

2015 Alabama Newborn Screening Conference



**Marriott Hotel and Conference Center
Prattville, Alabama
Friday, September 18, 2015**

Filtering Through the Filter Paper

**Will Adams
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**

CERTIFICATE OF ANALYSIS

Machine ID: 0000

Item	Unit	Value	Target	Acceptance	Lot	Lot	Lot
1.0000	g	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000
2.0000	g	2.0000	2.0000	2.0000	2.0000	2.0000	2.0000
3.0000	g	3.0000	3.0000	3.0000	3.0000	3.0000	3.0000
4.0000	g	4.0000	4.0000	4.0000	4.0000	4.0000	4.0000
5.0000	g	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000
6.0000	g	6.0000	6.0000	6.0000	6.0000	6.0000	6.0000
7.0000	g	7.0000	7.0000	7.0000	7.0000	7.0000	7.0000
8.0000	g	8.0000	8.0000	8.0000	8.0000	8.0000	8.0000
9.0000	g	9.0000	9.0000	9.0000	9.0000	9.0000	9.0000
10.0000	g	10.0000	10.0000	10.0000	10.0000	10.0000	10.0000

Signature: [Signature]

**Tested by the
CDC**

Certificate of Analysis

This certifies that the Paper Product described below was manufactured in accordance with ☐ (Medline approved specifications and/or met physical attributes per the paper grade specification.

CDC Code: 903

Lot Number: 0001

Paper Description: 100% pure cotton fibers, with no additives

Individual Data	Mean	Std. Deviation
Mean (g)	0.5	0.1
Mean (mm) (g) (1.00 g)	1.0	0.1
Mean (mm) (g) (1.00 g)	1.0	0.1
Mean (mm) (g) (1.00 g)	1.0	0.1

Note: The Absorbency (g) was determined by the method described in section 2.1.

Signature: [Signature]
Quality Assurance Representative

Date: 10/26/2015

**Tested by us
for
Absorbency:**

903 Blood Absorbency Test Results

Sample	Pressure (mmHg)	Time (min)	Absorbency (g)	Notes
1	1.0	1.0	0.5	
2	1.0	1.0	0.5	
3	1.0	1.0	0.5	
4	1.0	1.0	0.5	
5	1.0	1.0	0.5	
6	1.0	1.0	0.5	
7	1.0	1.0	0.5	
8	1.0	1.0	0.5	
9	1.0	1.0	0.5	
10	1.0	1.0	0.5	
11	1.0	1.0	0.5	
12	1.0	1.0	0.5	
13	1.0	1.0	0.5	
14	1.0	1.0	0.5	
15	1.0	1.0	0.5	
16	1.0	1.0	0.5	
17	1.0	1.0	0.5	
18	1.0	1.0	0.5	
19	1.0	1.0	0.5	
20	1.0	1.0	0.5	

Signature: [Signature]

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

DOE Master Lot-W/H

Date: 10/26/2015

Tester: [Signature]

Run: 1.00, 2.00, 3.00, 4.00, 5.00, 6.00

Press (mmHg)	Time (min)	Temp (°C)	Humidity (%)	Average	Temp (°C)	Humidity (%)
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0
1.0	1.0	20.0	60.0	0.5	20.0	60.0

Signature: [Signature]

Date: 10/26/2015

DOE Master Lot-W/42

Date: 5-6-2015

Master # W/H/H/001A
Reel # 1ES, 2ES, 1WS, 2WS

	Press Stretch	24 Hours Stretch	Caliper				Temperature	Humidity
			#1	#2	#3	Average		
CS #1ES1	D/D	1/16 Long	.015	.019	.020	.020	66	42
PT #1ES2	D/D	1/16 Long	.020	.025	.020	.020	66	42
CS #2ES1	1/32 Short	1/32 Long	.020	.015	.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	.015	.015	.020	.020	66	42
PT #1WS2	1/16 Short	D/D	.015	.019	.020	.020	66	42
CS #2WS1	1/8 Short	1/16 Short	.020	.025	.021	.021	66	42
PT #2WS2	1/8 Short	1/16 Long	.019	.015	.019	.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/42

