



**DIAGNOSTIC AUTOMATION, INC.**

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## MATERIAL SAFETY DATA SHEET

# Strep A RapiCard™ InstaTest

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY NAME.

**Supplier:** Diagnostic Automation Inc.  
21250 Califa St. Suite 102 and 116  
Woodland Hills, CA 91367 USA

**Emergency Telephone number:** Please contact the regional poison Control Center.

**Product Name:** Strep A RapiCard™ InstaTest  
**Product classification:** In-Vitro diagnostics  
**Catalog No:** 176550-1-44

### 2. HAZARDS IDENTIFICATION

## 2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Chemical Ingredient Chemical Data / Information

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

## 2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard pictograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

## 2.3 Other hazards

At this concentration (0.02%) of Proclin 300, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested. ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

# 3. COMPOSITION / INFORMATION ON INGREDIENTS

## 3.1 Substances

This product is a mixture

## 3.2 Mixtures

Hazardous ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301 H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	0.001%

Lowest generic cut-off value according to Table 1.1 Annex I:  $\geq 0.1$

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 C  $\geq 0.6$  %

Skin Irrit. 2; H315:  $0.06$  %  $\leq C < 0.6$  %

Eye Irrit. 2; H319:  $0.06$  %  $\leq C < 0.6$  %

Skin Sens. 1; H317: C  $\geq 0.015$  %

# 4. FIRST-AID MEASURES

## 4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
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After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

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

Not applicable.

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

No data available.

## **5. FIRE-FIGHTING MEASURES**

### **5.1 Extinguishing media**

Suitable extinguishing media: The common fire extinguish media can be used

Unsuitable extinguishing media: Not investigate

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

Not find yet

### **5.3 Advice for fire-fighters**

Dry-chemical fire extinguisher

## **6. ACCIDENTAL RELEASE MEASURES**

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

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

### **6.2 Environmental precautions**

Avoid release to the environment.

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

Clean up with broom.

### **6.4 Reference to other sections**

Collect material and dispose of waste according to section 13.

## **7. HANDLING AND STORAGE**

### **7.1 Precautions for safe handling**

**General hygiene measures:** Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.

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

**Information about storage conditions:** Note the storage conditions on product packaging.

**Requirements for storage rooms and containers:** Store in a cool dry place.

### 7.3 Specific end uses

Rapid chromatographic immunoassay for the qualitative detection of Strep A antigen in human throat swab.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### 8.2.2 Personal protective equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

#### 8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<i>Physical State:</i>	Solid
<i>Colour:</i>	White appearance and some content of the test strip is purple
<i>Odours:</i>	Tastiness
<i>Odours threshold</i>	Not established
<i>Flash point</i>	Not established
<i>Self-igniting:</i>	Product is not known to be self-igniting

<i>Danger of explosion:</i>	There is no substances in the kit could lead to the danger of explosion
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	The product almost could not solute in the water

## 9.2 Other safety information

No

# 10. STABILITY AND REACTIVITY

## 10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

## 10.2 Chemical stability

All the chemicals in the test kits are stable.

## 10.3 Possibility of hazardous reactions

Almost impossible

## 10.4 Conditions to avoid

High humidity and the temperature out of 2-30°C

## 10.5 Incompatible materials

No

## 10.6 Hazardous decomposition products

No

# 11. TOXICOLOGICAL INFORMATION

## 11.1 Information on toxicological effects (Mixture)

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
Sensitisation	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Repeated dose toxicity	Not yet investigate
Carcinogenicity:	Not yet investigate

Mutagenicity:	Not yet investigate
Toxicity for reproduction:	No reproductive toxic effect known.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

No data available

### 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 Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

## 14. TRANSPORT INFORMATION

### 14.1 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods  
IATA: Not dangerous goods

#### **14.2 Transport hazard class**

ADR/RID: - IMDG: - IATA: -

#### **14.3 Packing group**

ADR/RID: - IMDG: - IATA: -

#### **14.4 Environmental hazards**

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No  
Marine Pollutant: No

#### **14.5 Special precautions for user**

See sections 6-8

#### **14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Delivery will only be taken in suitable and regulatory approved packaging

## **15. REGULATORY INFORMATION**

#### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

#### **15.2 Chemical Safety Assessment**

The mixture was not subjected to security assessment

## **16. OTHER INFORMATION**

#### **General information**

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.

