

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 lot as an electronic submission by Electronic Submissions Gateway (ESG). All test conducted on this lot are reported and pass specifications as required.

Proper name of product

<u>STN</u>	<u>Lot Number</u>	<u>Lot Type</u>	<u>Electronic Protocol Filename</u>
000000_0	000000000	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 date _____

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) (4)	(b) (4)	

ATTACHMENT 4 – Identity Test

cc: STN / License No. –C or –B or –FC

Page x of y

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			
		2			
		3			
Negative PCR Control		1			
		2			
		3			
Negative (b) (4) Control		1			
		2			
		3			

ATTACHMENT 5 – In Vitro Expression

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

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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)

