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The Development of a shop floor control software module for a new branding and packaging scheme

George Diaz

THE DEVELOPMENT OF A

SHOP FLOOR CONTROL SOFTWARE MODULE FOR

A NEW

BRANDING & PACKAGING SCHEME

BY

GEORGE DIAZ

MASTER'S DEGREE PROJECT

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CERTIFICATE OF APPROVAL

M.S. DEGREE PROJECT

The M.S. degree Project of George Diaz
has been examined and approved
by the Project committee as satisfactory
for the Project requirements for the
Master of Science Project

May 14th 2012

COPY RELEASE

THE DEVELOPMENT OF A SHOP FLOOR CONTROL SOFTWARE MODULE FOR THE IMPLEMENTATION OF A NEW BRANDING & PACKAGING SCHEME AT DIFFINITY GENOMICS

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To all of you…. Muchas Gracias!

DEDICATION

This Project is dedicated to my family: my wife, Mariella, and my two sons, Austin George and Alex George. Your patience and understanding through our journey was much appreciated. I love you.

THE DEVELOPMENT OF A SHOP FLOOR CONTROL SOFTWARE MODULE FOR THE IMPLEMENTATION OF A NEW BRANDING & PACKAGING SCHEME AT DIFFINITY GENOMICS

By

George Diaz

ABSTRACT

In the near future, Diffinity Genomics will launch several new products into the market-place. Key to Diffinity Genomics' success will be its ability to coordinate and manufacture multiple products quickly. The development and successful implementation of a Shop Floor Control database solution will ensure that Diffinity Genomics' product launch will be a company success story. This solution will involve the development of a relational database in the FileMaker Pro software platform. To achieve this goal, significant efforts will need to be invested in the development of an all-encompassing process flow diagram. This development will lead to the development of repository tables in which data will be collected and stored. The integration of these repository tables into the process flow diagram will lead the developer to the establishment of a data relationship map; hence a relational database has been proposed as a potential solution to the management of Diffinity Genomics' product development growth. Successful completion of the relational database solution will involve the development of agile scripting, a software development style in which the developer controls the user's fate through clever manipulation of the user's navigational and transactional options within the database dashboard.

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1 Introduction: Diffinity Genomics Story

Imagine you are the manager of an ice cream shop. Your shop only sells plain vanilla-flavored ice cream in a plain cone. Your shop has sold plain vanilla ice cream cones for the past year…

One day you are approached by the owner(s) of the company, and they share the following information:

> George, we have some news to share… Our R&D team has discovered a new spice, it's called "chocolate." We have completed field testing and feedback is very positive. In the near future, this shop will sell 3-4 unique ice cream flavors in several different formats: flavored cones and various dish sizes. With these new changes, our marketing team wants to roll out a new product "look," including several new packaging schemes! Oh yes, be prepared to sell this product through the store as well as through regional distributors; they too have unique packaging requirements. George, are you ready for this mission? How quickly can you complete all of it?

1.1 The Mission

Although Diffinity Genomics does not sell ice cream, the story shared resembles a recent moment in time within the company's history. The following section provides an overview of the project's goals and objectives and the proposed solutions.

1.2 Project Goal

Over the next six months, Diffinity Genomics will be launching several new products in several different configurations. This product expansion has provided the opportunity for Diffinity Genomics to launch several new product packaging configurations that embrace a new branding look.

The key to Diffinity Genomics' success will be its ability to coordinate and manufacture multiple products quickly. The development and successful implementation of a Shop Floor Control database solution will ensure that Diffinity Genomics' product launch would be a company success story. This solution will involve the development of a relational database in the FileMaker Pro software platform. To achieve this goal, significant efforts will need to be invested in the development of an all-encompassing process flow diagram. This development will lead to the development of repository tables in which data will be collected and stored. The integration of these repository tables into the process flow diagram will lead the developer to the establishment of a data relationship map; hence a relational database has been proposed as a potential solution to the management of Diffinity Genomics' product development growth.

Successful completion of the relational database solution will involve the development of agile scripting, a software development style in which the developer controls the user's fate through clever manipulation of the user's navigational and transactional options within the database dashboard.

This project is divided into three major areas of discussion:

1) The first portion of the project will provide an insight into Diffinity Genomics and its core technology. A product roadmap section will provide an insight to the company's product expansion
2) The second portion of the project will provide guidance into the fundamental theory of database technology with specific discussions on relational databases.
3) The third section will elaborate on the project's solution: a shop floor control software database.

2 The Company: "Diffinity Genomics"

The following company information has been referenced from Diffinity Genomics' company brochure:

"Diffinity Genomics is a closely held New York State 503C Corporation that has developed proprietary technologies for separating molecules in solution for a large span of applications. We are currently selling high-volume, high-margin, single-use products to the rapidly growing $1.2 billion non-regulated life science market for nucleic acid (e.g., DNA) extraction and purification products. Our products provide dramatic improvements in customer productivity, ease of use, labor requirements, capital costs, and environmental waste.

Our initial target is the market for nucleic acid extraction and purification tools, one of the largest and fastest growing segments of the life science industry (13.6% CAGR). Diffinity's Rapidtip® is targeting a severe bottleneck in the ubiquitous process for extracting and purifying nucleic acids for many downstream applications. The Rapidtip® reduces the time required to purify nucleic acids by more than 10 to 25 fold while reducing labor and capital costs. Its simple design integrates seamlessly into existing laboratory workflows.

Our high-margin Rapidtip® consumable is a single-use, completely self-contained "functional" pipette tip that enables very rapid sample purification in a single simple step with no additional reagents or capital equipment. There are approximately 670 million extraction and purifications performed each year by approximately 390,000 life science professionals working in 45,000 labs worldwide.

A box containing 96 Rapidtip® lists at $160. We are currently selling direct in the U.S., have already recruited 12 U.S. and international distributors and expect to add to this list, including the leading worldwide supplier to the biological, chemical and laboratory consumable markets. The Company's products do not require regulatory approval.

Diffinity Genomics is committed to building jobs in Western New York. The Company manufactures its consumables at its factory in Rochester, NY. Diffinity uses local vendors for services, components, and supplies. We currently have 12 employees, with 4 additional product sales and marketing positions to be filled over the next 12 months.

Having already spent a number of years incubating the technology, product designs and manufacturing processes, our goal is now to profitably achieve a valuation greater than $40 million within the next 3-4 years and realize a successful exit event for our genomic business, prior to commercializing non-genomic applications of the Company's molecular separation technologies. We are positioned for rapid growth through the introduction of products that offer a strong value proposition for other unmet nucleic acid extraction/purification needs and other molecular separation applications, all by leveraging previously developed technologies, product designs, manufacturing processes and marketing expertise. We now seek additional funding to introduce portfolio products, grow sales and earnings, and position the Company as a market leader as a precursor to a successful exit event.

Diffinity's technology and initial product were awarded a Top 10 Life Science Innovation Award for 2010 by *The Scientist* (finishing 4th and ahead of several billion-dollar companies). The company was also awarded the North American 2011 Entrepreneurial Company of the Year – Life Science Research Tools, by a leading business research firm and was selected by the White House Business Council as an example of a technology-based economic development success story.

Diffinity's management team includes multiple, successful serial entrepreneurs accomplished in R&D, operations, sales and marketing, business development, finance, mergers/acquisitions, and substantial knowledge of the genomics industry."[1]

2.1 Product Overview: DNA amplification and purification

In simple terms, a sample of DNA needs to be amplified (increased in quantity, typically increased concentration) in order to be analyzed. The process of DNA amplification involves the cyclic heating and cooling of the sample in a solution of primer and dimer solution. Once the DNA amplification is completed, the solution (containing the wanted DNA protein and the unwanted building blocks of primers and dimers) needs to be removed or "purified."

The following section illustrates the two-step process involved in the amplification and purification of a typical DNA sample.

2.1.1 Step 1: DNA Amplification: The science of DNA replication

The following section explains, in simple terms, the amplification and purification of a DNA solution. The images and information shared in section 2.1.1 have been carefully extracted from the following reference video:

http://www.youtube.com/watch?v=_YgXcJ4n-kQ&feature=g-hist

[1] **Helfer, Jeffrey, Diffinity Genomics Executive Summary, Diffinity Genomics reference material, 150 Lucius Gordon Drive, West Henrietta NY, 14586. (Referenced information included in attachment #1.)**

1) A double stranded DNA sample is prepared for analysis.

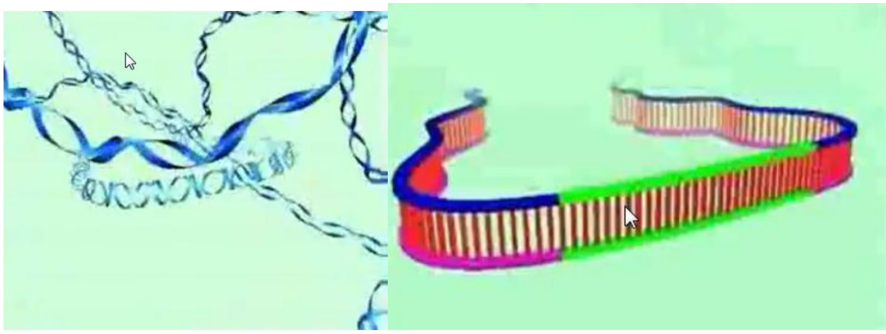


Figure 1: Examples of double stranded DNA images.

2) At room temperature, a specific portion of the DNA strand is identified to be amplified (duplicated). This portion of the DNA chain is known to be the target sequence.

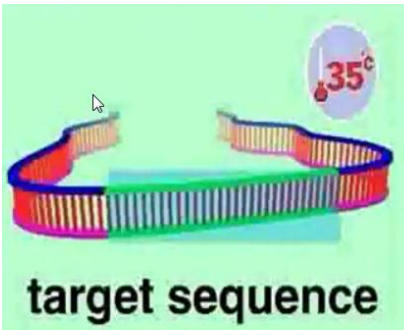


Figure 2: DNA target sequence.

3) When the DNA sample is heated to 95ºC, the double stranded DNA sample separates into two single stranded DNA samples.

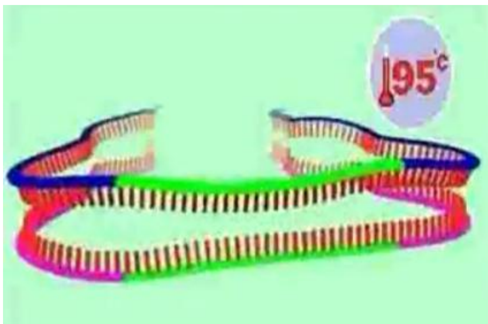


Figure 3: Separation of DNA sample when heated to 95ºC.

4) When the sample is cooled to 60ºC in a pool of specifically engineered primer and dimer solution, the single stranded DNA samples recombines with the “free” primers and dimers.

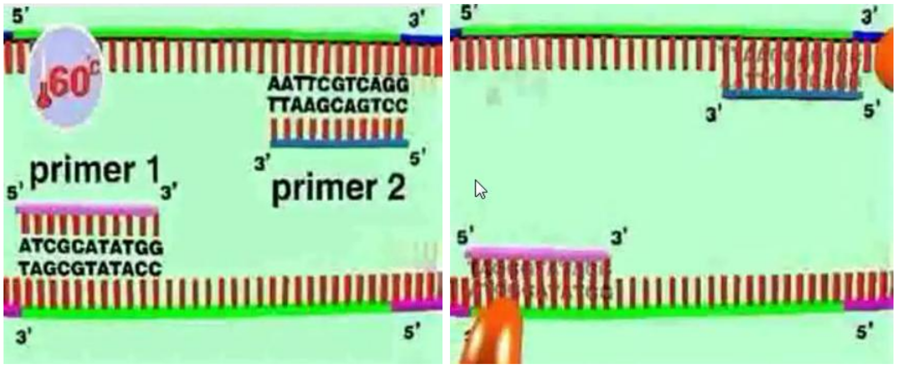


Figure 4: DNA Sample recombining at 60ºC.

5) The sample is then heated to a temperature (72ºC), a Taq polymerase reaction takes place, and the remaining single stranded DNA chain is reconstructed.

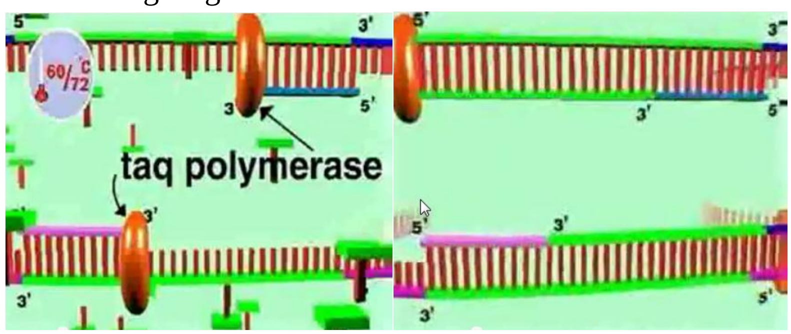


Figure 5: Taq polymerase reaction completed and DNA is reconstructed.

6) Once the Taq polymerase is completed, the process yields two exact replicates of the starting DNA sample.

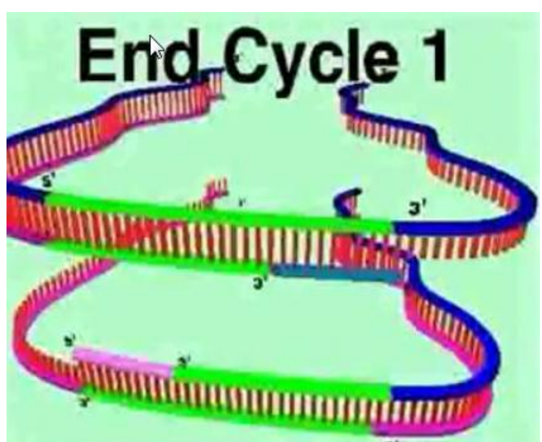


Figure 6: Duplication of DNA strand.

7) When the stated thermo cycle is repeated, the DNA sample is perfectly duplicated. If a total 30 heat cycles are completed, a single stranded DNA sample yields approximately 1 billion perfectly duplicated double stranded DNA samples.

2.1.2 Step 2: DNA Purification: The science of cleaning up a "dirty" DNA solution

Once the DNA solution has been replicated to a specific concentration, the unwanted "free" primers and dimer in solution need to be removed.

2.1.2.1 Conventional technology:

The most prevalent solution to this challenge involves the "bind, wash elute" process. This process initially binds all DNA components (wanted and unwanted) to a specific surface. This technology selectively removes the unwanted DNA components by leveraging unique solubility properties of the DNA protein. Once the unwanted DNA components are removed from the solution, one final step is completed whereby the double stranded DNA sample is eluted from the surface of the binding material. This process involves the use of multiple liquid handling pipette tips and sampling trays that are sold as kits and can take as long as 20-40 minutes.

