Material Safety Data Sheet

H. Pylori Antigen ELISA

IDENTIFICATION OF THE PREPARATION AND COMPANY NAME.

1. IDENTIFICATION OF THE PREPARATION AND COMPANY NAME.

   **Product Name:** H. Pylori Antigen ELISA  
   **Catalog No:** 1506-11  
   **Synonyms:** N/A  
   **Intended Use:** Laboratory Use

2. COMPOSITION of the kit COMPONENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>Identification</th>
<th>Quantity</th>
<th>Main Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Microwell Strips</td>
<td>8 Wells x 12 Strips In</td>
<td>96 wells</td>
<td>Anti-H. pylori Ag Antibody coated on Polystyrene wells</td>
</tr>
<tr>
<td></td>
<td>sealed pouch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Enzyme Conjugate</td>
<td>Red Color Solution</td>
<td>12 ml</td>
<td>Anti-human H. pylori conjugate to Horseradish peroxidase in TBS buffer with bovine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>serum and ProClin-300</td>
</tr>
<tr>
<td>3. Negative Control</td>
<td>White Cap</td>
<td>1000 µl</td>
<td>Buffer solution contain bovine, serum and sodium azide</td>
</tr>
<tr>
<td>4. Calibrators</td>
<td>0, 6.3,12.5,25,50,100 ng/ml</td>
<td>1000 µl</td>
<td>Diluted H. pylori Ags in buffer solution contain bovine, serum and sodium azide</td>
</tr>
<tr>
<td>5. Positive Control</td>
<td>Violet Cap</td>
<td>1000 µl</td>
<td>Diluted H. pylori Ags in buffer solution contain bovine, serum and sodium azide</td>
</tr>
<tr>
<td>6. Washing Concentrate 20X</td>
<td>Black Cap</td>
<td>50 ml</td>
<td>PBS buffer with detergent</td>
</tr>
<tr>
<td>7. Sample Treatment solution</td>
<td>White Cap</td>
<td>100 ml</td>
<td>Buffer solution</td>
</tr>
<tr>
<td>8. TMB Chromogenic Substrate</td>
<td>Amber Bottle</td>
<td>12 ml</td>
<td>TMB (&lt;0.1%) Hydrogen Peroxide (&lt;0.03%) DMSO (&lt;3%)</td>
</tr>
<tr>
<td>9. Stop Solution</td>
<td></td>
<td>12 ml</td>
<td>HCl (≤ 1 molar) H₂SO₄ (≤ 0.25 molar)</td>
</tr>
<tr>
<td>10. Package Insert</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

3.1. Potential Biohazard:

The components 3, 4, and 5 (Calibrators and Controls) are formulated with a buffer base, animal serum, and purified H. pylori Antigens. The material represents purified proteins from bacteria. However, as with all biological materials, it should be handled as potentially infectious.
All bovine sera have been derived from animals of US origin and processed in USDA licensed facilities.

3.2. **Chemical Hazard:**

The components 3, 4, and 5 (Calibrators and Controls) are formulated with 0.1 % sodium azide. Concentrated Sodium Azide may react with copper and lead plumbing to form explosive metal azides. May react with acids to form explosive hydrazoic acid. If drain disposed, flush with large amounts of water to prevent azide build-up.

The component 8 (TMB Chromogenic Substrate) containing TMB, is formulated with DMSO, an irritant and mucous membranes. In case of contact with any of these reagents, wash thoroughly with water. TMB is a suspected carcinogen.

Component 9 (Stop Solution) is an acidic and corrosive agent. Avoid contact with skin.

4. **FIRST AID**

4.1. **Skin Contact:** Remove contaminated clothing and wash the exposed skin area thoroughly with soap and water.

4.2. **Eye Contact:** Flush with copious amounts of water for at least 15 minutes. Seek medical attention.

4.3. **Inhalation:** Remove to fresh air, give oxygen if breathing becomes difficult and seek medical attention.

4.4 **Ingestion:** Flush mouth with copious amounts of water, provided that the person is conscious and seek medical attention.

5. **MEASURES IN CASE OF FIRE**

5.1. Suitable Extinguishing Media: Chemical or water fire extinguisher.

5.2. Extinguishing Media Not to be Used: None known.

5.3. Special Fire Fighting Procedures: None Known.

5.4. Unusual Fire and Explosion Hazards: N/A

5.5. NFPA Rating: Health: 2, Flammability: 0, Reactivity: 1

6. **MEASURES IN CASE OF ACCIDENTAL SPILL**

6.1. **Body Precautions:** Wear rubber gloves, impermeable shoe covers and long laboratory coat.

6.2. **Environmental Precautions:** Contain the spill to the smallest area possible.

6.3. **Cleaning Measures:** Take care not to contaminate body. Absorb the material with disposable towels. Soak area with a 10% bleach solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations.

7. **MANIPULATION AND STORAGE**

7.1. **Manipulation:** Wear suitable personal protective equipment. Take care not to splash spill or splatter reagents. Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette samples or reagents by mouth.

7.2. **Storage:** Store the test kits in 2 - 8°C refrigerators designated and labeled to contain human blood products.

8. **EXPOSURE CONTROLS/PERSONAL PROTECTION**

8.1. **Body Protection:** Wear long laboratory coat.
8.2. Respiratory protection: In case of fire, wear self-contained breathing apparatus.
8.3. Hand Protection: Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated.
8.4. Eyes Protection: Wear safety glasses or goggles when a splash hazard exists.

9. ECOLOGICAL EFFECTS None known.

10. DISPOSAL REQUIREMENTS
10.1. Disposal of Preparation Left: Dispose according to current regional and national rules.
10.2. Contaminated Containers: Dispose of following current regulations.

11. TRANSPORTATION INFORMATION (Due to the sulfuric acid preparation in the kit):
11.1. Road / Railway Haulage ADR/RID: Class 8, Corrosive, limited quantity of material, excepted package.
11.2. Sea Freight IMO (IMDG): Class 8, Corrosive, limited quantity of material, excepted package.
11.3. Air Freight IATA (ICAO): Class 8, Corrosive, limited quantity of material, excepted package.
11.4. UN Number: 2796

12. INFORMATION ON REGULATION
12.1. Classification: This preparation is classified and labeled in accordance with applicable national and international regulations.
12.2. Symbols of Danger: N/A
12.3. "R" Phrases Indicating Specific Risks: Irritant
   R36/37/38, Irritating to the eyes, respiratory system and skin.
12.4. "S" Phrases Indicating Caution:
   S26, In case of contact with any reagents rinse with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
   S36, Wear suitable protective clothing.

13. OTHER INFORMATION

Recommended Use: For research or clinical investigational use only.
Not for use on or in human and animals.

Information contained in this MSDS relies upon our best knowledge of the product upon issue of this document to describe the use, storage, transport and disposal under safe and secure measures. Such information is not a guarantee of the characteristics and specific quality of the product. This MSDS concerns the stated preparation and cannot apply to the product if used with other materials or in a process other than those specifically stated.
ISO 13485
ISO 9001

Diagnostic Automation/Cortez Diagnostics, Inc.
21250 Califa Street, Suite 102 and d116,
Woodland Hills, CA 91367 USA

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REF 1506-11 AccuDia®™ H. Pylori Antigen ELISA Test Kit

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