

CERTIFICATE OF ANALYSIS

BioProcess Container Systems

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

Lot #: BLF117244
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.

Ainda Potts 09 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

R55480102

07/09/2025 13:35:50 GMT
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Customer Name:	Thermo Fisher (Life Tech.)- 1726 HyClone	Processing Facility:	West Memphis	Work Order #	3788477
P.O.#	276889			Sales Order #	3839515
25.0 - 45.0 kGy		THF-A, Gamma Treatment	Irradiation Date/Time:	07/05/2025 21:17:22 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	11	CA	18X14X6	500 mL Labtainer	BLF117300	LEB_SH30662.11
	Dose Map		138_2222	MIN 0C1 MAX 16E7		
102.000	8	CA	18X14X6	500 mL Labtainer	BLF117259	LEB_SH30961.16
	Dose Map		138_2222	MIN 0C1 MAX 16E7		
103.000	2	CA	18X14X6	500 mL Labtainer	BLF127400	LEB_SH31090.01
	Dose Map		138_2222	MIN 0C1 MAX 16E7		
104.000	27	CA	25X17X4	Harvestainer 3L	BLF117285	LEB_SH31078.01
	Dose Map		138_2243	MIN-0C1 MAX-14E5		
105.000	6	CA	35X25X4	Harvestainer 12L	BLF117250	LEB_SH31078.02
	Dose Map		138_2242	MIN-0C1 MAX-6E9		
106.000	50	CA	M 36x23x12	Labtainer	BLF117244	LEB_SH30712.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
107.000	5	CA	M 36x23x12	Labtainer	BLF122413	LEB_SH3B18299.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
108.000	2	CA	M 36x23x12	Labtainer	BLF124861	LEB_SH3B24085.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
109.000	4	CA	M 36x23x12	Labtainer	BLF118922	LEB_SH3B13390.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
110.000	3	CA	M 36x23x12	Labtainer	BLF125645	LEB_SH30649.03
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
111.000	1	CA	M 36x23x12	Labtainer	BLF128988	LEB_SH31134.01
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
112.000	7	CA	M 36x23x12	Labtainer	BLF117270	LEB_SH30652.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
113.000	2	CA	M 36x23x12	Labtainer	BLF117238	LEB_SH30963.05
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
114.000	10	CA	M 36x23x12	Labtainer	BLF122409	LEB_SH3B16512.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
115.000	13	CA	L 47x23x12	20x20 Labtainer	BLF117223	LEB_SH30980.04
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
116.000	107	CA	L 47x23x12	20x20 Labtainer	BLF1083416	LEB_SH3B16939.01
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
	258	CA	Total			

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	26.6 KGY	Pass	LWARREN	07/07/2025 04:48:33 GMT
		Reason Code Test				LAWTON WARREN	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	36.8 KGY	Pass	LWARREN	07/07/2025 04:48:53 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.

R.C.P. 09 Jul 2025

Electronically Signed By: WILLIAM WILSON
Reason: Work Order Completions

Date: 07/09/2025 13:35:10 GMT



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P.O.#

Thermo Fisher (Life Tech.)- 1726 HyClone
278889

Processing Facility:

West Memphis

Work Order # 3788477
Sales Order # 3839515

25.0 - 45.0 kGy

THF-A, Gamma Treatment

Irradiation Date/Time:

07/05/2025 21:17:22 GMT

J.C.P. 09 Jul 2025