

## Product Troubleshooting/Complaint Form

### Section 1: Identification

Complaint #:		RMA #:		Bio SB Invoice #:	
Date:		Invoice Date:			
Contact Name:		Customer PO:			
Institution:					
Address:					
Phone#:		Email:			
Product Complaint:					
Product Name:					
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 (Customer Input)

Specimen Used (Tissue, Cell Line, etc.):		Bio SB Approved Specimen?			
Fixation & Fixative Specimen:		Time of Fixation:			
<b>Pretreatment:</b>					
Enzyme or heat treatment solution used and times:		Time:		Temp:	
Heat source used (pressure cooker, water bath, etc.):					
<b>Slide Handling:</b>					
Manual or automated staining					
Type of autostainer, if applicable:					
<b>Antibody:</b>					
Antibody used and brand name:					
Dilution used:					
Age of diluted antibody or fresh:					
Antibody incubation time:					
Antibody incubation temperature:					
Tissue and reagent controls used:					

<b>Detection:</b>			
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):						
Taken by:	Name:		Signature:		Date:	

<b>Investigation:</b>		
Action:	By:	Date:

Conclusion:	Confirmed:	Yes	No	(If yes, investigate and report.)
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References:

<b>Resolution:</b>		
Action:	By:	Date:

<b>Other:</b>					
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:	

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