

CERTIFICATE OF ANALYSIS

BioProcess Container Systems

Product: 10L LABTAINER W/QUICK CONNECTS, CX5-14

Lot #: BLF810361
Drawing #: 06266

Catalog #: SH30712.02
Drawing Rev: "J"

Expiration Date: JUN/2028
Manufacture Date: JUN/2025

Test	Specification	Units	Results
Irradiation Dose			
	25.0 – 45.0	kGy	Pass

- **Inspection:** This lot of BioProcess Container Systems has been 100% visually inspected per specification.
- **Biological Reactivity:** All product contact materials have passed USP Class VI testing (USP <88>) and/or ISO10993.
- **Cytotoxicity:** All Thermo Scientific product contact films have passed cytotoxicity testing (USP <87> MEM Elution)
- **Physicochemical:** All Thermo Scientific product contact films have passed USP Physicochemical Tests for Plastics (USP <661>).
- **EP Testing:** All Thermo Scientific product contact films have passed EP <3.2.2.1> "Plastic Containers for Aqueous Solutions for Parenteral Infusion".
- **Endotoxin:** Samples of representative BioProcess Container Systems are routinely tested in periodic validations for the presence of endotoxin per the USP Bacterial Endotoxin Test (USP <85>). Aqueous extracts contained <0.25 EU/ml as determined by the Limulus Amebocyte Lysate Test (LAL).
- **Particulate:** Samples of representative BioProcess Container Systems have been routinely tested in periodic validations and have passed requirements per Particulate Matter in Injections Light Obscuration Particulate Count Test (USP <788>).
- **Sterility:** Routine sterility testing is performed on representative samples of Thermo Scientific BioProcess Container Systems following ANSI/AAMI/ISO 11137 guidelines. Periodic validation has determined that an irradiation dose of 25.0 – 45.0 kGy provides a minimum Sterility Assurance Level (SAL) of 10^{-6} for product contact surfaces.

Hinda Potter 17 Jun 2025
Quality Department / Date Issue



Certificate of Processing

STERIGENICS 1700 College Boulevard West Memphis AR 72301
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06/13/2025 14:59:12 GMT
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Customer Name: Thermo Fisher (Life Tech.)- 1726 HyClone Processing Facility: West Memphis Work Order # 3776593
P.O.# 278889 Sales Order # 3824741
25.0 - 45.0 kGy THF-A, Gamma Treatment Irradiation Date/Time: 06/12/2025 00:41:41 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	47	CA	18X14X6	500 mL Labtainer	BLE810369	LEB_SH30658.15
	Dose Map		138_2222	MIN 0C1 MAX 16E7		
102.000	15	CA	M 36x23x12	Labtainer	BLF981476	LEB_SH3B4270.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
103.000	2	CA	M 36x23x12	Labtainer	BLE981459	LEB_SH3B19538.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
104.000	3	CA	M 36x23x12	Labtainer	BLF550644	LEB_SUT111219
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
105.000	50	CA	M 36x23x12	Labtainer	BLF548437	LEB_SH30712.03
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
106.000	50	CA	M 36x23x12	Labtainer	BLF716414	LEB_SH30712.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
107.000	50	CA	M 36x23x12	Labtainer	BLF810361	LEB_SH30712.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
108.000	35	CA	M 36x23x12	Labtainer	BLF981389	LEB_SH3B15029.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
109.000	3	CA	M 36x23x12	Labtainer	BLF118899	LEB_SUT16325
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
110.000	2	CA	M 36x23x12 ST	Labtainer	BLF114861	LEB_SUT16041
	Dose Map		138_2234	Min: 0C1 Max: 7E5		
111.000	1	CA	24X18X10	Labtainer	BLE109157	LEB_SH3B6504
	Dose Map		138_2223	MIN -1C1 MAX - TE5		
112.000	4	CA	L 47x23x12	20x20 Labtainer	BLF112657	LEB_LT3B0688.03
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
113.000	1	CA	L 47x23x12	20x20 Labtainer	BLE546000	LEB_SH3B19546.01
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
114.000	1	CA	L 47x23x12	20x20 Labtainer	BLE109149	LEB_SH31050.16
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
115.000	2	CA	L 47x23x12 ST	20x20 Labtainer	BLE981418	LEB_SUT10475
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
116.000	1	CA	M 36x23x12 ST	Labtainer	DUNNAGE	DUNNAGE
	Dose Map		138_2234	Min: 0C1 Max: 7E5		
117.000	1	CA	24X18X10	Labtainer	DUNNAGE	DUNNAGE
	Dose Map		138_2223	MIN -1C1 MAX - TE5		
	268	CA	Total			

Processing Summary

Op#	Operation Name	Location	Date/Time In (GMT)	Date/Time Out (GMT)
400.00	Receive Product	UNPROC	06/09/2025 17:00:52	06/09/2025 18:21:16
410.00	Prepare Product	UNPROC	06/09/2025 18:21:16	06/12/2025 00:41:41
420.00	Load Product	UNPROC	06/12/2025 00:41:41	06/12/2025 00:41:56
430.00	Process Product	UNPROC	06/12/2025 00:41:56	06/12/2025 00:42:01
440.00	Unload Product	UNPROC	06/12/2025 00:42:01	06/12/2025 09:48:23
450.00	Collect Run Data	UNPROC	06/12/2025 09:48:23	06/13/2025 00:07:13

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By----- User	Date / Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.7 KGY	Pass	JMASSEY	06/13/2025 00:06:18 GMT
	Reason Code Test					JESSE MASSEY	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.5 KGY	Pass	JMASSEY	06/13/2025 00:06:52 GMT
	Reason Code Test					JESSE MASSEY	

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the

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ISO 9001 and ISO 13485 Registered



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P.O.#	278889			Sales Order #	3824741
	25.0 - 45.0 kGy	THF-A, Gamma Treatment	Irradiation Date/Time:		06/12/2025 00:41:41 GMT

8.C.P. 17 Jun 2025

dosimetry system employed.

Electronically Signed By: TREVON MOORE
Reason: Work Order Completions

Date: 06/13/2025 14:57:39 GMT