

**Safety Data Sheet**  
**PolyVue Plus HRP/DAB Detection System (EU)**



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**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1 Product identifier**

Product name	PolyVue Plus HRP/DAB Detection System
Product number	PVP25D, PVP100D, PVP250D, PVP1000D
Brand	PolyVue Plus HRP/DAB Detection System

**Other means of identification**

Component 1. K054: Tissue Primer  
Component 2. K023: Background Blocker  
Component 3. K047: Stable DAB/Plus

**1.2 Relevant identified uses of the substance or mixture and uses advised against**  
In Vitro Diagnostic Use

**1.3 Details of the supplier of the safety data sheet**

Name	Diagnostic Biosystems
Address	6616 Owens Drive Pleasanton CA 94588 USA
Telephone	(888) 896-3350
email	customersupport@dbiosys.com

**1.4 Emergency telephone number**

(925) 484-3350 (9AM-6PM, Monday - Friday, Pacific Standard Time)

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**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

**Classification according to Regulation (EC) No 1272/2008 (CLP)**

- Acute toxicity, inhalation (chapter 3.1), Cat. 5, H333
- Acute toxicity, oral (chapter 3.1), Cat. 5, H303
- Carcinogenicity (chapter 3.6), Cat. 1B, H350
- Germ cell mutagenicity (chapter 3.5), Cat. 2, H341
- Serious eye damage/eye irritation (chapter 3.3), Cat. 1, H318

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- Skin corrosion/irritation (chapter 3.2), Cat. 1A, H314
- Toxic to reproduction (chapter 3.7), Cat. 1B, H360

For the full text corresponding to the "H"-codes displayed in this section, refer to Section 16.

### 2.2 Label elements

#### Labelling according to Regulation (EC) No 1272/2008 [CLP]

##### Hazard pictograms



1. Exclamation mark; 2. Health hazard; 3. Corrosion

##### Signal word

**Danger**

##### Hazard statements

H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H332	Harmful if inhaled
H341	Suspected of causing genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child

##### Precautionary statements

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302+P352	IF ON SKIN: Wash with plenty of water.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P310	Immediately call a POISON CENTER/doctor.
P312	Call a POISON CENTER/doctor if you feel unwell.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P363	Wash contaminated clothing before reuse.
P405	Store locked up.
P501	Dispose of contents/container to a licensed disposal company.

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## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

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### Components

#### Component 1.

##### 1. Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)

Concentration < 0.1 % (volume)

Other names / synonyms 3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-isothiazolone; Kathon 886;

EC no. —

CAS no. 55965-84-9

Index no. 613-167-00-5

- Acute toxicity, inhalation (chapter 3.1), Cat. 2
- Acute toxicity, dermal (chapter 3.1), Cat. 2
- Acute toxicity, oral (chapter 3.1), Cat. 3
- Skin corrosion/irritation (chapter 3.2), Cat. 1C
- Eye damage/irritation (chapter 3.3), Cat. 1
- Sensitization - skin (chapter 3.4), Cat. 1A
- Hazardous to the aquatic environment, short-term (acute) (chapter 4.1), Cat. 1
- Hazardous to the aquatic environment, long-term (chronic) (chapter 4.1), Cat. 1

H301 Toxic if swallowed  
H310 Fatal in contact with skin  
H314 Causes severe skin burns and eye damage  
H317 May cause an allergic skin reaction  
H318 Causes serious eye damage  
H330 Fatal if inhaled  
H400 Very toxic to aquatic life  
H410 Very toxic to aquatic life with long lasting effects  
SCLs/M-factors/ATEs Skin Corr. 1C; : C ≥ ,6 %  
Skin Irrit. 2; H315: ,06 % ≤ C < ,6 %  
Eye Dam. 1; : C ≥ ,6 %  
Eye Irrit. 2; H319: ,06 % ≤ C < ,6 %  
Skin Sens. 1A; : C ≥ ,0015 %  
M=100  
M=100