Date Adopted	2017-09-18
REF 176550-1-44	<b>Strep A RapiCard™ InstaTest</b>



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**ISO 13485-2003**



Version No.1





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## MATERIAL SAFETY DATA SHEET

# Strep A RapiCard™ InstaTest Extraction Reagent 1

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY NAME.

**Supplier:** Diagnostic Automation Inc.  
21250 Califa St. Suite 102 and 116  
Woodland Hills, CA 91367 USA

**Emergency Telephone number:** Please contact the regional poison Control Center.

**Product Name:** Strep A RapiCard™ InstaTest Extraction Reagent 1  
**Product classification:** In-Vitro diagnostics  
**Catalog No:** NA

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

#### Classification according to regulation (EC) No. 1272/2008 appendix VII:

Oxidizing solids (Category 3), H272

Acute toxicity, Oral (Category 3), H301

Eye irritation (Category 2), H319

Acute aquatic toxicity (Category 1), H400

For the full text of the H-Statements mentioned in this Section, see Section 16.

#### Chemical Ingredient Chemical Data / Information

#### Classification according to regulation 67/548/EEC or regulation 1999/45/EC:

O Oxidising R8

T Toxic R25

N Dangerous for the environment R50

For the full text of the R-phrases mentioned in this Section, see Section 16.

### 2.2 Labe elements

#### Labelling according to regulation (EC) No. 1272/2008

Labelling should be according to regulation (EC) No. 1272/2008

#### Hazard pictograms and Signal word:



Danger

#### Hazardous components for labeling:

##### Hazard statements:

H272 May intensify fire; oxidiser.

H301 Toxic if swallowed.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

##### Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P273 Avoid release to the environment.

P280 Wear protective gloves/ eye protection/ face protection.

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. Rinse mouth.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P391 Collect spillage.

Supplemental Hazard None

Statements

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### 3.1 Substances

This product is a mixture

#### 3.2 Mixtures

Component	CAS No.	EINECS No.	Classification:	Conc %
Sodium Nitrite	7632-00-0	231-555-9	Ox. Sol. 3; Acute Tox. 3; Eye Irrit. 2; Aquatic Acute 1; H272, H301, H319, H400	≤100%

For the wording of the listed phrases refer to section 16

### 4. FIRST-AID MEASURES

#### 4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Can be irritating to skin, prolonged contact can be more severe, no adverse effects during normal usage. In case of skin contact, rinse area for at least 15 minutes. Remove contaminated clothes and shoes; wash thoroughly before reuse. Get immediately medical attention if irritation persists.
After eye contact	In case of eye contact, immediately rinse eye thoroughly with plenty of water. Remove contact lenses and continue rinsing for at least 15 minutes. Get immediate medical attention.
After Ingestion	If desiccant or other components are swallowed seek medical attention.

#### 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.

### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.  
Unsuitable extinguishing media: No data available

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

No data available

### **5.3 Advice for fire-fighters**

Wear self-contained breathing apparatus for firefighting if necessary.

## **6. ACCIDENTAL RELEASE MEASURES**

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

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

### **6.2 Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

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

Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area.

### **6.4 Reference to other sections**

Collect material and dispose of waste according to section 13.

## **7. HANDLING AND STORAGE**

### **7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Keep away from sources of ignition.

No smoking.

Keep away from heat and sources of ignition.

For precautions see section 2.2.

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

No specific storage is required. Use shelves or cabinets sturdy enough to bear the weight of the chemicals. Be sure that it is not necessary to strain to reach materials, and that shelves are not overloaded.

