

Montage[™] PolyVue Plus Auto Detection System

Catalog No: PVP100-AUTO PACK SIZE: 100 TESTS

Document #: DS-6022-C **Effective Date:** 12/18/2023

Intended Use: For In Vitro Diagnostic Use

Principles of the Procedure:

The Montage™ PolyVue Plus Auto Detection System is a non-biotin, two-step detection system suitable for labeling antigens in formalin-fixed paraffin-embedded tissues and cryostat sections. Montage™ PolyVue Plus Auto Detection System may also be used with blood smears, cytosmears, and cell preparations. This System has been developed by directly labeling immunoglobulins with enzymes using a proprietary tandem hyperlabelling technology. This ensures consistent and reproducible immunostaining for all types of nuclear, cytoplasmic and membrane antigens in different types of tissues with significantly lower background than detection systems using biotin and avidin conjugates.

Montage™ PolyVue Plus Auto Detection System can simultaneously detect both mouse and rabbit antibodies. This System is suitable for use with mouse IgG, IgM and rabbit primary antibodies, both monoclonal and polyclonal. This Detection System has been designed for automated staining using the DBS Montage 360™. The increased sensitivity of the Montage™ PolyVue Plus Auto Detection System enables faster staining procedures without compromising results.

Material Safety Data Sheet: Tissue Primer

1. Identification of the Substance/preparation and of the company/undertaking

Identification of the Product: Montage™ PolyVue Plus Detection System, Catalog No. PV100D-AUTO Tissue

Primer

2. Composition/Information on Ingredients

Dilute solution of Hydrogen Peroxide Chemical Abstracts Registry Number 7722-84-1

3. Hazard Identification:

The material contains a dilute solution of hydrogen peroxide. Although the concentration of hydrogen peroxide is very low (less than 4% v/v), appropriate care should be taken when handling this material.

4. First Aid Measures

Eye Contact: Immediately flush with continuously running water.

Skin Contact: Immediately wash affected area with soap and water.

Ingestion: Rinse mouth with water. Induce vomiting. Immediately seek medical attention

and call poison control center.

Inhalation: Move to well-ventilated area and seek medical attention if necessary.

5. Firefighting Measures

Extinguishing Media: Extinguish using suitable agents.

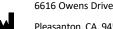
Special Firefighting Procedure: Wear protective clothing containing self-contained breathing apparatus.

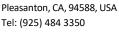
Unusual Fire & Explosions Hazards: Toxic fumes of phosphorus oxides and/or phosphine, carbon monoxide,

carbon dioxide, nitrogen oxides and hydrogen chlorides may results from

thermal decompositions.

Switzerland





Diagnostic BioSystems











6. Accidental Release Measures

Person related precautionary measures: Avoid substance contact.

Procedures for cleaning/absorption: Use liquid absorbent material. Clean up affected area.

Environmental Protection measure: Do not allow to enter sewage system.

7. Storage and Handling Store at 2-8°C. Reagent is light sensitive; protect from exposure to light and

store in dark environment or opaque bottle.

8. Exposure Controls / Personal Protection

Eye protection: Wear splash protecting goggles or safety glasses.

Hand protection: Wear rubber or vinyl gloves.

Respiratory protection: Required when vapors/aerosols are generated.

Ventilation: Use in well-ventilated laboratory.

Other protective equipment: Use lab coat or apron to prevent contact with eyes, skin and clothing.

9. Physical and Chemical Properties

Appearance: Clear liquid Odor: Odorless

Solubility: Miscible with water

10. Stability and Reactivity

Stability: Stable for 24 months. Refer to product label for expiration.

Conditions to be avoided: High and prolonged heat.

Substances to be avoided: Strong oxidizing agents.

Hazardous decomposition products: No information available

11. Toxicological Information

Quantitative data on the toxicity of this product is not available. No toxic

effects are to be expected when the product is handled appropriately.

12. Ecological Information No data available.

13. Disposal Considerations

Contact professional waste disposal companies. Follow local, state, and

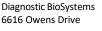
federal regulations for disposal.

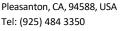
14. Transport Information Not subject to transport regulations.

