

**K-ASSAY®**

# H. pylori Calibrator

**Cat. No. KAI-241C**

## INTENDED USE

The **K-ASSAY®** H. pylori Calibrator is for the calibration of the **K-ASSAY®** H. pylori Test Reagent. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

## SUMMARY

The calibrators in this kit contain known quantities of anti-*H. pylori* antibodies. They are to be used as calibrators for the **K-ASSAY®** H. pylori Test Reagent.

## KIT COMPOSITION

### Calibrators (Liquid Stable)

## MATERIALS PROVIDED

Calibrator 1-5 Anti-*H. pylori* antibodies 5 x 2 mL  
Contains 5 levels with assigned values for Anti-*H. pylori* antibodies

## WARNINGS AND PRECAUTIONS

For research use only in the U.S. Not for use in diagnostic procedures in the U.S.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Do not mix or use calibrators from one test kit with those from a different lot number.

Do not use calibrators past their expiration date stated on each calibrator container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Although these calibrators do not contain any human origin material, no test method can completely assure the absence of viruses or other infection agents. This product should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Calibrators in this kit contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in lead drain lines. When disposing of calibrators through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA.

## CALIBRATOR PREPARATION

The calibrators are ready to use.

## STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used up to the expiration date on the package and bottle labels.

## CALIBRATOR STABILITY

Opened bottles of calibrators can be used for 5 weeks if tightly capped and stored at 2-8°C. Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

Calibrator transferred to the instrument sample cup may concentrate over time. Therefore, calibrators should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrators should be used for each calibration.

## INSTRUMENT

Measurements of absorbance are to be made with a chemistry analyzer able to accurately read absorbance at approximately 570 nm. Refer to the instrument manual from the manufacturer regarding the following:

- a) Use or function
- b) Installation procedures and requirements
- c) Principles of operation
- d) Performance characteristics, operating instructions
- e) Calibration procedures including materials and / or equipment to be used
- f) Operational precautions, limitations, and hazards
- g) Service and maintenance information

## PROCEDURE

Calibrators should be used as specified in the **K-ASSAY®** H. pylori Test Reagent assay package inserts.

## Materials Supplied

Calibrator 1	1 x 2 mL
Calibrator 2	1 x 2 mL
Calibrator 3	1 x 2 mL
Calibrator 4	1 x 2 mL
Calibrator 5	1 x 2 mL

## Materials Required But Not Supplied

**K-ASSAY**® H. pylori Test Reagent

Saline (0.9% NaCl) as 0 U/mL (blank) calibrator.

Two Reagent Chemistry Analyzer:

- Capable of accurate absorbance readings at 570 nm
- Capable of accurately dispensing the required volumes
- Capable of maintaining 37°C

## Details of Procedure

NOTE: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

The **K-ASSAY**® H. pylori Calibrator is assayed using the same procedure as the test samples run in the test procedure. See package insert from the **K-ASSAY**® H. pylori Test Reagent.









## CALIBRATOR VALUES

	H. pylori (U/mL)	Cap Color
Calibrator 1	10	Blue
Calibrator 2	20	Pink
Calibrator 3	40	Light Green
Calibrator 4	70	Dark Red
Calibrator 5	100	Dark Brown

Note: An additional saline blank (0 U/mL H. pylori) is required.

The values for the **K-ASSAY**® H. pylori Calibrator are continually being revised through ongoing quality assurance. As a result, the expected values may change from lot to lot. Please refer to the package insert for each lot for the exact calibrator values.

## LABELING SYMBOLS

	Lot Number
	Calibrator
	Expiration or "Use By" Date
	Catalog Number
	2-8°C Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
	Consult Package Insert for Instructions for Use
	Authorized Representative in the European Community

## EU AUTHORIZED REPRESENTATIVE



**Advena Ltd.**

Tower Business Centre, 2<sup>nd</sup> Flr.,  
Tower Street, Swatar, BKR 4013 Malta

## ORDERING / PRICING / TECHNICAL INFORMATION



**KAMIYA BIOMEDICAL COMPANY**

12779 Gateway Drive  
Seattle, WA 98168 USA  
TEL: (206) 575-8068 / (800) 526-4925  
FAX: (206) 575-8094