Date: 5-7-2015

Master # W/H/H/001A
Reel # 1ES, 2ES, 1WS, 2WS

	Press Stretch	48 Hours Stretch	Caliper				Temperature	Humidity
			#1	#2	#3	Average		
CS #1ES1	D/D	3/16 Long	.015	.019	.020	.020	68	42
PT #1ES2	D/D	3/16 Long	.015	.019	.020	.020	68	42
CS #2ES1	1/32 Short	1/32 Long	.015	.015	.015	.020	68	42
PT #2ES2	1/32 Short	1/32 Long	.015	.015	.015	.020	68	42
CS #1WS1	1/16 Short	1/32 Long	.015	.019	.020	.020	68	42
PT #1WS2	1/16 Short	1/32 Long	.015	.015	.020	.020	68	42
CS #2WS1	1/8 Short	1/32 Short	.020	.020	.015	.020	68	42
PT #2WS2	1/8 Short	1/32 Short	.015	.015	.020	.020	68	42

Pressman Signature: *[Signature]* Date: 5/6/15
 Supervisor Signature: *[Signature]* Date: 5-7-15
 Production Manager: *[Signature]* Date: 5-14-15

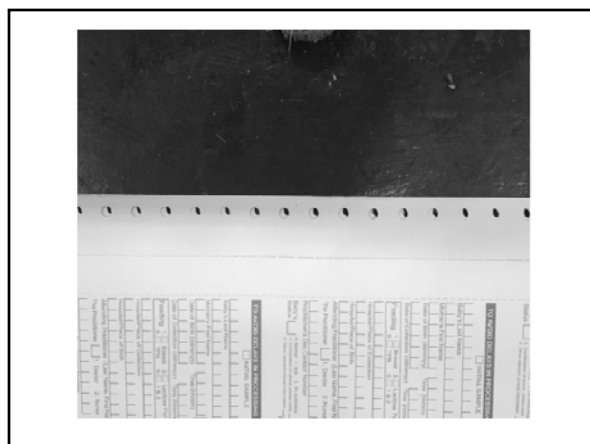
DOE Master Lot-W/42

Date: 5-11-2015

Master # W/H/H/001A
Reel # 1ES, 2ES, 1WS, 2WS

	Press Stretch	144 Hours Stretch	Caliper				Temperature	Humidity
			#1	#2	#3	Average		
CS #1ES1	D/D	D/D	.015	.015	.020	.020	67	42
PT #1ES2	D/D	1/32 Long	.019	.019	.015	.019	67	42
CS #2ES1	1/32 Short	1/32 Long	.015	.019	.021	.020	67	42
PT #2ES2	1/32 Short	1/32 Long	.020	.020	.020	.020	67	42
CS #1WS1	1/16 Short	1/32 Long	.021	.015	.015	.020	67	42
PT #1WS2	1/16 Short	1/32 Long	.015	.020	.020	.020	67	42
CS #2WS1	1/8 Short	1/32 Short	.020	.015	.015	.020	67	42
PT #2WS2	1/8 Short	1/32 Short	.015	.020	.020	.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

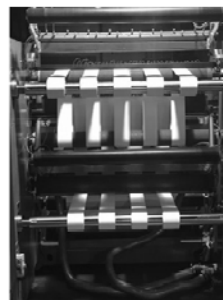



When order is entered and 903 paper is assigned, the Master Rolls are moved into the slitting area:

Master Reels are loaded onto the Slitter:



Reels are slit according to job specification:





WYCOMBTONA N Lot W-241
Job N. 7012435 Weight: 3'4'
Rolls: 53 X 2215

$\Delta H^\circ_{\text{f}}(\text{g})$	$\Delta H^\circ_{\text{f}}(\text{aq})$	$\Delta H^\circ_{\text{f}}(\text{aq})$
	SO_4^{2-}	SO_4^{2-}
	H_2SO_4	H_2SO_4

