thermo scientific

CERTIFICATE OF ANALYSIS

BioProcess Container Systems

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

Lot #: BLF117245 **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.

Linda Potter 16 Jul 2025

Quality Department / Date Issue

Sterigenics
A Sotera Health company

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 18:47:24 GMT

Customer Name:	**Thermo Fisher (Life Tech.)- 1726 HyClone**	**Processing Facility:**	**West Memphis**	**Work Order #**	**3790281**
P.O.#	**278889**			**Sales Order #**	**3841992**
25.0 - 45.0 kGy		**THF-A, Gamma Treatment**	**Irradiation Date/Time:**	07/07/2025 22:17:03 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	20	CA	18X14X6	500 mL Labtainer	BLF124195	LEB_SH30658.15
	Dose Map		138_2222	MIN 0C1 MAX 16E7		
102.000	10	CA	M 36x23x12	Labtainer	BLF117248	LEB_SH30967.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
103.000	21	CA	M 36x23x12	Labtainer	BLF117247	LEB_SH30967.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
104.000	1	CA	M 36x23x12	Labtainer	BLF633401	LEB_SUT15333
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
105.000	50	CA	M 36x23x12	Labtainer	BLF117245	LEB_SH30712.02
	Dose Map		138_2224	REF(TC1) AFmin0.822 AFmax1.123		
106.000	60	CA	L 47x23x12	20x20 Labtainer	BLF118980	LEB_SH3B1323.04
	Dose Map		138_2230	MIN-1C1 MAX-12E7		
	162	**CA**	**Total**			

Processing Summary

Op#	Operation Name	Location	Date/Time In (GMT)	Date/Time Out (GMT)
400.00	Receive Product	UNPROC	07/01/2025 13:15:00	07/01/2025 17:23:46
410.00	Prepare Product	UNPROC	07/01/2025 17:23:46	07/07/2025 22:17:03
420.00	Load Product	UNPROC	07/07/2025 22:17:03	07/08/2025 05:30:21
430.00	Process Product	UNPROC	07/08/2025 05:30:21	07/08/2025 05:30:26
440.00	Unload Product	UNPROC	07/08/2025 05:30:26	07/08/2025 05:30:30
450.00	Collect Run Data	UNPROC	07/08/2025 05:30:30	07/08/2025 23:37:49

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 Reason Code Test	45.0 kGy	27.6 KGY	Pass	JCLAY JAMES D CLAY	07/09/2025 17:03:24 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	37.7 KGY	Pass	JCLAY JAMES D CLAY	07/09/2025 17:03:24 GMT

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.

K.CP. 16Jul2025

Electronically Signed By: DEBRA MACK
Reason: Work Order Completions

Date: 07/09/2025 18:46:56 GMT