2015 Alabama Newborn Screening Conference

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Prattville, Alabama
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Filtering Through the Filter Paper

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Newborn Screening
Customer Service Leader

Who Are We?

- Founded in 1964, our primary focus was servicing the Textile Industry in the Southeast
- In 1968 a group of doctors from New York, North Carolina, and Duke University approached us about manufacturing medical devices for DBS

Who Are We?

- Through trial and error, we were able to develop a satisfactory DBS product
- A year later, we produced our first product for testing in the state of NC - we soon began to sell regionally in the Southeast
- Since that time, we have grown our NBS business, providing Newborn Screening devices in the US and throughout the world

What is 903 Paper?

- Cotton-based paper
- Manufactured from a paper mill that has over 30 years' experience perfecting the cotton blend:
  - Cotton fibers vary from region to region throughout the US
  - 903 paper made up of short and long cotton fibers, along with a percentage of shaved cotton fibers from seed

What is 903 Paper?

  - Cotton blend combined with water comprises the slurry
  - Most consistent filter paper on the market
- Filter paper is relatively unstable – this must be accounted for during production

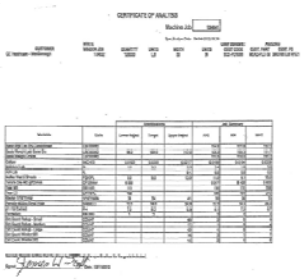
What are the Factors that may affect Blood Absorption of 903 Paper?

- **Paper contamination (glue, inks, etc.)**
- **Paper compression (Calendering)**
- **Environment (Temperature / Humidity)**

What happens to the filter paper before it arrives at our facility?

Tested by Manufacturer

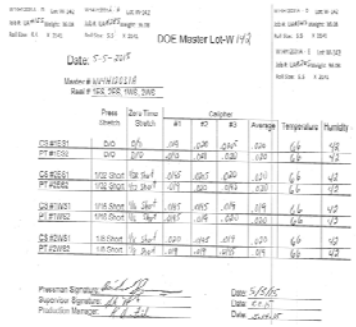
During the manufacturing, Independent QC team is there to observe



Tested by the CDC

Tested by us for Absorbency:

We also test paper for stability and stretch. This is done over a 6 day time period:



DOE Master Lot-W 142

Date: 5-6-2015

Master # W14H1201A
Reel # 1ES, 2ES, 1WS, 2WS

	Press Stretch	24 Hours Stretch	Caliper #1	#2	#3	Average	Temperature	Humidity
CS #1ES1	D/O	1/16 Long	.0155	.019	.020	.020	66	42
PT #1ES2	D/O	1/16 Long	.020	.0205	.020	.020	66	42
CS #2ES1	1/32 Short	1/32 Long	.0205	.0195	.019	.020	66	42
PT #2ES2	1/32 Short	1/32 Long	.021	.019	.020	.020	66	42
CS #1WS1	1/16 Short	1/32 Long	.0195	.0195	.020	.020	66	42
PT #1WS2	1/16 Short	D/O	.0195	.019	.020	.020	66	42
CS #2WS1	1/8 Short	1/16 Short	.020	.0205	.021	.021	66	42
PT #2WS2	1/8 Short	1/32 Long	.019	.019	.0195	.019	66	42

Pressman Signature: [signature] Date: 5/6/15
Supervisor Signature: [signature] Date: 5-6-15
Production Manager: [signature] Date: 5-14-15

DOE Master Lot-W 142

Date: 5-7-2015

Master # W14H1202A
Reel # 1ES, 2ES, 1WS, 2WS

	Press Stretch	48 Hours Stretch	Caliper #1	#2	#3	Average	Temperature	Humidity
CS #1ES1	D/O	3/64 Long	.0195	.019	.0205	.020	68	42
PT #1ES2	D/O	3/64 Long	.0195	.019	.0205	.020	68	42
CS #2ES1	1/32 Short	1/32 Long	.0205	.0195	.0195	.020	68	42
PT #2ES2	1/32 Short	1/32 Long	.0195	.019	.0205	.019	68	42
CS #1WS1	1/16 Short	1/32 Long	.0195	.019	.020	.020	68	42
PT #1WS2	1/16 Short	1/32 Long	.0195	.0185	.0205	.020	68	42
CS #2WS1	1/8 Short	1/32 Short	.0205	.020	.0195	.020	68	42
PT #2WS2	1/8 Short	1/32 Short	.0195	.0195	.020	.020	68	42

Pressman Signature: [signature] Date: 5/7/15
Supervisor Signature: [signature] Date: 5-7-15
Production Manager: [signature] Date: 5-14-15

