

SAFETY DATA SHEET

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

- 1.1 Product identifier**
Trade name Determine™ HIV-1/2 Ag/Ab Combo, Test Device
Reference No. 7D2648, 7D2649
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) In vitro diagnostic reagent. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074 - United States
Telephone +1 (207) 730-5750
E-Mail (competent person) ts.scr@abbott.com
- 1.4 Emergency telephone number**
Emergency Phone No. +1 (800) 424-9300

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** No measures required.
- 2.3 Other hazards** None anticipated.

► SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent test device. Preparation. 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 only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.
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 doctor in case of complaint.
Ingestion Wash out mouth with water. Consult a doctor.
- 4.2 Most important symptoms and effects, both** None.



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acute and delayed

- 4.3 Indication of the immediate medical attention and special treatment needed None.

SECTION 5: FIRE-FIGHTING MEASURES

- 5.1 **Extinguishing media**
Suitable Extinguishing Media CO₂, 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: Hazardous fumes, 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

- 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** Collect material and dispose of as waste according to Section 13
- 6.4 **Reference to other sections** 8, 13

SECTION 7: HANDLING AND STORAGE

- 7.1 **Precautions for safe handling** This product should be handled as a potentially infectious material, as no known test method can offer complete assurance that materials of human origin will not transmit infectious agents.
Specimens should be handled as potentially infectious materials. Refer to OSHA Regulation 29 CFR 1910.1030 for handling biohazardous materials.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.
- 7.2 **Conditions for safe storage, including any incompatibilities** Store in original container at 2 to 30°C.
- 7.3 **Specific end use(s)** Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 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**

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Eye/face protection



Safety glasses recommended.

Hand protection



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

Laboratory coat.

Respiratory protection

Not normally required.

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.

Colour

White.

Odour

No odour.

Odour Threshold (ppm)

Not applicable

pH (Value)

Not determined

Melting Point (°C) / Freezing Point (°C)

Not determined

Boiling point/boiling range (°C):

Not determined

Flash Point (°C)

Not applicable

Evaporation rate (BA = 1)

Not applicable

Flammability (solid, gas)

Not determined

Explosive limit ranges

Not applicable

Vapour Pressure (mm Hg)

Not applicable

Vapour Density (Air=1)

Not applicable

Density (g/ml)

Not determined

Solubility (Water)

Not determined

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 determined

Explosive properties

Not explosive.

Oxidising properties

Not oxidising

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 polymerisation will not occur.

10.4 Conditions to avoid

None

10.5 Incompatible materials

Strong Acids, Strong Alkalis, Strong oxidising agents.

10.6 Hazardous Decomposition Product(s)

None known.



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► SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	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	None anticipated.
12.4 Mobility in soil	The product is predicted to have low mobility in soil.
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 should be disposed of as potentially biohazardous material 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.
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Packaging:

Disposal should be in accordance with local, state or national legislation.
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.

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 Carcinogen listings IARC: NTP: ACGIH: OSHA: EPA: Californian Proposition 65 Chemicals known to cause cancer: Chemicals known to cause reproductive toxicity: SARA Section 355 (extremely hazardous substances): Section 313 (specific toxic chemical listings):	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809 None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. Sodium azide (trace). Sodium azide (trace).
15.2	Chemical Safety Assessment	Not applicable.

► SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

Additional Information

Reason for update:

SECTION 3: SECTION 11: SECTION 16:
► Indicates altered section.



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Supersedes:

Version: 1

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