

<b>MERIDIAN LIFE SCIENCE, INC.</b> 5171 Wilfong Road, Memphis, Tennessee 38134 - USA		Page 1 of 1 <b>CERTIFICATE OF ANALYSIS</b>	
<b>Part Number: 7507</b>		<b>Document Number: COA-221</b>	
<b>Revision Number: 003</b>			
<b>Product:</b>	<b>CMV Grade III Antigen</b>		
<b>Supplied In:</b>	<b>0.1 M Glycine, pH 9.3 – 9.7</b>		
<b>Lot Number:</b>	M2933307	<b>Date of Expiration:</b>	10 Nov. 2021

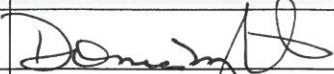

**CERTIFICATE OF ANALYSIS**

- Cell Line: Human Fibroblast (HF) Cells
- Viral Strain: AD169
- Animal Source Products / Country of Origin: Product manufactured in the United States using only domestic animal materials processed in U.S. facilities.
- Storage Conditions: ≤ -65 °C
- Shipment On: Dry Ice
- Antigen is inactivated during extraction process.

Reference Antigen Lot Number: M10961010

TEST	SPECIFICATION	METHOD	RESULTS
ELISA Midpoint Titer: Test Antigen	-15% to +50% of Reference Antigen	ELISA	Midpoint Titer: <u>840.91</u> % of Reference <u>10.15</u>
ELISA Midpoint Titer: Reference Antigen	To Report	ELISA	Midpoint Titer: <u>763.454</u>
Background ELISA Ratio	Ratio ≤ 2	ELISA	<u>1.951</u>
Sensitivity / Specificity <b>Negative</b> Control	To Report	ELISA	<u>ACCEPTABLE</u>
Sensitivity / Specificity <b>Medium</b> Positive Control	Medium / Negative Ratio ≥ 3	ELISA	<u>24.849</u>
Sensitivity / Specificity <b>High</b> Positive Control	High / Negative Ratio ≥ 8	ELISA	<u>35.151</u>
Protein Concentration	0.8 – 1.2 mg / mL	BCA	<u>1.0</u> mg/mL

- Required Attachments: (1.) Graph of ELISA Titration  
(2.) Western Blot  
(3.) Silver Stain

APPROVED BY	SIGNATURE	DATE
Product Manager		<u>06 Dec 2016</u>
Quality Assurance		<u>15 Dec 2016</u>