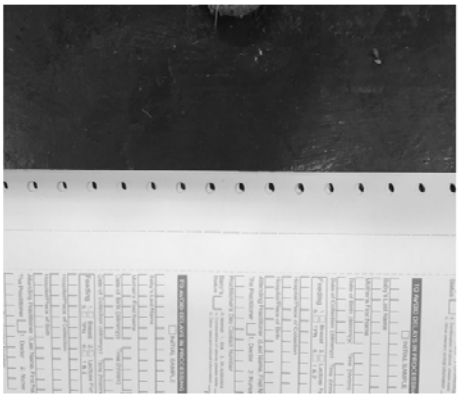
DOE Master Lot-W 142

Date: 5-11-2015

Master # W14H1203A
Reel # 1ES, 2ES, 1WS, 2WS

	Press Stretch	144 Hours Stretch	Caliper #1	#2	#3	Average	Temperature	Humidity
CS #1ES1	D/O	D/O	.019	.0195	.020	.020	67	42
PT #1ES2	D/O	1/32 Long	.019	.019	.0195	.019	67	43
CS #2ES1	1/32 Short	1/32 Long	.0195	.019	.021	.020	67	42
PT #2ES2	1/32 Short	1/32 Long	.020	.020	.020	.020	67	43
CS #1WS1	1/16 Short	1/32 Long	.021	.0195	.0195	.020	67	42
PT #1WS2	1/16 Short	1/32 Long	.019	.020	.020	.020	67	43
CS #2WS1	1/8 Short	1/32 Short	.0205	.0195	.0195	.020	67	42
PT #2WS2	1/8 Short	1/32 Short	.0195	.020	.0205	.020	67	42

Pressman Signature: [signature] Date: 5/11/15
Supervisor Signature: [signature] Date: 5-11-15
Production Manager: [signature] Date: 5-14-15

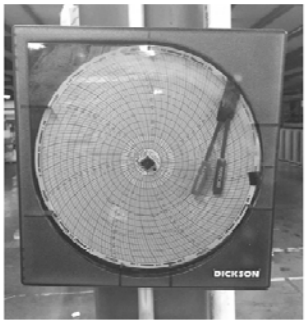


How do we handle the paper from receipt, to manufacturing of the cards, to shipment?

- Master Rolls come well protected from the manufacturer
- Protected with a heavy wax paper

- Paper inspected prior to receipt - refused if damage noted

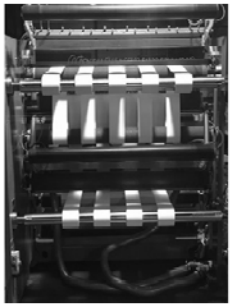
- Paper stored in a temperature controlled environment



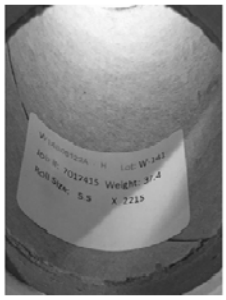
When order is entered and 903 paper is assigned, the Master Rolls are moved into the slitting area:

Master Reels are loaded onto the Slitter:

Reels are slit according to job specification:



Each Slit reel is labeled with Master Reel Number and Job:



Slit Reels then packaged back into protective bag and carton to await manufacturing:

During Manufacturing and Printing of the Medical Device, periodic inspection is performed to ensure High Quality:

- **1 Bar sheet taken off each 903 roll and measured with a micrometer to ensure proper paper thickness (Testing for Paper Calendering)**
- **The number range is also noted to allow for traceability back to a specific roll**

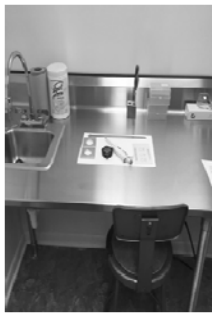
After Cards are Printed and Manufactured, QC samples are pulled from Beginning, Middle, and End of the job and taken to the QC/Final Inspection

Here they are Inspected for Construction Quality:

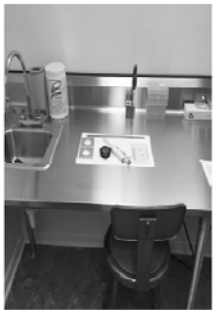
After the QC tester completes visual testing of the cards, they are taken to the Blood Lab for further testing

Here, the paper is tested for absorbency, which is measured by:

- **Speed (must be 5 to 30 seconds per *CLSI)**
- **Blood Spot Diameter (must be 15 to 17mm per *CLSI)**



***CLSI - The Clinical and Laboratory Standards Institute which determines the appropriate guidelines and standards for all procedures and processes related to the newborn screening**



Blood Lab Parameters:

- **Human Whole Blood supplied by an approved supplier that complies with current CLSI NBS01-A6 standards for Blood Collection Paper for NBS Programs**
- **Blood comes with a Hematocrit adjusted to 55% from one donor, with a 30 day expiration date**
- **Whole Blood is stored in the lab at a temperature of 35 to 47 degrees Fahrenheit**

Instrument used to dispense blood (Micropipette) is calibrated to eject the correct amount of blood:

- **100 ul for 15mm circle**

Our Phlebotomist is responsible for conducting the testing:

Absorbency Time & Diameter is recorded for each job:

Blood Test results must fall within CLSI standards before QC release:

- **5-30 seconds**
- **15-17mm circle diameter**

Packaging and Shipping of Product

- **All cards loose wrapped in 50s or 100s:**

Packs are then placed into shipping cartons:

Cartons then placed on pallet (3 high), with corner braces placed around each end, and strapped to pallets before shrink wrapped:

All pallets are marked with 'Do not stack' on all four sides:

We select only the most reputable carriers for transporting, HOWEVER this can occasionally happen:

What do I do if this happens to us?

Refuse shipment and contact supplier immediately!

What are some things that YOU can do to protect the Filter Paper to insure accurate readings?

- Limit the handling of the filter paper
- Keep out of direct sunlight
- Do not store in high humidity environment
- Allow cards to acclimate to the environment if coming from very hot warehouse
- Do not stack cartons more than 3

- In lab, avoid storing near any sources of heat (i.e. infant warmers or computer monitors)
- In lab, keep away from water sources (sinks, food/drinks, etc)

Faculty

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