

# STERIS: Gamma Certificate Of Processing

Prepared for: APPLIED LABORATORIES INC (1589)

Gamma Process Run ID: 1073-3916A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
(900-500594) Recovery Sterile Saline Spray 7.4oz/36ct.	C10538	1096	Case
(900-500594) Recovery Sterile Saline Spray 7.4oz/36ct.	C10538 (Retention Samples)	1	Case

Processing Run Start Date: 29-May-21 09:59 AM                      Approx. Downtime (hours): 1.32  
Processing Run End Date: 29-May-21 06:52 PM

<b>Minimum Specified Dose (kGy):</b> 19.6	<b>Minimum Delivered Dose (kGy):</b> 22.1
<b>Maximum Specified Dose (kGy):</b> 36.3	<b>Maximum Delivered Dose (kGy):</b> 31.8

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

**Signature Manifest**  
Reviewed and E-Signed By: **Brittany Soto (QS & RC Technician)**  
Date/Time E-Signed: 2021-06-01 10:31 AM  
Document Content Revision: 1

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, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

**Processing Location**  
2500 Commerce Drive  
Libertyville IL 60048  
Phone: 847-247-4782

**STERIS: Gamma Dosimetry Record**  
**APPLIED LABORATORIES INC (1589)**

Irradiator / Method: IR-218 - ON-STD

Run ID  
**1073-3916A**

Carrier    Seq    Coordinate    Barcode ID    Insert    Instrument    Dose (kGy)    Final Dose (kGy)    Comment

**Signature Manifest**  
Prepared By: Kevin Peraza (Operator III)  
Date/Time E-Signed: 2021-05-30 04:03 AM  
Document Content Revision: 1

Processing Location  
2500 Commerce Drive  
Libertyville IL 60048  
Phone: 847-247-4782

**STERIS: Gamma Dosimetry Record**  
**APPLIED LABORATORIES INC (1589)**

Irradiator / Method: IR-218 - ON-STD

Run ID  
**1073-3916A**

<u>Carrier</u>	<u>Seq</u>	<u>Coordinate</u>	<u>Barcode ID</u>	<u>Insert</u>	<u>Instrument</u>	<u>Dose (kGy)</u>	<u>Final Dose (kGy)</u>	<u>Comment</u>
1	1	1C1	0BY608001404	TH0033	0454	22.1	22.1	
1	2	9A5	0BY608049722	TH0033	0454	28.0	28.0	
1	3	9E5	0BY608038224	TH0033	0454	28.6	28.6	
11	1	1C1	0BY608001426	TH0033	0454	22.1	22.1	
11	2	9A5	0BY608049873	TH0033	0454	28.0	28.0	
11	3	9E5	0BY608049791	TH0033	0454	28.9	28.9	
22	1	1C1	0BY608049792	TH0033	0454	23.4	23.4	
22	2	9A5	0BY608049869	TH0033	0454	28.1	28.1	
22	3	9E5	0BY608049974	TH0033	0454	28.6	28.6	
33	1	1C1	0BY608049983	TH0033	0454	22.3	22.3	
33	2	9A5	0BY608001392	TH0033	0454	27.7	27.7	
33	3	9E5	0BY608049763	TH0033	0454	29.1	29.1	
44	1	1C1	0BY608049876	TH0033	0454	22.5	22.5	
44	2	9A5	0BY608049509	TH0033	0454	27.8	27.8	
44	3	9E5	0BY608049717	TH0033	0454	28.7	28.7	
52	1	1C1	0BY608049762	TH0033	0454	23.1	23.1	
52	2	9A5	0BY608049760	TH0033	0454	28.3	28.3	
52	3	9E5	0BY608049730	TH0033	0454	29.1	29.1	
53	1	0C1	0BY608049790	TH0033	0454	23.0	23.0	
53	2	TBA5	0BY608049859	TH0033	0454	30.7	30.7	
53	3	TBE5	0BY608049898	TH0033	0454	31.8	31.8	

Minimum Dose for Record (kGy): 22.1

Maximum Dose for Record (kGy): 31.8