2.1.2.2 Diffinity Genomics Rapidtip® technology:

This proprietary technology leverages the differential affinity of the DNA components (wanted and unwanted). By design, the Rapidtip® material attracts the unwanted primers in the DNA solution and repels the wanted double stranded DNA. This disruptive technology enables the purification of a "dirty" DNA solution quickly and effectively. This process involves the use of a Rapidtip® functional pipette tip and a pipetor unit. The user aspirates and dispenses the (dirty) DNA solution. During this process, the DNA solution comes in contact with the Rapidtip® proprietary particles enabling a dirty solution to be purified (cleaned) in 60 seconds.

The following section describes the Rapidtip® purification process:

1) A Rapidtip® functionalized tip is ready to be used.

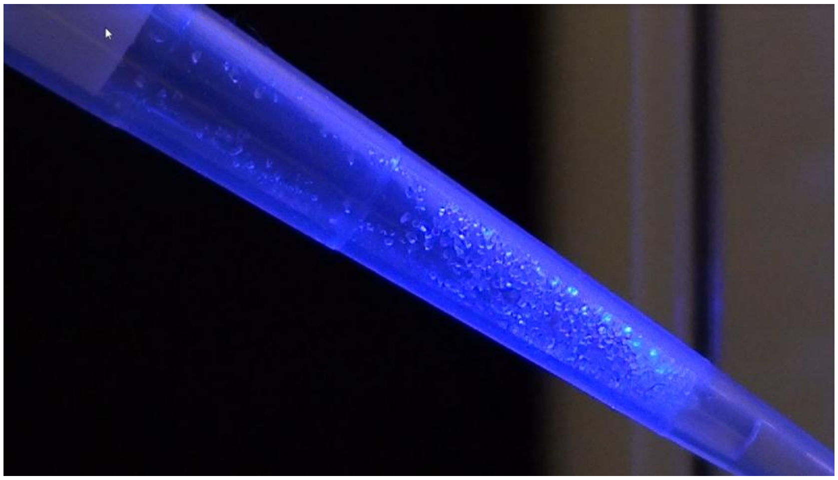
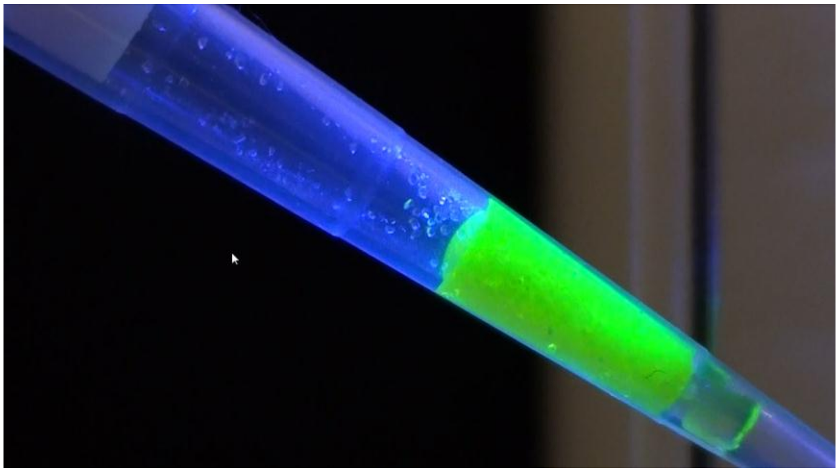


Figure 7: Rapidtip® functional pipette tip.

2) Aspiration of DNA "dirty" solution and mixing of solution with Rapidtip® particles.



3) Figure 8: Aspiration of DNA "dirty" solution.Dispensing DNA solution

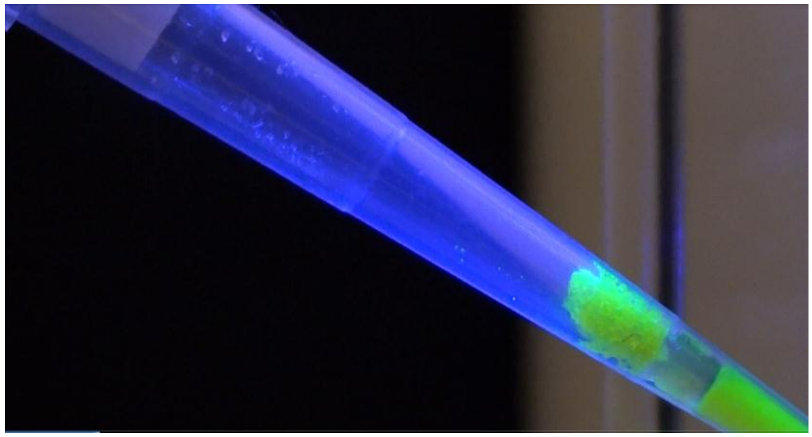


Figure 9: Dispensing of DNA solution.

4) Continued aspiration and dispensing of DNA solution for a total of 60 seconds.

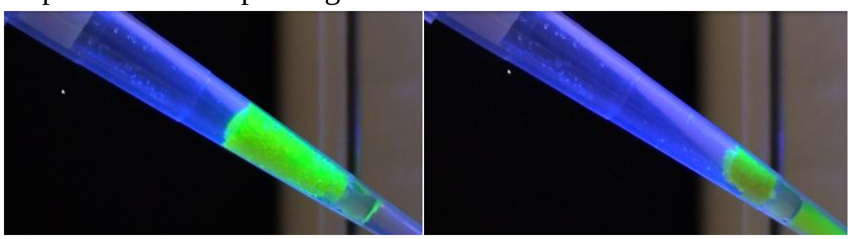


Figure 10: Aspiration and dispensing of DNA solution with Rapidtip®.

5) Final dispensing of solution. After 60 seconds of product mixing, the DNA solution is comprised of the “wanted” double strand DNA, and the unwanted DNA impurities are bonded to the Diffinity Rapidtip® proprietary particles.

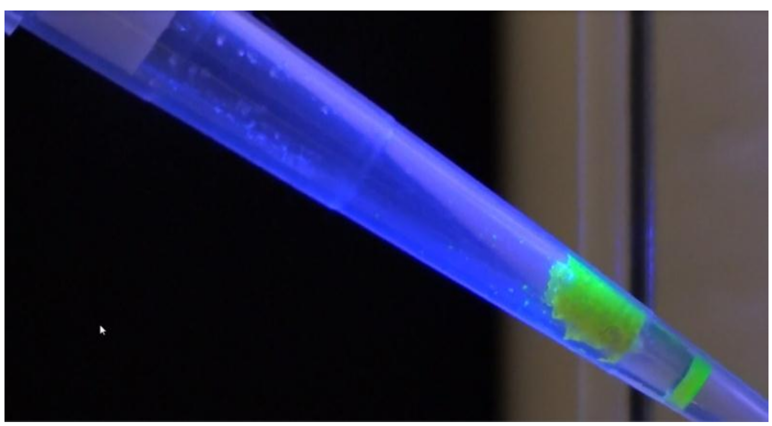


Figure 11: Final dispensing of (purified) DNA solution.

3 Diffinity Genomics' Product Roadmap

Diffinity Genomics, a start-up company located in Rochester NY, currently develops and manufactures functional pipette tips for use during DNA sample preparation. This process transforms a simple pipette tip (typically used for fluid transfer) into a functional device that performs and delivers unique value to the user. Using proprietary technology, Diffinity Genomics' functional pipette tips encapsulate proprietary active particles within the pipette tip internal space. As users aspirate solutions into the pipette tip, the solution comes in contact with these active particles, and during this mixing a chemical reaction takes places. After approximately 60 seconds of fluidic particle mixing, the Diffinity Genomics' functional pipette tip dispenses a purified DNA solution ready for sequencing analysis.

Diffinity Genomics' ability to manufacture unique proprietary particles enables the company to produce functional pipette tips for unique DNA applications. The use of the proprietary particles in distinct pipette designs enables Diffinity Genomics to manufacture specific products for use in unique pipette configurations.

3.1 New Product Development

Product application: Diffinity Genomics' core competency resides in the company's ability to formulate materials (particles) for unique product applications in the DNA world. For each product application, a unique material formulation is functionalized into a pipette tip under a unique product name. Diffinity Genomics has secured the rights to the "Rapidtip®" name; hence the proposed product development strategy will incorporate the Rapidtip® name for each unique application. Diffinity Genomics' new product development strategy will launch several new product applications under the Rapidtip®1, Rapidtip®2, Rapidtip®3, and so on, trademark name.

<u>Sample volume use</u>: Diffinity Genomics' proprietary material technology has the ability to be scaled for a particular sample volume use; hence each product application will be qualified for a specific sample volume use.

<u>Product use:</u> Each manufactured pipette tip is intended to interface to a particular pipetor tip configuration. As a result, the current pipette tip market is segmented by specific manufacturers that mutually exclude the use of their pipette tips on competitors' pipetors. Therefore, Diffinity Genomics' functional pipette technology is manufactured for a specific pipette tip design.

3.2 New Product Branding

The proposed product development roadmap provides the opportunity to redefine the way the Rapidtip® product will look in the future. This initiative will be driven by Diffinity Genomics' VP of Marketing; however, the implementation of all these initiatives will be part of the scope of this project.

3.3 Needed capabilities

The development and implementation of a shop floor control (software) tool will be particularly important to the successful implementation of Diffinity Genomics' product expansion. The primary goal of this tool will be its ability to guide users through Diffinity Genomic's new product map ensuring that the finished product conforms to the new packaging and marketing schemes. The proposed shop flow control tool will enable Diffinity Genomics' members to print final product information onto pre-printed master labels that incorporate new branding graphics.

4 Diffinity Genomics' Product Expansion: To Diffinity and Beyond!

With the development of new proprietary particles, Diffinity Genomics' future will embrace the launch of multiple product applications in various pipette tip designs. The following sections describe the company's product launch (past and future).

4.1 Diffinity Genomics' 2010 Initial Product Launch

Diffinity Genomics launched its first product in April 2010. This product intended to address the nucleic acid extraction / purification needs of a 25ul DNA specimen intended to be decoded in a Sanger Sequencing reader.

The table below summarizes the company's initial product configuration:

			(Direct Sales or Distribution Channels)		
[redacted]					
Product	Pipette tip	Sample volume	Sample pack	48 Tip Box	96 tip Box
Rapidtip®	Universal	25 ul	For sale	For sale	For sale

Table 1: Packaging configurations available in 2010

In summary, the Rapidtip® product was initially offered for a 25ul solution in three packaging configurations: 8 tip sample pack, 48 tip box, and 96 tip box. The following figures provide image samples of these product configurations:

1) Rapidtip® sample pack

Figure 12: Rapidtip® sample pack.

2) Rapidtip® 48 tip box

Figure 13: Rapidtip® 48 tip box.

3) Rapidtip® 96 tip box

Figure 14: Rapidtip® 96 tip box.

4.2 Diffinity Genomics 2012: New products, new look!

Diffinity Genomics intends to launch a variety of new products. Some of these products will be product extensions derived from the Rapidtip® product application, while other products will be derived from new product applications.

4.2.1 Current Product expansion plan

The original Rapidtip® product was configured to interface with a "universal" handheld pipetor unit. The universal pipetor is by far the manual unit most used across the world. Although universal pipetor users are a large portion of the market, there are pockets of markets that specifically use other pipetor handheld units. In the last four months, Rapidtip® pipette technology has been successfully transferred to a variety of other unique pipette tip designs.

4.2.2 Rapidtip® in a Rainin Pipette Format.

Diffinity Genomics has recently announced the introduction of the Rapidtip® application in a Rainin Tip format. This (current product) expansion has led to increased sales and the development of Rainin-compatible products in the following packaging configurations: sample pack, 48 tip box, and 96 tip box. However, the launch of this product configuration has triggered increased interest from other pipette manufacturers.

The table below provides an outline of the packaging configurations currently available. Also, the table provides insight into future product launches.

[redacted]					
			Packaging Configurations		
Product	Pipette tip	Sample Volume	Sample pack	48 tip box	96 tip box
Rapidtip®1	Universal	25 ul	For Sale	For Sale	For Sale
	Rainin LTS	25 ul	For Sale	For Sale	For Sale
	Tip #3	TBD ul	Planned	Planned	Planned
	Tip #4	TBD ul	Planned	Planned	Planned
	Tip #5	TBD ul	Planned	Planned	Planned

Table 2: Diffinity Genomics Rapidtip®1 product growth roadmap

4.2.3 New product development "To Diffinity and Beyond!"

Diffinity Genomics has recently developed a new material platform that is able to address the removal of the Polymerase agents in a PCR solution. This new product application, Rapidtip®2, expands the use of Diffinity's technology to a variety of new applications such as restriction digest and T-A cloning while still maintaining a presence in the Sanger Sequencing market. The Rapidtip®2 product is expected to be launched initially in the universal and Rainin LTS pipette tip designs for a 50ul solution sample. An additional tip design is currently in development that will address this application in a 10ul sample (tip #5). The table below illustrates the intended Rapidtip®2 product launch:

[redacted]					
			Packaging Configurations		
Product	Pipette tip	Sample Volume	Sample pack	48 tip box	96 tip box
Rapidtip®2	Universal	50 ul	Product will launch Q2-2012		
	Rainin LTS	50 ul			
	Tip #3	TBD	Product will launch Q3-2013		

Table 3: Diffinity Genomics' Rapidtip®2 product growth roadmap

4.3 The NEW Diffinity Genomics

The planned product launches expected for the 2012 calendar year offer an opportunity to implement a new branding look for the company. As a result, Diffinity Genomics' VP of Marketing and Sales has developed a new product labeling strategy including the adoption of a new color scheme for the Rapidtip®2 product application.

The current labeling process at Diffinity Genomics involves the use of sheet label stock and specific Word document templates. Unfortunately, this process will not meet the proposed branding strategy, since the new labeling requirements will use pre-printed labels materials.

4.3.1 New Product - New Look

Diffinity Genomics' product development roadmap will require the commercialization of several product expansions in the Rapidtip® platform as well as the launch of several new products in the Rapidtip®2 product platform. The table below better describes the product expansion at hand:

Packaging configurations			Sample pack	48 tip Box	96 tip Box	Sample pack	48 tip Box	96 tip Box
			Diffinity Product (Direct Sales or Distribution Channels)			Private Label		
Product	Pipette tip	Sample volume						
Rapidtip®	Universal	25ul						
	Rainin LTS	25ul						
	Tip 3	TBD						
	Tip 4	TBD						
	Tip 5	TBD						
	Etc.	TBD						
Rapidtip®2	Universal	50ul						
	Rainin LTS	50ul						
	Tip 3	TBD						
	Tip 4	TBD						
	Tip 5	TBD						
Rapidtip®3	Universal	TBD						
	Rainin LTS	TBD						
	Tip 3	TBD						
	Tip 4	TBD						
	Tip 5	TBD						
Current portfolio								
Growth plans								

Table 4: Diffinity Genomics' overall product growth roadmap

The product configurations depicted in green represent the current product configurations commercially available. The product configurations depicted in yellow represent the proposed product expansion. Besides the obvious growth in the application (Rapidtip®1, Rapidtip®2, Rapidtip®3, etc.) and the sample volume use (25ul, 50ul, etc.), the product expansion suggests the consideration for private labeling scenarios. The overall product expansion will increase the product sku from 3 to somewhere between 24-48 sku in the year 2012.