### **7.3 Specific end uses**

Extract the Strep A antigen before testing.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **8.1 Control parameters**

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### **8.2 Exposure controls**

#### **8.2.1 Appropriate engineering controls**

Not applicable.

### 8.2.2 Personal protective equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

### 8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<i>Physical State:</i>	Liquid
<i>Colour:</i>	Red or purple
<i>Odours:</i>	Odourless
<i>Odours threshold</i>	Not established
<i>Flash point</i>	Not established
<i>Self-igniting:</i>	The Product is not self-igniting
<i>Danger of explosion:</i>	Product does not present an explosion hazard
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	Easy to solute in water

### 9.2 Other safety information

Other physical-chemical data were not determined

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

### 10.2 Chemical stability

The product is stable in accordance with the recommended storage conditions.

### 10.3 Possibility of hazardous reactions

None Known

**10.4 Conditions to avoid**

None Know

**10.5 Incompatible materials**

Avoid contact with strong acids, bases and strong oxidizing agents

**10.6 Hazardous decomposition products**

None know

**11. TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects (Mixture)**

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Not applicable
Sensitisation	Not applicable
Repeated dose toxicity	Not applicable
Carcinogenicity:	The concentration of Sodium Nitrite in this product is 2M. No carcinogenic materials are contained.
Mutagenicity:	Not applicable
Toxicity for reproduction:	Not applicable

**12. ECOLOGICAL INFORMATION****12.1 Toxicity**

Toxicity of products of Biodegradation: The products of degradation are toxic

**12.2 Persistence and degradability**

Possibility hazardous short term degradation products are not likely. Long term degradation products may arise. The products of degradation are toxic.

**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 Other adverse effects**

No data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.
<i>General information</i>	Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

## 14. TRANSPORT INFORMATION

### 14.1 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### 14.2 Transport hazard class

ADR/RID: - IMDG: - IATA: -

### 14.3 Packing group

ADR/RID: - IMDG: - IATA: -

### 14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant: No

### 14.5 Special precautions for user

See sections 6-8

**14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**  
Delivery will only be taken in suitable and regulatory approved packaging

## 15. REGULATORY INFORMATION

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

EU regulations: Not application

National regulation (Germany): Not application

**15.2 Chemical Safety Assessment**

The mixture was not subjected to security assessment

## 16. OTHER INFORMATION

### General information

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user`s responsibility to determine the suitability of the information for their particular purposes.

### Hazard Statement

Acute Tox. Acute toxicity

Aquatic Acute Acute aquatic toxicity

Eye Irrit. Eye irritation

H272 May intensify fire; oxidiser.

H301 Toxic if swallowed.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

Ox. Sol. Oxidizing solids

### Risk phrases

R28 very toxic if swallowed

R32 contact with acids liberates very toxic gas

R50/53 very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

R60 May impair fertility

R61 May cause harm to the unborn child

<b>Date Adopted</b>	<b>2017-09-18</b>
<b>REF</b> NA	<b>Strep A RapiCard™ InstaTest Extration Reagent 1</b>





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## MATERIAL SAFETY DATA SHEET

# Strep A RapiCard™ InstaTest Extraction Reagent 2

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY NAME.

**Supplier:** Diagnostic Automation Inc.  
21250 Califa St. Suite 102 and 116  
Woodland Hills, CA 91367 USA

**Emergency Telephone number:** Please contact the regional poison Control Center.

**Product Name:** Strep A RapiCard™ InstaTest Extraction Reagent 2  
**Product classification:** In-Vitro diagnostics  
**Catalog No:** NA

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Chemical Ingredient Chemical Data / Information

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

### 2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008: Not applicable

Hazard pictograms and Signal word: Not applicable

Hazardous components for labeling

Hazard statements: Not applicable

Precautionary statements: Not applicable

### 2.3 Other hazards

No

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### 3.1 Substances

This product is a mixture

### 3.2 Mixtures

Component	CAS No.	EINECS No.	Classification:	Conc %
Citric acid	77-92-9	201-069-1	Eye Irrit. 2; H319	≤100%

