



# **Helicobacter pylori IgM ELISA Kit (For Human)**

Enzyme Immunoassay for the qualitative screening of IgM autoantibodies to Helicobacter pylori in serum or plasma.

Catalog number: ARG80560

distributed in the US/Canada by:  
**EAGLE BIOSCIENCES, INC.**  
20A NW Blvd, Suite 112 Nashua, NH 03063  
Phone: 617-419-2019 FAX: 617-419-1110  
[www.EagleBio.com](http://www.EagleBio.com) • [info@eaglebio.com](mailto:info@eaglebio.com)



For research use only. Not for use in diagnostic procedures.

---

## **TABLE OF CONTENTS**

<b>SECTION</b>	<b>Page</b>
PRINCIPLE OF THE ASSAY .....	3
MATERIALS PROVIDED & STORAGE INFORMATION .....	3
MATERIALS REQUIRED BUT NOT PROVIDED .....	4
TECHNICAL HINTS AND PRECAUTIONS .....	4
SAMPLE COLLECTION & STORAGE INFORMATION .....	5
REAGENT PREPARATION.....	5
ASSAY PROCEDURE .....	6
CALCULATION OF RESULTS .....	7
EXAMPLE OF TYPICAL STANDARD CURVE .....	7
Expected Values.....	7
INTERPRETATION OF RESULTS .....	8
QUALITY ASSURANCE.....	8

**MANUFACTURED BY:**

Arigo Biolaboratories Corporation

Address: No. 22, Ln. 227, Gongyuan Rd., Hsinchu City 300, Taiwan

Phone: +886 (3) 562 1738

Fax: +886 (3) 561 3008

Email: [info@arigobio.com](mailto:info@arigobio.com)

## Helicobacter pylori IgM ELISA Kit ARG80560

---

### PRINCIPLE OF THE ASSAY

This assay employs the qualitative enzyme immunoassay technique. Helicobacter antigen has been pre-coated onto a microtiter plate. Standards or samples are pipetted into the wells and any Ab present is bound by the immobilized antigen. After washing away any unbound substances, a HRP-conjugated anti human antibody is added to each well and incubate. After washing away any unbound antibody-enzyme reagent, a substrate solution (TMB) is added to the wells and color develops in proportion to the amount of Ab bound in the initial step. The color development is stopped by the addition of acid and the intensity of the color is measured at a wavelength of 450 nm  $\pm$ 2 nm. The concentration of Ab in the sample is then determined by comparing the O.D of samples to the standard curve.

### MATERIALS PROVIDED & STORAGE INFORMATION

Store the unopened kit at 2-8 °C. Use the kit before expiration date.

Component	Quantity	Storage information
Antigen-coated microplate	8 X 12 strips	4°C. Unused strips should be sealed tightly in the air-tight pouch.
Calibrator A (Negative Control)	2 ml (Ready-to-use)	4°C.
Calibrator B (Cut-Off standard)	2 ml (Ready-to-use)	4°C.
Calibrator C (Weak Positive Control)	2 ml (Ready-to-use)	4°C.
Calibrator D (Positive Control)	2 ml (Ready-to-use)	4°C.

## Helicobacter pylori IgM ELISA Kit ARG80560

---

HRP-Antibody conjugate	15 ml (Ready-to-use)	4°C
10X Wash buffer	60 ml	4°C
Sample Diluent	60 ml (Ready-to-use)	4°C
TMB substrate	15 ml	4°C (Protect from light)
STOP solution	15 ml	4°C

### MATERIALS REQUIRED BUT NOT PROVIDED

- Microplate reader capable of measuring absorbance at 450nm
- Pipettes and pipette tips
- Deionized or distilled water
- Automated microplate washer (optional)

### TECHNICAL HINTS AND PRECAUTIONS

- Wear protective gloves, clothing, eye, and face protection especially while handling blood or body fluid samples.
- Store the kit at 4°C at all times.
- Briefly spin down the antibody conjugate concentrate and HRP-Streptavidin concentrate before use.
- If crystals are observed in the 20X Wash buffer, warm to RT (not more than 50°C) until the crystals are completely dissolved.
- Ensure complete reconstitution and dilution of reagents prior to use.
- It is highly recommended that the standards, samples and controls be assayed in duplicates.
- Change pipette tips between the addition of different reagent or samples.

### **SAMPLE COLLECTION & STORAGE INFORMATION**

The sample collection and storage conditions listed below are intended as general guidelines. Sample stability has not been evaluated.

**Serum** - Use a serum separator tube (SST) and allow samples to clot for 30 minutes before centrifugation for 15 minutes at 1000 x g. Remove serum and assay immediately or aliquot and store samples at  $\leq -20$  °C. Avoid repeated freeze-thaw cycles.

**Plasma** - Collect plasma using EDTA or heparin as an anticoagulant. Centrifuge for 15 minutes at 1000 x g within 30 minutes of collection. Assay immediately or aliquot and store samples at  $\leq -20$  °C. Avoid repeated freeze-thaw cycles.