QUALITY CONTROL FORM			
MATERIAL FORMER PART NO. <u>12-002</u>		DIN. <u>22-000000</u>	
MATERIAL COMBINATION <u>ALU. / AL</u>		DATE <u>11-02-2018</u> - <u>08-02-2019</u>	
CONSTRUCTION			
SPECS FOR THE PARTS			
REV.	DESCRIPTION	DATE	BY
01	12-002-001	11-02-2018	ALU
02	12-002-002	11-02-2018	ALU
03	12-002-003	11-02-2018	ALU
04	12-002-004	11-02-2018	ALU
05	12-002-005	11-02-2018	ALU
06	12-002-006	11-02-2018	ALU
07	12-002-007	11-02-2018	ALU
08	12-002-008	11-02-2018	ALU
09	12-002-009	11-02-2018	ALU
10	12-002-010	11-02-2018	ALU
11	12-002-011	11-02-2018	ALU
12	12-002-012	11-02-2018	ALU
13	12-002-013	11-02-2018	ALU
14	12-002-014	11-02-2018	ALU
15	12-002-015	11-02-2018	ALU
16	12-002-016	11-02-2018	ALU
17	12-002-017	11-02-2018	ALU
18	12-002-018	11-02-2018	ALU
19	12-002-019	11-02-2018	ALU
20	12-002-020	11-02-2018	ALU
21	12-002-021	11-02-2018	ALU
22	12-002-022	11-02-2018	ALU
23	12-002-023	11-02-2018	ALU
24	12-002-024	11-02-2018	ALU
25	12-002-025	11-02-2018	ALU
26	12-002-026	11-02-2018	ALU
27	12-002-027	11-02-2018	ALU
28	12-002-028	11-02-2018	ALU
29	12-002-029	11-02-2018	ALU
30	12-002-030	11-02-2018	ALU
31	12-002-031	11-02-2018	ALU
32	12-002-032	11-02-2018	ALU
33	12-002-033	11-02-2018	ALU
34	12-002-034	11-02-2018	ALU
35	12-002-035	11-02-2018	ALU
36	12-002-036	11-02-2018	ALU
37	12-002-037	11-02-2018	ALU
38	12-002-038	11-02-2018	ALU
39	12-002-039	11-02-2018	ALU
40	12-002-040	11-02-2018	ALU
41	12-002-041	11-02-2018	ALU
42	12-002-042	11-02-2018	ALU
43	12-002-043	11-02-2018	ALU
44	12-002-044	11-02-2018	ALU
45	12-002-045	11-02-2018	ALU
46	12-002-046	11-02-2018	ALU
47	12-002-047	11-02-2018	ALU
48	12-002-048	11-02-2018	ALU
49	12-002-049	11-02-2018	ALU
50	12-002-050	11-02-2018	ALU
51	12-002-051	11-02-2018	ALU
52	12-002-052	11-02-2018	ALU
53	12-002-053	11-02-2018	ALU
54	12-002-054	11-02-2018	ALU
55	12-002-055	11-02-2018	ALU
56	12-002-056	11-02-2018	ALU
57	12-002-057	11-02-2018	ALU
58	12-002-058	11-02-2018	ALU
59	12-002-059	11-02-2018	ALU
60	12-002-060	11-02-2018	ALU
61	12-002-061	11-02-2018	ALU
62	12-002-062	11-02-2018	ALU
63	12-002-063	11-02-2018	ALU
64	12-002-064	11-02-2018	ALU
65	12-002-065	11-02-2018	ALU
66	12-002-066	11-02-2018	ALU
67	12-002-067	11-02-2018	ALU
68	12-002-068	11-02-2018	ALU
69	12-002-069	11-02-2018	ALU
70	12-002-070	11-02-2	

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:

