T AND EXPORT

Helicobacter Pylori Detector

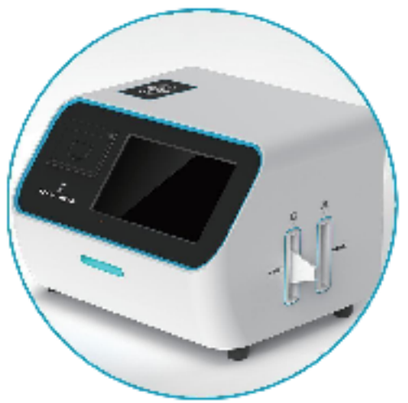


PRODUCT INTRODUCTION



LZS-HP-200A

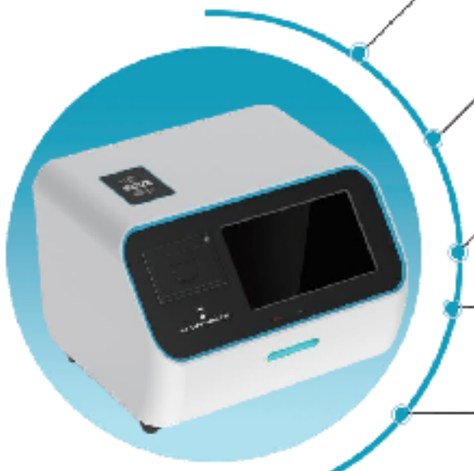
With one sample measurement chamber and upper computer software, the LZS-HP-200A can be used to test a single sample.



LZS-HP-200B

With two sample measurement chambers and upper computer software, the LZS-HP-200B can be used for simultaneous testing of two samples.

PRODUCT ADVANTAGES



01 New appearance design, beautiful and refreshing.

02 Good man–machine interaction interface, intuitive and simple.

03 Automatic detection, convenient and fast.

04 Available be connected to LAN for information sharing.

05 With high specificity and sensitivity, safe and accurate.

06 Supporting single card detection and double cards detection, fast and efficient.

JUDGMENT OF TEST RESULTS

1. Negative: If DPM≤99, Hp (−), it indicates an absence of Helicobacter pylori (Hp) infection.
2. Positive: If 99<DPM≤149, Hp, it indicates an infection with Hp.
3. Positive+: If 149<DPM≤499, Hp(+), it indicates an infection with Hp.
4. Positive++: If 499<DPM≤1499, Hp(++), it indicates an infection with Hp.
5. Positive+++: If 1499<DPM≤2499, Hp(+++), it indicates an infection with Hp.
6. Positive++++: If DPM>2499, Hp(++++), it indicates an infection with Hp.

LZS–HP–200 SERIES HP TEST METHOD



Expiration Card



Manufacturer:
Shanghai Xinke Pharmaceutical Co., Ltd.

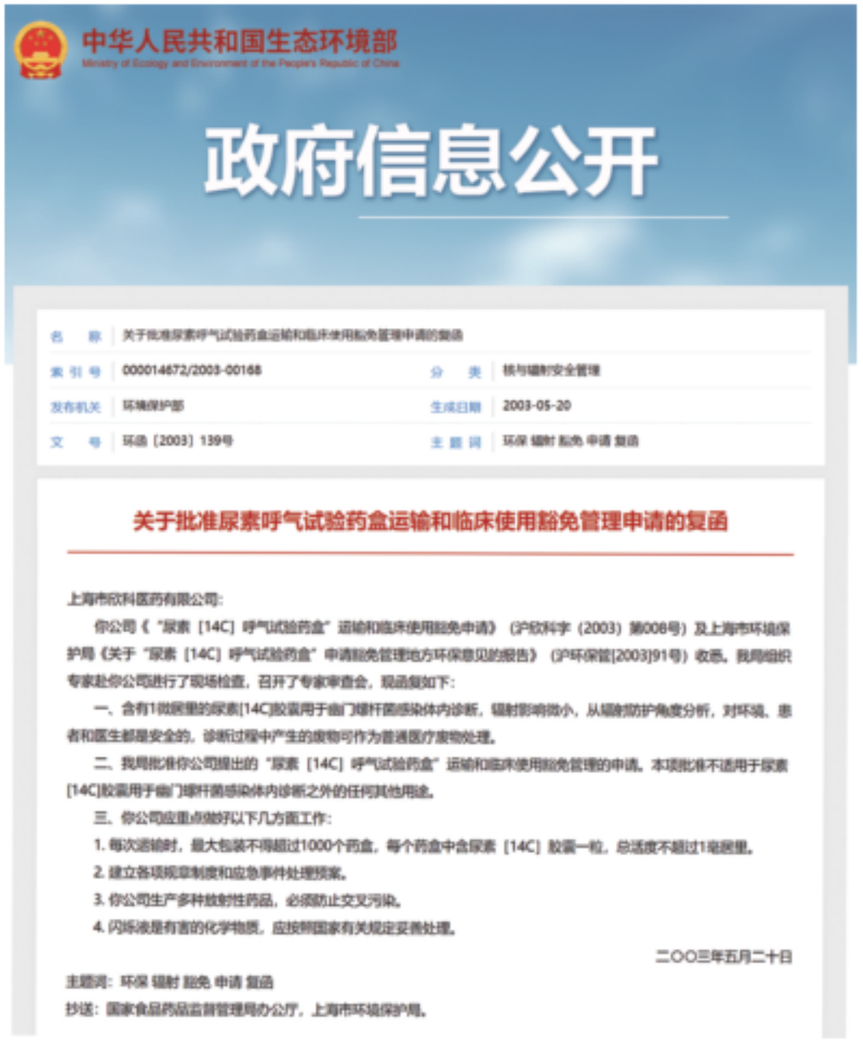
1. The person to be tested should perform the 14C– urea breath test on an empty stomach and is required to rinse the mouth before being tested;
2. Take urea [14C] capsules with appropriate amount of warm water, and then sit still for about 15 minutes;
3. Blow into a dedicated expiration card and collect exhalations;
4. Insert the expiration card with the exhalations of the person to be tested into this series of detectors, and then the diagnostic results will be displayed and printed automatically after 250 seconds;
5. The detector is equipped with a graphic printing workstation that can be connected to a standard printer to print reports in a standard format. It also supports customers to customize the format of the printed pages according to bias and preference.

