

K-ASSAY®

H. pylori Control

(For the **K-ASSAY®** H. pylori Test Reagent)

Lot 123456, Exp. 2022-02-28

Cat. No. K242C-2M and K242C-4M

INTENDED USE

The **K-ASSAY®** H. pylori Control is intended to be used as a consistent test sample of known concentration for monitoring the performance of the **K-ASSAY®** H. pylori Test Reagent for automated chemistry analyzers. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

SUMMARY

The controls in this set contain anti-*H. pylori* antibodies. They are to be used as controls for the **K-ASSAY®** H. pylori Test Reagent for automated chemistry analyzers.

SET COMPOSITIONK242C-2M

Level 1 Anti- <i>H. pylori</i> control (liquid)	1 x 2 mL
Level 2 Anti- <i>H. pylori</i> control (liquid)	1 x 2 mL

K242C-4M

Level 1 Anti- <i>H. pylori</i> control (liquid)	2 x 2 mL
Level 2 Anti- <i>H. pylori</i> control (liquid)	2 x 2 mL

K-ASSAY® H. pylori Control contains 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 controls from one test set with those from a different lot number.

Do not use controls past their expiration date stated on each control container label.

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

Although these controls 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.

Controls in this set contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of controls 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 Centers for Disease Control, Atlanta, GA.

CONTROL PREPARATION

Controls are liquid and ready to use.

STORAGE AND HANDLING

Store controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used for up to 12 months from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

CONTROL STABILITY

Opened controls can be used for 5 weeks if stored at 2-8°C.

Discard controls if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

PROCEDURE**Materials Supplied**K242C-2M

Level 1 Anti- <i>H. pylori</i> control (Negative)	1 x 2 mL
Level 2 Anti- <i>H. pylori</i> control (Positive)	1 x 2 mL

K242C-4M

Level 1 Anti- <i>H. pylori</i> control (Negative)	2 x 2 mL
Level 2 Anti- <i>H. pylori</i> control (Positive)	2 x 2 mL

Materials Required But Not Supplied

K-ASSAY® H. pylori Test Reagent kits

K-ASSAY® H. pylori Calibrator

Two-reagent chemistry autoanalyzer capable of accurate absorbance reading at 570 nm, accurately dispensing the required volumes, and maintaining 37°C.

Assay Procedure

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

The **K-ASSAY**® H. pylori Control 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 kits.

LIMITATIONS OF PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. Erroneous results can occur from improper storage and technical errors associated with assay procedures.

This product is intended for use as an assayed control for the qualitative **K-ASSAY**® H. pylori Test Reagent kits. This product is not intended for use as a calibrator.

The expected values for the **K-ASSAY**® H. pylori Control 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 appropriate control values.

EXPECTED RESULTS

KAMIYA BIOMEDICAL COMPANY has established the expected values using **K-ASSAY**® reagents and calibrators. Actual values recovered depend on the instrument and reagent used. The assignment of mean values was derived from analysis of vials representative of the entire lot.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of H. pylori Control correspond to the lot numbers listed for the Assay Data.

H. pylori Assay Data:

Control	Cap Color	Lot 123456, Exp. 2022-02-28		
		Assigned Value (U/mL)	Range (U/mL)	Assay Result
H. pylori Control, Level 1 (Negative)	White	5.0	3.0 – 7.0	Negative
H. pylori Control, Level 2 (Positive)	Yellow	20.0	16.0 – 24.0	Positive

LABELING SYMBOLS

	Lot Number
	Control
	Expiration or "Use By" Date
	Catalog Number
	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, 2nd Fl.,
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

Printed February 2021