### **REAGENT PREPARATION**

- **1X Wash buffer:** Dilute 10X Wash buffer into distilled water to yield 1X Wash buffer.
- **Patient sample:** Dilute patient sample 1:100 with sample buffer before assay.

### ASSAY PROCEDURE

All materials should be equilibrated to room temperature (RT) before use. Standards, samples and controls should be assayed in duplicates.

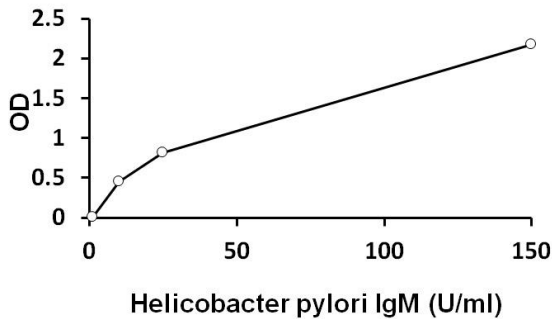
1. Remove excess microplate strips from the plate frame, return them to the foil pouch containing the desiccant pack, and reseal it.
2. Add 100  $\mu$ l of diluted samples, Calibrators and controls into wells. Leave one well empty for the substrate blank.
3. Incubate for 60 minutes at RT.
4. Aspirate each well and wash, repeating the process 2 times for a total 3 washes. Wash by filling each well with 1 $\times$  Wash Buffer (350  $\mu$ l) using a squirt bottle, manifold dispenser, or autowasher. Complete removal of liquid at each is essential to good performance. After the last wash, remove any remaining Wash Buffer by aspirating, decanting or blotting against clean paper towels.
5. Add 100  $\mu$ l 1X Antibody solution into each well (expect the substrate blank). Incubate for 30 minutes at RT.
6. Wash as according to step 4.
7. Add 100  $\mu$ l of TMB Reagent to each well. Incubate for 20 minutes at room temperature.
8. Add 100  $\mu$ l of Stop Solution to each well.
9. Read the OD with a microplate reader at 450 nm immediately.

### **CALCULATION OF RESULTS**

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may be estimated from the calibration curve by interpolation.

Using data reduction software a 4-parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

### **EXAMPLE OF TYPICAL STANDARD CURVE**



### **Expected Values**

In an in-house study apparently healthy subjects showed the following results:

Ig Isotype	n	Interpretation		
		Positive	Equivocal	Negative
IgM	72	1.4%	2.8%	95.8%

## **INTERPRETATION OF RESULTS**

Negative: < 8 U/ml

Equivocal: 8-12 U/ml

Positive: >12 U/ml

## **QUALITY ASSURANCE**

### **Limit of detection**

Functional sensitivity was determined to be 1.04 U/ml.

### **Cross-Reactivity**

No cross-reactivity to Yersinia enterocolitis.

### **Interferences**

No interferences to bilirubin up to 0.3 mg/mL, hemoglobin up to 8.0 mg/mL and triglycerides up to 5.0 mg/mL.

### **Intra-assay and Inter-assay precision**

The CV value of intra-assay precision was 8.1% and inter-assay precision was 9.4%.

### **Recovery**

113-126%



---

distributed in the US/Canada by:

## EAGLE BIOSCIENCES, INC.

20A NW Blvd, Suite 112 Nashua, NH 03063  
Phone: 617-419-2019 • FAX: 617-419-1110  
[www.EagleBio.com](http://www.EagleBio.com) • [info@eaglebio.com](mailto:info@eaglebio.com)



***For further information about this kit, its application or the procedures in this kit insert, please contact the Technical Service Team at Eagle Biosciences, Inc. at [info@eaglebio.com](mailto:info@eaglebio.com) or at 866-411-8023.***

---

### **Warranty Information**

Eagle Biosciences, Inc. warrants its Product(s) to operate or perform substantially in conformance with its specifications, as set forth in the accompanying package insert. This warranty is expressly limited to the refund of the price of any defective Product or the replacement of any defective Product with new Product. This warranty applies only when the Buyer gives written notice to the Eagle Biosciences within the expiration period of the Product(s) by the Buyer. In addition, Eagle Biosciences has no obligation to replace Product(s) as result of a) Buyer negligence, fault, or misuse, b) improper use, c) improper storage and handling, d) intentional damage, or e) event of force majeure, acts of God, or accident.

Eagle Biosciences makes no warranties, either expressed or implied, except as provided herein, including without limitation thereof, warranties as to marketability, merchantability, fitness for a particular purpose or use, or non-infringement of any intellectual property rights. In no event shall the company be liable for any indirect, incidental, or consequential damages of any nature, or losses or expenses resulting from any defective product or the use of any product. Product(s) may not be resold, modified, or altered for resale without prior written approval from Eagle Biosciences, Inc.

For further information about this kit, its application or the procedures in this kit, please contact the Technical Service Team at Eagle Biosciences, Inc. at [info@eaglebio.com](mailto:info@eaglebio.com) or at 866-411-8023.