



Read Highlighted Changes: Revised November 2014.

INTENDED USE

The ARCHITECT Anti-HCV Calibrator is for 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

1 Bottle (4 mL) of ARCHITECT Anti-HCV Calibrator is prepared in recalcified human plasma (inactivated); reactive for anti-HCV. Preservative: Sodium Azide.

Calibrator	Color
CAL 1	Green*

* Dyes: Acid Yellow No. 23 and 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 Calibrator 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: CAL 1	
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

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








PREPARATION FOR ANALYSIS

Calibrator 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
CAL 1	Calibrator 1
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot Number
PRODUCT OF GERMANY	Product of Germany
REF	List Number

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Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

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