In addition, the product expansion will adopt a new product branding look. The images below provide a sample of the branding proposal:

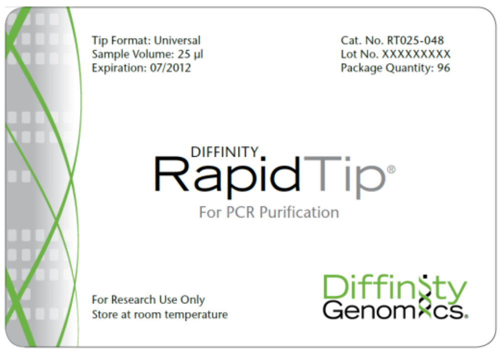


Figure 15: Rapidtip®1 Branding proposal.

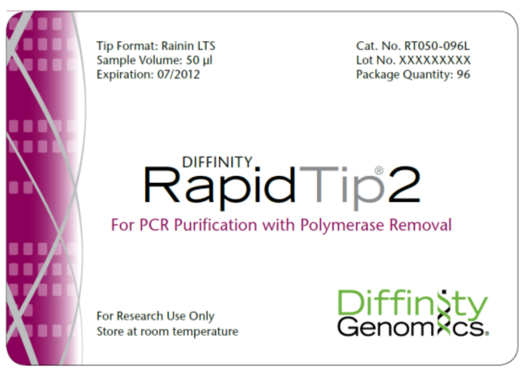


Figure 16: Rapidtip®2 Branding proposal.

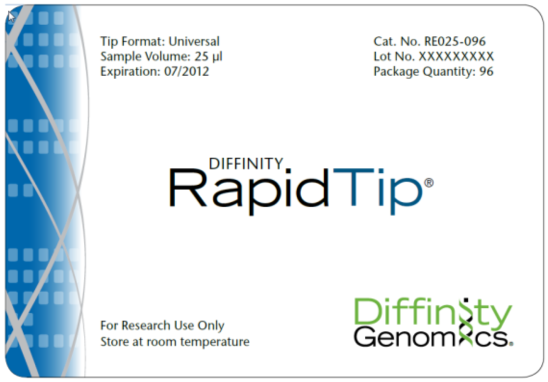


Figure 17: Rapidtip®3 Branding proposal.

4.3.2 Proposed Packaging Configurations (tip box)

Diffinity Genomics' packaging strategy was developed on a trial-by-use model. In essence, customers try a Rapidtip® product via an 8 tip sample pack (typically at a competitive price). Once customers obtain satisfactory results, they either order the product in 48 or 96 tip box quantities.

The product expansion will not change the current product configuration (tip quantity); however, for each of the product applications (Rapidtip®1, Rapidtip®2, etc.), a unique tip box had to be procured to embrace the proposed branding color scheme.

The scope of this project included coordination and development of the various tip boxes as follows:

		Application	
		Rapidtip®1	Rapidtip®2
Tip format	Universal	Currently available	New
	Rainin	New	New

Table 5: List of existing and new tip box requirements

The images below provide examples of the current Rapidtip®1 tip box and the final Rapidtip®2 tip box configurations. For each application, two box types are shown since the Universal and Rainin tips have unique part geometry it became impossible to identify a particular box for both tips.

Figure 18: Rapidtip®3 Branding proposal.

Figure 19: Rapidtip®3 Branding proposal

4.3.3 Proposed Packaging Configurations (Labeling)

Diffinity Genomics' initial product labeling involved the use of pre-cut feedstock readily available through Avery Dennison Corp. The printing process involved the use of Word templates in which the variable printing information (lot number, expiration date, etc.) was typed as needed. The printing process involved the use of sheet stock manually fed through a laser jet or ink jet printer.

The new branding strategy required the use of a label size that was not commercially available in sheet stock. As a result, a new label size (3" x 4") was identified for the proposed packaging scheme. This new label format would be manufactured in a roll form; however, Diffinity Genomics did not have the capability to print labels in a roll format.

4.3.4 In search of a new label printer

It became quite evident that the identification and procurement of a new printer with a label roll feeding capability would be key to the implementation of Diffinity Genomics' new branding plans. An initial search for such printer led to the identification of several elegant solutions. These solutions involved the purchase of a very capable printer with related custom-tailored software to meet the company's needs. These solutions, however, became quickly cost prohibitive and thus a much more cost effective solution needed to be identified.

Interestingly enough, the painful journey to identify a printer solution highlighted the need for a much more holistic approach to solving the label printing process. In simple terms, printing the label would become the easy portion of the project, and the biggest challenge would become the manipulation and integrity of the variable printing information on the label.

4.3.5 Oh my… so much data, so little time!

Diffinity Genomics' product expansion would require the careful management and tracking of critical product attributes through its manufacturing process. The final product-labeling exercise would become a critical outcome of the manufacturing process (and not the beginning as originally envisioned). Nowhere in my packaging engineering classroom teachings did we discuss (or learn) the use of software tools that could handle the management and traceability of critical product properties that would eventually be summarized in a simple label.

5 And Then There was Light…

The use of database software always interested the author of this project. On many occasions, useful applications were defined and written to handle multiple data applications. For example, during the holiday season I found it interesting that I could address 50-100 envelopes for our holiday Christmas cards utilizing password management. I wrote a password-protected routine to handle (and remember) passwords for the critical access of information and websites on the Internet.

So I asked myself if it would be possible to home grow a software to help me address Diffinity Genomics' product explosion, new branding requirements, and related finish-product labeling. The answer to this question resides in the body of this research project.

So the journey to a (cost effective) manufacturing shop floor control software began with the identification and initial testing of my favorite database tool: FileMaker Pro.

5.1 The Evolution of Database Systems

"Database management systems were first introduced during the 1960s and have continued to evolve during subsequent decades.

In early 1960, database structure was comprised of traditional flat files. Much of this effort was driven by the Apollo moon landing project. During this period initial standardization was initiated by a Data Base Task Group.

In the 1970s, database management became a commercial reality. Hierarchical and network database management systems were developed largely to cope with increasingly complex data structures such as manufacturing bills of materials. During this decade the relational model was first defined by E. F. Codd, an IBM research fellow, in a paper published in 1970.

In the 1980s, computing power allowed code writers to develop the Structured Query Language (SQL), a valuable tool which enabled the use of fast and efficient data retrieval.

In the 1990s, the appearance of first generation client / server computing and the Internet drove database structures to increasingly more important roles. To cope with increasingly complex data (including graphics, sound, images, and video), object-oriented database structure was developed and refined, and by the year 2000, artificial intelligence became a reality."[2]

5.2 A basic review of database theory

A database, in its simplest form, is an "organized collection of logically related data. It is important to note that raw data on its own cannot be considered a database; however organized data (i.e., information) is most commonly associated with a database because it leads a user to

[2] **McFadden, Fred, Hoffer, Jeffrey, Prescott, Mary (1999), Modern Database Management, Massachusetts, Addison-Wesley (pp. 27-29).**

increased knowledge."[3] Central to a database is the connection or, better stated, the relationship between the data.

In a database, a set of data is grouped in a TABLE. Thus a table is a repository of data in a form of records. The figure below describes the dataset in two unique tables, Table (Husband) and Table (Wife). For each table there are six unique records.

Record	Table (Husband)
1	Jeff
2	John
3	Jack
4	Rob
5	Michael
6	Charlie

Record	Table (Wife)
1	Sandy
2	Marry
3	Beth
4	Sarah
5	Ann
6	Julie

Table 6: Example of two sets of tables

5.3 The Relationship between the dataset

Records in one table can be related to records in a second table via a common connection: The Relationship. The relationship between data can be divided into two different groups, one-to-one relationship and one-to-many relationships.

5.4 The "One-to-One" Relationship

In its simplest form, records in one table can be related to records in a second table in a "one-to-one" relationship. Using the example below, a set of data in the "Husband" table is related to a set of data in the "Wife" table as follows:

[3] **McFadden, Fred, Hoffer, Jeffrey, Prescott, Mary, <u>Modern Database Management,</u> p 4.**

Record	Table (Husband)		Record	Table (Wife)
1	Jeff	is married to	1	Sandy
2	John		2	Marry
3	Jack		3	Beth
4	Rob		4	Sarah
5	Michael		5	Ann
6	Charlie		6	Julie

Table 7: Development of a relationship between two tables

The example above represents a scenario in which two sets of tables are related in a way that one record in the "Husband" table is related **<u>in one way</u>** to a record in the "Wife" table.

5.5 The "one-to-many" relationship

This particular relationship can be summarized using two tables; however, in this particular relationship, the primary table is related to multiple records in the secondary table. For example, take a dataset comprised of TABLE (Students) and a TABLE (Classes) as follows:

Record	Table (Students)
1	Beth
2	John
3	Sarah
4	Ann
5	Michael
6	Charlie

Record	Table (Class)
1	Math
2	English
3	Music
4	Science
5	Art
6	Chemistry

Table 8: Lists of Table (Students) and Table (Class)

In this example, each student will be attending a set of classes each day as follows:

Student	Attending
Beth	Math, Science, Chemistry
John	Art, Music, English
Sarah	Math, Chemistry
Ann	Music, English, Math
Michael	Science, Art, Music
Charlie	English

Table 9: List of students' class attendance

The following diagram provides a description of the relationship between the TABLE (Student) and the TABLE (Class). For each student record, there exists a unique set of arrows pointing to specific records in the second table. (For the sake of clarity, the one-to-many relationship is only included for students Beth, John and Sara.)

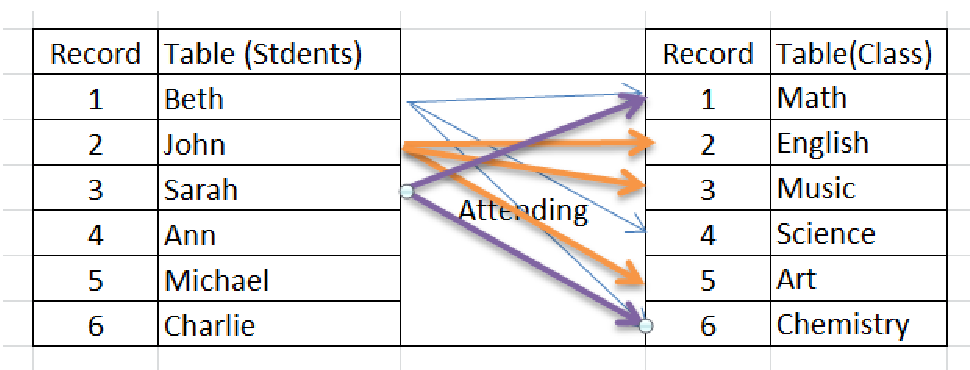


Table 10: Depiction of related fields between Table (Students) and Table (Class)

In general, database structure relates a record in one table to a record (or records) in a second table through a specific relationship. This process, the actual connection of records, takes place using a very specific structure. The table below summarizes the general structure reviewed so far:

Name	Description
Table	A repository of information
Record	A set of data within a table

Table 11: Definition of terms

5.6 Database Design

The development of a database requires the management of three database structures: (1) tables, (2) fields, and (3) relationships. FileMaker Pro, a relational database software, provides a user friendly “front end” to define the said structures.

5.6.1 Database tables

The development of tables in FileMaker Pro is a straightforward process. The image below provides a screen capture of the database management front end used to establish database tables.

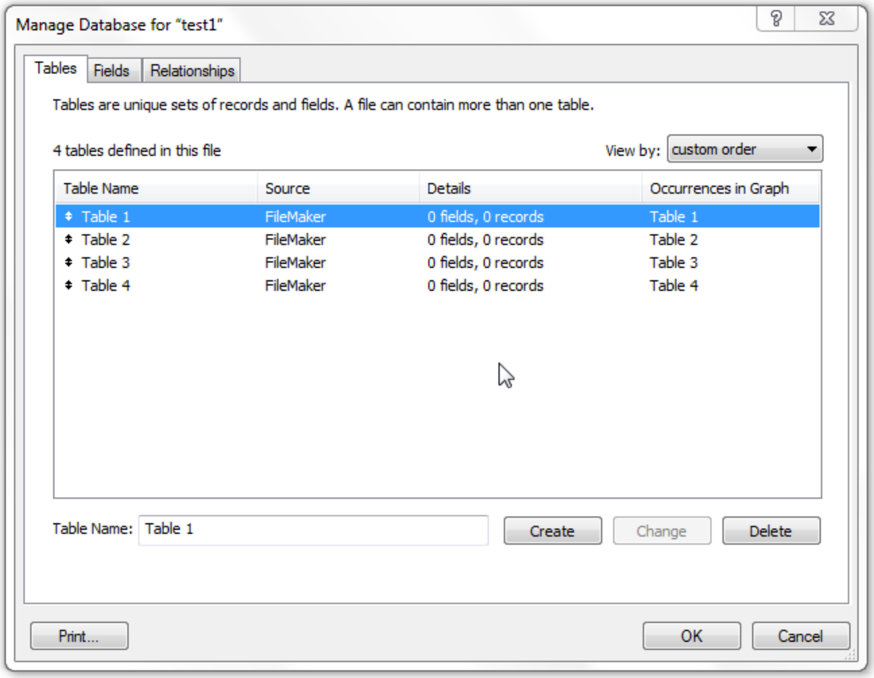


Figure 20: Database table list.

This example established four unique tables (table 1, table 2, table 3, and table 4). The process involved the establishment of a unique name. In this environment, table names can be changed, added, or deleted in a simple manner.

5.6.2 Database fields

For each specific table, a set of specific placeholders (i.e., fields) can be created to house specific data. The image below provides an example of FileMaker Pro's field front end. In this particular example, table 1 has 4 unique fields: field 1 (text), field 2 (text), field 3 (number), field 4 (date).

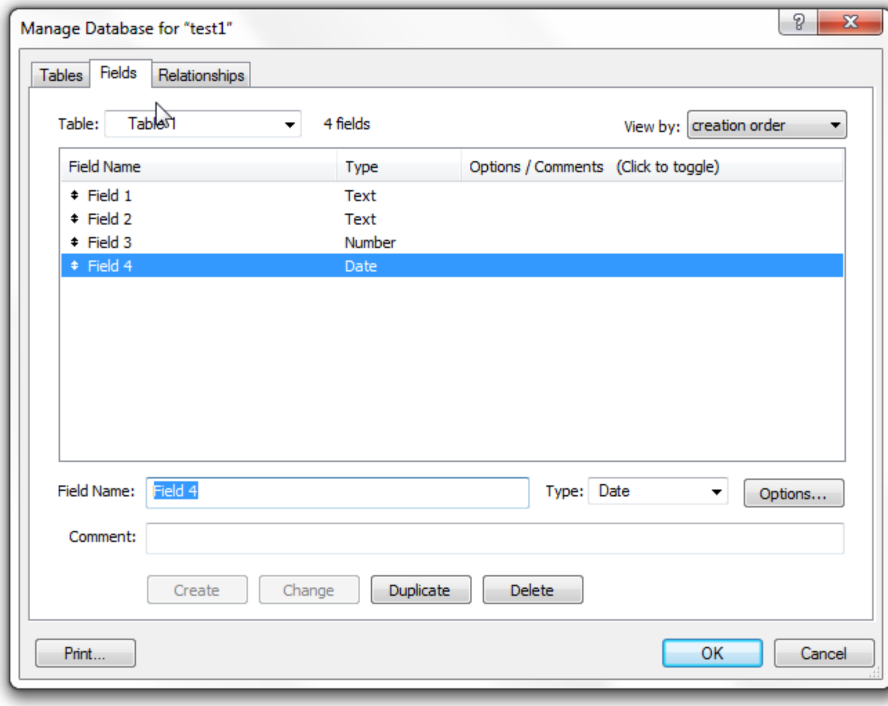


Figure 21: Database field list.

