Overview

Useful For
Assessing pure isolates of *Helicobacter pylori* to predict clarithromycin resistance or susceptibility

Reflex Tests

<table>
<thead>
<tr>
<th>Test Id</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
<tr>
<td>PCRID</td>
<td>Identification by PCR</td>
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Testing Algorithm
When this test is ordered, the reflex test may be performed at an additional charge.

For more information see *Helicobacter pylori Diagnostic Algorithm*.

Special Instructions
- *Helicobacter pylori Diagnostic Algorithm*
- *Infectious Specimen Shipping Guidelines*

Highlights
This test detects the *Helicobacter pylori* 23S ribosomal RNA gene and the three most common 23S ribosomal RNA gene single nucleotide variations (A2143G, A2142G, and A2142C) leading to resistance to clarithromycin using viable or nonviable isolates to molecularly predict clarithromycin resistance or susceptibility.

Method Name
Real-Time Polymerase Chain Reaction (PCR)

NY State Available
Yes

Specimen

Specimen Type
Varies

Ordering Guidance
This test uses isolates of *Helicobacter pylori* for testing. If testing directly from feces is desired, order HPFRP / *Helicobacter pylori* with Clarithromycin Resistance Prediction, Molecular Detection, PCR, Varies.
**Additional Testing Requirements**
1. If identification testing is needed; also order IDENT / Organism Referred for Identification, Aerobic Bacteria.
2. If susceptibility testing is needed; also order ZMMLS / Antimicrobial Susceptibility, Aerobic Bacteria, MIC, Varies.

**Shipping Instructions**
1. For shipping information see [Infectious Specimen Shipping Guidelines](#).
2. Place specimen in a large infectious container and label as an etiologic agent/infectious substance, if appropriate.

**Necessary Information**
Organism identification and specimen source are required.

**Specimen Required**

**Supplies**: Infectious Container, Large (T146)  
**Container/Tube**: Agar slant or other appropriate media  
**Specimen Volume**: Isolate  

**Collection Instructions**:
1. Perform isolation of *Helicobacter pylori* in culture.  
2. *H pylori* isolate must be submitted in pure culture. **Do not submit mixed cultures.**

**Forms**
If not ordering electronically, complete, print, and send [Gastroenterology and Hepatology Client Test Request](#) (T728) with the specimen

**Specimen Minimum Volume**
See Specimen Required

**Reject Due To**

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<th>Temperature</th>
<th>Time</th>
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<tr>
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<tr>
<td>ESwab</td>
<td>Frozen</td>
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<tr>
<td>Port-a-Cult</td>
<td>Refrigerated</td>
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**Specimen Stability Information**

**Clinical & Interpretive**

**Clinical Information**
*Helicobacter pylori* is the main cause of peptic ulcer disease and a risk factor for gastric cancer when left untreated. Traditionally, *H pylori* diagnosis has included noninvasive tests (eg, urea breath test, fecal antigen test) or invasive tests (eg, gastric biopsy). Antimicrobial resistance in *H pylori* is poorly studied but is rising, challenging its treatment. In 2012, an international clinical consortium study group recommended monitoring of clarithromycin resistance rates and ceasing its use at a threshold range of 15% to 20%.(1) Local monitoring has been practically impossible as not all patients undergo invasive testing, which yields a culture isolate that can be subjected to susceptibility testing. Even if invasive testing is performed, the organism can be difficult to isolate in culture and is highly fastidious once isolated, oftentimes not being amenable to phenotypic susceptibility testing. Further, there are only a handful of specialized clinical microbiology laboratories that perform *H pylori* susceptibility testing. In an internal study of local and referred isolates, clarithromycin resistance was observed to be most commonly due to A2143G (70/88 isolates, 79.6%), followed by A2142G (12/88 isolates, 13.6%) and A2142C (3/88 isolates, 3.4%) alterations in the 23S ribosomal RNA gene.(2) Overall, one of these alterations was found in 97% of clarithromycin-resistant *H pylori* isolates studied.

**Reference Values**
Not applicable

**Interpretation**
A detected result indicates the presence of *Helicobacter pylori* 23S ribosomal RNA gene; the presence or absence of the 3 most common 23S ribosomal RNA gene single nucleotide variations (A2143G, A2142G, and A2142C) is reported.

