Overview

Useful For

Recovery of *Helicobacter pylori* from gastric specimens for antimicrobial susceptibility testing of the organism (amoxicillin, clarithromycin, levofloxacin, metronidazole and tetracycline are routinely tested)

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>GID</td>
<td>Bacteria Identification</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>TISSR</td>
<td>Tissue Processing</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>MIC</td>
<td>Sensitivity, MIC</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>SUS</td>
<td>Susceptibility</td>
<td>No, (Bill Only)</td>
<td>No</td>
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<tr>
<td>ISAE</td>
<td>Aerobe Ident by Sequencing</td>
<td>No, (Bill Only)</td>
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</tr>
<tr>
<td>HPCR1</td>
<td>H pylori + Clarithro Resistance PCR</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm

When this test is ordered, the reflex tests may be performed at an additional charged.

When *Helicobacter pylori* is isolated, identification will be confirmed and susceptibility testing performed. The routine susceptibility panel includes amoxicillin, clarithromycin, levofloxacin, metronidazole, and tetracycline.

See *Helicobacter pylori Diagnostic Algorithm* in Special Instructions.

Special Instructions

- *Helicobacter pylori Diagnostic Algorithm*

Method Name

Conventional Culture Techniques

NY State Available

Yes

Specimen

Specimen Type

Varies

Shipping Instructions

Specimen must be received in laboratory within 48 hours of collection. Specimen should be collected and packaged as close to shipping time as possible.

Necessary Information
Specimen source is required; include the specific anatomic source.

**Specimen Required**

**Preferred:**

**Specimen Type:** Gastric biopsy  
**Container/Tube:** Sterile container  
**Specimen Volume:** Entire collection  
**Collection Instructions:** Acquire biopsied tissue; moisten with sterile saline.

**Acceptable:**

**Specimen Type:** Gastric brushings or gastric aspirate  
**Container/Tube:** Sterile container  
**Specimen Volume:** Entire collection  

**Forms**

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

- [Microbiology Test Request](#) (T244)  
- [Gastroenterology and Hepatology Client Test Request](#) (T728)

**Specimen Minimum Volume**

0.5 mL or 0.5 x 0.2 x 0.2-cm sized piece of tissue

**Reject Due To**

| Biopsy submitted in fluid other than sterile saline | Reject |

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated</td>
<td>48 hours</td>
<td></td>
</tr>
</tbody>
</table>

**Clinical and Interpretive**

**Clinical Information**

*Helicobacter pylori* is a spiral-shaped gram-negative bacterium that may cause chronic gastritis, peptic ulcer disease, or gastric neoplasia. In adults of industrialized countries, an estimated 0.5% of the susceptible population becomes infected each year, although the incidence has been decreasing over time. The organism may asymptomatically colonize humans. In suspected *H pylori*-associated disease, the noninvasive stool antigen or urea breath test is recommended. If patients fail to respond to treatment and antimicrobial resistance is suspected, gastric biopsy,
gastric brushings, or gastric aspirate may be cultured to attempt to recover the organism for antimicrobial susceptibility testing to assess for resistance.

Multidrug regimens are required to attain successful cure of *H pylori* infection. Antimicrobial resistance in *H pylori* is increasing. Disease caused by *H pylori* resistant to clarithromycin is associated with a greater incidence of treatment failure than disease caused by a susceptible strain.

The Clinical and Laboratory Standards Institute (CLSI) recommends agar dilution for *H pylori* antimicrobial susceptibility testing. Amoxicillin, clarithromycin, levofloxacin, metronidazole and tetracycline are routinely tested. CLSI has defined interpretive categories for clarithromycin. The antimicrobials for which European Committee on Antimicrobial Susceptibility Testing defines interpretive categories include amoxicillin, clarithromycin, levofloxacin, metronidazole and tetracycline.

**Reference Values**

No growth after 7 days

Susceptibility results are reported as minimal inhibitory concentration (MIC) in mcg/mL and as susceptible, intermediate, or resistant according to breakpoint setting organizations, either the Clinical and Laboratory Standards Institute (CLSI) or the European Committee on Antimicrobial Susceptibility Testing (EUCAST), as applicable.