5.6.3 Database relationship

In FileMaker Pro, the relationship front end enables the user to have full visibility to all tables (including their fields). By graphical manipulation, database relationships can be created between fields. The example below contains the following relationships:

(a) Table 1: field 1 and Table 2 field 1
(b) Table 1: field 2 and Table 3 field 3
(c) Table 3: field 3 and Table 4 field 1

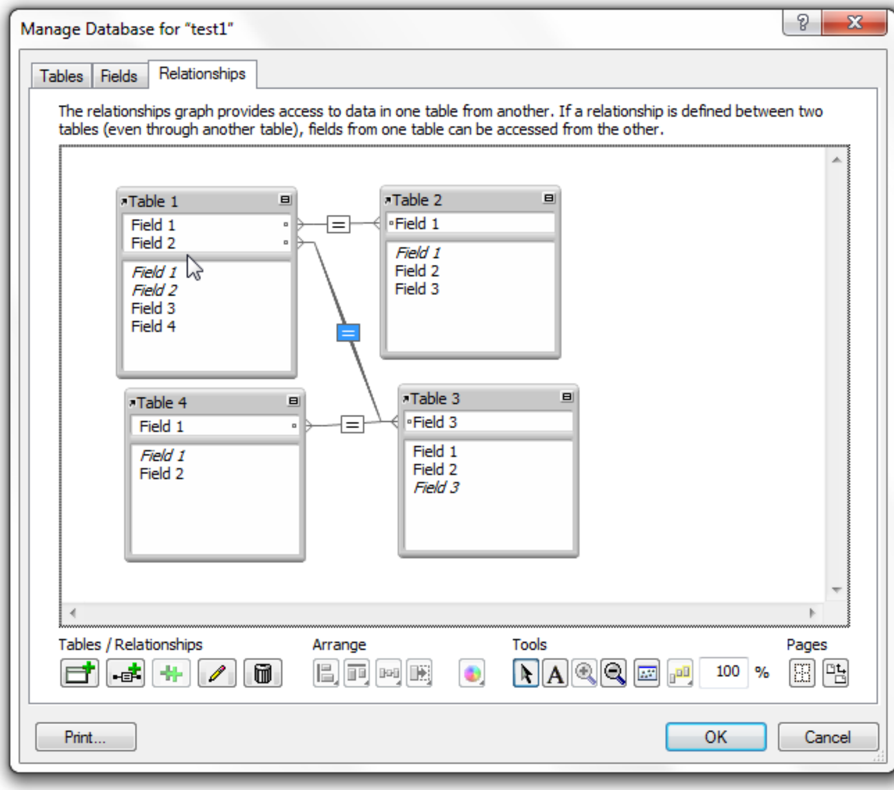


Figure 22: Database relationship map.

5.6.4 FileMaker Pro: The simple solution

FileMaker Pro, a Macintosh-based software, provides a database development tool that is intuitive, friendly, and easy to learn. Given these benefits, the author of this project has selected FileMaker Pro as the software of choice in the development of Diffinity Genomics' solution to address the new product development expansion as well as the introduction of a new branding scheme.

6 The Solution

The previous sections of this report have elaborated on details related to Diffinity Genomics' rapid product expansion and new marketing initiatives. As stated in section 1.2.3, the development and implementation of a shop floor control (software) tool will be particularly important to the successful implementation of Diffinity Genomics' product expansion. The primary goal of this tool will be its ability to guide users through Diffinity Genomics' new product map ensuring that the finished product conforms to the new packaging and marketing schemes. The proposed shop floor control tool will enable Diffinity Genomics' members to print final product information onto pre-printed labels that incorporate the new branding appearance. So… what does this solution look like?

Before a formal solution can be proposed, it may be necessary to define some additional requirements that address the interface and role of the proposed shop floor control tool. We will start defining these requirements by initially defining Diffinity Genomics' workflow through a process flow diagram. Once this diagram is defined, each process flow step will be further detailed and specific input and output requirements will be defined (for each step).

The information developed through the process flow diagram also will drive specific requirements related to database tables, fields, and relationships. These requirements eventually will lead to a software workflow environment coded in the FileMaker Pro software database.

6.1 Diffinity Genomics product workflow

Diffinity Genomics product workflow is described in the figure below. In order to understand the rationale behind this process flow, it may be important to understand the customer and customer order process.

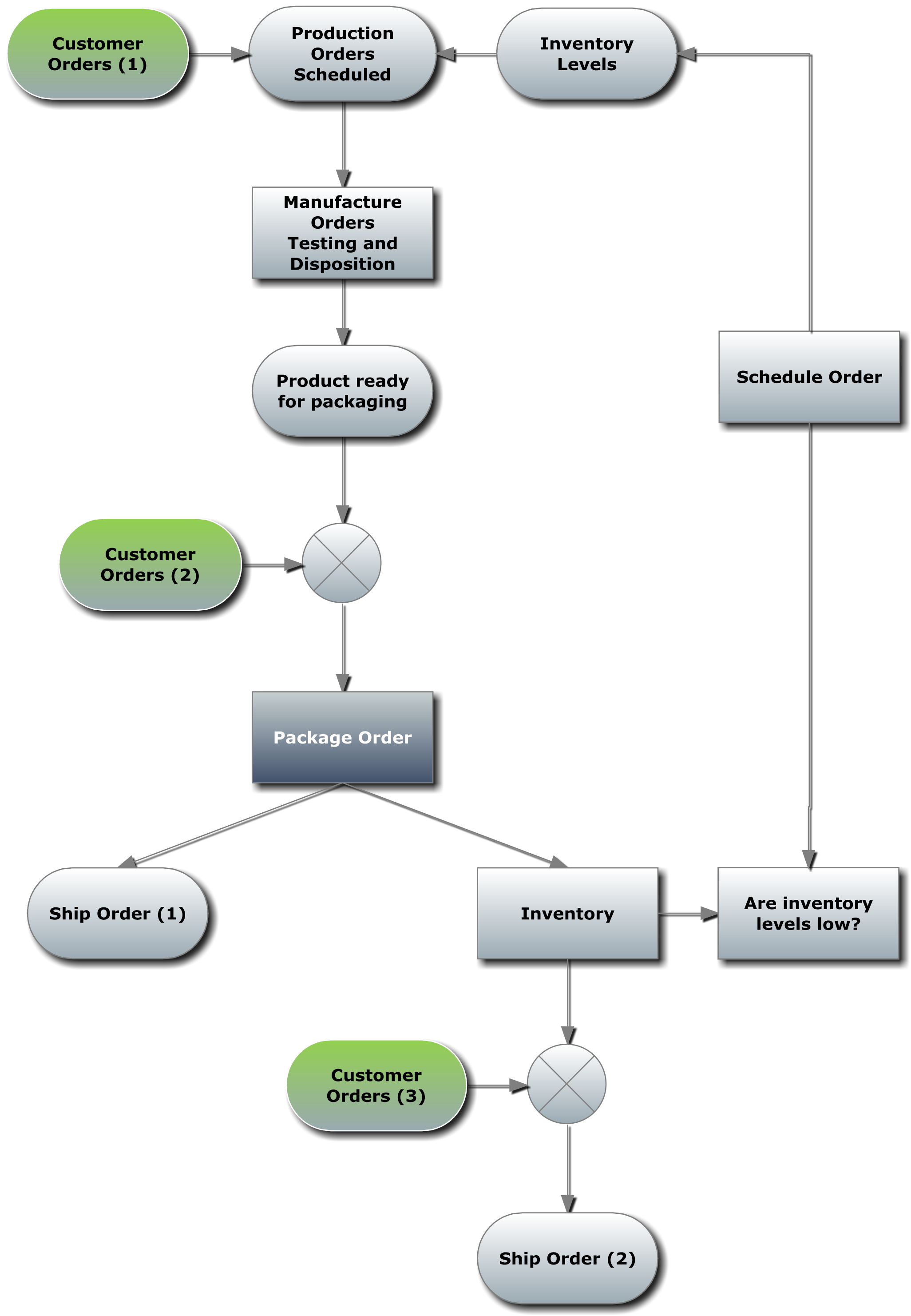


Table 12: Diffinity Genomics product workflow diagram

6.1.1 Diffinity Genomics' Customers

Over the past six months, Diffinity Genomics' customer base initially followed a direct sales model approach. Customers visited the company's website and placed orders directly through a sales portal. As the product grew in popularity, Diffinity Genomics' ability to secure national distributors became possible. Soon the company expanded its distribution capabilities to international markets. Most recently, Diffinity Genomics secured a global distribution agreement with a large "laboratory supply catalog" company, and the birth of Diffinity's private labeling offering was established.

All in all, Diffinity Genomics strives to fulfill customer orders as quickly as possible. In order to do so, Diffinity's process flow incorporates the input of customer orders in three different locations.

<u>Customer Order #1:</u> These orders are typically high volume orders. Given the relatively large size, the company's strategy is to fulfill these orders in a make-to-order modality. Most of these orders are typically private label orders.

<u>Customer Order #2:</u> These orders are typically large-to-medium volume; however, these orders are not private label orders placed by smaller distributors.

<u>Customer Order #3:</u> These orders are typically medium-to-small orders placed by national distributors or direct sales through Diffinity's point-of-sale website portal.

6.1.2 Diffinity Genomics Orders Options

Diffinity Genomics customers can place product orders through a multitude of options. The table below provides a summary of these options:

Parameter	Customer Order Options
Application	Customer Options: Rapidtip®1, Rapidtip®2, Rapidtip®3, etc.
Packaging configurations	Customer options: Sample packs, 48 tip box, 96 tip box
Application solution volume	Customer options: 50ul, 25ul, 10ul.
Pipette tip	Customer options: Universal, Rainin, Tip 3, Tip 4, Tip 5, etc.
Packaging configuration	Customer option: Diffinity Genomics (OEM) or private label
Order quantity	In general, order quantity is not constrained; however, international distributors tend to purchase in large quantities to reduce shipping expense. Some distribution contracts require minimum purchases.
Shipping	Customer options: Next day air to ground. Customer typically pays for shipping cost.

Table 13: Diffinity Genomics customer order options

6.1.3 Diffinity Genomics Manufacturing: Testing and Disposition

Diffinity Genomics' rapid growth has driven the manufacturing capacity to its limits. The need for additional capacity is evident; however, the delivery of additional equipment cannot come soon enough. In the meantime, the company leverages overtime opportunities to address these capacity constraints.

Customer orders are reviewed on a daily basis. Each customer order drives a production order to be scheduled accordingly. Careful consideration is taken to maximize the combination of orders to reduce the number of product changeovers. The final output from this process is a weekly production plan. This plan roughly defines the number of lots to be produced on a daily basis.

For each lot scheduled, a specific recipe is followed to ensure the raw materials selected are consistent with the customer order. Careful consideration is taken to ensure that the product manufactured is fully accountable (tip count per lot). The table below provides a summary of the tip count form that needs to be filled out for each product lot:

Item	Term	Definition
1	Number of tips	Total number of tips manufactured for the specific lot
2	Number of retains	Total number of tips saved for product retains
3	Waste	Total number of tips lost due to mishandling
4	Testing samples	Total number of tips consumed for testing purpose
5	Unaccounted tips	Total number of tips that cannot be accounted for anywhere else
6	Tips ready for packaging	Item #1 minus items (2, 3, 4, 5)

Table 14: Lot accountability sheet

Manufactured product must meet the highest quality levels possible. Diffinity Genomics follows a strict quality system that requires production lots to be fully tested prior to shipment. Careful consideration must be taken when considering customer order fulfillment given the potential for product retest or product lot failures. Although these events are atypical, the probability for these occurrences is never zero. As a result, item #4 in the lot accountability sheet provides an opportunity to account for all product used for testing purposes.

When production lots meet product specifications, these lots are considered acceptable product (for sale product). Lots released are placed in a work-in-progress inventory called "Ready for Packaging."

6.1.4 The fine art of packaging product at Diffinity Genomics

Each "ready-for-packaging" lot contains a specific number of tips. Although the final tip count per lot was originally predicted by the original production order, the reality is that the final tip count is typically less than the scheduled order since in most cases product is lost due to additional product testing (unplanned).

Diffinity Genomics' tips are sold in sample packs of 8 tips and tip boxes of 48 and 96. Therefore, a delicate but critical process takes places each time a lot is packaged to minimize the number of tips that are "excess "after packaging. The table below provides several packaging scenarios for a tip lot with a quantity of 831:

Tips ready for packaging	831	831	831
8 packs	103	1	1
48 tip box	0	17	1
96 tip box	0	0	8
Tips left over	7	7	7

Table 15: Example of various ways to package 831 tips

Based on a lot size of 831, the lot could be packaged as:

a) 103- 8 pack with 7 tips left over
b) 17- 48 tip boxes with 7 tips left over
c) 8 -96 tip boxes, 1-48 tip box and 7 tips left over.

The three scenarios above provide interesting outcomes depending on the packaging configuration for the lot. To make matters more interesting, the sample retained quantity can sometimes come into play to maximize the tip packaging efficiency. In other words, for all three scenarios shown, if one tip is removed from the retained pool (and added to the ready-to-package count), the leftover tip count would be eight tips, and this number would yield another sample pack. This type of tip manipulation takes place for every lot produced. This process is sometimes called lot reconciliation.

The likelihood of a lot yielding 100% of the intended tip quantity is low; therefore, the production order quantity is typically scheduled on the "heavy side." This conservative approach ensures that enough product is manufactured to meet each customer order. If, however, the product yield for a particular lot is unusually good, then excess product has been manufactured and the remaining package product ends up in the finished product inventory.

The previous example described the scenario in which a production order leads to various packaging scenarios. In reality, each production order, generally speaking, is manufactured with the intention of being packaged in a particular packaging option: 8 pack, 48 tip, or 96 tip boxes. Most customer orders, however, are placed in a way that several packaging options are included in the order. For example, a customer may order 50 sample packs, 24-48 tip boxes, and 12-96 tip boxes in one order. Therefore, careful consideration must be taken to ensure that the weekly production orders consider multiple customer orders all together.