#### 2. Hydrogen peroxide

Concentration < 5 % (volume)

Other names / synonyms ALBONE; DIHYDROGEN DIOXIDE; HYDROGEN DIOXIDE; HYDROGEN PEROXIDE; Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>); hydrogen peroxide solution; hydrogen peroxide solution; HYDROGEN PEROXIDE SOLUTION; Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide; Hydrogenii peroxidum; HYDROGENPEROXIDE; HYDROPEROXIDE; PEROXIDE; SUPEROXOL; T-STUFF

EC no. 231-765-0

CAS no. 7722-84-1

Index no. 008-003-00-9

- Acute toxicity, inhalation (chapter 3.1), Cat. 4
- Acute toxicity, oral (chapter 3.1), Cat. 4
- Oxidizing liquids (chapter 2.13), Cat. 1
- Skin corrosion/irritation (chapter 3.2), Cat. 1A

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H271 May cause fire or explosion; strong oxidizer  
H302 Harmful if swallowed  
H314 Causes severe skin burns and eye damage  
H332 Harmful if inhaled  
SCLs/M-factors/ATEs Ox. Liq. 1; H271: C ≥ 70 %\*\*\*\*  
Ox. Liq. 2; H272: 50 % ≤ C < 70 % \*\*\*\*  
\*  
Skin Corr. 1A; H314: C ≥ 70 %  
Skin Corr. 1B; H314: 50 % ≤ C < 70 %  
Skin Irrit. 2; H315: 35 % ≤ C < 50 %  
Eye Dam. 1; H318: 8 % ≤ C < 50 %  
Eye Irrit. 2; H319: 5 % ≤ C < 8 %  
STOT SE 3; H335: C ≥ 35 %

### 3. Hydrochloric acid

Concentration < 0.05 % (volume)

Other names / synonyms Acidum hydrochloricum; HYDROCHLORIC ACID; Hydrogen chloride  
EC no. 231-595-7  
CAS no. 7647-01-0  
Index no. 017-002-01-X

- Specific target organ toxicity, single exposure (chapter 3.8), Cat. 3
- Skin corrosion/irritation (chapter 3.2), Cat. 1B

H314 Causes severe skin burns and eye damage  
H335 May cause respiratory irritation  
SCLs/M-factors/ATEs Skin Corr. 1B; H314: C ≥ 25 %  
Skin Irrit. 2; H315: 10 % ≤ C < 25 %  
Eye Irrit. 2; H319: 10 % ≤ C < 25 %  
STOT SE 3; H335: C ≥ 10 %

### Component 2.

#### 1. SODIUM AZIDE

Concentration < 0.1 % (weight)

Other names / synonyms Sodium azide (Na(N<sub>3</sub>))  
EC no. 247-852-1  
CAS no. 26628-22-8  
Index no. 011-004-00-7

- Acute toxicity, dermal (chapter 3.1), Cat. 1
- Acute toxicity, inhalation (chapter 3.1), Cat. 2
- Acute toxicity, oral (chapter 3.1), Cat. 2
- Specific target organ toxicity, repeated exposure (chapter 3.9), Cat. 2
- Hazardous to the aquatic environment, short-term (acute) (chapter 4.1), Cat. 1
- Hazardous to the aquatic environment, long-term (chronic) (chapter 4.1), Cat. 1

### Component 3.

#### 1. 3,3'-Diaminobenzidine tetrahydrochloride hydrate

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Concentration	1 - 5 % (weight)
Other names / synonyms	[1,1'-Biphenyl]-3,3',4,4'-tetramine; biphenyl-3,3',4,4'-tetrayltetraamine; diaminobenzidine tetrahydrochloride hydrate
EC no.	231-018-9
CAS no.	868272-85-9

- Eye damage/irritation (chapter 3.3), Cat. 2
- Acute toxicity, oral (chapter 3.1), Cat. 4
- Carcinogenicity (chapter 3.6), Cat. 1B
- Germ cell mutagenicity (chapter 3.5), Cat. 2