For the wording of the listed phrases refer to section 16

## 4. FIRST-AID MEASURES

### 4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Can be irritating to skin, prolonged contact can be more severe, no adverse effects during normal usage. In case of skin contact, rinse area for at least 15 minutes. Remove contaminated clothes and shoes; wash thoroughly before reuse. Get immediately medical attention if irritation persists.
After eye contact	In case of eye contact, immediately rinse eye thoroughly with plenty of water. Remove contact lenses and continue rinsing for at least 15 minutes. Get immediate medical attention.
After Ingestion	If desiccant or other components are swallowed seek medical attention.

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

Not applicable

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

No data available.

### **5. FIRE-FIGHTING MEASURES**

#### **5.1 Extinguishing media**

Suitable extinguishing media: No special fire-fighting procedure require

Unsuitable extinguishing media: Use fire-extinguishing methods suitable to surrounding conditions

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

Not find yet

#### **5.3 Advice for fire-fighters**

No specific procedure.

### **6. ACCIDENTAL RELEASE MEASURES**

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

Refer to Section 8 for protective measures when handling the spillage.

#### **6.2 Environmental precautions**

Avoid release to the environment.

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

Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area.

#### **6.4 Reference to other sections**

Collect material and dispose of waste according to section 13.

### **7. HANDLING AND STORAGE**

#### **7.1 Precautions for safe handling**

Do not ingest. Do not breathe dust. Wear suitable protective clothing if ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes keep away from incompatibles such as oxidizing agents.

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

No specific storage is required. Use shelves or cabinets sturdy enough to bear the weight of the chemicals. Be sure that it is not necessary to strain to reach materials, and that shelves are not overloaded.

#### **7.3 Specific end uses**

Extract the Strep A antigen before testing.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls

Not applicable.

#### 8.2.2 Personal protective equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

#### 8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<i>Physical State:</i>	Liquid
<i>Colour:</i>	Colorless
<i>Odours:</i>	Odourless
<i>Odours threshold</i>	Not established
<i>Flash point</i>	Not established
<i>Self-igniting:</i>	The Product is not self-igniting
<i>Danger of explosion:</i>	Product does not present an explosion hazard
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	Easy to solute in water

### 9.2 Other safety information

Other physical-chemical data were not determined

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

### 10.2 Chemical stability

The product is stable in accordance with the recommended storage conditions.

### 10.3 Possibility of hazardous reactions

None Known

### 10.4 Conditions to avoid

None Know

### 10.5 Incompatible materials

Avoid contact with strong acids, bases and strong oxidizing agents

### 10.6 Hazardous decomposition products

None know

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects (Mixture)

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Not applicable
Sensitisation	Not applicable
Repeated dose toxicity	Not applicable
Carcinogenicity:	The concentration of Citric acid in this product is 0.027M. No carcinogenic materials are contained within this product.
Mutagenicity:	Not applicable
Toxicity for reproduction:	Not applicable

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

Toxicity of products of Biodegradation: The products of degradation are toxic

### 12.2 Persistence and degradability

Possibility hazardous short term degradation products are not likely. Long term degradation products may arise. The products of degradation are toxic.

### 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 Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.
<i>General information</i>	Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

## 14. TRANSPORT INFORMATION

### 14.1 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

#### 14.2 Transport hazard class

ADR/RID: - IMDG: - IATA: -

#### 14.3 Packing group

ADR/RID: - IMDG: - IATA: -

#### 14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant: No

#### 14.5 Special precautions for user

See sections 6-8

#### 14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging

### 15. REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations: Not application

National regulation (Germany): Not application


#### 15.2 Chemical Safety Assessment

The mixture was not subjected to security assessment

### 16. OTHER INFORMATION

#### General information

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user`s responsibility to determine the suitability of the information for their particular purposes.

Date Adopted	2017-09-18
 NA	<b>Strep A RapiCard™ InstaTest Extraction Reagent 2</b>





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## MATERIAL SAFETY DATA SHEET

# Strep A RapiCard™ InstaTest Positive Control

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY NAME.