6.1.5 Diffinity Genomics' subsequent packaging options (secondary)

Given the current customer consumption trends, Diffinity Genomics has adopted a unique secondary packaging strategy as follows: Each tip count box (48 tip or 96 tip) will be packaged individually in a corrugated container. This scenario provides a strong message to our customers: each tip box is packaged individually because its contents are of high value. In the future, Diffinity should consider secondary packaging scenarios of 6, 12 and 24 tip boxes (48 tips or 96 tips). These options will become more palatable as customer order size increases.

The current secondary packaging scheme for sample packs is typically in quantities of 1 (new customer trial) or multiples of 50 (in support of large distributor campaigns).

6.1.6 Diffinity Genomics Tertiary packaging and shipping

Given the 48 and 96 tip corrugated container, Diffinity Genomics has purchase standard corrugated containers to ship 12, 24, 36, and 48 tip boxes in a shipper. Fortunately, the corrugated tip container has a width of six inches, making it simple to purchase corrugated boxes in increments of six inches in all three major axes (L x W x H). As stated previously, product shipping is paid by the customer (most of the time). Diffinity Genomics has accounts with all major shipping companies worldwide.

6.1.7 Summary: Diffinity Genomics' workflow

Section 5.1 of this report has provided a detailed overview of Diffinity Genomics current workflow. This information will provide a foundation for the development of the proposed shop floor control software module. The next section of the report will elaborate on the details of the shop floor control software solution.

6.2 The Solution: Diffinity Genomics' Shop Flow Control Database

The following section will describe in great detail the functionality of the proposed shop flow control database using the FileMaker Pro database software. The database functionality will be presented in the same manner as a real user would interface with the database while processing a production. Once this user interface review is completed, the database functionality will be reviewed from a technical perspective, highlighting the actual tables, fields, and database relationships used to compile the data.

6.3 Database Front End: Main Menu

When the database is initially started, the user software opens the user interface to the main navigational page (Main Menu). The figure below provides a screen capture of the main menu view:

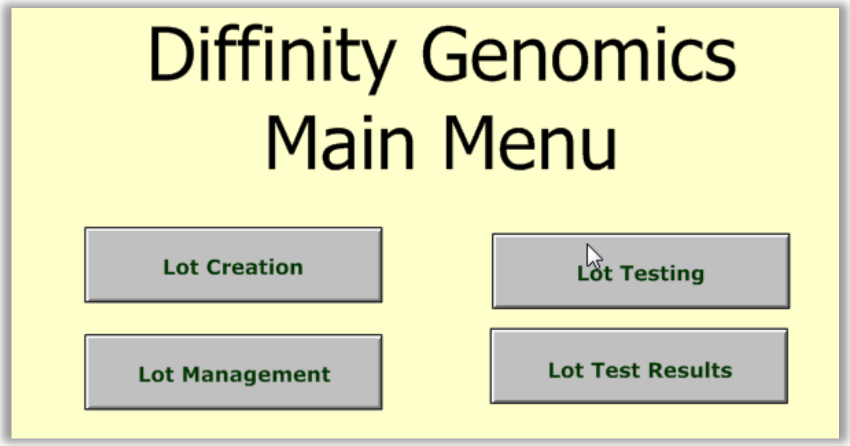


Figure 23: Program Main menu.

The main menu page contains four navigation buttons. Each button navigates the user to the corresponding page as noted on the button.

As noted in the process flow diagram in section 5.1, Diffinity Genomics' manufacturing process starts with the production order scheduling process driven by customer orders. Each week this schedule is planned and posted. Based on this information, each morning the manufacturing team is expected to produce a specific product lot.

This process starts with the creation of a manufacturing lot. The table below provides a summary of the lot properties and the corresponding product options available. Note that the menu options available include the proposed product configurations (product expansion) discussed earlier in this report.

Lot Property	Options
Product application	Rapidtip®1 Rapidtip®2 Rapidtip®3
Product generation	Gen 2 Gen 3
Tip type	Universal Rainin Tip 3 Tip 4 Tip 5
Sample volume	10ul 25ul 50ul
Diffinity proprietary lot	WJB1-153-2 WJB1-153-3 WJB1-153-4
Lot number of the day	1 2 3 4

Table 16: Lot property field options

When the user selects the lot creation button, the database takes the user to the lot creation screen. This screen is divided into two sections.

The top section provides the user with the necessary options to create a new lot. The creation of a new lot is complete by choosing a selectable option from each field's pull- down menu. The figure below provides a screen capture of the top section of the lot creation screen:

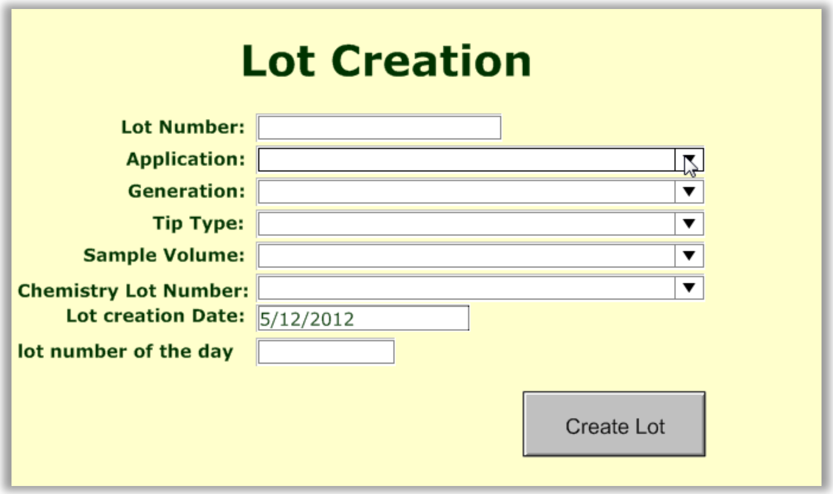


Figure 24: Lot creation screen capture.

For each field, a pull-down menu provides guidance (to the user) for the options available in each field. The screen below provides a screen shot of the pull-down menu for the application field:

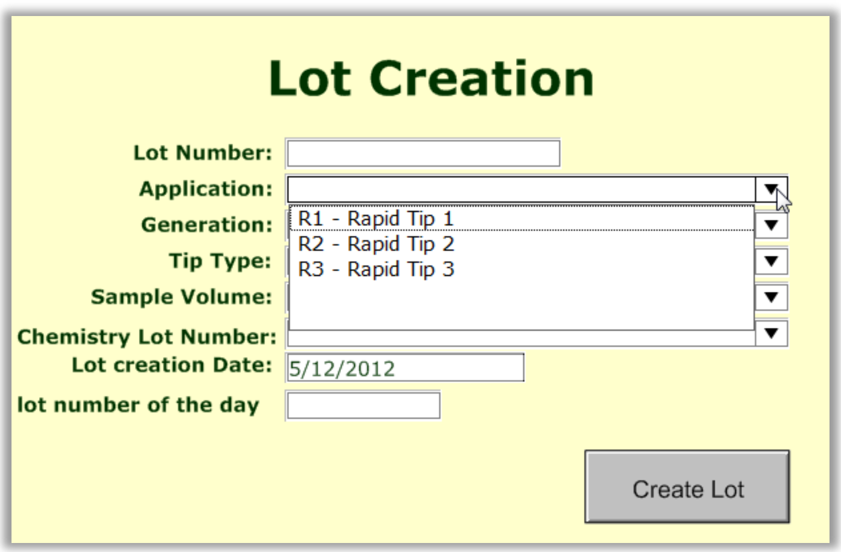


Figure 25: Lot creation pull-down menu.

Once the user selects the appropriate options for each of the required fields, a unique lot number is recorded (stamped) in the database.

6.3.1 Lot number nomenclature

The assignment of a lot number (based on the selectable menu options in the database) requires significant effort. The final outcome for the lot number is a five-digit, alphanumeric descriptor (XXXXX), followed by a (second) five-digit, alphanumeric descriptor (YYYYY). In between the descriptors, a dash was inserted to help user readability. Therefore, Diffinity Genomics new lot number assignment will have the following format:

$X_1\ X_2\ X_3\ X_4\ X_5$ - $Y_1\ Y_2\ Y_3\ Y_4\ Y_5$

The assignment of the lot number in the database is best described when referring to the table below:

Lot digit	Lot property	Options	Lot digit reference
X_1	Product application	Rapidtip®1 Rapidtip®2 Rapidtip®3	A B C
X_2	Product generation	Gen 2 Gen 3	2 3
X_3	Tip type	Universal Rainin Tip 3 Tip 4 Tip 5	U L TBD TBD TBD
X_4 X_5	Sample volume	10ul 25ul 50ul	10 25 50
Dash			
Y_1 Y_2 Y_3	Julian day		
Y_4	Year	2009 2010 2011 2012	A B C D
Y_5	Lot number of the day	First Second Third etc.	1 2 3

Table 17: Lot number nomanclature

Based on the table above, a lot number defined as A2U25-133D1 would be decoded as:

Lot digit	Lot property	Options	Lot digit reference
X_1	Product application	Rapidtip®1	A
X_2	Product generation	Gen 2	2
X_3	Tip type	Universal	U
X_4 X_5	Sample volume	25ul	25
Dash			
Y_1 Y_2 Y_3	Julian day = May 12 (133 day of the year)		
Y_4	Year	2012	D
Y_5	Lot number of the day	First	1

Table 18: Decoded information from lot # A2U25-133D1

6.3.2 Lot menu management

Within the lot creation screen, there exists a lower section defined as the lot menu management. The image below contains a screen caption of this section:

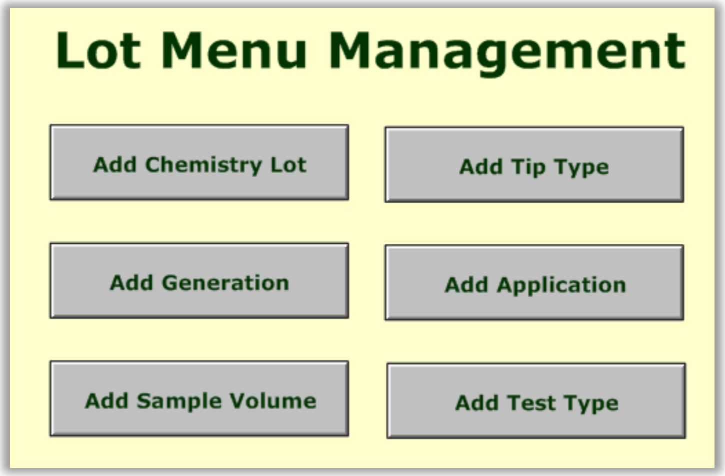


Figure 26: Lot Menu Management screen capture.

The lot menu management section provides the database user the opportunity to define additional lot options for the pull-down menus. For example, if a new product application was developed (Rapidtip®3, for example), the user would select the "Add Application" button and the database would navigate to the following layout:

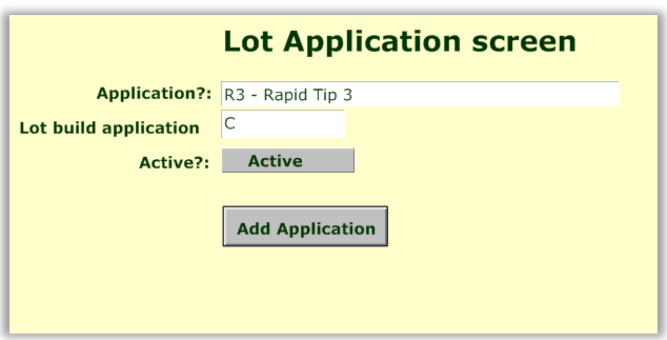


Figure 27: Lot application screen capture.

6.4 Production lot management

Once a new production lot is defined, the production team manufactures the intended product by appropriately selecting the related raw materials. The end product of this process is the manufacture of Diffinity Genomics' pipette tips. Once the lot has been completed, the operator needs to input the product manufactured into the system. To do so, the operator would navigate through the main database page (Diffinity Genomics' Main Menu) and select the Lot Management button.

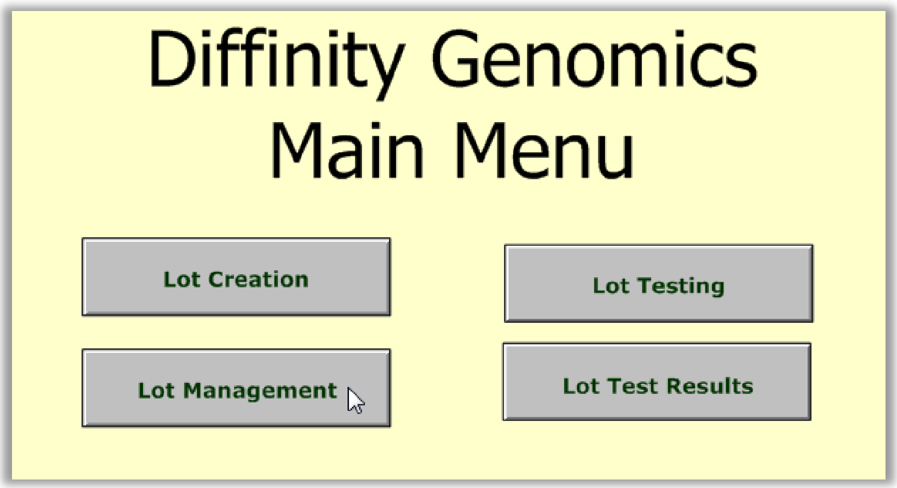


Figure 28: Main menu highlighting the Lot Creation button.

Once the lot management button is selected, the database navigates to the lot management screen as shown below:

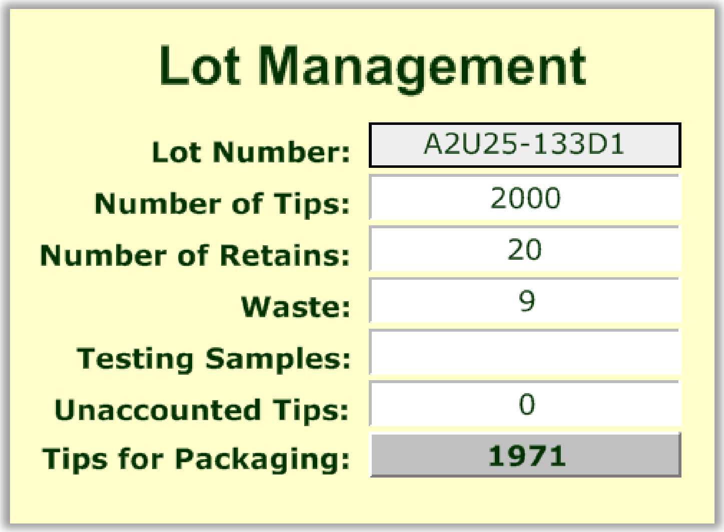


Figure 29: Lot Management screen caption.

