

CERTIFICATE OF ANALYSIS
BioProcess Container Systems

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

Lot #: BLF117243

Catalog #: SH30712.02

Expiration Date: JUN/2028

Drawing #: 06266

Drawing Rev: "J"

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.

Shinda Potts 08 Jul 2025

Quality Department / Date Issue



Certificate of Processing

STERIGENICS 1700 College Boulevard West Memphis AR 72301
TEL 870 735-8400 FAX 870 735-9977 www.sterigenics.com

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07/07/2025 18:17:53 GMT
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Customer Name: Thermo Fisher (Life Tech.)- 1726 HyClone Processing Facility: West Memphis Work Order # 3788420
P.O.# 278889 Sales Order # 3839441
25.0 - 45.0 kGy THF-A, Gamma Treatment Irradiation Date/Time: 07/06/2025 04:38:06 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	113	CA	18X14X6	500 mL Labtainer	BLF117296	LEB_SH30658.11
	Dose Map		138_2222	MIN 0C1 MAX 16E7		
102.000	1	CA	18X14X6	500 mL Labtainer	BLF125629	LEB_SH30657.14
	Dose Map		138_2222	MIN 0C1 MAX 16E7		
103.000	1	CA	M 36x23x12	Labtainer	BLF118915	LEB_SH3B13390.03
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
104.000	3	CA	M 36x23x12	Labtainer	BLF118936	LEB_SH3B13390.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
105.000	3	CA	M 36x23x12	Labtainer	BLF118884	LEB_SH3B12747.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
106.000	2	CA	M 36x23x12	Labtainer	BLF109118	LEB_SH3B15575.03
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
107.000	44	CA	M 36x23x12	Labtainer	BLF116560	LEB_SH30667.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
108.000	50	CA	M 36x23x12	Labtainer	BLF117243	LEB_SH30712.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
109.000	22	CA	L 47x23x12	20x20 Labtainer	BLF116554	LEB_SH30667.03
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
110.000	52	CA	L 47x23x12	20x20 Labtainer	BLF118951	LEB_LT3B0546.01
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
111.000	15	CA	XL 47x32x12	Labtainer	BLF1083360	LEB_SH3B2283.02
	Dose Map		138_2225	REF(TC1)AFmin0.872 AFmax1.098		
	306	CA	Total			

Processing Summary

Op#	Operation Name	Location	Date/Time In (GMT)	Date/Time Out (GMT)
400.00	Receive Product	UNPROC	06/27/2025 15:40:00	06/27/2025 18:43:21
410.00	Prepare Product	UNPROC	06/27/2025 18:43:21	07/06/2025 04:38:06
420.00	Load Product	UNPROC	07/06/2025 04:38:06	07/06/2025 16:06:50
430.00	Process Product	UNPROC	07/06/2025 16:06:50	07/06/2025 16:07:01
440.00	Unload Product	UNPROC	07/06/2025 16:07:01	07/06/2025 16:07:10
450.00	Collect Run Data	UNPROC	07/06/2025 16:07:10	07/07/2025 04:47:36

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	27.5 KGY	Pass	LWARREN	07/07/2025 04:47:06 GMT
	Reason Code Test					LAWTON WARREN	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.0 KGY	Pass	LWARREN	07/07/2025 04:47:25 GMT
	Reason Code Test					LAWTON WARREN	

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

J.C.R. 08 Jul 2025

Electronically Signed By: TREVON MOORE
Reason: Work Order Completions

Date: 07/07/2025 18:17:32 GMT



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Handwritten in blue ink: J.L.P. 08 Jul 2025