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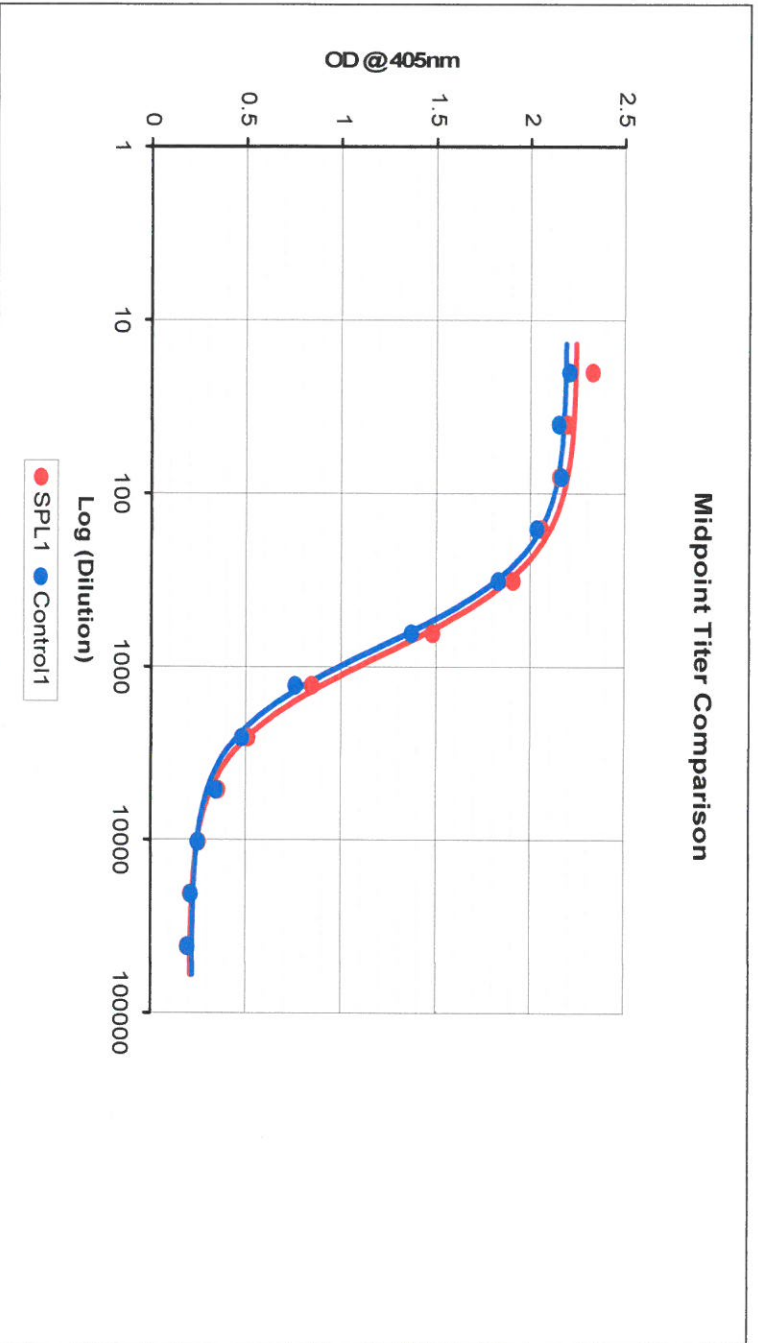
**Meridian Life Science, Inc.**  
ELISA QC: OEM Antigens Midpoint Titer Comparison

Product: CMV III  
Part #: 7507

TA Lot #: M29333017  
Std Lot #: M16961010

Protocol: AP FR ELISA 1-20.ppt  
Analyst: S Clark

### Midpoint Titer Comparison



Curve Fit							
Lot #	ID	Max OD	Slope	Midpoint	Min OD	R	R <sup>2</sup>
M29333017	SPL1	2.245	1.575	840.91	0.205	0.999	0.998
M16961010	Control1	2.191	1.662	763.456	0.218	1	0.999

Sensitivity / Specificity		
High Positive	Medium Positive	Background Ratio
35.151	24.849	1.951

% Difference = **10.15%**

is: **ACCEPTABLE**

Sensitivity / Specificity is:

**ACCEPTABLE**

ML S-Memphis Quality Control 11/18/2016 12:55 PM

*S. Clark*  
18 Nov 2016



# Meridian

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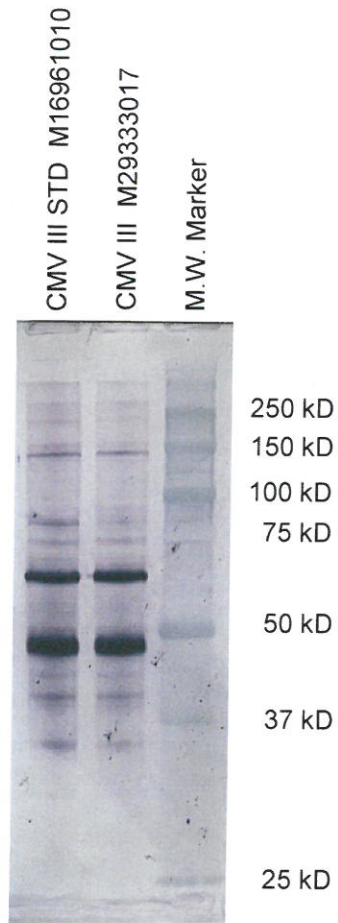
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### CMV III

Part #: 7507

Lot # M29333017

### Western Blot



am  
01 Dec 2016

## CMV III

Part #: 7507

Lot # M29333017

## Silver Stain



am  
01 Dec 2016