Once the user lands at the Lot Management screen, he or she would input the following information:

Lot Management Field	Definition
Number of tips	Input: Total number of tips manufactured
Number of retains	Input: Total number of tips kept for product retains samples
Waste	Input: Total number of tips wasted / lost / damaged
Testing samples	This is a calculated field and will be addressed in the following report section
Unaccounted tips	Input: This field was defined to enable user to manipulate the final count if the actual product count does not match the field "Tips for packaging"
Tips for packaging	This is a calculated field (no user input required): Tips for packaging = Number of tips minus (number of retains, waste, testing samples and unaccounted tips). This is the number of tips that will be packaged as saleable product.

Table 19: Lot management field definitions

6.5 Production lot testing

Once it has been accounted for, the production lot must be tested to ensure it meets minimal product performance specifications. Unfortunately, this process also consumes product tips, thus affecting the final lot count. In order to account for tested product losses, the database provides (within the main menu), a menu selection to record the lot testing tip consumption. The user would select the Lot Testing button from the main menu as follows:

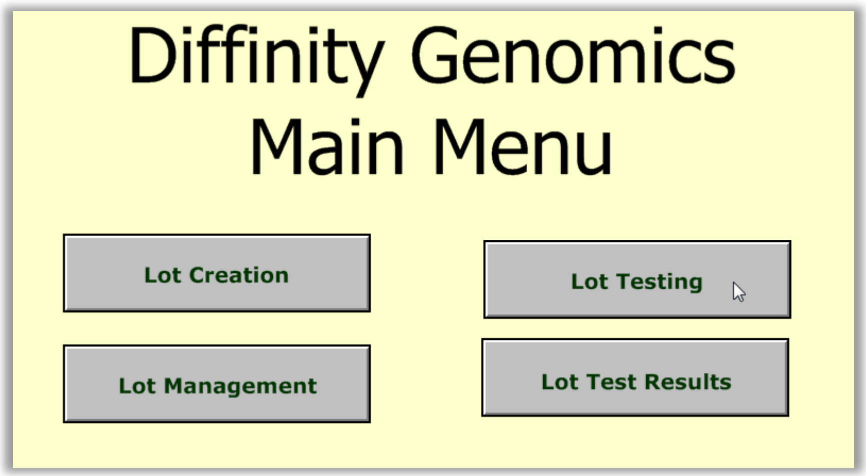


Figure 30: Main menu highlighting the Lot Testing button.

Once the lot testing button is selected, the database will navigate to the lot testing screen described below:

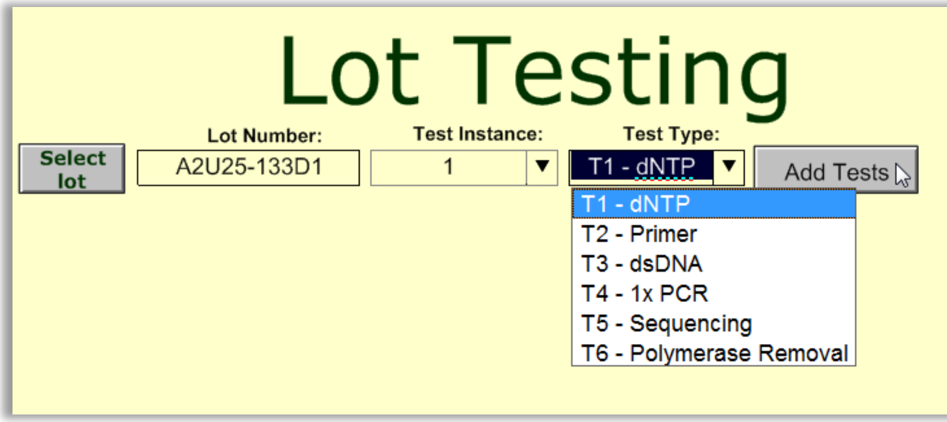


Figure 31: Lot Testing screen.

The user would select the required test for the product (i.e., T1, T2……T6) and select the "Add Test" button. If, for example, for lot A2U25-133D1 testing was completed for T1-T5 (a total of five tests) and, assuming a sampling plan n=3, a total of 15 tips would be used to complete the test.

It is important to note that once the testing samples are allocated for the specific lot, the lot management screen accounts for the tips used. The screen below shows how the 15 tips for lot A2U25-133D1 were accounted for under the testing sample field:

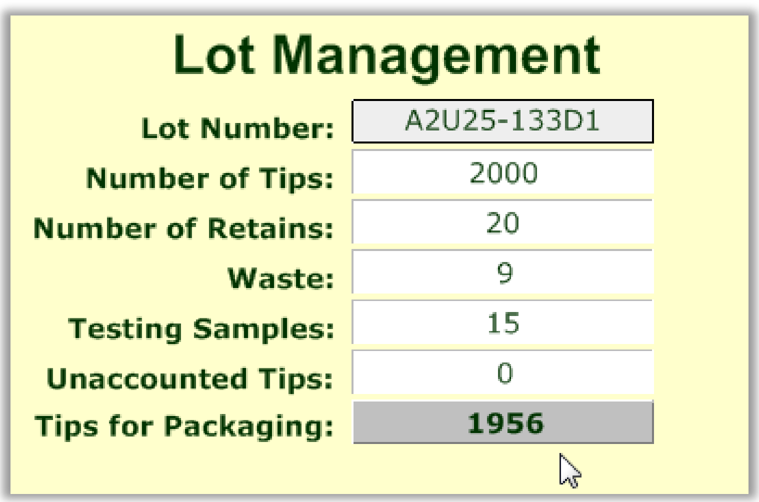


Figure 32: Screen capture of lot A2u25-133D1 management.

6.6 Production lot testing outcome

Once the testing samples are submitted for testing, test results are generated for each tip. The tip test results are captured in the Lot Test Results screen. A typical example of this layout is described in the screen capture below:

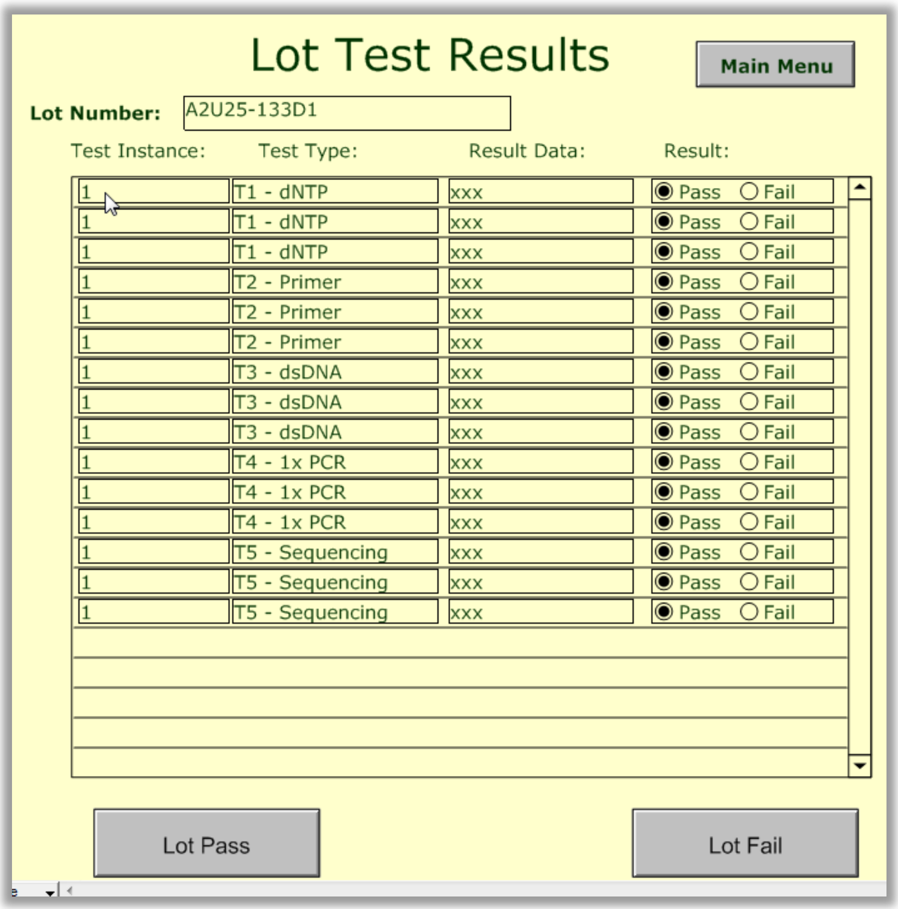


Figure 33: Screen Capture of Lot Test Results.

For each tested tip, a line item is provided. The test result is incorporated in the result data field as a number XXX. For each tested tip, a pass / fail field must be selected. Once all the data is inputted, the user would make a decision to pass or fail the lot by pressing the appropriate button.

6.7 Primary packaging product

Once a manufacturing lot has passed the required internal quality guidelines, the lot can be fully packaged. The key to this process is the generation (printing) of product labels. The diagram below provides the logic (decision process) needed to arrive at the proper finish product label configuration. It is important to note that at this point of the process, the product has been manufactured and, therefore, inherent product properties such as product application, application volume, and tip type have been already established when the raw materials were selected to manufacture the lot.

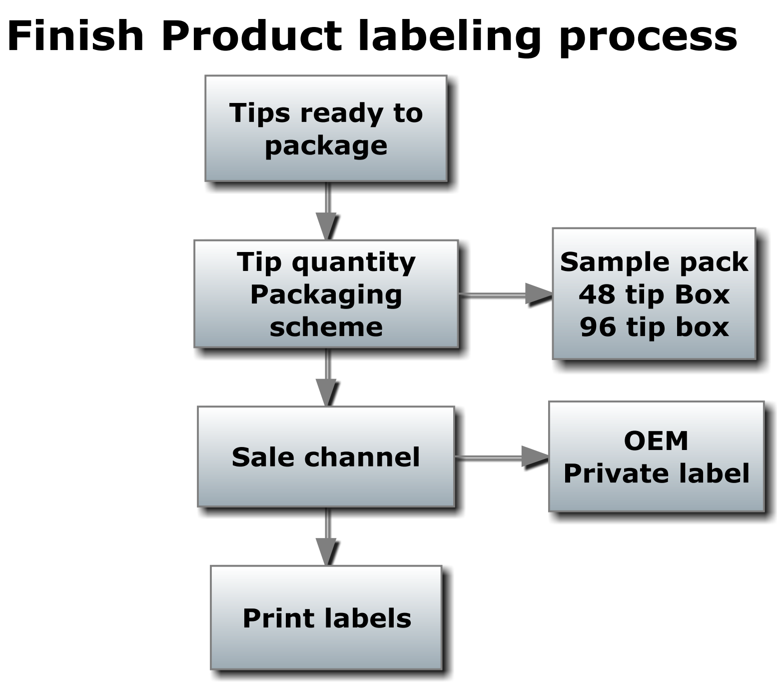


Figure 34: Finish Product Labeling Process.

For each manufactured lot, a decision on the packaging scheme must be made. This proposed database tool provides a method to complete this process in a simple manner.

Figure 35: Ready to be packaged, example 1.

Lot A2U25-133D1 contains a total of 1956 tips ready to be packaged. The information included in the layout suggests to the user that with 1956 available tips, one can package 244 sample pack units,40 boxes of 48 tip boxes, or 20 boxes of 96 tips. Also, this process suggests that the use has a multitude of options to package the lot. The key to the decision process is the fact that this order was originally scheduled through the production order schedule. Therefore, this lot has been informally committed to produce a specific packaging configuration scheme.

The final packaging scheme, however, can be changed during this decision process. As a result, a multitude combination of packaging schemes can be constructed based on the database logic built into the layout.

Take, for instance, a scenario in which 10 sample packs and 10-48 tip boxes are desperately needed in an OEM product. If this was the case, the user would input this information on the layout. The screen capture below provides an example of such inputted information:

Figure 36: Ready to be packaged,. example 2

The result of this input indicates that there are 1396 tips left over (still available to be packaged), and this amount of tips yields new suggested values for the various packaging options. To further illustrate the capabilities of the database, let us suggest that for this lot, we will package an additional 72 single packs, 5-48 tip boxes, and 6-96 tip boxes, all items for private label (Sigma Aldrich). The screen capture below provides the example suggested:

Figure 37: Ready to be packaged, example 2 (box example).

The suggested packaging scheme results in three tips left over. Since a single pack contains eight tips, a residual quantity of four tips cannot be packaged in any acceptable manner. The goal of this process is to arrive at a zero quantity of excess tips, and several options are available to achieve this goal. During the lot reconciliation stage, tips were collected as retain samples. Perhaps if four tips are pulled from this allocation, one can complete an additional single pack, or perhaps four tips can be added to the tip allocation pool. In this case we will release four tips from allocation. (See image below for tip allocation before and after:)

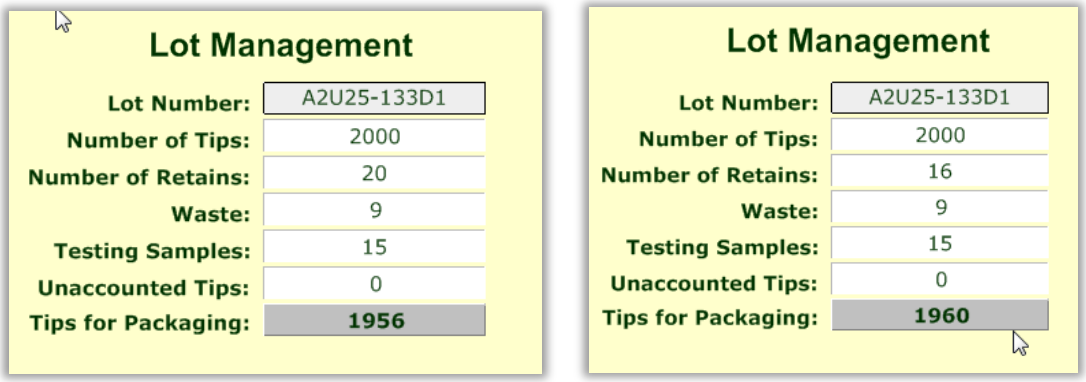


Figure 38: Lot management before and after allocation of four tips from the retained sample.

The result of this transaction allows for the allocation of an additional sample pack (73 vs. original quantity of 72) and a tip left over balance of zero tips. Refer to diagram below for screen capture:

Figure 39: Ready to be packaged, example 2.

6.8 Label Printing process

Once the packaging scheme has been completed and a zero tip excess balance has been reached, Diffinity personnel move to printing labels. To do so, sufficient logic has been built into the database to successfully print the appropriate labels using a one-touch button. Take, for instance, the printing of the ten Diffinity sample pack labels. By pressing the "Print Sample pack labels" button, a software script is executed to print these labels. The screen capture below provides an example of the label generated for the Diffinity Sample pack as well as the Diffinity 48 tip box label using the proposed database software. It is important to note that for each of the labels shown, all the variable printed information has been extracted from multiple tables and relationships within the database. The scope of this report does not include the development of standard operating procedures to address the specific application (location) of the label or a line clearance on the production area to ensure each lot is treated independently during the labeling process.

