
 <p><b>Fenwal™</b> A Fresenius Kabi Company La Châtre, Etallé, 36400 Lacs, France</p>	<p align="center"><b>CERTIFICATE OF CONFORMITY INTERCEPT PRODUCT</b></p> <p align="center"><b>cerus</b> </p>	<p>Formulaire N° : C22-TEST-F Révision N° : B SOP N° : TEST-F Page 1 of 1</p>

CODE	INT2504B	LOT	CE24K25A01
		Expiry Date	2027-01

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE25A30L13	Amotosalen
	2	CE25A31L11	1
	3	N/A	2
PCT sub-assembly	1	CE24K25A01	CAD material
			3
			40325C / 40412A / 40415B / 40411B / 40410C

DESCRIPTION : INTERCEPT Platelet Processing Set with Dual Storage Containers

CONFORMITY OF TESTS RESULTS

PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)			
Product	Limits (≤)	Date Passed	Results
Final product	0.125 EU / mL	February 5, 2025	PASS
Amotosalen solution sub-assembly	<input checked="" type="checkbox"/> 3 mM → 2.0 EU / mL OR <input type="checkbox"/> 6 mM → 0.8 EU / mL	1	February 6, 2025
		2	February 6, 2025
		3	N/A
PCT sub-assembly	0.25 EU / mL	1	February 7, 2025
			PASS

Disposition : **PASS** ☒

BACTERIOLOGY-BIOBURDEN (TEST-B-17 / TEST-B-09)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
FINAL PHYSICAL TESTING (TEST-C)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
pH ANALYSIS ON CONNECTED KIT (TEST-A)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
AMOTOSALEN FINAL CHEMICAL ANALYSIS (TEST-A-01)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>

STERILITY		
Amotosalen solution	Steam sterilization cycle according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
PCT sub-assembly	Gamma irradiation according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
Connected product	E-Beam irradiation according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
Sterility Test (TEST-B-13)	No positives	CONFORM <input checked="" type="checkbox"/>

Disposition : **PASS** ☒

Note : N/A means Not Applicable PCT means Photo Chemical Treatment

QUANTITY **8616 UNITS**

Reviewed by Fenwal  
QA MANAGER or DELEGATE  
Date & Signature

M. TESSIER

26 FEB. 2025

Released by Cerus  
QA MANAGER or DELEGATE  
Date & Signature

Signed by:



Signer Name: Amanda Nguyen  
Signing Reason: I approve this document  
Signing Time: 2/27/2025 | 8:46:20 AM PST  
3637C4358FF748BD8FDBB9D4642645CD

This is to certify that this product was manufactured according to current Good Manufacturing Practice and fulfills the requirements of the Device Master Record.