ATTACHMENT 1 - Electronic Protocol Page 1

cc: 000000 _0/Lic #/C or -B or -FC

Lot Number: License Name of Product:

	Reason For Submission
Manufacturer Name: Manufacturer Address:	 For Release For Surveillance For Licensing Action STN: Corrected Protocol
Trade name:	
Date of Manufacturing: 00/00/0000	Expiration Date: 00/00/0000
Label Strength: 00%	
Source Material:	
Processing Method:	
Stabilizer:	
Stabilizer: Manufacturer / Lot Number Other:	-
Reprocessing/Heating:	
Fill Information	
Filling Date: 00/00/0000	
Location:	
Total Volume: 000 mL	Volume per Vial: 000 mL
Number of Vials filled: 0000	Number of Rejected Vials: 0000
Recommended Reconstitution Volume:	
Storage Temperature:	

All tests conducted on this lot are reported and pass specifications as required.

Signature:		D	Date:	
Title:	Authorized Official			
Electronic	e Protocol # - 202xxxxx.P0			

Page 1 of y

ATTACHMENT 2 - eLRP Signature letter

Company Header			
Food and Drug Administration Center for Biologics Evaluation and Research Sample Custodian 10903 New Hampshire Avenue WO75-G707 Silver Spring, MD 20993-0002	Reason for Submission □ For Release □ For Surveillance □ For Licensing Action* STN: □ For Corrected Letter		
[DATE] Subject: Electronic Protocol Signature Page			
License No.: 0000 Company Name:			
[COMPANY NAME] hereby submits the following I Submissions Gateway (ESG). All test conducted on as required.			
Proper name of product			

1	1		Electronic Protocol
<u>STN</u>	Lot Number	Lot Type	<u>Filename</u>
000000_0	00000000	C/B/FC	20100001.P0

Sample Status

□ Sample Not Required

□ Sample Submitted with Protocol

□ Sample Previous Submitted: [DATE]

Virus Verification

Software Name:	
Company Name:	Version:
Date of Definitions: DD/MM/YYYY	Date of Scan: DD/MM/YYYY

I certify that the submission is virus-free. The approximate file size of this submission is _____ KB/MB.

Comments:

Signature of Authorized Official Printed Name and Title of Signatory Title

ATTACHMENT 3 - RNA content template

cc: STN / License No. -C or -B or -FC

Page x of y

Lot Number:

License Name of Product

RNA encapsulation and content test

Test method

Sample/Control	Specification	Result
R ² for Standard A	(b) (4)	
R ² for Standard B	(b) (4)	
^{(b) (4)} RNA (mg/mL)	(b) (4)	
Total RNA (mg/mL)		
Encapsulated RNA (mg/mL)		
Encapsulated RNA (^{b) (6)})	(b) (4)	

ATTACHMENT 4 - Identity Test

cc: STN / License No. -C or -B or -FC

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Lot Number:

License Name of Product

Identity of encoded RNA sequence test

Test method RT-PCR

Test date

Specification

Identity confirmed Result

Sample/Control	Lot number	Replicate	Ct value	Acceptance criteria	Pass/Fail
DP Sample		1		(b) (4)	
		2		-	
		3		-	
Positive PCR Control		1		-	
		2		-	
		3		-	
Positive (b) (4) Control		1		-	
Control		2			
		3		-	
Negative PCR Control		1			
		2		-	
		3			
Negative (b) (4) Control		1			
Control		2			
		3			

ATTACHMENT 5 – In Vitro Expression

cc: STN / License No. –C or –B or – FC

Page *x* of *y*

Lot Number:

License Name of Product

In Vitro Expression Assay

Test date

Test method _____

Specification (b) (4) cells positive

(b) (4) Lot number			
Positive Control lot number			
% cell viability			
Average Number of Cells Counted for Sample			
Test Result (% positive cells)			

ATTACHMENT 6 - Limulus Amebocyte Lysate Test template

cc: STN / License No. –C or –B or – FC

Page x of y

Lot Number:

License Name of Product

Limulus Amebocyte Lysate Test

(b) (4)