

SSP033, 169 Month Stability Report for Adenovirus Type 5 Reference Material, Lots 001504, 001505, and 001506

Product Name: Adenovirus Type 5 Reference Material

ATCC Cat. Number: VR-1516

Lot Numbers: 001504, 001505, and 001506

Study Number: SSP033-3.0

Temperature Conditions: $\leq -60^{\circ}\text{C}$ (-70°C at ATCC)

Time Point: 169 Month

Report Date: 05 Dec 15

SSP033, 169 MONTH STABILITY REPORT FOR ADENOVIRUS TYPE 5 REFERENCE MATERIAL, LOTS 001504, 001505, AND 001506

RESULTS

Test	Method #	Specification	Time Point Results			Units
			Lot 001504 169 Month 01Sep15	Lot 001505 169 Month 01Sep15	Lot 001506 169 Month 01Sep15	
Physical Description of Liquid Samples	TR113	Report Result	Clear, colorless solution essentially free of particles	Clear, colorless solution essentially free of particles	Clear, colorless solution essentially free of particles	-
Purity by IEX HPLC	TR057	Report Result	98.6	98.9	98.4	%
Virus Particle Enumeration by IEX HPLC	TR057	Report Result	5.9E11	5.6E11	5.9E11	vp/mL
Adenoviral Infectious Titer Using HEK 293 Cells	TR097	Report Result	7.0E10	1.2E11	1.1E11	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 three remaining lots of Adenoviral Reference Material (L/N 001504, 001505 and 001506). These materials are stored at the ATCC and vials were sent to Lonza Houston for testing. Testing was performed in September of 2015.

Assay results for the 169 month time point are as expected. The infectious titer result for lot 001504 is lower than the previous stability time point testing at 134 month, where a result of 1.2E11 IU/mL was obtained. Assay variability for the infectious titer assay (TR097) presents an expected range of results, $\pm 0.5\log$ from a nominal or mean value. The 7.0E10 IU/mL result for lot 001504 is within a 0.5log range of the 134 month time point result of 1.2E11 IU/mL; the range being 3.8E10 – 3.8E11 IU/mL. As well, none of the other test results, for lot 001504, indicate the lot is showing a decrease in stability at 169 months.

The results obtained at the 169 month time point for lot numbers 001504, 001505 and 001506 indicate that these materials are stable for at least 169 months at a storage temperature of $\leq -60^{\circ}\text{C}$ (-70°C at ATCC).

REFERENCES

Documents and Testing References Log	
Test	Issued Method Number
Physical Description of Liquid Samples	TRF113-2.0-130
Virus Particle Enumeration and Purity by IEX HPLC	TRF057-4.0-106
Adenoviral Infectious Titer Using HEK 293 Cells	TRF097-3.0-70

APPROVAL



 Quality Control

19 Jan 16

 Date



 Quality Assurance

20 JAN 16

 Date