



DEVELOPMENT PROJECT

TheraSphere Label Integrity Report

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Signatures

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Document History

Date	Version	Comments	Prepared by	Reviewed by	Approved by
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Report on TheraSphere Label Integrity Test

4 Preparation

4.1 Materials

- 4.1.1 Label material to be evaluated, to be noted in the report document.
- 4.1.2 Tex-wipe sterile alcohol swipes
- 4.1.3 Whatman AG/2 filter paper disks – 5cm diameter
- 4.1.4 Wet wipes (water)
- 4.1.5 250mL beaker filled with water
- 4.1.6 Three (3) TheraSphere lead pots
- 4.1.7 Three (3) TheraSphere Lucite shields
- 4.1.8 Three (3) TheraSphere Administration Sets

4.2 Equipment

- 4.2.1 HP LaserJet IV Printer – KOB1-ISO TECHPOOL-Q
- 4.2.2 Fisher Isotemp Vacuum Oven – model 281
- 4.2.3 Calibrated thermocouple – Type K
- 4.2.4 Calibrated Type K Thermocouple Thermometer – FLUKE 52 K/J Thermometer
- 4.2.5 Humidity Meter – Omega Model RH70
- 4.2.6 Microbiology Freezer Room 1229
- 4.2.7 Digital Camera

5 Procedure

Label Material: *laser stock - standard paper based (matte finish) 'A'*

5.1 Alcohol Swipe Test

- 5.1.1 Print the TheraSphere label production template, using dummy lot numbers and expiry dates, on label samples using the HP Laser Jet IV located in Radiopharm. Print nine (9) copies of each sample. Properly identify each sample by the following numbering system (p1, p2, p3 – for pots; s1, s2, s3 – for shields, a1, a2, a3 – for administrative sets).
- 5.1.2 Label all pots, shields, and administrative sets with the label samples.
- 5.1.3 Swipe in circular motions the paper label with a Tex-wipe alcohol swipe, ensuring to swipe over all printed areas.

Performed by	Witnessed by
<i>ca</i>	
<i>ca</i>	

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	Performed by	Witnessed by
5.1.4 Observe if the ink smeared, if the printed image is clear and if the paper integrity was damaged from the alcohol swipe test. The ink should not smear, the image should remain clear, and the paper integrity should not be damaged.	ca	
5.1.5 Repeat steps 5.1.3 to 5.1.4 two additional times on the same paper sample.	ca	
5.1.6 Repeat steps 5.1.3 to 5.1.5 for <u>all</u> remaining samples. Observe the clarity of the printed image and paper integrity of the samples. Take pictures of all label samples and attach to this document. Record all observations.	ca	

Table I: Label Integrity Observations – Alcohol Swipe Test

Samples	Observations						Performed by	Date
	Ink Smearing			Paper Integrity				
	Trial #1	Trial #2	Trial #3	Trial #1	Trial #2	Trial #3		
pot #1	• some	• very little	no smearing	ok	ok	ok	ca	4/12/98
pot #2	black ink on wipe	black ink on wipe	clear print	↓	↓	↓	↓	↓
pot #3	• no	no	↓	↓	↓	↓	↓	↓
shield #1	smearing	smearing	↓	↓	↓	↓	↓	↓
shield #2	• clear print	clear print	↓	↓	↓	↓	↓	↓
shield #3	↓	↓	↓	↓	↓	↓	↓	↓
admin #1	↓	↓	↓	↓	↓	↓	↓	↓
Admin #2	↓	↓	↓	↓	↓	↓	↓	↓
Admin #3	↓	↓	↓	↓	↓	↓	↓	↓
Label Integrity Acceptance Criteria Met? (YES or NO)								
Lead Pot:	Yes						ca	4/12/98
Lucite Shield:	Yes						↓	↓
Administration Sets:	Yes						↓	↓

5.2 Dry Swipe Test

	Performed by	Witnessed by
5.2.1 Swipe the labels on the pots, shields, and administration sets using a circular motion with a Whatman filter paper disk. Ensure all printed areas are wiped.	ca	
5.2.2 Observe if the ink smears, if the printed image is clear and if the paper integrity is damaged from the alcohol swipe test. The ink should not smear, the image should remain clear, and the paper integrity should not be damaged.	ca	
5.2.3 Repeat steps 5.2.1 to 5.2.2 two additional times on the same paper sample.	ca	

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5.2.4 Repeat steps 5.2.1 to 5.2.3 for all remaining samples. Observe the clarity of the printed image and paper integrity of the samples. Take pictures of label samples if a change is noticed and attach to this document. Retain all samples for the wet swipe test.