H341	Suspected of causing genetic defects
H350	May cause cancer

### 2. Imidazole

Concentration	0.1 - 0.5 % (weight)
Other names / synonyms	1H-Imidazole;
EC no.	206-019-2
CAS no.	288-32-4
Index no.	613-319-00-0

- Reproductive toxicity (chapter 3.7), Cat. 1B
- Acute toxicity, oral (chapter 3.1), Cat. 4
- Skin corrosion/irritation (chapter 3.2), Cat. 1C

H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H360D	May damage the unborn child

### 3. Polysorbate 21

Concentration	< 0.15 % (volume)
Other names / synonyms	Polyoxyethylene sorbitan monolaurate; Polysorbate 20; Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs; Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.; Tween 20
EC no.	500-018-3
CAS no.	9005-64-5

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## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General notes	Consult a physician. Show this safety data sheet to the doctor in attendance.
Following inhalation	If breathed in, move person into fresh air. If not breathing, give artificial respiration.

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Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Following skin contact

Rinse with plenty of water. Get medical attention if irritation develops and persists.

Following eye contact

Rinse thoroughly with plenty of water for at least 15 minutes. Get medical attention if symptoms occur.

Following ingestion

Call a poison center or doctor if you feel unwell. If vomiting occurs naturally, have victim lean forward to reduce the risk of aspiration. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Acute and delayed symptoms and effects: May cause gastrointestinal irritation. Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Self-protection of the first aider

Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

### 4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

### 4.3 Indication of any immediate medical attention and special treatment needed

No data available

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Use extinguishing media appropriate for surrounding fire.

### 5.2 Special hazards arising from the substance or mixture

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Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): Carbon oxide. Nitrogen oxides.

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SODIUM AZIDE: Sodium oxides

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3,3'-Diaminobenzidine: Carbon oxides, Nitrogen oxides (NO<sub>x</sub>)

### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

#### Further information

No data available.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

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Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

### 6.2 Environmental precautions

Should not be released into the environment. See Section 12 for additional ecological information.

### 6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

### 6.4 Reference to other sections

For disposal see section 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### CAS: 26628-22-8 (EC: 247-852-1)

Sodium azide

ACGIH: 0.29 mg/m<sup>3</sup> (C); 0.1 ppm (C) hydrazoic acid vapor TLV® inhalation; NIOSH: 0.29 mg/m<sup>3</sup> (C); 0.1 ppm (C) hydrazoic acid vapor REL-C inhalation

#### CAS: 7647-01-0

Hydrochloric acid

Ca/OSHA: (C) 5 ppm PEL inhalation; NIOSH: (C) 5 ppm REL inhalation; OSHA: (C) 5 ppm PEL inhalation; (C) 7 mg/m<sup>3</sup> PEL inhalation

#### CAS: 7722-84-1

Hydrogen peroxide

ACGIH (USA): 1 ppm TLV® inhalation; Ca/OSHA (USA): 1 ppm PEL inhalation; NIOSH (USA): 1 ppm REL inhalation; OSHA (USA): 1 ppm PEL inhalation; 1.4 mg/m<sup>3</sup> PEL inhalation

### 8.2 Exposure controls

#### Appropriate engineering controls

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Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

### Individual protection measures, such as personal protective equipment

#### Pictograms



#### Eye and face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

#### Body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

#### Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

#### Thermal hazards

No data available

#### Control banding approach

No data available.

#### Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear
Colour	Varies by component
Odour	Odorless
Odour threshold	No data available.
pH	No data available.
Melting point/freezing point	No data available.
Boiling point or initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability	No data available.
Lower and upper explosion limit/flammability limit	No data available.
Vapor pressure	No data available.
Relative vapor density	No data available.
Density and/or relative density	No data available.



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Solubility	No data available.
Partition coefficient n-octanol/water (log value)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Kinematic viscosity	No data available.
Explosive properties	No data available.
Oxidizing properties	No data available.

