



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
<b>CONTROL -</b>	Natural	N/A*	≤ 0.60
<b>CONTROL +</b>	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.<sup>1-4</sup>
- 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: <b>CONTROL -</b> / <b>CONTROL +</b>	
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](http://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

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. 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
<b>CONTAINS: AZIDE</b>	Contains Sodium Azide. Contact with acids liberates very toxic gas.
<b>CONTROL -</b>	Negative Control
<b>CONTROL +</b>	Positive Control
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device
<b>LOT</b>	Lot Number
<b>PRODUCT OF GERMANY</b>	Product of Germany
<b>RANGE</b>	Range
<b>REF</b>	List Number
<b>TITER</b>	Titer

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