Performed by	Witnessed by
CA	

Table II: Label Integrity Observations – Dry Swipe Test

Samples	Observations						Performed by	Date
	Ink Smearing			Paper Integrity				
	Trial #1	Trial #2	Trial #3	Trial #1	Trial #2	Trial #3		
pot #1	some ink	some ink	some ink	OK	OK	OK	CA	4/12/98
pot #2	on wipe	clear	clear	↓	↓	↓	↓	↓
pot #3	no smearing	print	print	↓	↓	↓	↓	↓
shield #1	clear	no	no	↓	↓	↓	↓	↓
shield #2	print	smearing	smearing	↓	↓	↓	↓	↓
shield #3	↓	↓	↓	↓	↓	↓	↓	↓
admin #1	↓	↓	↓	↓	↓	↓	↓	↓
admin #2	↓	↓	↓	↓	↓	↓	↓	↓
admin #3	↓	↓	↓	↓	↓	↓	↓	↓
Label Integrity Acceptance Criteria Met? (YES or NO)								
Lead Pot:	Yes						CA	4/12/98
Lucite Shield:	Yes						↓	↓
Administration Sets:	Yes						↓	↓

5.3 Wet Swipe Test

5.3.1 Swipe the label sample with a wet wipe using a circular motion. Ensure all printed areas are wiped.

5.3.2 Observe if the ink smears, if the printed image is clear and if the paper is damaged from the swipe test.

5.3.3 Repeat steps 5.3.1 to 5.3.2 two additional times on the same sample. Use a new wet rag for every wet swipe test.

5.3.4 Repeat steps 5.3.1 to 5.3.3 for all remaining samples. Observe the clarity of the printed image and paper integrity of the samples. Take pictures of label samples if a change is noticed and attach to this document.

Performed by	Witnessed by
CA	
CA	
CA	

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Table III: Label Integrity Observations – Wet Swipe Test

Samples	Observations						Performed by	Date
	Ink Smearing			Paper Integrity				
	Trial #1	Trial #2	Trial #3	Trial #1	Trial #2	Trial #3		
pot #1	no smearing	OK	OK	OK	OK	OK	ca	4/12/98
pot #2	↓	↓	↓	↓	↓	↓	↓	↓
pot #3	↓	↓	↓	↓	↓	↓	↓	↓
shield #1	clear print	(no smearing clear print)	↓	↓	↓	↓	↓	↓
shield #2	↓	↓	↓	↓	↓	↓	↓	↓
shield #3	↓	↓	↓	↓	↓	↓	↓	↓
admin #1	↓	↓	↓	↓	↓	↓	↓	↓
admin #2	↓	↓	↓	↓	↓	↓	↓	↓
admin #3	↓	↓	↓	↓	↓	↓	↓	↓
Label Integrity Acceptance Criteria Met? (YES or NO)								
Lead Pot:	Yes						ca	4/12/98
Lucite Shield:	Yes						↓	↓
Administration Sets:	Yes						↓	↓

5.4 Humidity/Temperature and Dry Swipe Test

Equipment	ID #	Calibration Date	Calibration Due Date	Performed by	Date
Thermocouple	6-750-372	Nov 98	Nov 99	ca	4/12/98
Thermocouple meter	6-809-280	Nov 98	Nov 99	↓	↓
Humidity meter	6-809-292	Nov 98	Nov 99	↓	↓
Oven	6-330-020	N/A	N/A	↓	↓

		Performed by	Witnessed by
5.4.1	Fill the 250mL beaker with water and place on the bottom shelf of the Fisher Isotemp Vacuum Oven.	ca	
5.4.2	Record thermocouple and thermocouple meter calibration and expiry dates and MDS Nordion identification numbers Insert the thermocouple in the oven. Close the oven.	ca	
5.4.3	Set the oven at 40+° C and allow the oven time to stabilise and condensation to be seen on the oven door (indicating that the oven is saturated with water). Record the temperature and humidity level.	ca	
	Temperature	ca	
	Humidity level:	ca	