### Particle characteristics

No data available.

## 9.2 Other information

### 9.2.1 Information with regard to physical hazard classes

No data available.

### 9.2.2 Other safety characteristics

No data available.

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

None under normal use conditions.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

None under normal use conditions.

### 10.4 Conditions to avoid

Exposure to moisture.

Avoid storing in direct sunlight and avoid extremes of temperature.

Heat, flames and sparks.

### 10.5 Incompatible materials

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Hydrogen peroxide: Zinc, Powdered metals, Iron, Copper, Nickel, Brass, Iron and iron salts.

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3,3'-Diaminobenzidine: Strong oxidizing agents

### 10.6 Hazardous decomposition products

Other decomposition products - No data available In the event of fire: see section 5

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Hydrogen peroxide: Hazardous decomposition products formed under fire conditions. - Nature of decomposition products not known.

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## SECTION 11: Toxicological information

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### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### Acute toxicity

The ATE (gas inhalation) of the mixture is: 90000 ppmV

The ATE (oral) of the mixture is: 5000 mg/kg bw

3,3'-Diaminobenzidine

LD50 Oral - Mouse - 1,834 mg/kg

Polyoxyethylene sorbitan monolaurate

LD50 Oral - Rat - 40,554.0 mg/kg

Sodium azide

LD50 Oral - Rat - 27 mg/kg

#### Skin corrosion/irritation

Sodium azide

LD50 Skin - Rat - 20 mg/kg

#### Serious eye damage/irritation

Causes serious eye irritation.

#### Respiratory or skin sensitization

Sodium azide

LC50 Inhalation - Rat - 0.054 - 0.52 mg/l - 4 hr

#### Germ cell mutagenicity

May cause genetic defects.

#### Carcinogenicity

3,3'-Diaminobenzidine

Oral - Rat

Result: Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Skin and Appendages: Other: Tumors.

Presumed to have carcinogenic potential for humans

#### Reproductive toxicity

May damage fertility or the unborn child

#### STOT-single exposure

No data available.

#### STOT-repeated exposure

No data available.

#### Aspiration hazard

No data available.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

No data available.

#### Other information

No data available.

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### SECTION 12: Ecological information

#### 12.1 Toxicity

Sodium azide

LC50 - Oncorhynchus mykiss (rainbow trout) - 2.96 mg/l - 96 h

Sodium azide

EC50 - Pseudokirchneriella subcapitata (green algae) - 0.348 mg/l - 96 h

#### 12.2 Persistence and degradability

No data available.

#### 12.3 Bioaccumulative potential

No data available.

#### 12.4 Mobility in soil

No data available.

#### 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

#### 12.6 Endocrine disrupting properties

No data available.

#### 12.7 Other adverse effects

No data available.

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

##### Product disposal

Offer surplus and non-recyclable solutions to a licensed disposal company.

##### Packaging disposal

Dispose of as unused product.

##### Waste treatment

No data available

##### Sewage disposal

Do not let product enter drains

##### Other disposal recommendations

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

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### SECTION 14: Transport information

14.1 UN Number	None
14.2 UN Proper Shipping Name	None
14.3 Transport hazard class(es)	None
14.4 Packing group	None
14.5 Environmental hazards	None
14.6 Special precautions for user	None

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14.7 Maritime transport in bulk according to IMO instruments None

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### SECTION 15: Regulatory information

#### 15.2 Chemical Safety Assessment

The supplier of this product has not conducted any Chemical Safety Assessment

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### SECTION 16: Other information

#### Full text of hazard statements referenced in Section 2

H303	May be harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H333	May be harmful if inhaled
H341	Suspected of causing genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child

SDS-0090, Rev. B

#### Further information/disclaimer

DISCLAIMER: The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigation to determine the suitability of information for their particular purposes. In no event shall Diagnostic BioSystems be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, whatsoever arising, even if Diagnostic BioSystems has been advised of the possibility of such damages.