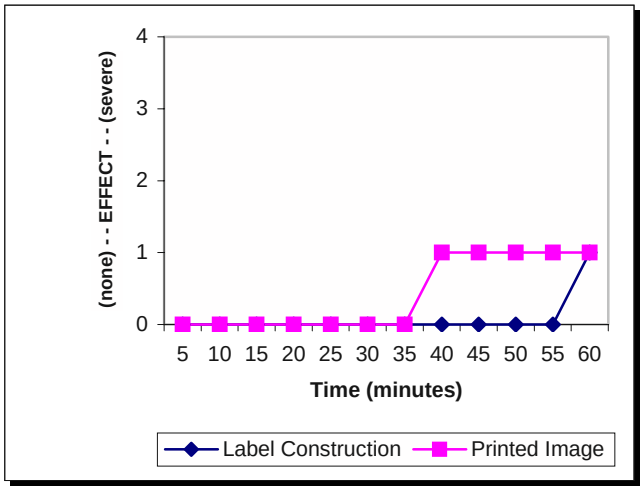
Each sample was evaluated for thermal activation caused by exposure to heat. Activation was measured as a percentage of black, from 0% (calibrated from whiteness of non-activated label) to 100% (black calibrated from fully activated label). A GRETAG D19C densitomer was used for this measurement.

Barcode scannability for each sample was also measured using a HHP QuickCheck™ PC600 barcode verifier. An ANSI grade less than "C" was considered failure.

Test: Xylene

Observations: Label showed slight adhesive infiltration at 20 minutes, but no significant progression for the duration of the test. The adhesive integrity was never compromised. The printed image was untouched for the first 55 minutes, then showed only slight breakup at 60 minutes.

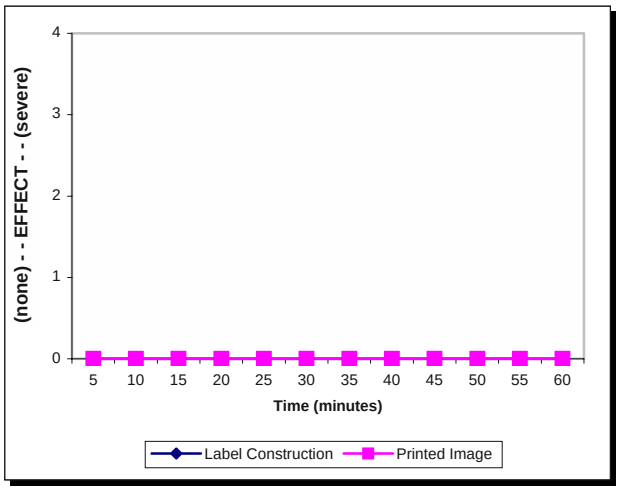
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	1	C	0	
25	1	C	0	
30	1	C	0	
35	1	C	0	
40	1	C	0	C
45	1	C	0	C
50	1	C	0	C
55	1	C	0	C
60	1	C	1	C



Test: 4% Acetic Acid

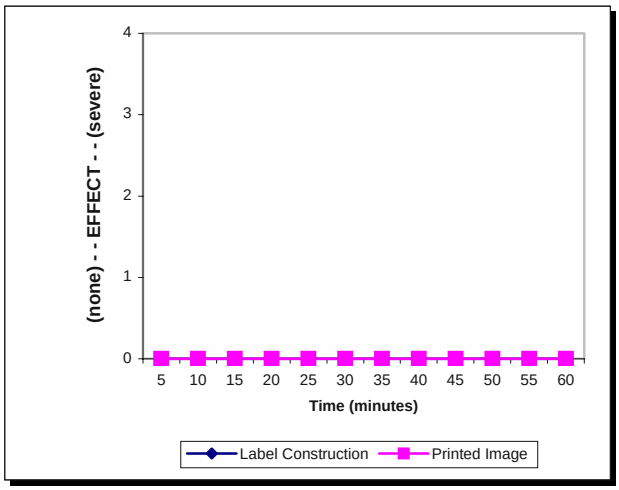
Observations: No effect observed for duration of test.