**Supplier:** Diagnostic Automation Inc.  
21250 Califa St. Suite 102 and 116  
Woodland Hills, CA 91367 USA

**Emergency Telephone number:** Please contact the regional poison Control Center.

**Product Name:** Strep A RapiCard™ InstaTest Positive Control  
**Product classification:** In-Vitro diagnostics  
**Catalog No:** NA

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Chemical Ingredient Chemical Data / Information

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

### 2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008:

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard pictograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

### 2.3 Other hazards

At this concentration (0.02%) of Proclin 300, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested. ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### 3.1 Substances

This product is a mixture

### 3.2 Mixtures

Hazardous ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H - isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301 H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	<0.001%

Lowest generic cut-off value according to Table 1.1 Annex I:  $\geq 0.1$

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 C  $\geq 0.6$  %

Skin Irrit. 2; H315:  $0.06$  %  $\leq C < 0.6$  %

Eye Irrit. 2; H319:  $0.06$  %  $\leq C < 0.6$  %

Skin Sens. 1; H317: C  $\geq 0.0015$  %

## 4. FIRST-AID MEASURES

### 4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

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

Not applicable

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

No data available.

## **5. FIRE-FIGHTING MEASURES**

### **5.1 Extinguishing media**

Suitable extinguishing media: The common fire extinguish media can be used

Unsuitable extinguishing media: Not investigate

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

Not find yet

### **5.3 Advice for fire-fighters**

Dry-chemical fire extinguisher

## **6. ACCIDENTAL RELEASE MEASURES**

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

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

### **6.2 Environmental precautions**

Avoid release to the environment.

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

Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area.

### **6.4 Reference to other sections**

Collect material and dispose of waste according to section 13.

## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

**General hygiene measures:** Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.

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

**Information about storage conditions:** Note the storage conditions on product packaging.

**Requirements for storage rooms and containers:** Store in a cool dry place.

### 7.3 Specific end uses

As the external control for the Strep A Rapid Test.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls

Not applicable.

#### 8.2.2 Personal protective equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

#### 8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<i>Physical State:</i>	Liquid
------------------------	--------

<i>Colour:</i>	Colorless
<i>Odours:</i>	Odourless
<i>Odours threshold</i>	Not established
<i>Flash point</i>	Not established
<i>Self-igniting:</i>	The Product is not self-igniting
<i>Danger of explosion:</i>	Product does not present an explosion hazard
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	The product could solute in water easily

## 9.2 Other safety information

No

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

### 10.2 Chemical stability

All the chemicals in the test kits are stable.

### 10.3 Possibility of hazardous reactions

Almost impossible

### 10.4 Conditions to avoid

Temperature out of 2-30°C

### 10.5 Incompatible materials

No

### 10.6 Hazardous decomposition products

No

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects (Mixture)

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
Sensitisation	Contains a small volume of a very dilute, sensitizing preservative

	(ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Repeated dose toxicity	Not yet investigate
Carcinogenicity:	Not yet investigate.
Mutagenicity:	Not yet investigate
Toxicity for reproduction:	No reproductive toxic effect known.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

No data available

### 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 Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

## **14. TRANSPORT INFORMATION**

### **14.1 UN proper shipping name**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### **14.2 Transport hazard class**

ADR/RID: - IMDG: - IATA: -

### **14.3 Packing group**

ADR/RID: - IMDG: - IATA: -

### **14.4 Environmental hazards**

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant: No

### **14.5 Special precautions for user**

See sections 6-8

### **14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Delivery will only be taken in suitable and regulatory approved packaging

## **15. REGULATORY INFORMATION**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

### **15.2 Chemical Safety Assessment**


The mixture was not subjected to security assessment

## **16. OTHER INFORMATION**

### **General information**

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.



