

Meridian Life Science, Inc. 5171 Wilfong Road, Memphis, Tennessee 38134 - USA		Page 1 of 1	
		CERTIFICATE OF ANALYSIS	
Part Number: 8099	Document Number: COA-112	Revision Number: 004	
Product:	Mumps Virus Antigen		
Supplied In:	0.1M Glycine Buffer, pH = 9.3 to 9.7		
Lot Number:	M28428016	Date of Expiration:	22 JUN 2021

CERTIFICATE OF ANALYSIS

- Cell Line: LLC-MK₂
- Viral Strain: Enders
- Animal Source Products / Country of Origin: Product Manufactured in the U.S.A. using only domestic animal materials processed in U.S. facilities.
- Storage Conditions: -65 to -80°C

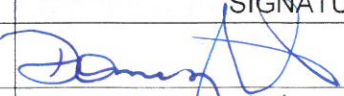
Reference Antigen Lot Number: M14138009

TEST	SPECIFICATION	METHOD	RESULTS
Protein Concentration	0.6 to 1.0 mg/mL	OD 260 / 280 nm	<u>0.85</u> mg/mL
ELISA Titer: Reference Antigen	To Report	ELISA	540.3
ELISA Titer: Test Antigen	-15% to +50% of Reference Antigen	ELISA	Midpoint Titer: <u>468.2</u> % of Reference: <u>15.4</u>
Background ELISA Ratio	Ratio ≤ 2	ELISA	1.9
Sensitivity / Specificity Negative Control	To Report	ELISA	ACCEPTABLE
Sensitivity / Specificity Medium Positive Control	Medium / Negative Ratio ≥ 3	ELISA	4.2
Sensitivity / Specificity High Positive Control	High / Negative Ratio ≥ 8	ELISA	11.3
Infectivity	Negative CPE	Cell Culture*	Pass / Fail

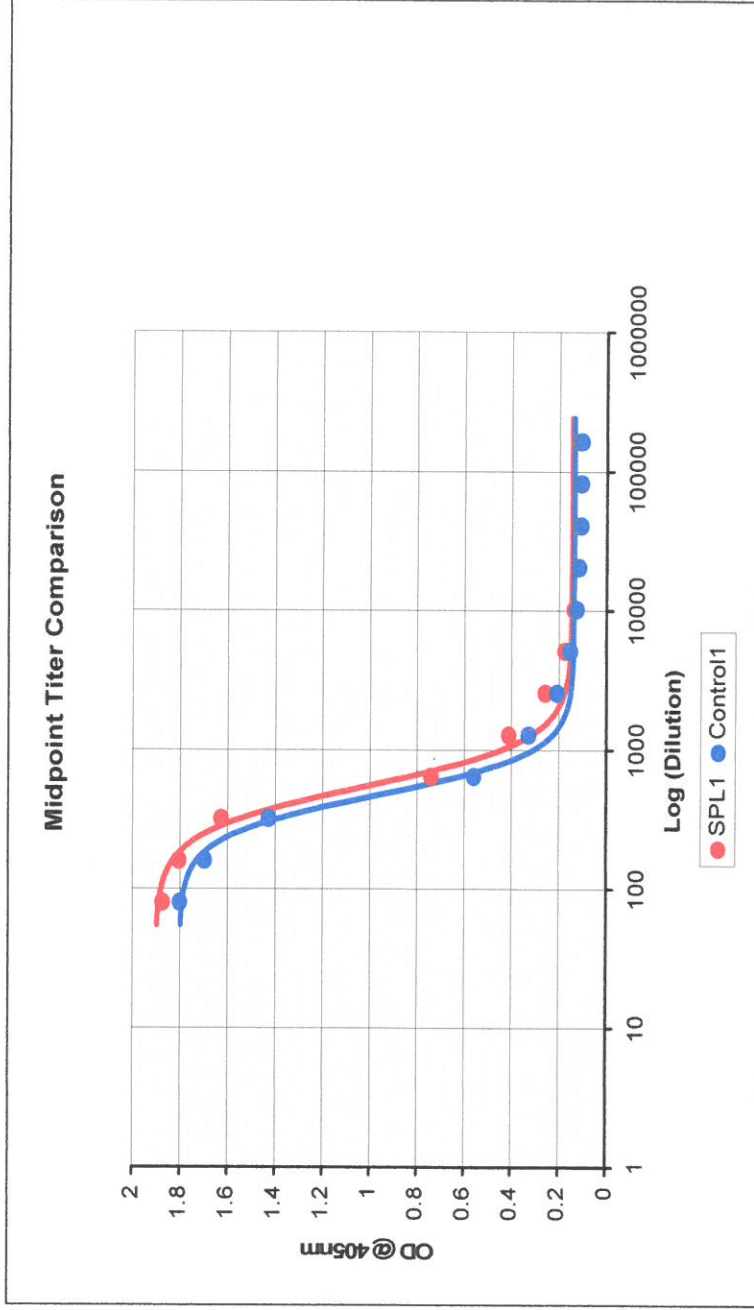
* Negative infectivity for Mumps virus is defined as the inability of an inactivated virus preparation to produce CPE after six (6) days of incubation on a monolayer of LLC-MK₂ cells.

** Since no test method can offer complete assurance that infectious agents are absent, this material should be handled as though capable of transmitting disease.

Required Attachments: (1) Graph of ELISA Titration

APPROVED BY	SIGNATURE	DATE
Product Manager		08 Jul 2016
Quality Assurance	Tammy Wing	25 July 2016

Product: Mumps Virus 8099
 Part #: M14138009
 TA Lot #: M28428016
 Std Lot #: M14138009
 Protocol: AP FR ELISA 1-80.prt
 Analyst: Danita Herron



Curve Fit

Lot #	ID	Max OD	Slope	Midpoint	Min OD	R	R ²
M28428016	SPL1	1.901	2.596	540.273	0.147	0.997	0.993
M14138009	Control1	1.801	2.867	468.187	0.139	0.998	0.995

% Difference = **15.40%** is: **ACCEPTABLE**

Sensitivity / Specificity

High Positive	Medium Positive	Background Ratio
11.309	4.159	1.917

Sensitivity / Specificity is: **ACCEPTABLE**

Danita Herron
07 Jul 2014