	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0		0	
25	0		0	
30	0		0	
35	0		0	
40	0		0	
45	0		0	
50	0		0	
55	0		0	
60	0		0	



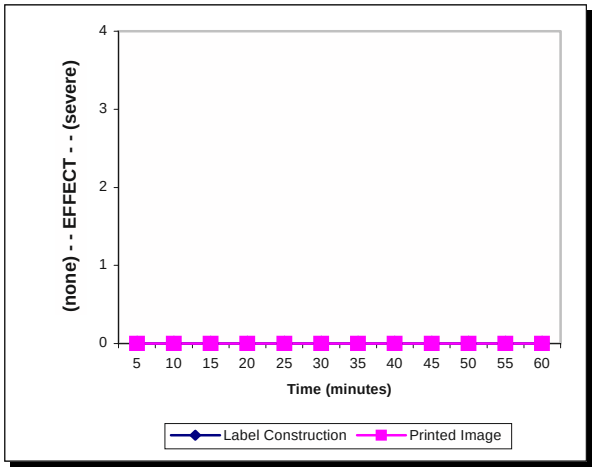
Test: Ammonia
Observations: No effect observed for duration of test.

	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0		0	
25	0		0	
30	0		0	
35	0		0	
40	0		0	
45	0		0	
50	0		0	
55	0		0	
60	0		0	



Test: 100% Isopropyl Alcohol
Observations: No effect observed for the duration of the test.

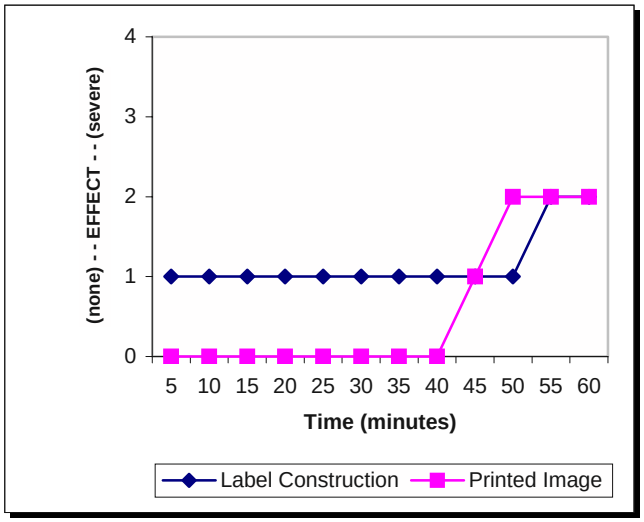
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0		0	
25	0		0	
30	0		0	
35	0		0	
40	0		0	
45	0		0	
50	0		0	
55	0		0	
60	0		0	



Test: Define

Observations: Slight infiltration into the label edges at 5 minutes; no significant progression observed afterward. Printed image untouched for 40minutes; slight break-up observed at 45 minutes, gradually increasing at 50 minutes and leveling off for the duration.

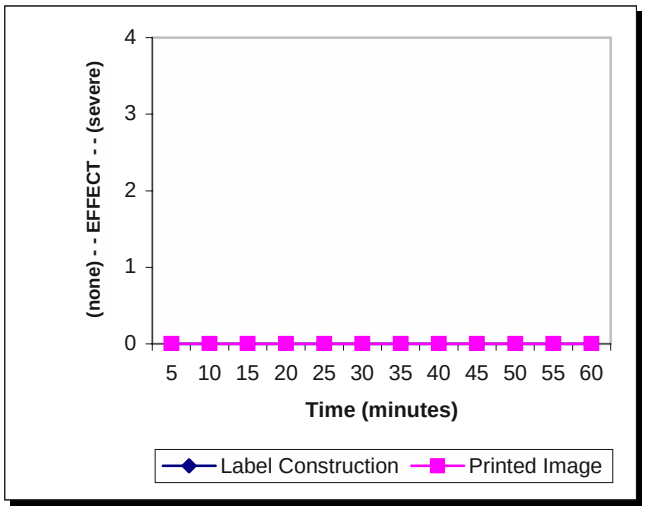
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	1	B	0	
10	1	B	0	
15	1	B	0	
20	1	B	0	
25	1	B	0	
30	1	B	0	C
35	1	B	0	C
40	1	B	0	C
45	1	B	1	C
50	1	B	2	C
55	2	B	2	C
60	2	B	2	C



Test: Scott's Tap Water

Observations: No effect observed for duration of test.

