| MERIDIAN LIFE SCIENCE, INC.<br>5171 Wilfong Road, Memphis, Tennessee 38134 - USA | | | Page 1 of 2<br>CERTIFICATE OF ANALYSIS |
|---|---|---|---|
| Part Number: 8198 | | Document Number: COA-155 | Revision Number: 004 |
| Product: | HAV | | |
| Supplied In: | NTE Buffer (0.01M Tris, 0.15M NaCl, 1.0mM EDTA, pH 8.0 – 8.4) with 0.085% Sodium Azide | | |
| Lot Number: | M28105016 | Date of Expiration: | 06NOV2021 |

## CERTIFICATE OF ANALYSIS

- 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
- Viral Strain: pHM175
- Cell Line: FRhK-4

Reference Antigen Lot Number: M23406014

| TEST | SPECIFICATION | METHOD | RESULTS |
|---|---|---|---|
| Protein Concentration | ≥4 µg / mL | BCA (Calculation) | 4.2 µg / mL |
| Integrity | 0 CFU / mL | Bioburden Assay | 0 |
| ELISA Titer: Test Antigen | > 270 | Capture ELISA | Titer: 565 |
| ELISA Titer: Reference Antigen | To Report | Capture ELISA | Titer: 300 |
| Identity | The test lot must demonstrate 1 protein band in the 33 kD region and 1 protein band in the 24-27 kD region. The band in the 33 kD region must co-migrate with that in the standard lane. | Silver Stain | Pass / Fail |
| Identity | The test lot must demonstrate an immunoreactive band in the 33 kD region and an immunoreactive band in the 24-27 kD region. The band in the 33 kD region must co-migrate with that in the standard lane. | Western Blot | Pass / Fail |
| Infectivity* | <1 PFU / mL | Cell Culture | 0 PFU / mL |

* Formalin inactivated – Formalin concentration: < 1:8000 by volume
** 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
(2.) Silver Stain (Photocopy)
(3.) Western Blot (Photocopy)

| APPROVED BY | SIGNATURE | DATE |
|---|---|---|
| Product Manager | | 16 Nov 2016 |
| Quality Assurance | | 17 Nov 2016 |



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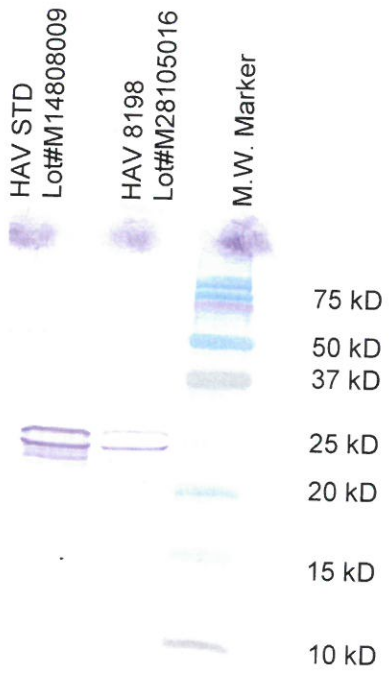
# Hepatitis A Antigen Grade 2

Part #: 8198

Lot # : M28105016

## Western Blot

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15 NOV 2016

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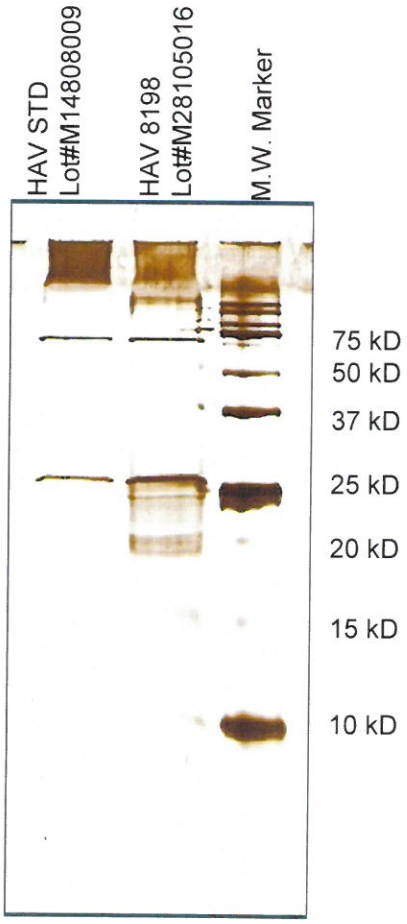
# Hepatitis A Antigen Grade 2

Part # 8198

Lot # : M28105016

## Silver Stain

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15 NOV 2016