



SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier	
Trade name	Influenza A & B Test, Dipstick
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Identified use(s)	<i>In vitro</i> diagnostic reagent. For professional use only.
1.3 Details of the supplier of the safety data sheet	
Company Identification	Alere Scarborough Inc., 10 Southgate Road, Scarborough, Maine 04074, USA.
Telephone	+1 207-730-5750
E-Mail (competent person)	ts.scr@alere.com
1.4 Emergency telephone number	
Emergency Phone No.	+1 207-730-5750

► SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS	Not classified as hazardous.
2.2 Label elements	Not applicable.
2.3 Other hazards	None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures	
Description:	<i>In vitro</i> diagnostic reagent. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.
Dangerous components:	The product does not contain reportable quantities of dangerous components.

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures	
General information	The following first aid measures are not expected to be required unless there is severe misuse of the product
Inhalation	Supply fresh air; consult doctor in case of complaint.
Skin Contact	Wash skin with soap and water.
Eye Contact	Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion	Wash out mouth with water. Consult a doctor.



SAFETY DATA SHEET

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| 4.2 | Most important symptoms and effects, both acute and delayed | None. |
| 4.3 | Indication of the immediate medical attention and special treatment needed | None. |

SECTION 5: FIRE-FIGHTING MEASURES

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| 5.1 | Extinguishing media
Suitable Extinguishing Media | CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| 5.2 | Special hazards arising from the substance or mixture | In case of fire, the following can be released: Carbon oxides (CO _x), nitrogen oxides (NO _x), |
| 5.3 | Advice for fire-fighters | Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

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| 6.1 | Personal precautions, protective equipment and emergency procedures | Refer to Section 8 for protective measures when handling the spillage. |
| 6.2 | Environmental precautions | No special requirements. |
| 6.3 | Methods and material for containment and cleaning up | Collect material and dispose of as waste according to Section 13. |
| 6.4 | Reference to other sections | 8, 13 |

SECTION 7: HANDLING AND STORAGE

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|-----|---|---|
| 7.1 | Precautions for safe handling | Specimens should be handled as potentially infectious materials. Refer to Regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with skin and eyes.
Keep out of reach of children.
Wash hands and exposed skin after use.
Clean work areas with hypochlorite or other disinfecting agent. |
| 7.2 | Conditions for safe storage, including any incompatibilities | Store in the original container at 4 to 30°C. |
| 7.3 | Specific end use(s) | Use as per instructions for use. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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| 8.1 | Control parameters | |
| 8.1.1 | Occupational Exposure Limits | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| 8.2 | Exposure controls | |
| 8.2.1 | Appropriate engineering controls | Not relevant for this material. |
| 8.2.2 | Personal protection equipment | |
| | Eye/face protection | Not normally required. |
| | Hand protection (Hygiene Measures) | Disposable gloves. |



Material of gloves: Latex / natural rubber, Nitrile rubber.
 Penetration time of glove material: Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection
 Respiratory protection Laboratory coat.

8.2.3 Environmental Exposure Controls No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	
Appearance	Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.
Color	White.
Odor	No odor.
Odor Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not available.
Boiling point/boiling range (°C):	Not applicable.
Flash Point (°C)	Not applicable
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapor Pressure (Pascal)	Not applicable.
Vapor Density (Air=1)	Not applicable.
Density (g/ml)	Not determined.
Solubility (Water)	Not applicable.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.
9.2 Other information	Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None known.
10.2 Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3 Possibility of hazardous reactions	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerization will not occur.
10.4 Conditions to avoid	None.
10.5 Incompatible materials	Strong Acids.
10.6 Hazardous Decomposition Product(s)	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects



SAFETY DATA SHEET

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitization	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The product is likely to persist in the environment.
12.3 Bioaccumulative potential	The product has low potential for bioaccumulation.
12.4 Mobility in soil	No data.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other adverse effects	Not applicable

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Packaging:	Disposal should be in accordance with applicable federal, state and 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



SAFETY DATA SHEET

providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable
14.2	Proper Shipping Name	Not applicable
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special precautions for user	Not applicable
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Chemical inventory listings relevant to US regulations	
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	
	Section 355 (extremely hazardous substances):	Sodium azide (< 1.0%)
	Section 313 (specific toxic chemical listings):	Sodium azide (< 0.1%)
15.2	Chemical Safety Assessment	Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Additional Information

Reason for update: Update in accordance with GHS.
Changes to section 2
► Indicates altered section

Supersedes: Version: 1

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SAFETY DATA SHEET

unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.