15. Regulatory Information US Regulatory Information: SARA listed - No

Other Information: The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. The information provided is without any representation or warranty, express of implied, regarding its accuracy or correctness. The safe usage of this product is the sole responsibility of the user, who is obligated to review this data in the sobligated to review this data in the specific context of the intended use and determine applicability. The MSDS should be retained in an accessible place to employees during all use of this material.

















Material Safety Data Sheet: Montage[™] DAB Reagent Components

1. Identification of the Substance/Preparation and of the Company/Undertaking

Identification of the Product: Montage™ PolyVue Plus Detection System, Catalog No. PV100D-AUTO

Montage™ DABChromogen/Substrate Components

Montage[™] DAB Buffer Montage[™] DAB Chromogen

2. Composition/Information on Ingredients

3-3 Diaminobenzidine: Chemical Abstracts Registry Number 7411-49-6 Hydrogen Peroxide: Chemical Abstracts Registry Number 7722-84-1

3. Hazard Identification:

DAB has been classified as a suspected carcinogen and can cause skin irritation upon contact. Avoid contact with clothes and exposed skin. If accidentally contacted, flush with tap water immediately. Follow instructions of local authorities for disposal.

4. First Aid Measures

Eye Contact: Immediately flush with continuously running water.

Skin Contact: Immediately wash affected area with soap and water.

Ingestion: Rinse mouth with water. Induce vomiting. Immediately seek medical attention and call poison control center.

Inhalation: Move to well-ventilated area. Seek medical attention if necessary.

5. Firefighting Measures

Extinguishing Media: Extinguish using suitable agents.

Special Firefighting Procedure: Protective clothing containing self-contained breathing apparatus.

Unusual Fire & Explosions Hazards: Toxic fumes of phosphorus oxides and/or phosphine, carbon monoxide, carbon dioxide,

nitrogen oxides and hydrogen chlorides may results from thermal decompositions.

6. Accidental Release Measures

Person related precautionary measures: Avoid substance contact.

Procedures for cleaning/absorption: Use absorbent material designated for liquids to absorb spill.

Environmental Protection measure: Do not allow to enter sewage system.

Handling and Storage

Handling: See section 8

Storage: Store at 2 - 8°C. Reagents are light sensitive; protect from exposure to light and store in dark environment or opaque bottle.

8. Exposure Controls / Personal Protection

Eye protection: Wear goggles or safety glasses. Hand protection: Wear latex or vinyl gloves.

Respiratory protection: Required when vapors/aerosols are generated.



Pleasanton, CA, 94588, USA Tel: (925) 484 3350

Diagnostic BioSystems 6616 Owens Drive







Switzerland



MedEnvoy Global B.V. Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands



Ventilation: Use in well-ventilated laboratory.

Other protective equipment's: Use lab coat/apron to prevent contact with eyes, skin and clothing.

9. Physical and Chemical Properties

Appearance: Clear and colored liquid

Odor: Odorless

Solubility: Miscible with water

pH: Neutral

10. Stability and Reactivity

Stability: Stable for 18 months. Refer to product labels for expiration.

Conditions to be avoided: Strong and prolonged heat

Substances to be avoided:

Dimethyl sulfate, acid chlorides, homogenate solvents, metals, acids, lead/copper plumbing; forms highly explosive metal azides.

Hazardous decomposition products: No information available.

11. Toxicological Information

Quantitative data on the toxicity of this product is not available. No toxic effects expected when product is handled appropriately.

12. Ecological Information

No ecological problems expected when this product is used with care. Do not allow to enter sewage system.

13. Disposal Considerations

Contact professional waste disposal companies. Follow local, state, and federal regulations for disposal.

14. Transport Information

Not subject to transport regulations.

15. Regulatory Information

US Regulatory Information: SARA listed - No

16. Other Information:

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. The information provided is without any representation or warranty, express of implied, regarding its accuracy or correctness. The safe usage of this product is the sole responsibility of the user, who is obligated to review this data in the specific context of the intended use and determine applicability.