Sample	Batch/ID	Time	Result	Notes
1	100-100	10:00	15.0	100-100
2	100-100	10:05	15.0	100-100
3	100-100	10:10	15.0	100-100
4	100-100	10:15	15.0	100-100
5	100-100	10:20	15.0	100-100
6	100-100	10:25	15.0	100-100
7	100-100	10:30	15.0	100-100
8	100-100	10:35	15.0	100-100
9	100-100	10:40	15.0	100-100
10	100-100	10:45	15.0	100-100
11	100-100	10:50	15.0	100-100
12	100-100	10:55	15.0	100-100
13	100-100	11:00	15.0	100-100
14	100-100	11:05	15.0	100-100
15	100-100	11:10	15.0	100-100
16	100-100	11:15	15.0	100-100
17	100-100	11:20	15.0	100-100
18	100-100	11:25	15.0	100-100
19	100-100	11:30	15.0	100-100
20	100-100	11:35	15.0	100-100
21	100-100	11:40	15.0	100-100
22	100-100	11:45	15.0	100-100
23	100-100	11:50	15.0	100-100
24	100-100	11:55	15.0	100-100
25	100-100	12:00	15.0	100-100
26	100-100	12:05	15.0	100-100
27	100-100	12:10	15.0	100-100
28	100-100	12:15	15.0	100-100
29	100-100	12:20	15.0	100-100
30	100-100	12:25	15.0	100-100
31	100-100	12:30	15.0	100-100
32	100-100	12:35	15.0	100-100
33	100-100	12:40	15.0	100-100
34	100-100	12:45	15.0	100-100
35	100-100	12:50	15.0	100-100
36	100-100	12:55	15.0	100-100
37	100-100	13:00	15.0	100-100
38	100-100	13:05	15.0	100-100
39	100-100	13:10	15.0	100-100
40	100-100	13:15	15.0	100-100
41	100-100	13:20	15.0	100-100
42	100-100	13:25	15.0	100-100
43	100-100	13:30	15.0	100-100
44	100-100	13:35	15.0	100-100
45	100-100	13:40	15.0	100-100
46	100-100	13:45	15.0	100-100
47	100-100	13:50	15.0	100-100
48	100-100	13:55	15.0	100-100
49	100-100	14:00	15.0	100-100
50	100-100	14:05	15.0	100-100
51	100-100	14:10	15.0	100-100
52	100-100	14:15	15.0	100-100
53	100-100	14:20	15.0	100-100
54	100-100	14:25	15.0	100-100
55	100-100	14:30	15.0	100-100
56	100-100	14:35	15.0	100-100
57	100-100	14:40	15.0	100-100
58	100-100	14:45	15.0	100-100
59	100-100	14:50	15.0	100-100
60	100-100	14:55	15.0	100-100
61	100-100	15:00	15.0	100-100
62	100-100	15:05	15.0	100-100
63	100-100	15:10	15.0	100-100
64	100-100	15:15	15.0	100-100
65	100-100	15:20	15.0	100-100
66	100-100	15:25	15.0	100-100
67	100-100	15:30	15.0	100-100
68	100-100	15:35	15.0	100-100
69	100-100	15:40	15.0	100-100
70	100-100	15:45	15.0	100-100
71	100-100	15:50	15.0	100-100
72	100-100	15:55	15.0	100-100
73	100-100	16:00	15.0	100-100
74	100-100	16:05	15.0	100-100
75	100-100	16:10	15.0	100-100
76	100-100	16:15	15.0	100-100
77	100-100	16:20	15.0	100-100
78	100-100	16:25	15.0	100-100
79	100-100	16:30	15.0	100-100
80	100-100	16:35	15.0	100-100
81	100-100	16:40	15.0	100-100
82	100-100	16:45	15.0	100-100
83	100-100	16:50	15.0	100-100
84	100-100	16:55	15.0	100-100
85	100-100	17:00	15.0	100-100
86	100-100	17:05	15.0	100-100
87	100-100	17:10	15.0	100-100
88	100-100	17:15	15.0	100-100
89	100-100	17:20	15.0	100-100
90	100-100	17:25	15.0	100-100
91	100-100	17:30	15.0	100-100
92	100-100	17:35	15.0	100-100
93	100-100	17:40	15.0	100-100
94	100-100	17:45	15.0	100-100
95	100-100	17:50	15.0	100-100
96	100-100	17:55	15.0	100-100
97	100-100	18:00	15.0	100-100
98	100-100	18:05	15.0	100-100
99	100-100	18:10	15.0	100-100
100	100-100	18:15	15.0	100-100

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

**Will Adams
Newborn Screening
Customer Service Leader**