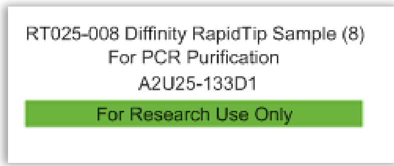


Figure 40: Sample pack label example.

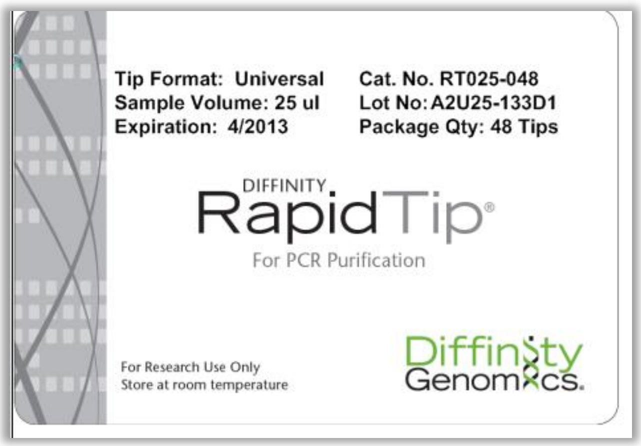


Figure 41: Label 48 tip.

Below are additional examples of labels that the database software has been designed to print:

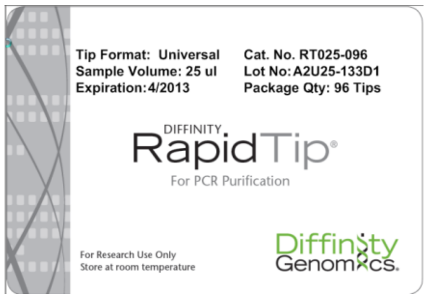
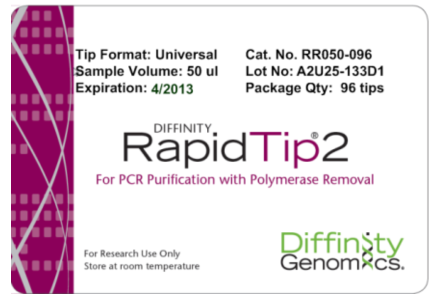
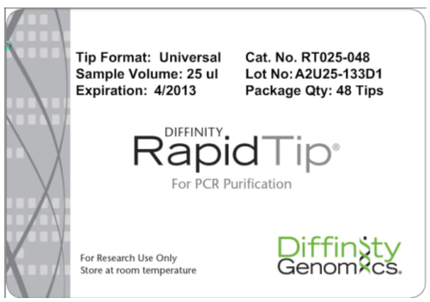
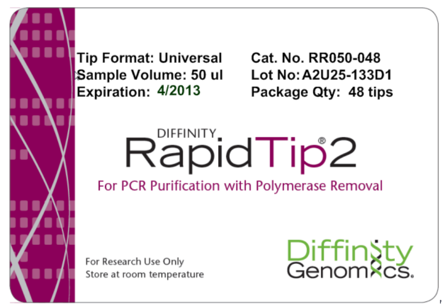
	Rapidtip®1	Rapidtip®2
96 tip box		
48 tip box		
Sample pack	RT025-008 Diffinity RapidTip Sample (8) For PCR Purification A2U25-133D1 For Research Use Only	RR050-008 Diffinity RapidTip2 Sample (8) PCR Purification with Polymerase Removal A2U25-133D1 **For Research use only**

Table 20: Rapidtip®1 and Rapidtip®2 labels printed using proposed database software.

6.8.1 Label traceability and label control

The proposed shop floor control software provides a user-friendly tool to address Diffinity Genomics' product expansion. It is important to note that although the solution meets immediate company needs, several areas of consideration should be noted.

The current software solution provides strong software traceability starting from the issuance of the lot number through the printing of the corresponding labels. However, this software traceability requirement does not ensure that each production lot gets the appropriate labels. The author of this report recognizes that this responsibility falls on the user(s) of the tool. In the future, strong consideration will be given to a bar code system to connect real product (boxes of tips) with software information. The use of barcode labels and barcode readers would provide a confirmation that the manufactured lot is labeled using the right printed labels.

Also, the author recognizes that the actual label printing quantity is calculated through software code; however, the software does not address the need to reprint specific labels due to misprinting or handling errors. In other words, the printing process (as proposed in this project) does not have a feedback loop to ensure that the labels printed were actually used properly. The author of this project believes that a label accountability process step can be easily added to the software to ensure that all printed labels were used, or, if needed, additional labels can be printed to address misprints or label mishandlings.

Finally, the author recognizes that the current shop floor control software does not provide a well-defined solution that addresses data entry errors. To address this requirement, the author recommends that the software address these opportunities by enabling certain users the authority to overwrite specific fields. Fundamental to this solution is the need to define user accounts and associated user "editing rights" to correct data entry errors.

6.9 The Final Product

The table below provides photographs of actual finished product examples. All labels were printed using the proposed FileMaker Pro Shop Floor Control Database software. All labels shown conform to the proposed branding look that the marketing team requested.

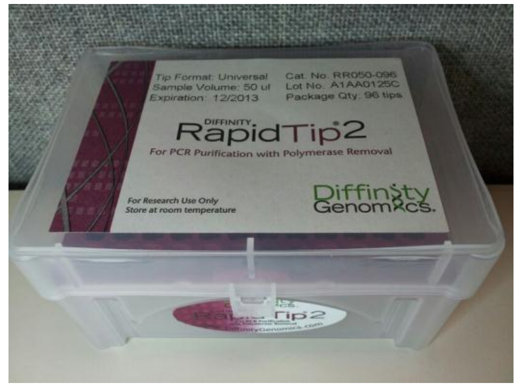
<table>
<tr><th></th><th>Rapidtip®1</th><th>Rapidtip®2</th></tr>
<tr><td>96 tip box</td><td>
</td><td>
</td></tr>
<tr><td>Sample pack</td><td>
</td><td>
</td></tr>
</table>

Table 21: List of new packaging scenarions incorporating new branding scheme

7 The Important Details Behind The Solution

There is a saying, “behind every great man there is a greater woman.” One also can say that behind every great database there exists a great relationship. So perhaps it may make sense to review the database structure behind the Shop Floor Control database solution recently reviewed.

7.1 The database table structure

Perhaps a way to dissect the database structure for the Shop Floor Control solution resides in the database tables that support its functionality. The screen capture below provides a summary of the data tables used in the solution:

13 tables defined in this file

Table Name	Source	Details	Occurrences in Graph
TEMPLATE	FileMaker	5 fields, 6 records	TEMPLATE
LOT	FileMaker	21 fields, 5 records	global_LOT__by_is_active, LOT
LOT_TEST_JOIN	FileMaker	11 fields, 29 records	LOT_TEST_JOIN
TEST	FileMaker	6 fields, 3 records	TEST
CHEMISTRY	FileMaker	14 fields, 9 records	CHEMISTRY
GENERATION	FileMaker	8 fields, 2 records	GENERATION
TIP_TYPE	FileMaker	8 fields, 4 records	TIP_TYPE
SAMPLE_VOLUME	FileMaker	8 fields, 5 records	SAMPLE_VOLUME
APPLICATION	FileMaker	8 fields, 3 records	APPLICATION
READY_FOR_PACKAGING	FileMaker	21 fields, 5 records	READY_FOR_PACKAGING
TEST_TYPE	FileMaker	7 fields, 6 records	TEST_TYPE
TEST_RESULTS	FileMaker	7 fields, 0 records	
GLOBALS	FileMaker	2 fields, 1 record	GLOBALS

Figure 42: Database tables used in the Shop Floor Control Software.

The table below provides an insight into the tables used in the database:

Table #	Table Name	Description
1	Template	Starting table template
2	Lot	Table containing all lots
3	Lot_test_join	Table that combines lot info with disposition test instances
4	Test	Table containing the disposition test instances
5	Chemistry	Table containing critical material information
6	Generation	Table containing available product generation instances
7	Tip type	Table containing the available tip types instances
8	Sample vol	Table containing the sample volume instances
9	Application	Table containing the application instances
10	Ready for packaging	Table containing all information yielding to the ready for packaging process
	Test type	Table containing the tip type test
	Test results	Table containing the tip type test result
	Global	Table containing global variable

Table 22 : Sumary of Tables available in FileMaker Pro Shop Floor Control software

7.2 Database relationships

The following screen capture provides the actual relationships between the tables listed in section 6.1:

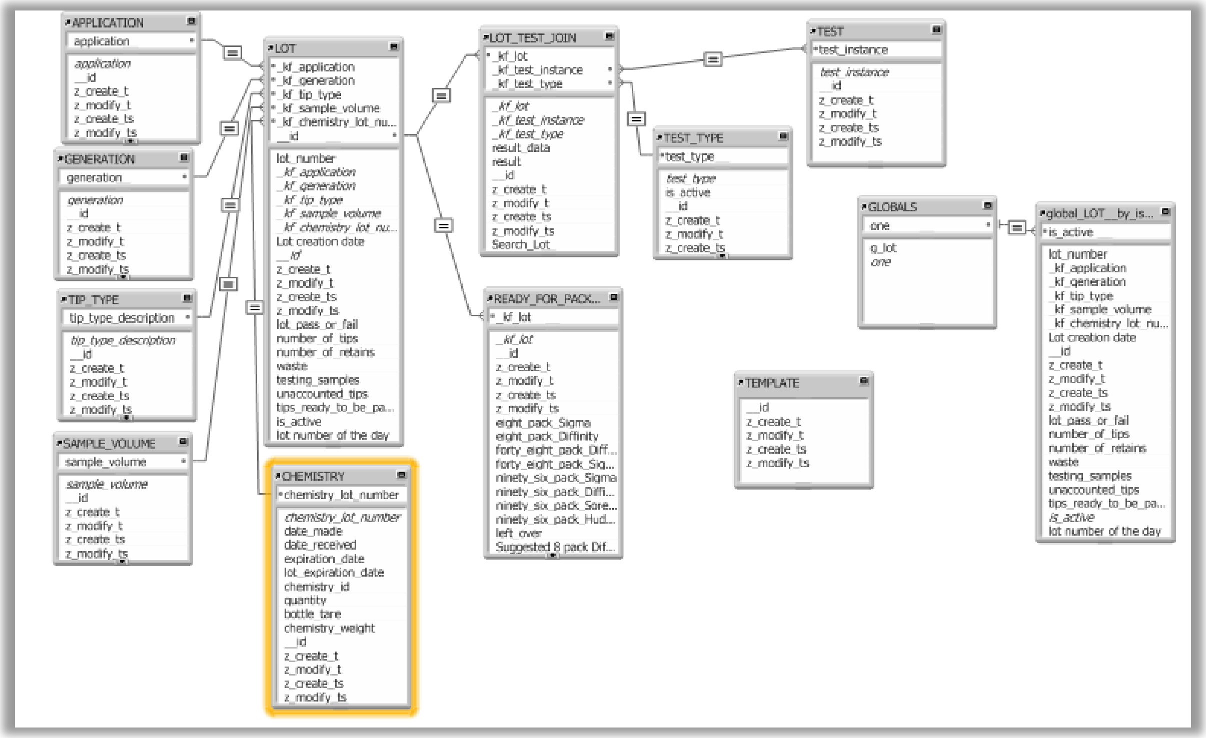


Table 43: Pictorial description of the database relationships.

The key to the success of the Shop Floor Control database is the lot database. The lot table provides a very practical manner in which to order and manipulate the related information necessary to complete transactions amongst the other tables. There also exists several orphan tables with associated relationships: the Global table, for example, contains data fields that are global references for all other tables. The information contain in the Global table provides critical information that enables scripting to be written and executed while referencing data and table instances very effectively. The navigation from screen to screen for a single lot is an example of the use of Global reference information.

7.3 Database Scripting

In FileMaker Pro, the word "scripting" is associated with the use of computer code that, when executed, produces automated functionality. Just like macros in Excel, scripting also provides a means to program routines to complete repeated tasks. The table below provides a screen capture of the various scripts included in the Shop Floor Control solution:

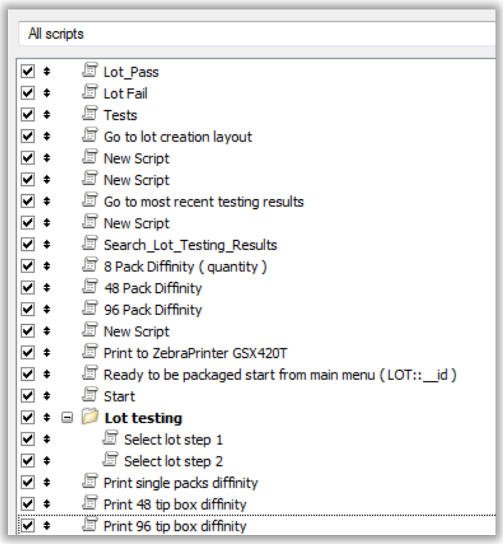


Figure 44 List of Scripts in database.

7.4 Database implementation and validation

As summarized early in this project, Diffinity Genomics will be developing and launching several new products in 2012. The coordination and approval of these new products needs to be orchestrated in a way that only approved and validated products can be processed and packaged as saleable products. The table below provides an up-to-date product launch schedule (5/2012) of the currently validated products as compared with the intended new product development roadmap.

Packaging configurations			Sample pack	48 Tip Box	96 tip Box	Sample pack	48 Tip Box	96 tip Box
			Diffinity Product (Direct Sales or Distribution Channels)			Private Label		
Product	Pipette tip	Sample volume						
Rapidtip®	Universal	25ul						
	Rainin LTS	25ul						
	Tip 3	TBD						
	Tip 4	TBD						
	Tip 5	TBD						
	Etc.	TBD						
Rapidtip®2	Universal	50ul						
	Rainin LTS	50ul						
	Tip 3	TBD						
	Tip 4	TBD						
	Tip 5	TBD						
Rapidtip®3	Universal	TBD						
	Rainin LTS	TBD						
	Tip 3	TBD						
	Tip 4	TBD						
	Tip 5	TBD						

Table 23: Diffinity Genomics product launch as of 5/2012

The current database structure and functionality must manage the gating of new product (and related labeling) launches. This effort must be carried out in a way that developmental product combinations are not accidentally processed and finished as saleable products. To do so, the database built in logic will prevent printing of finished product labels. The screen capture below provides an example of a condition whereby a label is intended to be printed on a product lot that is currently not validated:

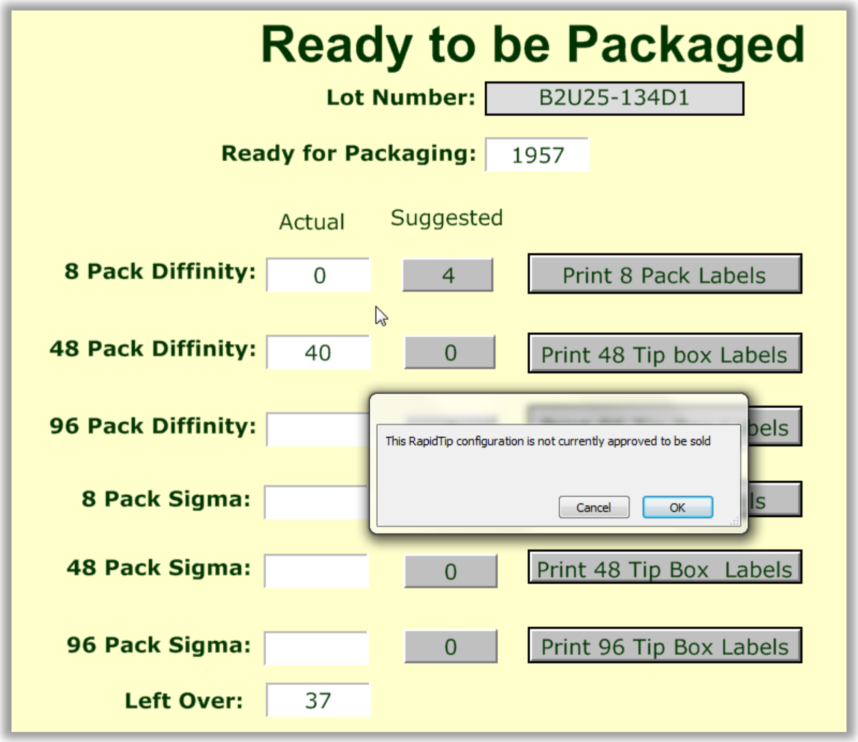


Figure 45: Screen capture of a label printing condition that has not been validated.