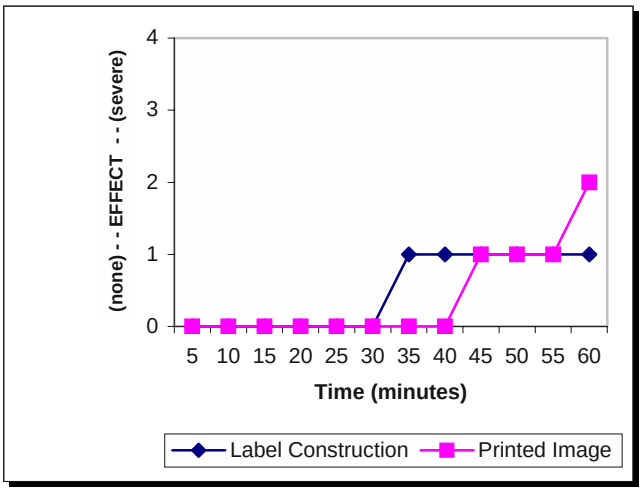
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0		0	
25	0		0	
30	0		0	
35	0		0	
40	0		0	
45	0		0	
50	0		0	
55	0		0	
60	0		0	



Test: Toluene

Observations: Label showed slight adhesive infiltration at 35 minutes, but no significant progression for the duration of the test. The adhesive integrity was never compromised. The printed image showed slight breakup at 45 minutes, stepping up to moderate at 60 minutes.

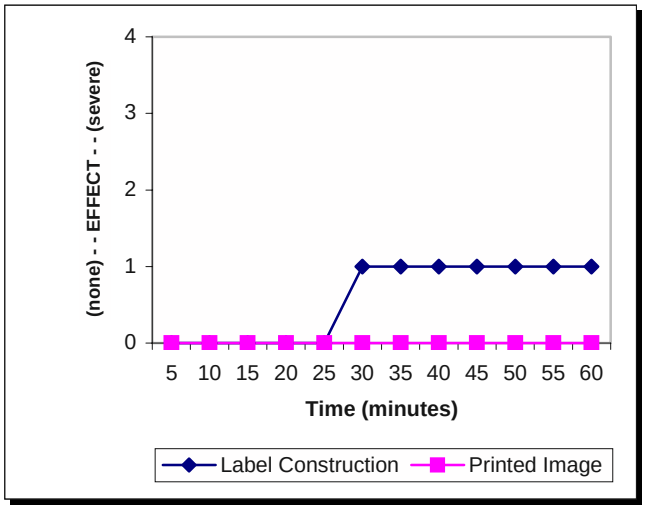
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0	C	0	
25	0	C	0	
30	0	C	0	
35	1	C	0	C
40	1	C	0	C
45	1	C	1	C
50	1	C	1	C
55	1	C	1	C
60	1	C	2	C



Test: Hexane

Observations: Slight adhesive infiltration at 30 minutes, with no significant progression for the duration of the test. The adhesive integrity was never compromised. There was no effect observed on the printed image for the duration of the test.

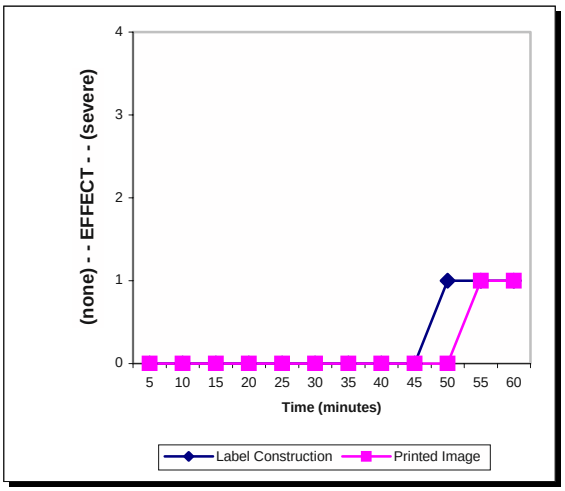
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0		0	
25	0		0	
30	1	C	0	
35	1	C	0	
40	1	C	0	
45	1	C	0	
50	1	C	0	
55	1	C	0	
60	1	C	0	



Test: 85% Ethanol

Observations: Slight chemical infiltration into label edges at 50 minutes; no progression observed for duration of test. No measurable effect on label performance. Printed image showed slight breakup at 55 minutes.