Susceptible (S):

A category defined by a breakpoint that implies that isolates with an MIC at or below the susceptible breakpoint are inhibited by the usually achievable concentrations of antimicrobial agent when the dosage recommended to treat the site of infection is used, resulting in likely clinical efficacy.

Intermediate (I):

A category defined by a breakpoint that includes isolates with MICs within the intermediate range that approach usually attainable blood and tissue levels and for which response rates may be lower than for susceptible isolates.

Note: The intermediate category implies clinical efficacy in body sites in which the drugs are physiologically concentrated. The intermediate category also includes a buffer zone for inherent variability in test methods, which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins.

Resistant (R):

A category defined by a breakpoint that implies that isolates with an MIC at or above the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and/or that demonstrate MICs that fall in the range in which specific microbial resistance mechanisms are likely, and clinical efficacy of the agent against the isolate has not been reliably shown in treatment studies. (Clinical and Laboratory Standards Institute: Performance Standards for Antimicrobial Susceptibility Testing. 29th Informational Supplement. CLSI Supplement M100. 2019)

**Interpretation**

A positive result provides definitive evidence of the presence of *Helicobacter pylori*.

Organisms may be detected in asymptomatic (colonized) individuals.

False-negative culture results may occur since the organism may die between biopsy collection and laboratory culture.
Cautions
Culture-negative results may occur due to the fastidious nature of the organism. Delays in specimen transportation will decrease recovery of the organism. Culture should be set up as soon as possible following specimen collection. Antimicrobial therapy may render the culture negative.

Due to *Helicobacter pylori*‘s fastidious nature and slow-growth, it may take 7 days to recover the organism and up to an additional 21 days to perform antimicrobial susceptibility testing.

When antimicrobial susceptibilities are performed, in vitro susceptibility does not guarantee clinical response. Therefore, the decision to treat with a particular agent should not be based solely on the antimicrobial susceptibility testing result. Clinical and Laboratory Standards Institute has defined interpretive categories for clarithromycin. The antimicrobials for which European Committee on Antimicrobial Susceptibility Testing has defined interpretive categories include amoxicillin, clarithromycin, levofloxacin, metronidazole and tetracycline.

Clinical Reference

Performance

Method Description
The selective *Helicobacter pylori* media used for isolation has a *Brucella* agar base with added vancomycin, trimethoprim, polymyxin B, and vitamin K1. Fresh medium and high humidity are essential for organism recovery. Plates are incubated at 35 degrees C in a microaerophilic atmosphere.(Couturier MR: *Helicobacter*. In Manual of Clinical Microbiology. 12th edition. Edited by KC Carroll, MA Pfaller. ASM Press. 2019, pp 1044-1057)

The agar dilution method is used for susceptibility testing. The antimicrobial is added to agar in various concentrations depending upon levels attainable in serum. A standardized suspension of the organism is applied to the agar plates that are incubated for 72 hours at 35 degrees C. Complete inhibition of all but 1 colony or a very fine residual haze represents the endpoint.(CLSI. Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria. Third edition. CLSI document M45. Clinical and Laboratory Standards Institute; 2015)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Sunday

Analytic Time
7 days

Maximum Laboratory Time
28 days

Specimen Retention Time
7 days

Performing Laboratory Location
Rochester
Fees and 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 Regional Manager. For assistance, contact Customer Service.

Test Classification
This test uses a standard method. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
87081-Helicobacter pylori culture
87077-Bacteria identification (if appropriate)
87153-Aerobe Ident by Sequencing (if appropriate)
87176-Tissue processing (if appropriate)
87181-Susceptibility (if appropriate)
87186-Sensitivity, MIC (if appropriate)
87798-H pylori + Clarithro Resistance PCR (if appropriate)

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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</thead>
<tbody>
<tr>
<td>HELIS</td>
<td>Helicobacter pylori Culture + Susc</td>
<td>587-6</td>
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</table>

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>HELIS</td>
<td>Helicobacter pylori Culture + Susc</td>
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