MAYO CLINIC LABORATORIES

Test Definition: HELIS

Helicobacter pylori Culture with Antimicrobial Susceptibilities, Varies

Overview

Useful For

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

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
GID	Bacteria Identification	No, (Bill Only)	No
ISAE	Aerobe Ident by Sequencing	No, (Bill Only)	No
TISSR	Tissue Processing	No, (BIll Only)	No
MIC	Susceptibility, MIC	No, (Bill Only)	No
SUS	Susceptibility	No, (Bill Only)	No
HPCR1	H pylori + Clarithro Resistance PCR	No, (Bill Only)	No

Testing Algorithm

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

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

If an isolate of *H pylori* does not grow for susceptibility testing, additional testing for *H pylori* with clarithromycin resistance prediction may be performed.

Special Instructions

- Helicobacter pylori Diagnostic Algorithm

Method Name

Conventional Culture Technique with Minimal Inhibitory Concentration (MIC) (Agar Dilution or Broth Microdilution or Gradient Diffusion) or Disk Diffusion if appropriate

NY State Available

Yes

Specimen

Specimen Type
Varies

Ordering Guidance
For test utilization options, see *Helicobacter pylori* Diagnostic Algorithm.

Shipping Instructions
1. Specimen must be received in laboratory within 48 hours of collection.
2. 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: Fresh tissue or biopsy
Sources: Gastric or duodenum
Container/Tube: Sterile container
Specimen Volume: 0.5 x 0.2 x 0.2-cm sized piece of tissue
Collection Instructions: Acquire biopsied tissue; moisten with sterile saline

Acceptable:
Specimen Type: Fluid
Sources: Gastric brushings, gastric aspirate
Container/Tube: Sterile container
Specimen Volume: Entire collection or 0.5 mL

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Microbiology Test Request (T244)
-Gastroenterology and Hepatology Test Request (T728)

Specimen Minimum Volume
See Specimen Required

Reject Due To

Biopsy submitted in fluid other than sterile saline	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated	48 hours	

Clinical & 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 *H pylori* with clarithromycin resistance prediction polymerase chain reaction (PCR) test or urea breath test is recommended for patients younger than 60 years old without alarming signs and symptoms (see *Helicobacter pylori* Diagnostic Algorithm). If clarithromycin resistance is predicted by the PCR test, endoscopy with biopsy should be considered for *H pylori* culture with antimicrobial susceptibility testing. For those 60 years old or older who have alarming signs and symptoms, endoscopy with biopsy is recommended, with consideration for *H pylori* culture with antimicrobial susceptibility testing on the gastric biopsy. If patients fail to respond to treatment, endoscopy with biopsy should be considered for *H pylori* culture with antimicrobial susceptibility testing.

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

Reference Values

No growth of *Helicobacter pylori*

Susceptibility results are reported as minimal inhibitory concentration (MIC) in mcg/mL. Breakpoints (also known as clinical breakpoints) are used to categorize an organism as susceptible, susceptible-dose dependent, intermediate, resistant, or nonsusceptible according to breakpoint setting organizations such as the Clinical and Laboratory Standards Institute (CLSI), the European Committee on Antimicrobial Susceptibility Testing (EUCAST), or the US Food and Drug Administration (FDA). Breakpoints are updated annually to reflect those published in the most current edition.

Breakpoints published by CLSI are used for routine susceptibility results. For those antimicrobials which do not have CLSI breakpoints, FDA breakpoints are used.

The CLSI breakpoint for clarithromycin and EUCAST breakpoints for antimicrobials other than clarithromycin are utilized for *Helicobacter pylori*.

In some instances, an interpretive category cannot be provided based on available data; therefore, the following comment will be included on the report: There are no established interpretive guidelines for agents reported without interpretations.

For information regarding CLSI and EUCAST susceptibility interpretations, see Susceptibility Interpretative Category Definitions.

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 antimicrobial susceptibility, testing result. The Clinical and Laboratory Standards Institute has defined interpretive categories for clarithromycin. The antimicrobials for which the European Committee on Antimicrobial Susceptibility Testing has defined interpretive categories include amoxicillin, clarithromycin, levofloxacin, metronidazole rifampin, and tetracycline.

Clinical Reference

Chen D, Cunningham SA, Cole NC, Kohner PC, Mandrekar JN, Patel R. Phenotypic and molecular antimicrobial susceptibility of *Helicobacter pylori.* Antimicrob Agents Chemother. 2017;61(4):e02530-16

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: Carroll KC, Pfaller MA, eds. Manual of Clinical Microbiology. 12th ed. ASM Press; 2019:1044-1057)

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.(Clinical and Laboratory Standards Institute [CLSI]. Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria. 3rd ed. CLSI document M45.CLSI; 2016)

PDF Report

No

Day(s) Performed
Monday through Sunday

Report Available
7 to 28 days

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

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 per drug and per organism for drugs not in routine battery (if appropriate)
87186-Antimicrobial Susceptibility, Aerobic Bacteria, MIC-per organism for routine battery (if appropriate)
87150-H pylori + Clarithro Resistance PCR (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HELIS	Helicobacter pylori Culture + Susc	587-6

Result ID	Test Result Name	Result LOINC® Value
HELIS	Helicobacter pylori Culture + Susc	587-6