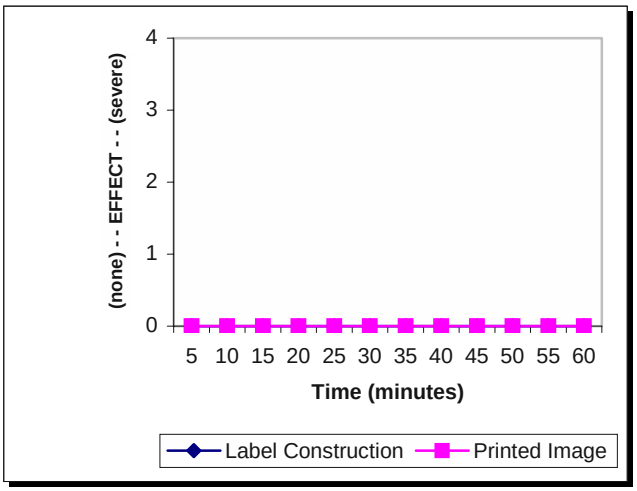
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0		0	
25	0		0	
30	0		0	
35	0		0	
40	0		0	
45	0		0	
50	1	B	0	
55	1	B	1	C
60	1	B	1	C



Test: Harris Hematoxylin (stain)

Observations: No effect to the label construction or printed image was observed for the duration of the test. Slight stain residue remained on top of the label, however this was easily wiped off and did not affect the label in any way.

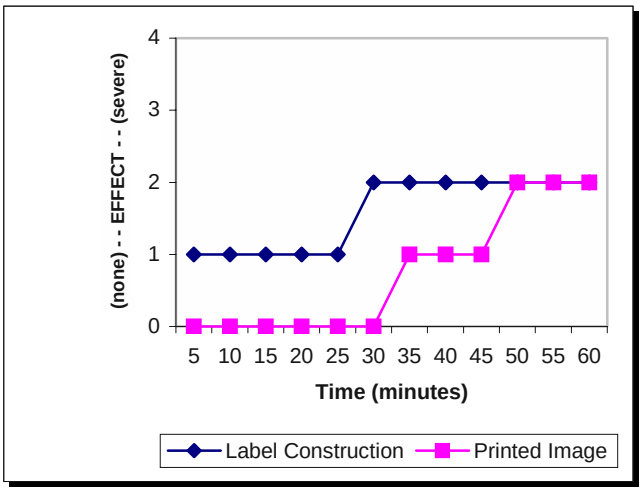
	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	0		0	
10	0		0	
15	0		0	
20	0		0	
25	0		0	
30	0		0	
35	0		0	
40	0		0	
45	0		0	
50	0		0	
55	0		0	
60	0		0	



Test: Eosin (stain)

Observations: Slight discoloration of the label surface was observed at 5 minutes, with progression to moderate tinting at 30 minutes. No further progression was observed for the duration of the test. Slight image breakup observed at 35 minutes, progressing to moderate at 50 minutes. Level of tinting did not affect readability of text or scannability of barcode. Washes or counterstains can reverse tinting effect.

	LABEL CONSTRUCTION		PRINTED IMAGE	
TIME (MIN)	EFFECT	DESC	EFFECT	DESC
5	1	A	0	
10	1	A	0	
15	1	A	0	
20	1	A	0	
25	1	A	0	
30	2	A	0	
35	2	A	1	C
40	2	A	1	C
45	2	A	1	C
50	2	A	2	C
55	2	A	2	C
60	2	A	2	C