Date Adopted	2017-09-18
 NA	<b>Strep A RapiCard™ InstaTest Positive Control</b>



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## MATERIAL SAFETY DATA SHEET

# Strep A RapiCard™ InstaTest Negative Control

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY NAME.

**Supplier:** Diagnostic Automation Inc.  
21250 Califa St. Suite 102 and 116  
Woodland Hills, CA 91367 USA

**Emergency Telephone number:** Please contact the regional poison Control Center.

**Product Name:** Strep A RapiCard™ InstaTest Negative Control  
**Product classification:** In-Vitro diagnostics  
**Catalog No:** NA

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Chemical Ingredient Chemical Data / Information

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

### 2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008:

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard pictograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

### 2.3 Other hazards

At this concentration (0.02%) of Proclin 300, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested. ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### 3.1 Substances

This product is a mixture

### 3.2 Mixtures

Hazardous ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H - isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301 H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	<0.001%

Lowest generic cut-off value according to Table 1.1 Annex I:  $\geq 0.1$

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 C  $\geq 0.6$  %

Skin Irrit. 2; H315:  $0.06$  %  $\leq C < 0.6$  %

Eye Irrit. 2; H319:  $0.06$  %  $\leq C < 0.6$  %

Skin Sens. 1; H317: C  $\geq 0.0015$  %

## 4. FIRST-AID MEASURES

### 4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

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

Not applicable

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

No data available.

## **5. FIRE-FIGHTING MEASURES**

### **5.1 Extinguishing media**

Suitable extinguishing media: The common fire extinguish media can be used

Unsuitable extinguishing media: Not investigate

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

Not find yet

### **5.3 Advice for fire-fighters**

Dry-chemical fire extinguisher

## **6. ACCIDENTAL RELEASE MEASURES**

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

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

### **6.2 Environmental precautions**

Avoid release to the environment.

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

Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area.

### **6.4 Reference to other sections**

Collect material and dispose of waste according to section 13.

## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

**General hygiene measures:** Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.

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

**Information about storage conditions:** Note the storage conditions on product packaging.

**Requirements for storage rooms and containers:** Store in a cool dry place.

### 7.3 Specific end uses

As the external control for the Strep A Rapid Test.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### 8.2.2 Personal protective equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

#### 8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<i>Physical State:</i>	Liquid
<i>Colour:</i>	Colorless
<i>Odours:</i>	Odourless
<i>Odours threshold</i>	Not established
<i>Flash point</i>	Not established
<i>Self-igniting:</i>	The Product is not self-igniting
<i>Danger of explosion:</i>	There is no substances in the kit could lead to the danger of explosion
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	The product could solute in water easily

## 9.2 Other safety information

No

# 10. STABILITY AND REACTIVITY

## 10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

## 10.2 Chemical stability

All the chemicals in the test kits are stable.

## 10.3 Possibility of hazardous reactions

Almost impossible

## 10.4 Conditions to avoid

Temperature out of 2-30°C

## 10.5 Incompatible materials

No

## 10.6 Hazardous decomposition products

No

# 11. TOXICOLOGICAL INFORMATION

## 11.1 Information on toxicological effects (Mixture)

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.

Sensitisation	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Repeated dose toxicity	Not yet investigate
Carcinogenicity:	Not yet investigate.
Mutagenicity:	Not yet investigate
Toxicity for reproduction:	No reproductive toxic effect known.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

No data available

### 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 Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further

## 14. TRANSPORT INFORMATION

### 14.1 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### 14.2 Transport hazard class

ADR/RID: - IMDG: - IATA: -

### 14.3 Packing group

ADR/RID: - IMDG: - IATA: -

### 14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant: No

### 14.5 Special precautions for user

See sections 6-8

### 14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging

## 15. REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

### 15.2 Chemical Safety Assessment

The mixture was not subjected to security assessment

## 16. OTHER INFORMATION

### General information

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.



<b>Date Adopted</b>	<b>2017-09-18</b>
<b>REF NA</b>	<b>Strep A RapiCard™ InstaTest Negative Control</b>



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