Material Safety Data Sheet: Montage[™] Hematoxylin

1. Identification of the Substance/preparation and of the company/undertaking

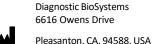
Identification of the Product: MontageTM PolyVue Plus Detection System

Montage™ Hematoxylin

2. Composition/Information on Ingredients

Water Chemical Abstracts Registry Number 7732-18-5
Glycerin Chemical Abstracts Registry Number 56-81-5
Aluminum Sulfate Chemical Abstracts Registry Number 7784-31-8
Acetic Acid Chemical Abstracts Registry Number 64-19-7
Hematoxylin Chemical Abstracts Registry Number 517-28-2

3. Hazard Identification:













This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

First Aid Measures

Eye Contact: Immediately flush with continuously running water.

Skin Contact: Immediately wash affected area with soap and water. Get medical attention if irritation develops. Ingestion: Rinse mouth with water. Induce vomiting. Immediately seek medical attention and call poison control center.

Inhalation: Move to well-ventilated area and seek medical attention if necessary.

Firefighting Measures

Extinguishing Media: Extinguish using suitable agents.

Special Firefighting Procedure: Wear protective clothing containing self-contained breathing apparatus.

Unusual Fire & Explosions Hazards: No unusual fire or explosion hazards expected.

Accidental Release Measures

Person related precautionary measures: Avoid substance contact.

Procedures for cleaning/absorption: Use liquid absorbent material. Clean up affected area.

Environmental Protection measure: Do not allow to enter sewage system.

Handling and Storage

Handling: See section 8

Storage: Store at 2-8°C. Reagent is light sensitive; protect from exposure to light and store in dark environment or opaque

bottle.

Exposure Controls / Personal Protection

Eye protection: Wear splash protecting goggles or safety glasses.

Hand protection: Wear rubber or vinyl gloves.

Respiratory protection: Required when vapors/aerosols are generated.

Ventilation: Use in well-ventilated laboratory.

Use lab coat or apron to prevent contact with eyes, skin and clothing. Other protective equipment:

Physical and Chemical Properties

Appearance: Purple liquid Odor: Slight vinegar Solubility: Soluble in water

10. Stability and Reactivity

Stability: Stable under normal temperatures and pressures. Refer to product label for expiration.

Conditions to be avoided: Fire, static electricity, direct sunlight.

Substances to be avoided: Strong oxidizing agents, reducing agents, metals, acids and alkalis.

Hazardous decomposition products: No information available

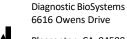
11. Toxicological Information

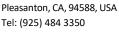
Quantitative data on the toxicity of this product is not available. No toxic effects are to be expected when the product is handled appropriately.

12. Ecological Information

No data available.

13. Disposal Considerations













MedEnvoy Global B.V. Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands





Contact professional waste disposal companies. Follow local, state, and federal regulations for disposal.

14. Transport Information Not subject to transport regulations.

15. Regulatory Information

US Regulatory Information: SARA listed - No

16. Other Information:

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. The information provided is without any representation or warranty, express of implied, regarding its accuracy or correctness. The safe usage of this product is the sole responsibility of the user, who is obligated to review this data in the specific context of the intended use and determine applicability.

Intended Use

The Montage™ PolyVue Plus Auto Detection System is a non-biotin, two-step detection system suitable for labeling antigens in formalin-fixed paraffin-embedded tissues and cryostat sections. Montage™ PolyVue Plus Auto Detection System may also be used with blood smears, cytosmears, and cell preparations. This System has been developed by directly labeling immunoglobulins with enzymes using a proprietary tandem hyperlabelling technology. This ensures consistent and reproducible immunostaining for all types of nuclear, cytoplasmic and membrane antigens in different types of tissues with significantly lower background than detection systems using biotin and avidin conjugates.

Montage™ PolyVue Plus Auto Detection System can simultaneously detect both mouse and rabbit antibodies. This System is suitable for use with mouse IgG, IgM and rabbit primary antibodies, both monoclonal and polyclonal. This Detection System has been designed for automated staining using the DBS Montage 360™. The increased sensitivity of the Montage™ PolyVue Plus Auto Detection System enables faster staining procedures without compromising results.

Format

Ready to Use

Introduction

Optimal immunostaining not only depends on the specificity of the primary antibody and other immunoreagents but also depends on obtaining a good signal to noise ratio. Binding of an antibody to its epitopes involves van der Waals forces, electrostatic forces and hydrophobic forces. Certain antibodies have tendency to bind loosely and nonspecifically to unrelated epitopes, which can create undesired background staining. In order to remove these nonspecifically bound antibodies, a thorough washing is required after each immunostaining step. Immuno Wash Buffer is specifically designed to remove such loosely bound antibodies effectively and efficiently and to provide a cleaner background staining.

