Test Definition: HELIS

Helicobacter pylori Culture with Antimicrobial Susceptibilities, Varies

Reporting Title: Helicobacter pylori Culture + Susc
Performing Location: Rochester

Ordering Guidance:

For test utilization options, see Helicobacter pylori Diagnostic Algorithm.

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 Requirements:

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

Specimen Minimum Volume:

See Specimen Required

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 Type	Temperature	Time	Special Container
Varies	Refrigerated	48 hours	

Ask at Order Entry (AOE) Questions:

Test ID	Question ID	Description	Type	Reportable
HELIS	Q00M0011	Specimen Source	Plain Text	No

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
HELIS	Helicobacter pylori Culture + Susc	Alphanumeric		587-6

LOINC and CPT codes are provided by the performing laboratory.

Supplemental Report:
No

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)

Reflex Tests:

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
GID	Bacteria Identification			No	No (Bill Only)
ISAE	Aerobe Ident by Sequencing			No	No (Bill Only)

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
TISSR	Tissue Processing			No	No (BIll Only)
MIC	Susceptibility, MIC			No	No (Bill Only)
SUS	Susceptibility			No	No (Bill Only)
HPCR1	H pylori + Clarithro Resistance PCR			No	No (Bill Only)

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, 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. 33rd. CLSI supplement M100. CLSI; 2023:8-10, 312-314)

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. Version 13.1, 2023. Available at www.eucast.org)