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		Performed by	Witnessed by
5.4.4	Once the temperature of the oven has stabilised, place the sample all pots and shields on the top shelf of the oven and close the oven door.	CA	
5.4.5	Leave the samples in the oven for 30+ minutes. Remove one sample at a time from the oven, closing the oven door afterwards.	CA	
5.4.6	Swipe, in circular motions, the label sample with a Whatman filter, ensuring to swipe over all the printed areas.	CA	
5.4.7	Observe if the ink smears, if the printed image is clear and if the paper is damaged from the swipe test. Place the sample back into the oven.	CA	
5.4.8	Repeat steps 5.4.4 to 5.4.7 for all samples in the oven. Once all pots and shields have been tested once, repeat steps 5.4.4 to 5.4.7 for each sample two additional times. Use a new Whatman paper filter for each swipe test.	CA	
5.4.9	Once all pots and shields have been tested, remove them from the oven and place the administration sets into the oven. Repeat steps 5.4.1 to 5.4.8 for <u>all</u> remaining administration sets. Remove the administration sets from the oven once each set has been tested three (3) times.	CA	
5.4.10	Observe the clarity of the printed image and paper integrity of the samples. Take pictures of label samples if a change is noticed and attach to this document	CA	

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Table IV: Label Integrity Observations – High Humidity/High Temperature and Dry Swipe Test

Samples	Observations						Performed by	Date
	Ink Smearing			Paper Integrity				
	Trial #1	Trial #2	Trial #3	Trial #1	Trial #2	Trial #3		
pot #1	OK	OK	OK	OK	OK	OK	CA	4/12/98
pot #2	↓	↓	↓	↓	↓	↓	↓	
pot #3	↓	↓	↓	↓	↓	↓	↓	
shield #1	↓	↓	↓	↓	↓	↓	↓	
shield #2	↓	↓	↓	↓	↓	↓	↓	
shield #3	small ink smearing	↓	↓	↓	↓	↓	↓	
admin #1	OK	OK	OK	↓	↓	↓	↓	
admin #2	↓	some print off	same as #2	↓	↓	↓	↓	
admin #3	↓	OK	OK	↓	↓	↓	↓	
Label Integrity Acceptance Criteria Met? (YES or NO)								
Lead Pot:	Yes						CA	4/12/98
Lucite Shield:	Yes						↓	↓
Administration Sets:	Yes (One sample tiny bit off)						↓	↓

5.5 Low Humidity/Low Temperature and Dry Swipe Test

Equipment	ID #	Calibration Date	Calibration Due Date	Performed by	Date
Thermocouple	6-750-288	Sept 98	Sept 99	CA	4/12/98
Thermocouple meter	6-445-045	July 98	July 99	↓	↓
Humidity meter	6-809-292	Nov 98	Nov 99	↓	↓
Freezer	6-710-15	Aug 98	Aug 99	↓	↓

- 5.5.1 Record thermocouple and thermocouple meter calibration and expiry dates and MDS Nordion identification numbers.
- 5.5.2 Measure and record the humidity level and temperature in the freezer
 Humidity: 12% RH
 Temperature: -16°C
- 5.5.3 Place the sample (pot, shield, or administration set) in the freezer and close the freezer door.

Performed by	Witnessed by
CA	
CA	
CA	
CA	

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		Performed by	Witnessed by
5.5.1	Void, remove, and retain the labels from the pots, shields, and administration sets.	CA	
5.5.2	Observe and record on the report document if the labels were removed without tearing from the pot, shield, and administration set.	CA	

Table V: Label Removal Observations

Samples	Observations	Performed by	Date
pot #1	Tears	CA	98/12/09
pot #2	↓	↓	↓
pot #3	↓	↓	↓
shield #1	Tears	CA	98/12/09
shield #2	↓	↓	↓
shield #3	↓	↓	↓
admin #1	Tears	CA	98/12/09
admin #2	↓	↓	↓
admin #3	↓	↓	↓
Acceptance Criteria Met: Is the label tore when removed? (YES or NO)			
Lead Pot:	Yes	CA	98/12/09
Lucite Shield:	Yes	↓	↓
Administration Set:	Yes	↓	↓

Comments: The paper stock has passed all tests.
 And will therefore be the material chosen for the labels.