

Certificate Of Processing

Prepared for ROCKY MOUNTAIN BIOLOGICALS



Isomedix Services


Gamma Process Run ID 66636A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
Porcine Serum	20130610PS	88	CS

Processing Run Start Date/Time: 12-Jul-2013 02:48:23 am Approx. Downtime (hours): 0.60
Processing Run End Date/Time: 12-Jul-2013 06:49:04 am

Minimum Specified Dose (kGy): 30.0	Minimum Delivered Dose (kGy): 31.8
Maximum Specified Dose (kGy): 45.0	Maximum Delivered Dose (kGy): 43.2
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.	

Signature Manifest

Reviewed and E-Signed By
 **Dale Sizemore (QS/RC Technician)**
Document Content Revision: 1

Signed On 7/12/2013 at 8:36 AM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS Isomedix Services
1880 Industrial Drive
Libertyville, IL 60048
Phone: 847-367-1911
Fax: 847-816-6068

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2003/2012, and in alignment with EN ANSI/AAMI/ISO 11137:2006. STERIS Isomedix certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

STERIS Isomedix Services Dosimetry Record

Prepared for ROCKY MOUNTAIN BIOLOGICALS -- Process Run ID 66636A

Date Prepared: 7/12/2013 8:35:39AM

Processing Location: **Libertyville I**
Irradiator / Method: **139, Nordion Cobalt-60 Batch JS 8900 Irradiator #139, ON-STD**
Dosimeter Batch: **Harwell, Batch MB, Calibration Date 10/16/2012 6:00:00PM**
Spectrophotometer: **Beckman, DU-640, Serial #4324261**
Digital Micrometer: **Metralight, MX, Serial #700977**

<u>Carrier</u>	<u>Seg</u>	<u>Coordinate</u>	<u>ABS</u>	<u>Thick (mm)</u>	<u>Final Dose (kGy)</u>	<u>Comment</u>
1	1	0C3	0.8189	2.897	32.2	
1	2	0C7	0.8526	3.036	31.8	
1	3	27A5	1.0083	3.150	41.0	
1	4	27E9	0.8271	2.544	42.3	
4	1	TBA5	0.9603	2.926	43.2	
4	2	TBE5	1.0292	3.168	42.3	

Minimum Dose for Record (kGy): 31.8

Maximum Dose for Record (kGy): 43.2

Last Dosimeter Absorbance Measurement Date/Time: 7/12/2013 7:43:06 AM

Signature Manifest

Prepared By:
 **Tony Lascola (Team Leader)**

Signed On 7/12/2013 at 7:44 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
 **Dale Sizemore (QS/RC Technician)**

Signed On 7/12/2013 at 8:35 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

Comment Legend: OUT = Calc Dose Out of Limits; PID = Pre-Irradiated Dosimeter; GRP = Dosimeter Group