



Read Highlighted Changes: Revised November 2014.

INTENDED USE

The ARCHITECT Anti-HCV Controls are for the verification of the calibration of the ARCHITECT iSystem when used for the qualitative detection of antibody to Hepatitis C virus (anti-HCV) in human serum and plasma.

Refer to the ARCHITECT Anti-HCV reagent package insert for additional information.

CONTENTS

2 Bottles (8 mL each) of ARCHITECT Anti-HCV Controls are prepared in recalcified human plasma (inactivated). The Positive Control is reactive for anti-HCV. Preservative: Sodium Azide.

The controls are at the following:

Control	Color	Titer	Control Range S/CO
CONTROL -	Natural	N/A*	≤ 0.60
CONTROL +	Blue**	≥ 1:1	1.71 - 5.13

* Not Applicable.

** Dye: Acid Blue No. 9

PRECAUTIONS

- IVD**
- For *In Vitro* Diagnostic Use

-  **CAUTION:** This product contains human-sourced and/or potentially infectious components. Refer to the **CONTENTS** section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.¹⁻⁴
- The human plasma used in the Negative Control is nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HCV, and anti-HIV-1/HIV-2.
- The human plasma used in the Positive Control is reactive for anti-HCV and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag and anti-HIV-1/HIV-2.

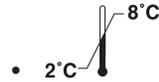
The following warnings and precautions apply to: CONTROL - / CONTROL +	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

STORAGE

- Controls are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.



PREPARATION FOR ANALYSIS

Controls should be mixed by gentle inversion prior to use.

BIBLIOGRAPHY

- US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
- US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
- World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
- Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Third Edition*. CLSI Document M29-A3. Wayne, PA: CLSI; 2005.

Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL -	Negative Control
CONTROL +	Positive Control
IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot Number
PRODUCT OF GERMANY	Product of Germany
RANGE	Range
REF	List Number
TITER	Titer

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