

***Helicobacter pylori* with Clarithromycin Resistance Prediction, Molecular Detection, PCR, Tissue**

Test ID: HPRP

Useful for:

Aiding in the diagnosis of *Helicobacter pylori* infection and prediction of clarithromycin resistance or susceptibility directly from gastric biopsies

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
TISSR	Tissue Processing	No	No

Methods:

Real-Time Polymerase Chain Reaction (PCR)

Reference Values:

Not detected

Specimen Requirements:

The high sensitivity of amplification by polymerase chain reaction requires the specimen to be processed in an environment in which contamination of the specimen by *Helicobacter pylori* DNA is unlikely.

Submit only 1 of the following specimens:

Specimen Type: Fresh tissue or biopsy

Sources: Stomach (or duodenum)

Container/Tube: Sterile container

Specimen Volume: Entire collection or 5 mm (3) approximate size of a pencil eraser

Collection Instructions:

1. Collect fresh tissue specimen.
2. Submit tissue in a sterile container (without adding anything).
3. Refrigerate or freeze the specimen.

Specimen Stability Information: Refrigerated (preferred) 7 days/Frozen 7 days

Preferred:**Supplies:** Tissue Block Container (T553)**Specimen Type:** Formalin-fixed, paraffin-embedded (FFPE) tissue block**Sources:** Stomach (or duodenum)**Container/Tube:** Tissue block**Collection Instructions:** Submit FFPE tissue block to be cut and returned.**Specimen Stability Information:** Ambient (preferred)/Refrigerated**Acceptable:****Specimen Type:** Formalin-fixed, paraffin-embedded (FFPE) tissue scroll**Sources:** Stomach (or duodenum)**Container/Tube:** Sterile container for each individual cut section (scroll)**Collection Instructions:** Perform microtomy and prepare five separate 10-micron sections. **Each section (scroll) must be placed in a separate sterile container for submission.****Specimen Stability Information:** Ambient (preferred)/Refrigerated**Specimen Stability Information:**

Specimen Type	Temperature	Time
Varies	Varies	Varies

Cautions:

Testing should be performed at least 4 weeks after completion of antibiotic (including bismuth) therapy and after proton pump inhibitor (PPI) or vonoprazan therapy has been withheld for 2 weeks. False-negative results may occur if testing occurs prior to these recommended timeframes. Histamine 2-receptor antagonists have been shown to slightly decrease the sensitivity of some *Helicobacter pylori* tests and, if possible, should be discontinued 2 weeks before testing. Antacids do not appear to impair test performance and may be taken until one day before testing.

Test results should be used as an aid in the diagnosis. The single assay should not be used as the only criterion to form a treatment decision; results of this test should be correlated with clinical presentation and results of other laboratory tests. A negative result does not negate the presence of the organism or active disease.

CPT Code:

87798

Day(s) Performed: Monday through Friday**Report Available:** 4 to 6 days**Questions**

Contact James Conn, Laboratory Resource Coordinator at 800-533-1710.