



# MATERIAL SAFETY DATA SHEET

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## SECTION 1. PRODUCT IDENTIFICATION

CATALOG #: 708101  
NAME: NOVA Lite™ HEp-2  
USE: For *In Vitro* Diagnostic Use, CLIA Complexity: High

## SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

Kit components  
NOTE: P/N = Product Number  
P/N 508100, HEp-2 (Human Epithelial Cell) substrate slides, 12 wells/slide  
P/N 508123, Anti-Human IgG Conjugate (Goat), <0.05% Fluorescein labeled in buffer containing <0.05% Evans blue and <0.1% Sodium Azide  
P/N 508171, ANA Titratable Endpoint Pattern Control, 1 vial of buffer containing <0.1% Sodium Azide and human serum antibodies to HEp-2  
P/N 508186, IFA System Negative Control, 1 vial of buffer containing <0.1% Sodium Azide and no known human serum antibodies to HEp-2  
P/N 508002, PBS (Phosphate Buffered Saline, solution) Concentrate  
P/N 508001, Mounting Medium, <0.1% Sodium Azide  
P/N 508122, Coverslips, glass

## SECTION 3. HAZARDS IDENTIFICATION

Primary Health Hazards:  
Some reagents contain less than (<) 0.1% total weight of Sodium Azide (NaN<sub>3</sub>) as a preservative, CAS # 26628-22-8, EINECS # 247-852-1.  
Some reagents contain trace amounts of Ethanol (fixative), CAS # 64-17-5, EINECS # 200-578-6  
Some reagents contain trace amounts of Acetone (fixative), CAS # 67-34-1, EINECS # 200-662-2  
The pigment on the glass slide(s) contains trace amounts of Cadmium, CAS # 7440-43-9, EINECS # 231-152-8  
Evans Blue, CAS # 314-13-6, EINECS # None  
Fluorescein, CAS # 2321-07-5, EINECS # 219-031-8  
PBS, CAS # None, EINECS # None  
Desiccant (Silica gel) CAS # 63231-67-4, EINECS # None  
Human Source Material: Treat as potentially infectious.  
Serum used in the preparation of this product has been tested by FDA approved methods and found non-reactive for the presence of Hepatitis B surface antigen (HBsAg), antibody to human immunodeficiency virus (HIV) and Hepatitis C virus (HCV). No known test method can offer complete assurance that Hepatitis B virus, HIV, HCV, or other infectious agents are absent. Handle these controls and all patient samples at Biosafety Level 2 as recommended in the Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention/National Institutes of Health, Fifth Edition, 2007.  
NOTE: Physical and health hazard information for the kit has not been determined. Any physical and health information noted is based on evaluation of data for pure ingredients and concentration of ingredients as packaged.  
Target Organs: None identified.

## SECTION 4. FIRST-AID MEASURES

Eye: Rinse immediately with plenty of clean running water for at least 20 minutes, separating the eyelid.  
Skin Contact: Wash off thoroughly with plenty of clean running water. Remove and wash contaminated clothing.  
Ingestion: Obtain immediate medical attention.  
Inhalation: Remove from exposure. If breathing is difficult, obtain medical attention if necessary.  
IN CASE OF ACCIDENT OR IF YOU DO NOT FEEL WELL, IMMEDIATELY SEEK MEDICAL ADVICE.

**SECTION 5. ----- FIRE FIGHTING MEASURES -----**

*Non-flammable preparation.*

Extinguishing media: Use media in adaption to materials stored in the immediate neighborhood, such as dry chemical.

Special firefighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. NFPA: HEALTH = 0, FLAMMABILITY = 0, REACTIVITY = 0

**SECTION 6. ----- ACCIDENTAL RELEASE MEASURES -----**

After spillage: Wipe up spills with inert absorbent materials and place in a suitable container. Use personal protective equipment (PPE), such as gloves, safety glasses/goggles to prevent exposure.

**SECTION 7. ----- HANDLING AND STORAGE -----**

Handling: Normal precautions for handling chemicals must be observed. Wash affected area after handling.

Storage: Keep containers tightly closed when not in use. Store in a dry, well ventilated storage area (2-8°C). Protect from physical damage.

