H.PYLORI CONTROL - POSITIVE-NEGATIVE SET **PRODUCT CODE: HPC-300**

LOT# HPC(P-N)1G6 **EXP: 07-2019**

INTENDED USE

The H.Pylori Control - Positive-Negative Set are intended for use as an assayed quality control material to monitor the consistency of performance of laboratory test procedures associated with determination and monitoring of the clinical status. This product is a human serum-based lyophilized control, stabilized with preservatives and can be used with all ELISA and CLIA methods.

SUMMARY AND EXPLANATION

The use of quality control material to assist in the assessment of precision in the clinical laboratory is an integral part of laboratory practices. Controls that contain varied levels of analytes are necessary to insure precision and accuracy in immunoassay systems.

REAGENTS

Monobind's H. Pylori Controls are intended to be used in the exact manner as patient samples. The control is packaged as six (6) vials of 1.0 ml lyophilized (3 negatives and 3 positives). The analyte activities are adjusted to concentrations in the positive and negative range in order to monitor the efficacy of the procedure in use.

INSTRUCTIONS FOR USE

1) Bring the vials to room temperature before use.
2) Carefully unscrew and remove cap.
3) Add one (1) ml of distilled or deionized water to each vial. Close the cap tightly and let the contents mix thoroughly for 30 minutes.
4) Aliquot the materials in 0.5 ml aliquots in cryo vials and store at -20ºC.
5) Controls and Patients Sample Dilution (1/100)
Dispense 0.010ml (10µl) of each patient specimen into 0.990ml of serum diluent. Cover and vortex or mix thoroughly by inversion. Store at 2-8ºC for up to forty-eight (48) hours.

STORAGE, STABILITY AND DISPOSAL

After reconstituting, controls should be tightly capped and returned to refrigerator 2 to 8° C as soon as practical after usage. (Long term room temperature storage is not supported.) After reconstituting, controls should be tightly capped and frozen within 2-hours. Once thawed, do not refreeze the control; discard remaining material. It is recommended that customers aliquot control into separate containers before freezing to allow for usage on different days. Outdated material should be discarded as a biohazardous component.

STORAGE	STABILITY	TEMPERATURE
Lyophilized, unopened	Three (3) years	< 8°C
Reconstituted, opened	Seven (7) days	2 – 8°C
Reconstituted, opened	Ninety (90) days	<-10°C

ASSIGNMENT OF VALUES & EXPECTED RANGE OF VALUES

EXPECTED RANGE OF VALUES FOR H.Pylori Controls - Positive-Negative Set MASTER LOT HPC(P-N)1B4			
Analyte	Positive HPC-P Range	Negative HPC-N Range	Method
Anti-H.Pylori IgG	>80	<15	MB ACCUBIND ELISA
	>80	<20	MB ACCULITE CLIA
Anti-H.Pylori IgM	>35	<10	MB ACCUBIND ELISA
	>35	<10	MB ACCULITE CLIA
Anti-H.Pylori IgA	>40	<12	MB ACCUBIND ELISA
	>35	<12	MB ACCULITE CLIA

The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by Monobind QC using representative lots of this product, as well as those of Monobind's AccuBind® ELISA and AccuLite® CLIA reagents.

Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Therefore, each laboratory should establish its own means and acceptable ranges for the product used, using Monobind's assignment only as guide. A trend log should be maintained for batch to batch consistency of the test. Variations over time and between laboratories may be caused by a) differences in laboratory personnel, b) improper technique, c) instrumentation and reagents, d) improper dilutions from the manufacturer's stated procedure, and/ or e) modifications in the manufacturer's test procedure.

Refer to http://www.monobind.com/site/qc-documents.html for any updated insert information.

WARNING AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE

All products that contain human serum have been found to be negative and non reactive for HIV 1&2, HIV-Ag, HBsAg, HCV and RPR by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

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