In this particular example, the lot nomenclature indicates that lot B2U25-134D has a Rapidtip®2 application for a 25ul solution. The current Rapidtip®2 validated product has been formulated for a sample of 50ul. As a result, lot B2U25-134D must not be processed as saleable product. The screen capture in this particular case is flagged by a window indicating that the lot configuration has not been approved to be sold.

7.5 Lot traceability and error proofing

The use of a relational database software structure for the proposed shop floor control provides several strategic advantages to the proliferation of data throughout the manufacturing of a production lot. The development of specific database tables and the creation of relationships between specific fields enable the developer to create drop-down selection options for users to select. This process ensures that users select information from pre-existing fields. Take, for instance, the selection of a lot for label printing.

As noted earlier in this report, the creation of a lot number is established by the selection of several critical fields. Each field contains a drop-down menu; therefore, only available inputs are "pre-defined" from a specific table of information. The following screen capture illustrates the lot creation process:

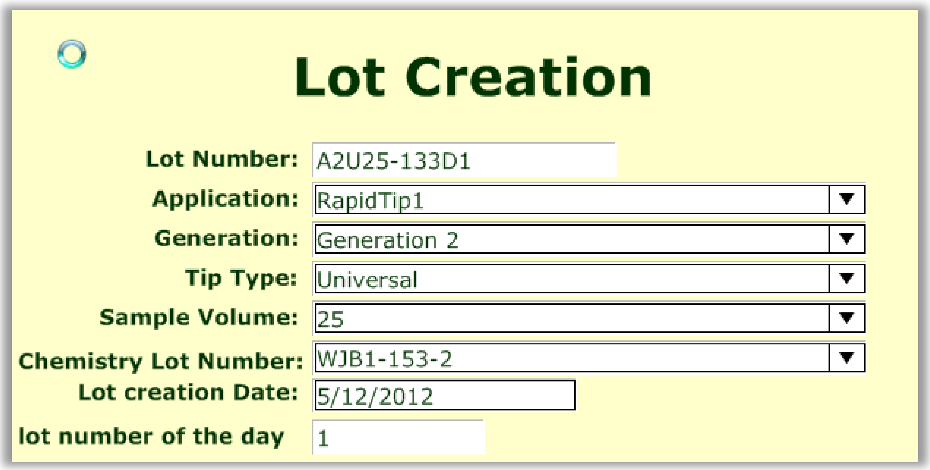


Figure 46: Screen capture of a lot creation scenario.

The creation of lot A2U25-133D1 was possible because the user was able to select a specific option from a drop-down menu for each field shown in the figure above. Once this lot has been established in the database, this lot number becomes part of the lot database table. When the label printing features of the database are triggered, the user can only select lot numbers that are generated from the lot database table. The nature of the established relationship ensures the user will select valid lot numbers and, more importantly, disables users from erroneously typing information into the database. The screen capture below provides an example in which the user can only select lot numbers that have been previously established:

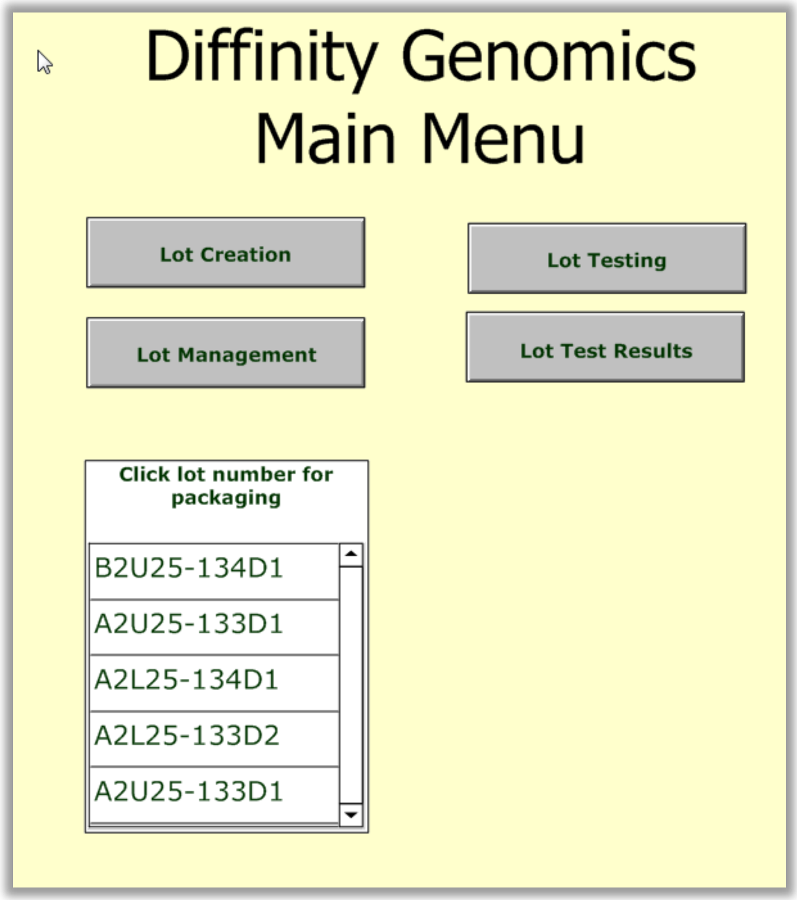


Fig 47: Screen capture of the menu options offered to user while processing a lot.

A similar relationship also has been established in the database structure to ensure that lot traceability can be enforced for each production lot.

8 CONCLUSIONS

Diffinity Genomics' new product development strategy has placed incredible strain on the company's manufacturing capabilities. In the next year, Diffinity Genomics will launch several new products that will expand the Rapidtip® product applications. The product expansion growth becomes exponentially complicated when one considers that for each application at hand, several versions of the product will be formulated. As an example, the recently validated Rapidtip®2 application is currently available for a 50ul sample. However, initial customer feedback is predicted to drive this application to sample volume uses ranging from 10ul to 100ul. How does a small start-up company handle such a diverse range of options in a cost effective manner?

The obvious solution, especially after reviewing this report is simple: design a relational database. The development of relational database software in recent decades has enabled novice computer users (such as myself) to roll up their sleeves and develop cost effective solutions that provide reasonable functionality. The key to successful development of a database solution is the determination of information flow (inputs and outputs) early in the planning stage. Once these have been defined, the human interaction between the data and the user also must be addressed. These interactions create events that are recorded as transactions within a database. At the end of the day, a good database records transactions when information is brought into or out of the database.

Process flow diagrams, as it turns out, provide a methodical means to define transactional interactions between the user and the database. Once these transactions are defined, the actual flow of information can be modeled. The key to modeling process is the development of “repository containers” (i.e., database tables) that collect the data. Interestingly enough, the development of database tables within the process flow diagram eventually lead the developer to reference the exact same information in a different location within the process flow diagram. Relational databases allow the user to “pull” this data from adjacent tables without having to build the table again. This unique phenomenon is accomplished through the establishment of relationships between tables. In general, relationships can be constructed in two modalities: a “one-to-one” relationship or a “one-to-many” relationship. Mastering the skill to identify relational database opportunities is not easy; however, given enough time, this skill can be developed. The key to this skill development is one’s ability to identify the relationship modality. Most database relationships can be modeled using a “one-to-one” relational modality. Diffinity Genomics’ Shop Floor Control database was developed using “one-to-one” relationships only.

Once the appropriate tables and relationships have been established, the user needs to define layouts that provide transactional opportunities to take place within the database environment. The key to this process is the development of “agile” scripting. Scripting (writing database code) is a liberating process. It empowers the database developer to control the user’s fate through clever manipulation of the user’s navigational and transactional actions. Agile scripting is defined as the development of code that is susceptible to outcomes based on transactional events. A good example of agile scripting can be found in the Shop Floor Control database as described in the “Ready to be Packaged” layout:

Figure 48: Screen capture of a ready-to-b- packaged scenario.

In this particular layout, the ultimate goal would be to reach a 0 tip excess quantity. This process can sometimes be achieved by allocating the right amount of sample packs, 48 tip boxes, and 96 tip boxes; however, 90% of the time, zeroing the tip excess quantity may require invocation of information and transactions in a different layout. Numerous hours were invested to accomplish this particular script; however, looking back at the database development journey, the author was appreciative of this investment since the outcome yielded significant success within the database.

Overall, the proposed Shop Floor Control database provided an elegant (and cost effective) solution to Diffinity Genomics' new product development roadmap. The database also fully embraced the need to adopt the new branding presentation as proposed by the sales and marketing team. Future efforts should integrate the use of raw material information in the manufacturing process as well as the customer ordering process as it impacts manufacturing, scheduling, and planning. The resulting database, however, should deliver quick value to the organization and its users.

9 References

1) Helfer, Jeffrey, Diffinity Genomics Executive Summary, Diffinity Genomics reference material, 150 Lucius Gordon Drive, West Henrietta, NY, 14586 (Referenced information included in attachment #1.)
2) McFadden, Fred, Hoffer, Jeffrey, Prescott, Mary, (1999), Modern Database Management, Massachusetts, Addison-Wesley
3) Shepherd, John C., (1990), Database Management: Theory and Application, Illinois, Irwin.
4) Yao, S. Bing (ed), (1985), Principles of Database Design, New Jersey, Prentice-Hall
5) You Tube video "PCR" uploaded by ayalush78 on May 6, 2007 http://www.youtube.com/watch?v=_YgXcJ4n-kQ&feature=g-hist
6) FileMaker Pro User's Guide

10 LIST OF TABLES

22	Sumary of Tables available in FileMaker Pro Shop Floor Control software.
23	Diffinity Genomics product launch as of 5/2012

11 LIST OF FIGURES

12 Attachments

Attachment #1 Diffinity Genomics Executive Summary

12.1 Attachment #1 Diffinity Genomics Executive Summary

Market Focus:
- Life science laboratories

Market Size:
- Disrupts existing $1.2 billion market
- CAGR = 13.6%
- 390,000 prospective customers working in 45,000 labs worldwide

Product Value Proposition:
- 10-25X savings of time
- Exceptionally easy to use
- Excellent purified sample quality
- Reduced labor and capital costs
- Seamless integration into existing lab workflows
- Reduced environmental impact

Intellectual Property:
- Portfolio includes materials, consumable designs, manufacturing processes and methods of use. Patents pending.

Key Customers:
- Biotech and pharmaceutical companies
- University, hospital and government labs
- Genome centers

Projected Revenues:
- 2011 - $80K
- 2012 - $1.2M
- 2013 - $5.3M
- 2014 - $13.2M
- Gross margins 50-70 %

Stage:
- Scale up
- Broad portfolio of products to be launched over the next 18 months

Funding:
- $1.8M dilutive (Angel) and $1.8M non-dilutive (grant) financing to date
- Seeking final $600K-$1.2M to grow worldwide product marketing and sales capabilities
- Debt free
- Federal investment credits are available to qualified investors

Executive Summary

Diffinity Genomics is a closely held New York State C Corporation that has developed proprietary technologies for separating molecules in solution for a large span of applications. We are currently selling high-volume, high-margin, single-use products to the rapidly growing $1.2 billion non-regulated life science market for nucleic acid (e.g. DNA) extraction and purification products. Our products provide dramatic improvements in customer productivity, ease of use, labor requirements, capital costs, and environmental waste.

Our initial target is the market for nucleic acid extraction and purification tools, one of the largest and fastest growing segments of the life science industry (13.6% CAGR). Diffinity's RapidTip™ is targeting a severe bottleneck in the ubiquitous process for extracting and purifying nucleic acids for many downstream applications. The RapidTip™ reduces the time required to purify nucleic acids by more than 10-25 fold while reducing labor and capital costs. It's simple design integrates seamlessly into existing laboratory workflows.

Our high-margin RapidTip™ consumable is a single-use, completely self-contained "functional" pipette tip that enables very rapid sample purification in a single simple step with no additional reagents or capital equipment. There are approximately 670 million extraction and purifications performed each year by approximately 390,000 life science professionals working in 45,000 labs worldwide.

A box containing 96 RapidTips™ lists at $160. We are currently selling direct in the U.S., have already recruited 12 U.S. and international distributors and expect to add to this list, including the leading worldwide supplier to the biological, chemical and laboratory consumable markets. The Company's products do not require regulatory approval.

Diffinity Genomics is committed to building jobs in Western New York. The Company manufactures its consumables at its factory in Rochester, NY. Diffinity uses local vendors for services, components, and supplies. We currently have 12 employees, with 4 additional product sales and marketing positions to be filled over the next 12 months.

Having already spent a number of years incubating the technology, product designs and manufacturing processes, our goal is now to profitably achieve a valuation greater than $40 million within the next 3-4 years and realize a successful exit event for our genomic business, prior to commercializing non-genomic applications of the Company's molecular separation technologies. We are positioned for rapid growth through the introduction of products that offer a strong value proposition for other unmet nucleic acid extraction/purification needs and other molecular separation applications, all by leveraging previously developed technologies, product designs, manufacturing processes and marketing expertise. We now seek additional funding to introduce portfolio products, grow sales and earnings, and position the Company as a market leader as a precursor to a successful exit event.

Diffinity's technology and initial product were awarded a Top 10 Life Science Innovation Award for 2010 by *The Scientist* (finishing 4th and ahead of several billion-dollar companies). The company was also awarded the North American 2011 Entrepreneurial Company of the Year – Life Science Research Tools, by a leading business research firm and was selected by the White House Business Council as an example of a technology-based economic development success story.

Diffinity's management team includes multiple, successful serial entrepreneurs accomplished in R&D, operations, sales and marketing, business development, finance, mergers/acquisitions, and substantial knowledge of the genomics industry.

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