A not detected result indicates the absence of detectable *H pylori* DNA.

**Cautions**
This assay is used for testing of isolates of *Helicobacter pylori*. Request HPFRP / *Helicobacter pylori* with Clarithromycin Resistance Prediction, Molecular Detection, PCR, Feces if testing directly from feces is desired.

Potential cross-reactivity may occur with the following non-pylori *Helicobacter* species: *Helicobacter acinonychis*, *Helicobacter cetorum*, and *Helicobacter mustalae* (not been reported to cause disease in humans) and *Helicobacter canis*, *Helicobacter cinaedi*, *Helicobacter bizzozeronii*, and *Helicobacter heilmannii* (infrequently found in humans).

This assay examines the 3 most common 23S ribosomal RNA point variants associated with clarithromycin resistance in *H pylori*. Other mechanisms of clarithromycin resistance are not assessed, nor are mechanisms of resistance to non-clarithromycin antimicrobial agents. The ZMMLS / Antimicrobial Susceptibility, Aerobic Bacteria, Varies assay is preferentially recommended for culture isolates to define a fuller spectrum of antimicrobial susceptibility (ie, to include antimicrobial agents beyond clarithromycin).

**Supportive Data**
During laboratory verification studies, 111 isolates of *Helicobacter pylori* (grown on Columbia agar with 5% sheep blood) with previous clarithromycin phenotypic susceptibility testing performed and which had undergone partial 23S ribosomal RNA gene sequencing were studied. This test matched phenotypic testing for 106/111 isolates (95.5% categorical agreement); a major error rate of 8.7% (2/23) and very major error rate of 3.4% (3/88) were observed. The assay results perfectly matched partial 23S ribosomal RNA gene sequencing data, including that performed on the 5 discordant isolates.
A subset of 45 of the isolates (including 1/5 isolates demonstrating a discordant result in the earlier study) were re-grown on tryptic soy agar with 5% sheep blood and re-assayed with this assay. The assay matched phenotypic testing in 44/45 isolates (97.8% categorical agreement); a major error rate of 0% and very major error rate of 3% (1/33) were observed. The polymerase chain reaction assay perfectly matched partial 23S ribosomal RNA gene sequencing data, including that performed on the single discordant isolates.

**Clinical Reference**


**Performance**

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**Method Description**

Viable and nonviable clinical isolates are processed by transferring up to a 1 mcL loop full of isolate into a swab neutralization buffer tube for thermal/physical lysis and then diluted 1:100 prior to testing. The polymerase chain reaction (PCR) assay employs a target-specific detection system including primers, as well TaqMan detection probes alongside a SimpleProbe for melt curve analysis-based genotyping targeting the 23S ribosomal RNA gene. The LightCycler 480 II instrument amplifies and monitors target nucleic acid sequences by fluorescence during PCR cycling. Detection of amplified product is based on the TaqMan probe principle. For PCR product detection, the TaqMan probe binds the complementary strand of amplified target. Specific PCR Taq polymerase with 5’-3’ exonuclease activity degrades the probe, releasing the fluorophore and breaking its proximity to the quencher molecule, allowing fluorescence of the fluorophores. At the conclusion of PCR cycling, amplified product is thermally denatured and then cooled to allow for a fluorescein labeled SimpleProbe to anneal to an 18-base pair region of the amplified target that includes the 2 position mutations associated clarithromycin resistance. The temperature is slowly raised while consistently monitoring fluorescence. The process is completed in a closed system to mitigate contamination. Further, contamination control is achieved through UNG enzymatic treatment and a master mix that includes deoxyuridine triphosphates.(Chen D, Cunningham SA, Cole NC, Kohner PC, Mandrekar JN, Patel R: Phenotypic and molecular antimicrobial susceptibility of *Helicobacter pylori*. Antimicrob Agents Chemother. 2017 Mar 24;61(4):e02530-16)

**PDF Report**

No

**Day(s) Performed**

Monday through Friday
Test Definition: HPCRP
Helicobacter pylori with Clarithromycin Resistance Prediction, Molecular Detection, PCR, Varies

Report Available
3 to 4 days

Specimen Retention Time
30 days

Performing Laboratory Location
Rochester

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87150

LOINC® Information

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