

Material Safety Data Sheet

SECTION 1 COMPANY AND MATERIAL IDENTIFICATION

SUPPLIER OF DATA: AccuBioTech Co., Ltd.
No. 28, Yu Hua Road,
Beijing 101300 P.R. China

PRODUCT NAME(S): **CATALOG NUMBER(S):**

Accu-Tell[®] Rapid H. pylori Antigen Feces Test ABT-IDT-B76

SECTION 2 PRODUCT COMPOSITION

INGREDIENT NOTES:

The self-contained rapid test device includes all the reagents necessary to complete one test. The test area consists of a nitrocellulose membrane strip treated with thin lines of antibodies and a fiberglass pad containing antibody/dye conjugate. The test area also contains low levels of stabilizers and preservatives. The unit does not contain any human source material.

| Component | Raw materials | Amount |
|--|--------------------------------------|----------------------|
| Test-Region (Components of main reaction) | Anti-H. pylori antibodies | ≅ 1 µg |
| Control-Region (Components of function-check) | Goat anti mouse pAb | ≅ 2 µg |
| Solid Phase | Nitrocellulose-Membrane | 1.25 cm ² |
| Conjugate Pad | Glass-fiber | 0.5 cm ² |
| | H. Pylori Antigen | ≅ 2 µg |
| | Colloidal gold | ≅ 1 µg |
| Further reagents | Tris(hydroxymethyl)aminomethane | ≅ 250 ng |
| | Casein | ≅ 200 ng |
| | Citric Acid | ≅ 400 ng |
| | Tween 20 | ≅ 1 µg |
| | Polyethylene Glycol (PEG) 15 – 20 kd | ≅ 15 µg |
| | Polyvinyl Pyrrolidone (PVP) 40 kd | ≅ 7 µg |
| | Sodium Hydroxide | ≅ 100 ng |
| | Sucrose | ≅ 300 µg |
| | Phenylisothiocyanate | ≅ 10 ng |
| | Carnation Non-fat Dry Milk | ≅ 100 µg |
| | Sodium Azide, NaN ₃ | ≅ 50 ng |
| | Backing plate, PE | 3.6 cm ² |
| | Plastic housing | 1 |
| | Desiccant | 1 |
| Aluminum pouch | 1 | |
| buffer bottle | 1 | |

SECTION 3 HEALTH HAZARDS

WARNING STATEMENT: For in vitro medical diagnostic use only.

Potential Routes of Exposure: No hazardous exposures anticipated under conditions of use as described in the product literature.

Eye: None

Skin: None

Inhalation: None

Ingestion: None

Chronic Toxicity: None known.

Reproductive and Developmental Toxicity: The components of this product are not considered reproductive or developmental toxins.

Carcinogenicity: None of the components of this product is listed by NTP, IARC, or OSHA as a carcinogen

Medical Conditions Aggravated by Exposure: Skin and eye conditions (e.g., dermatitis, conjunctivitis).

SECTION 4 FIRST AID MEASURES

Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes. If discomfort persists notify medical personnel.

Skin Contact: Immediately wash thoroughly with soap and water for 15 minutes. If discomfort persists notify medical personnel.

Inhalation: Immediately move to fresh air. If discomfort persists notify medical personnel.

Ingestion: Drink a moderate amount (8-12 oz.) of water and immediately notify medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 FIRE FIGHTING MEASURES

Unusual Fire and Explosion Hazards: The nitrocellulose membrane is classified as a flammable solid. Keep away from excessive heat, fire or flame.

Hazardous Combustion Products: Oxides of carbon and nitrogen.

Extinguishing Media: Water, carbon dioxide, multipurpose dry chemical or halon-fire extinguisher.

Special Fire Fighting Equipment: Wear full protective clothing and NIOSH/MSHA-approved positive pressure, self-contained breathing apparatus. Thoroughly wash all equipment after use.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Take proper precautions to minimize exposure by using appropriate personal protective equipment. Shut off all sources of ignition.

SECTION 7 HANDLING AND STORAGE

Avoid contact between test area and skin, eyes or clothing. Wash thoroughly after handling. Store at 2- 30°C in original sealed package.

SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits: There are no established exposure limits for this product, nor indicated for any ingredients.

Eye and Face Protection: Wear safety glasses with side shields or full face shield if eye contact is likely. The choice of protection should be based on the potential for exposure to the eyes and face.

Respiratory Protection: Inhalation not anticipated in intended use. Respiratory protection not necessary.

Skin Protection: Wear gloves, lab coat, or other protective overgarment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.

Engineering Controls: Minimize any anticipated skin and eye contact with test.

Other: Wash hands immediately after handling this material (especially before eating, drinking or smoking).

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance, Color, Odor: Flat, white plastic housing containing white, narrow membrane test strip; odorless.

pH: Not applicable.

Boiling Point: Not applicable.

Melting Point: Not applicable.

Molecular Weight: Not available.

Flash Point: 200° C (nitrocellulose membrane)

Low Limit: Not available.

High Limit: Not available.

Autoflammability: Not available.

Explosive Properties: None.

Oxidizing Properties: None.

Vapor Pressure (mmHg & temp.): Nil

Specific Gravity (H₂O=1): Not available.

Solubility: Water: Nitrocellulose: insoluble.

Reagents: soluble

Fat: Not available.

Partition Coefficient: Not available.

Percent Volatile (%): Nil.

Vapor Density (air=1): Nil.

Evaporation (Butyl Acetate=1): Nil.

SECTION 10 STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use. Hazardous polymerization is not expected to occur. Over many years nitrocellulose will polymerize and become brown. Polymerization reduces the flash point.

Hazardous Decomposition Products: Oxides of carbon and nitrogen.

Conditions to Avoid: Excessive heat, direct sunlight (nitrocellulose)

Incompatibility: Incompatible with strong acids or alkalies.

SECTION 11 TOXICOLOGICAL INFORMATION

See Section 3 for Additional Information on Health Hazards

Inhalation: None.

Skin (irritancy and Acute Toxicity): None.

Eye (irritancy and Acute Toxicity): None.

Ingestion: None.

Chronic Toxicity (Target Organ Effects): None.

Carcinogenicity: None.

Reproductive and Developmental Toxicity: None.

Mutagenicity: None.

SECTION 12 ECOLOGICAL INFORMATION

Persistence and Degradability: No data available.

Aquatic Toxicity: No data available for this product.

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose of waste materials according to prescribed national and local regulations

SECTION 14 TRANSPORT INFORMATION

Land Transport (ADRIRID): Not regulated.

Air Transport (ICAO/IATA): Not regulated.

Maritime Transport (IMO-IMDG): Not regulated.

SECTION 15 REGULATORY INFORMATION

EINECS Status: This product does not contain any hazardous ingredients above trigger levels.

EEC Classification and Labeling: None required.

SECTION 16 OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties, and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.