**SECTION 8. ----- EXPOSURE CONTROLS/PERSONAL PROTECTION -----**

Respiratory protection: Good local ventilation.

Eye protection: Protective glasses.

Hand protection: One-way gloves (latex or nitrile).

Use protective lab coat.

Recommend the use of safety pipette device.

**SECTION 9. ----- PHYSICAL AND CHEMICAL PROPERTIES -----**

Appearance:

Coverslip: solid glass

HEp-2 (Human Epithelial Cell) on solid glass microscope slide

Anti-Human IgG Conjugate (Goat) buffer: blue liquid

ANA Titratable Endpoint Pattern Control: colorless liquid

IFA System Negative Control: colorless liquid

PBS solution: colorless liquid

Mounting Medium: colorless viscous liquid

Odor: Solutions are odorless

Boiling point: N/A

Melting point: N/A

Flash point: N/A

Ignition temperature: N/A

Explosion limits: N/A

Vapor pressure: N/A

Density: N/A

Viscosity: N/A

Solubility in water: Solutions are soluble

**SECTION 10. ----- STABILITY AND REACTIVITY -----**

Stability: Stable under ordinary conditions of use and storage.

Hazardous Polymerization: Will not occur.

Conditions and materials to avoid: N/A

Hazardous reactions: N/A

Hazardous decomposition products: N/A

**SECTION 11. ----- TOXICOLOGICAL INFORMATION -----**

The toxicological properties of this kit and/or its components have not been fully investigated, data not available.

Teratogenicity: Data not available.

Reproductive effects: Data not available.

Neurotoxicity: Data not available.

Mutagenicity: Data not available.

**SECTION 12. ----- ECOLOGICAL INFORMATION -----**

Data not available.



**SECTION 13. ----- DISPOSAL CONSIDERATIONS -----**

Observe all Governmental environmental regulations for waste disposal. Chemical waste generators must determine if a discarded chemical is classified as a hazardous waste. Contact a licensed professional waste disposal service for disposal of unused product.

Remains of biological samples, reagents and controls should be collected in a suitable container for this purpose and autoclaved 1 hour at 121°C.

RCRA P-Series: None listed.

RCRA U-Series: None listed.

**SECTION 14. ----- TRANSPORT INFORMATION -----**

Special requirements: None.

**SECTION 15. ----- REGULATORY INFORMATION -----**

According to 1999/45/EC Directive and 91/155/EEC Directive and following modifications.

**OSHA Hazards:**

No known OSHA hazards.

**TSCA Status:**

Not on TSCA Inventory.

Antibody, liquid.

CAS-No. = None

**DSL Status**

This product contains the following components that are not on the Canadian DSL nor NDSL lists.

Antibody, liquid

CAS-No. = None

**SARA 302 Components:**

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components:**

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**SARA 311/312 Hazards:**

No SARA Hazards

**Massachusetts Right To Know Components:**

No Components Listed

**Pennsylvania Right To Know Components:**

No Components Listed

**New Jersey Right To Know Components:**

No Components Listed

**California Prop. 65 Components:**

This product does not contain any chemicals known to State of California to cause cancer, birth, or any other reproductive defects.

**SECTION 16. ----- OTHER INFORMATION -----**

Some reagents in this kit contain Sodium Azide as a preservative. Sodium Azide has been reported to form lead or copper azide in laboratory plumbing, which may explode on percussion. Use proper disposal procedures.

Each donor unit used in the preparation of the controls of this kit was tested by an approved method for the presence of the antibodies to HIV and HCV as well as for HBsAg and found to be negative. **WARNING:** Because no test method can offer complete assurance that HIV, HCV, HBsAg or other infectious agents are absent, the controls of this kit should be handled carefully using Universal Precautions.

INOVA Diagnostics, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by properly trained personnel using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. INOVA Diagnostics, Inc. makes no representations or warranties, either expressed or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with the respect to the information set forth herein or the product to which the information refers. Accordingly, INOVA Diagnostics, Inc. will not be liable for any claims, losses or damages resulting from use of or reliance upon this information.

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