

TITLE: EXTERNAL STATEMENT OF WORK			
<u>SOP No:</u> 244	<u>Form No:</u> 244-A	<u>Version #:</u> 08	<u>Page:</u> 1 of 2

1. CONTROL DESCRIPTION					
DATE		VERSION			
2. FORM OF CONTROL					
2.1 Form of Control	Liquid		Lyophilized		(Check One)
2.2 Storage Conditions					
3. QUANTITY OF CONTROLS					
3.1 The fill volume per vial/bottle:	mL/ vial/bottle				
3.2 Does each vial/bottle contain the same volume:	YES		NO		(If Not, Explain)
3.3 The number of vials/bottles per level					
3.4 Are there the same number of vials/bottles per level?	YES		NO		(If Not, Explain)
3.5 Is a pilot lot required?	YES		NO	Qty	
4. APPEARANCE OF CONTROLS					
4.1 Vial/bottle description and Part # if known					
4.2 Stopper description (include colors if applicable and Part # if known)					
4.3 Cap/seal description (include colors if applicable and Part # if known)					
4.4 Are these vials/bottles to be labeled?	YES		NO		(Check One)
4.5 Will labels be provided?	YES		NO		(Check One)
4.6 Information and specifications for labeling					
5. STABILITY OF CONTROLS					
5.1 Shelf life under storage conditions					
5.2 Stability requirement for reconstituted or thawed control					
5.3 Other stability testing required					
6. BASE MATRIX OF CONTROLS					
6.1 What is the matrix?					
6.2 What viral testing is required on the matrix?					
6.3 Other specifications for the matrix					
6.4 Preservative	Concentration				

