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.

In the event that an isolate of *Helicobacter pylori* does not grow for susceptibility testing, reflex testing for *H pylori* with clarithromycin resistance prediction may be added.

For test utilization options, see *Helicobacter pylori* Diagnostic Algorithm

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

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: Fresh tissue or biopsy
Sources: Gastric
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

Specimen Type: Fresh tissue or biopsy
Sources: 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

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
See Specimen Required

Reject Due To

Biopsy submitted in fluid other	Reject

than sterile saline	

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 less 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 greater than or equal to 60 years old or 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 after 7 days

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, either the Clinical and Laboratory Standards Institute (CLSI) or the European Committee on Antimicrobial Susceptibility Testing (EUCAST), as applicable.

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

Clinical and Laboratory Standards Institute (CLSI) Interpretive Category Definitions:
Susceptible:

A category defined by a breakpoint that implies that isolates with an MIC at or below or a zone diameter at or above 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.

Susceptible-Dose Dependent:
A category defined by a breakpoint that implies that susceptibility of an isolate depends on the dosing regimen that is used in the patient. To achieve levels that are likely to be clinically effective against isolates for which the susceptibility testing results (either MICs or zone diameters) are in the susceptible-dose dependent (SDD) category, it is necessary to use a dosing regimen (ie, higher doses, more frequent doses, or both) that results in higher drug exposure than that achieved with the dose that was used to establish the susceptible breakpoint. Consideration should be given to the maximum literature-supported dosage regimens because higher exposure gives the highest probability of adequate coverage of a SDD isolate. The drug label should be consulted for recommended doses and adjustment for organ function.

Intermediate:
A category defined by a breakpoint that includes isolates with MICs or zone diameters within the intermediate range that approach usually attainable blood and tissue levels and/or for which response rates may be lower than for susceptible isolates.
Note: The intermediate category implies clinical efficacy in body sites where the drugs are physiologically concentrated or when a higher-than-normal dosage of a drug can be used. This category also includes a buffer zone, which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins.

Resistant:
A category defined by a breakpoint that implies that isolates with an MIC at or above or a zone diameter at or below the resistant breakpoint are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and/or that demonstrate MICs or zone diameters 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.

Nonsusceptible:
A category used for isolates for which only a susceptible breakpoint is designated because of the absence or rare occurrence of resistant strains. Isolates for which the antimicrobial agent MICs are above or the zone diameters are below the value indicated for the susceptible breakpoint should be reported as nonsusceptible.
Note: An isolate that is interpreted as nonsusceptible does not necessarily mean that the isolate has a resistance mechanism. It is possible that isolates with MICs above the susceptible breakpoint that lack resistance mechanisms may be encountered within the wild-type distribution after the time the susceptible-only breakpoint was set.

Epidemiological Cutoff Value:
The MIC that separates microbial populations into those with and without phenotypically detectable resistance (non-wild-type or wild-type, respectively). The epidemiological cutoff value (ECV) defines the highest MIC for the wild type population of isolates. ECVs are based on in vitro data only, using MIC distributions. ECVs are not clinical breakpoints, and the clinical relevance of ECVs for a particular patient has not yet been identified or approved by CLSI or any regulatory agency.

When an ECV is reported, an interpretive category is not assigned, and the following comment will be included: "This MIC is consistent with the Epidemiological Cutoff Value (ECV) observed in isolates (WITH/WITHOUT) acquired resistance; however, correlation with treatment outcome is unknown."

Wildtype (WT): An interpretive category defined by an ECV that describes the microbial population with no phenotypically detectable mechanisms of resistance or reduced susceptibility for an antimicrobial agent being evaluated.

Non-wildtype (NWT): An interpretive category defined by an ECV that describes the microbial population with phenotypically detectable mechanisms of resistance or reduced susceptibility for the antimicrobial agent being evaluated.
Note: MIC values for which ECV's are defined are not to be interpreted or reported as susceptible, intermediate, or resistant but rather as WT or NWT. The ECV's should not be used as clinical breakpoints.(Clinical and Laboratory Standards Institute [CLSI]: Performance Standards for Antimicrobial Susceptibility Testing. 31st ed. CLSI supplement M100. CLSI; 2021:4-6, 268-269)

European Committee on Antimicrobial Susceptibility Testing (EUCAST) Interpretive Category Definitions:
S - Susceptible, standard dosing regimen: A microorganism is categorized as "Susceptible, standard dosing regimen", when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent.

I - Susceptible, increased exposure*: A microorganism is categorized as "Susceptible, Increased exposure*" when there is a high likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen or by its concentration at the site of infection.

R - Resistant: A microorganism is categorized as "Resistant" when there is a high likelihood of therapeutic failure even when there is increased exposure*.

*Exposure is a function of how the mode of administration, dose, dosing interval, infusion time, as well as distribution and excretion of the antimicrobial agent will influence the infecting organism at the site of infection.(The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. v11.0, 2021. Available at www.eucast.org)

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. 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

Theel ES: *Helicobacter pylori* infection: Test utilization strategies for diagnosis. Mayo Medical Laboratories Communique. 2013;38(6):1-8

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; 2015)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

7 to 28 days

Specimen Retention Time

7 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 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