Kit Contents

| Montage™ Tissue Primer | 20 mL |
|----------------------------------|----------|
| Montage™ PolyVue Enhancer | 20 mL |
| Montage™ Background Blocker | 20 mL |
| Montage™ PolyVue M/R HRP | 20 mL |
| Montage™ DAB Buffer | 5 x 8 mL |
| Montage™ DAB Substrate Chromogen | 2 mL |
| Montage™ Hematoxylin | 20 mL |





Diagnostic BioSystems 6616 Owens Drive











Preparation of Reagent

The reagents are provided in ready-to-use form, with the exception of DAB

Preparation of DAB Working Solution:

- For every 1 mL of the Stable DAB/Plus Buffer to a tube or mixing bottle add 1 drop (approximately 20 μL) of Stable DAB/Plus Chromogen to the buffer. Mix thoroughly.
- The substrate working solution is stable for two weeks refrigerated at 2-8°C. 2.
- Working solution volume can be scaled up using the same ratio of buffer to Chromogen
- 4. Dispose of unused Stable DAB/Plus Substrate working solution in appropriate waste stream according to local, state, and federal regulations.

Recommended Staining Protocol

- Paraffin embedded tissue sections must be deparaffinized with xylene or dewaxing agent and rehydrated with a graded series of ethanol and water washes before staining. Follow the standard dewaxing and rehydration protocol used in your lab.
- The investigator needs to optimize the incubation times for primary antibodies. 2.
- Each immunostaining run should include known positive and negative controls to assure proper functioning of the staining system and aid in valid interpretation of the results.
- 4. Consult the primary antibody datasheet for recommended for antigen recovery treatments. Perform epitope recovery pretreatments before starting the staining procedure.

Protocol Recommendations

- Pretreatment Solution/Protocol: Please refer to the respective primary antibody datasheet for recommended pretreatment solution and protocol.
- 2. Tissue Primer: Block for 5 minutes with DBS Montage™ Tissue Primer
- Background Blocker: Incubate for 5 minutes with the DBS Montage™ Background Blocker
- Primary Antibody: Please refer to the respective primary antibody datasheet for recommended primary antibody
- PolyVue Plus Enhancer: Incubate for 10 minutes at with DBS Montage™ PolyVue Plus Enhancer 5.
- PolyVue Plus HRP: Incubate for 10 minutes at with DBS Montage™ PolyVue Plus HRP
- Chromogen: Add 8 drops of Montage™ DAB Chromogen to 8mls of Montage™ DAB Substrate Buffer. Incubate tissue for 5 minutes using Montage™ DAB Substrate Buffer/Chromogen mixture
- Counterstain: Counterstain with Montage™ Hematoxylin for 2 minutes

Typical controls

Positive Control: A tissue known to contain the desired antigen, which has yielded positive staining in the past.

Negative Controls: Reagent Controls

- Substitute normal non-immune serum from the same host animal as the primary antibody (e.g. if using mouse monoclonal primary antibodies, use mouse non-immune serum).
- Substitute matching host species isotype control for primary antibody
- Use antigen-adsorbed primary antibody (i.e. antibody reagent which has been adsorbed with the target antigen to remove specific antibody)

Negative Controls: Tissue control – A tissue known to *not* contain the desired antigen.

Precautions

This product is a single-use, non-sterile, in vitro diagnostic device.

Specimens, before and after fixation and all materials exposed to them, should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. Microbial contamination of reagents may



Pleasanton, CA, 94588, USA









Diagnostic BioSystems 6616 Owens Drive



result in an increase in nonspecific staining. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change. The MSDS is available upon request.

Limitations and Warranties

There are no warranties, expressed or implied, which extend beyond this description.

Diagnostic BioSystems is not liable for property damage, personal injury, or economic loss caused by this product.

Storage and Stability

Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to

Stability is 12-24 months (see expiration date on reagent bottles)

Troubleshooting

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Diagnostic BioSystems Technical Support at 888-896-3350.











Switzerland

Diagnostic BioSystems 6616 Owens Drive