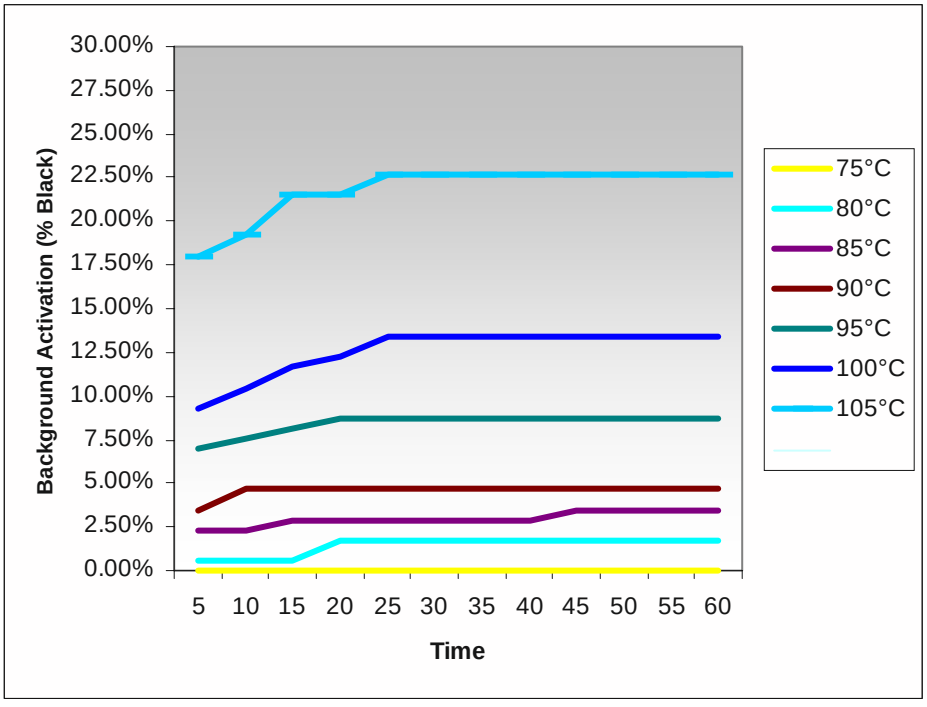
Test: Heat Resistance

Notes: Activation was measured as a percentage of black using a GRETAG D19C densitometer. Scannability was measured using a HHP QuickCheck™ PC600 barcode verifier. Any barcode scan graded at less than "C" was considered failure.

Observations: Label began to show very slight levels of activation at 80°C. For each temperature setting, activation seemed to plateau after a certain period of time. All temperature settings up to 105°C (for all time intervals) produced successful scans. Though 105°C at 60 minutes activated to a 22.67% density, the text was still readable and the barcode successfully scanned with a "C" rating. Anything above 105°C produced too much activation, and the barcode was not able to scan, and received an "F" rating.

Based on the results of these tests, we recommend StainerShield in environments up to and including 95°C.

TIME (MIN)	75°C	80°C	85°C	90°C	95°C	100°C	105°C
5	0.00%	0.58%	2.33%	3.49%	6.98%	9.30%	18.02%
10	0.00%	0.58%	2.33%	4.65%	7.56%	10.47%	19.19%
15	0.00%	0.58%	2.91%	4.65%	8.14%	11.63%	21.51%
20	0.00%	1.74%	2.91%	4.65%	8.72%	12.21%	21.51%
25	0.00%	1.74%	2.91%	4.65%	8.72%	13.37%	22.67%
30	0.00%	1.74%	2.91%	4.65%	8.72%	13.37%	22.67%
35	0.00%	1.74%	2.91%	4.65%	8.72%	13.37%	22.67%
40	0.00%	1.74%	2.91%	4.65%	8.72%	13.37%	22.67%
45	0.00%	1.74%	3.49%	4.65%	8.72%	13.37%	22.67%
50	0.00%	1.74%	3.49%	4.65%	8.72%	13.37%	22.67%
55	0.00%	1.74%	3.49%	4.65%	8.72%	13.37%	22.67%
60	0.00%	1.74%	3.49%	4.65%	8.72%	13.37%	22.67%



Summary And Conclusions

Improving accuracy, efficiency, productivity and patient safety is an ongoing concern for laboratory medicine. Labs can now use StainerShield labels as a foundation to base their barcode-based systems to identify and track tissue and specimen samples.

StainerShield labels are an innovative solution to the problem of pre-stainer labeling. They can withstand the harsh solvents, chemicals, stains and heat of laboratory staining and slide preparation protocols without degrading or separating from the slide.

General Data offers a wide range of identification media and demand printing solutions for healthcare, ranging from laboratory slide labels to patient-identification wristbands. Contact General Data today to learn more about how our products and expertise can help enhance your processes.

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