SAFETY DATA SHEET
H.pylori Test Kit

Date of issue - 29/07/2009.  

Section 1. Chemical Product and Company Identification  

<table>
<thead>
<tr>
<th>Product No.</th>
<th>DR0130</th>
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<tr>
<td>Trade name</td>
<td>H.pylori Test Kit</td>
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</table>
| Manufacturer| Oxoid Limited  
Wade Road  
Basingstoke  
Hants RG24 8PW  
ENGLAND  
Tel: +44 (0)1256 841144  
Fax: +44 (0)1256 463388 |
| Supplier    | Oxoid Limited  
Wade Road  
Basingstoke  
Hants RG24 8PW  
ENGLAND  
Tel: +44 (0)1256 841144  
Fax: +44 (0)1256 463388 |

Section 2. Hazards Identification

Most Important Hazards
Not classified as hazardous. This product is for in vitro diagnostic use only.
Specimen material may contain pathogenic organisms. Handle with the appropriate precautions.

Section 3. Composition, Information on Ingredients

Hazardous ingredients
This preparation does not contain any substances presenting a health hazard within the meaning of the Dangerous Substances Directive 67/548/EEC.

Section 4. First Aid Measures

First Aid - Skin
Wash skin with soap and water.

Section 5. Fire Fighting Measures

Extinguishing Media - Suitable
Select extinguishing agent appropriate to other materials involved.

Section 6. Accidental Release Measures

Personal Precautions
Wear appropriate protective clothing.
Spill
Properly disinfect any spills. Test specimens require decontamination with a bleach solution or appropriate germicide prior to pick up.

Section 7. Handling and Storage

Handling
For in vitro diagnostic use only. Read the package insert. Always follow good laboratory practices when using this product.
Storage
Store in a refrigerator at 2 to 8 °C (36 to 46° F). Under these conditions the reagents will retain their reactivity until the expiry date shown on the kit box.
## Section 8. Exposure Controls, Personal Protection

### Protective Measures - Hands

Disposable vinyl gloves.

## Section 9. Physical and Chemical Properties

### Physical state

- **TEST CARDS (DR131M)**: Four card packages, each containing two test cards with three reaction circles. Latex reagent sensitised with partially purified Helicobacter pylori antigens, and containing <1% sodium azide, is dried on the reaction circles.

- **POSITIVE CONTROL (DR133M)**: One vial (0.5 ml) of diluted rabbit serum having antibodies reactive to Helicobacter pylori, and containing <0.1% sodium azide as a preservative. This reagent is supplied ready for use. Allow the reagent to warm to 18-25°C prior to conducting an assay.

- **NEGATIVE CONTROL (DR134M)**: One vial (0.5 ml) of diluted newborn calf serum, non reactive to H. pylori, and containing <0.1% sodium azide as a preservative. This reagent is supplied ready for use. Allow the reagent to warm to 18-25°C prior to conducting an assay.

- **DILUTION BUFFER (DR132M)**: One bottle (30 ml) of PBS pH 7.2 containing <0.1% sodium azide as a preservative. The buffer is supplied ready for use, but should be allowed to warm to 18-25°C prior to use.

- **MIXING STICKS**: Thirty (30) double-ended mixing sticks for mixing latex and diluted serum.

- **PLASTIC STORAGE POUCH**: One plastic pouch for storage of the opened test card package containing unused test cards.

## Section 10. Stability and Reactivity

### Stability

Do not use after expiry date. Stable under recommended storage and handling conditions (see section 7).

## Section 11. Toxicological Information

### Acute toxicity

All components have a low order of acute toxicity.

## Section 12. Ecological Information

### Ecotoxicity

No relevant studies identified.

## Section 13. Disposal Considerations

### Disposal considerations

Dispose of in accordance with all applicable local and national regulations.
Section 14. Transport Information

UN : UN number
Not regulated.

Section 15. Regulatory Information

Risk Phrases
Not applicable.

Safety Phrases
Avoid contact with skin and eyes.

EC Classification
This product is not classified according to the EU regulations.

Section 16. Other Information

MSDS first issued 30/09/2004
MSDS data revised 29/07/2009

USES
Oxoid Pylori Test is a rapid late agglutination test for the qualitative detection of Helicobacter pylori total antibodies in serum as an aid in the diagnosis of infection by H. pylori. The product is intended for use to test patients 18 years and older with symptoms of gastrointestinal disorders.

Revisions Highlighted Date of issue

Notes Classification and labelling have been performed according to EU directives 67/548/EEC, 1999/45/EC, including amendments and the intended use.