

**SSP033, 195 MONTH STABILITY REPORT FOR ADENOVIRUS TYPE 5 REFERENCE MATERIAL, LOTS 001505, AND 001506**

**RESULTS**

Test	Testing Lab/ Method #	Specification	Time Point Results		Units
			Lot 001505 16Nov17	Lot 001506 16Nov17	
Physical Description of Liquid Samples	LHI/TR113	Report Result	Clear colorless solution essentially free of particles	Clear colorless solution essentially free of particles	-
Purity by IEX HPLC	LHI/TR057	Report Result	98.8	98.5	%
Virus Particle Enumeration by IEX HPLC	LHI/TR057	Report Result	5.0E11	4.8E11	vp/mL
Adenoviral Infectious Titer Using HEK 293 Cells	LHI/TR097	Report Result	1.4E11	1.0E11	IU/mL

**STABILITY SUMMARY**

Physical Description (TR113), % Purity by IEX HPLC (TR057), VP/mL concentration by IEX HPLC (TR057) and Infectious Titer (TR097) were performed on the two remaining lots of Adenoviral Reference Material (L/N 001505 and 001506). These materials are stored at the ATCC and vials were sent to Lonza Houston for testing in November 2017; testing was performed in December 2017.

Assay results for the 195 month time point are as expected. Assay variability for the infectious titer assay (TR097) presents an expected range of results,  $\pm 0.5\log$  from a nominal or mean value.

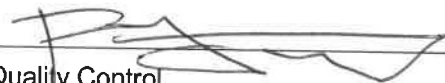
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**Test Method References**

<b>Documents and Testing References Log</b>			
<b>Test</b>	<b>Method No.</b>	<b>Issued TRF Version-Copy Numbers (001505)</b>	<b>Issued TRF Version-Copy Numbers (001506)</b>
Physical Description of Liquid Samples	TR113	3.0-26	3.0-27
Virus Particle Enumeration and Purity by IEX HPLC	TR057	6.0-45	6.0-45
Adenoviral Infectious Titer Using HEK 293 Cells	TR097	3.0-116	3.0-116

**APPROVAL**

  
Quality Control

03 Jan 18  
Date

  
Quality Assurance

07 FEB 2018  
Date