

Product Troubleshooting and Complaint Form

Bio SB Tracking Information:

Complaint #:		Date Received:		Taken By:		RMA #:	
--------------	--	----------------	--	-----------	--	--------	--

Section 1: Identification

Contact Name:		Bio SB Invoice #:	
Institution:		Invoice Date:	
Address:		Customer PO:	
Phone #:		Email:	

Product Complaint:			
Product Name:		Presentation / Volume:	
Catalog #:		Lot #:	
		Exp. Date:	
Intended Use:	<i>IVD</i>	<i>ASR</i>	<i>RUO</i>

Problem Description: (include adverse events, if any.)

Section 2: Assessment

Specimen Used (Tissue, Cell Line, etc.):		Bio SB Approved Specimen?	
		Yes	No

Fixation & Fixative Specimen:		Time of Fixation:	
-------------------------------	--	-------------------	--

Pretreatment:			
Enzyme or heat treatment solution used and times:		Time:	
Heat source used (pressure cooker, water bath, etc.):			

Slide Handling:			
Manual or automated staining			
Type of autostainer, if applicable:			

Antibody:			
Antibody used and brand name:			
Dilution used:			
Age of diluted antibody or fresh:			
Antibody incubation time:			
Antibody incubation temperature:			
Tissue and reagent controls used:			

Detection:			
Detection system and brand name:			
Secondary antibody:		Time:	
Tertiary antibody		Time:	
Substrate chromogen used:		Time:	
Counterstain used:		Time:	

Results and other relevant information:

Section 3: Investigation *Bio SB Use Only*****

Complaint #:		Category (SOP-17):	
--------------	--	--------------------	--

Investigation:		
Action:	By:	Date:

References:

Resolution:		
Action:	By:	Date:

Conclusion:	Confirmed:	Yes	No	Other
	(If yes, investigate and report.)	If other, explain:		
CAPA (SOP-19)	CAPA Number:	Required:	Yes	No
Medical Device Vigilance Reporting (SOP-28)	Reportable:	Yes	No	

Justification: (MDR/MDVR)

Closed:					
Closed By	Name:		Signature:		Date:
Reviewed By, QA	Name:		Signature:		Date:

Please include a picture of the product label you are issuing a complaint of, for our records. Please return by Fax (805-692-2769) or E-mail technical@biosb.com - Thank you!