MATTERS NEEDING ATTENTION

1. When collecting exhalations, please blow gently. You can change your breath, but it is strictly forbidden to breathe backwards.
2. It is recommended that this test be done in the morning, and the person to be tested should fast or fast for 4–6 hours and rinse the mouth before the test.
3. The following factors may have an impact on the test results:
   (1) HP–sensitive drugs such as antibiotics, bismuth preparations, and proton pump inhibitors were used within the last month.
   (2) There was a history of upper gastrointestinal bleeding within the last week.
   (3) Partial gastrectomy may lead to rapid depletion of isotopes from the stomach or a lack of acid in the patient's stomach.
   (4) Rupture of the capsule in the mouth can affect the test results.
4. Before a child being tested, it must be confirmed that the child is able to swallow the capsule and is able to blow through the mouthpiece.
5. Warm tips: pregnant and lactating women should not accept this test.

DETECTION SECURITY

*Urea [^{14}C] capsules containing 1 microcurie are with minimal radiation effects for in vivo diagnosis of Helicobacter pylori infection. From a radiation protection point of view, the test is safe for the environment, the patient as well as the doctor. The waste generated during the diagnostic process can be disposed of as general clinical waste.



中华人民共和国生态环境部
Ministry of Ecology and Environment of the People's Republic of China

政府信息公开

名　称	关于批准尿素呼气试验药盒运输和临床使用豁免管理申请的复函		
索 引 号	000014672/2003-00168	分　类	核与辐射安全管理
发布机关	环境保护部	生成日期	2003-05-20
文　号	环函〔2003〕139号	主 题 词	环保 辐射 豁免 申请 复函

关于批准尿素呼气试验药盒运输和临床使用豁免管理申请的复函

上海市欣科医药有限公司:

你公司《“尿素〔14C〕呼气试验药盒”运输和临床使用豁免申请》(沪欣科字(2003)第008号)及上海市环境保护局《关于“尿素〔14C〕呼气试验药盒”申请豁免管理地方环保意见的报告》(沪环保管[2003]91号)收悉。我局组织专家赴你公司进行了现场检查,召开了专家审查会,现函复如下:

一、含有1微居里的尿素[14C]胶囊用于幽门螺杆菌感染体内诊断,辐射影响微小,从辐射防护角度分析,对环境、患者和医生都是安全的,诊断过程中产生的废物可作为普通医疗废物处理。

二、我局批准你公司提出的“尿素〔14C〕呼气试验药盒”运输和临床使用豁免管理的申请。本项批准不适用于尿素[14C]胶囊用于幽门螺杆菌感染体内诊断之外的任何其他用途。

三、你公司应重点做好以下几方面工作:

1. 每次运输时,最大包装不得超过1000个药盒,每个药盒中含尿素〔14C〕胶囊一粒,总活度不超过1毫居里。
2. 建立各项规章制度和应急事件处理预案。
3. 你公司生产多种放射性药品,必须防止交叉污染。
4. 闪烁液是有害的化学物质,应按照国家有关规定妥善处理。

二〇〇三年五月二十日

主题词:环保 辐射 豁免 申请 复函
抄送:国家食品药品监督管理局办公厅,上海市环境保护局。

POPULAR SCIENCE WORLD

What is Helicobacter pylori?

Helicobacter pylori (Hp) is a Gram−negative bacterium that resides in the human gastric mucosa. In 1983, Marshall et al. cultured Hp from human gastric mucosal tissue and concluded that is the causative agent of chronic gastritis and peptic ulcer. Able to survive in high concentrations of stomach acid, Hp can not only coat the gastric mucosa, but can even cross the protective barrier of the stomach and cause lesions in the stomach.



What are the dangers of Helicobacter pylori?

- Class 1 carcinogen of gastric cancer, being able to destroy the normal structure and function of the stomach.
- Leading to a decrease or lack of stomach acid.
- Leading to acute and chronic gastritis.
- Leading to peptic ulcers and ulcer syndrome.
- Leading to gastric adenocarcinoma.