

<b>CODE</b>	<b>INT2504B</b>	<b>LOT</b>	<b>CE22H16L71</b>
		Expiry Date	2024-07

	Lot		Raw material batch		
Amotosalen solution sub-assembly	1	CE22I06L12	Amotosalen	1	210094
	2	CE22I07L11		2	210094
	3	N/A		3	N/A
PCT sub-assembly	1	CE22H16L71	CAD material	11222A / 11226B / 11226BB / 11217B / 11228A	

**DESCRIPTION : INTERCEPT Platelet Processing Set with Dual Storage Containers**

**CONFORMITY OF TESTS RESULTS**

Product	PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)			
	Limits (≤)	Date Passed	Results	
Final product	0.125 EU / mL	September 21, 2022	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	September 15, 2022	PASS
		2	September 15, 2022	PASS
		3	N/A	N/A
PCT sub-assembly	0.25 EU / mL	1	September 27, 2022	PASS

Disposition : **PASS**

<b>BACTERIOLOGY-BIOBURDEN</b> (TEST-B-17 / TEST-B-09)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>FINAL PHYSICAL TESTING</b> (TEST-C)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>pH ANALYSIS ON CONNECTED KIT</b> (TEST-A)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>AMOTOSALEN FINAL CHEMICAL ANALYSIS</b> (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 **9000 UNITS**

**Reviewed by Fenwal**  
QA MANAGER or DELEGATE  
Date & Signature  
P.MANDRELIER  
  
October 6, 2022

**Released by Cerus**  
QA MANAGER or DELEGATE  
Date & Signature  
R. LEVEURE  
Oct 06, 2022

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