



Read Highlighted Changes: Revised November 2014.

INTENDED USE

The ARCHITECT Anti-HBc II Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT iSystem when used for the qualitative detection of antibody to hepatitis B core antigen (anti-HBc) in human serum and plasma. Refer to the ARCHITECT Anti-HBc II reagent insert and the ARCHITECT System Operations Manual for additional information.

CONTENTS

2 Bottles (8.0 mL each) of ARCHITECT Anti-HBc II Controls: Negative Control and Positive Control. The Negative Control contains recalcified human plasma. The Positive Control contains recalcified human plasma and dye, and is reactive for anti-HBc. Preservatives: ProClin 950 and sodium azide.

The controls are at the following ranges:

Control	Color	Target S/CO	Control Range S/CO
CONTROL -	Natural	N/A	0.00 - 0.80
CONTROL +	Blue*	2.73	1.50 - 3.96

* 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 anti-HBc, HBsAg, anti-HIV-1/HIV-2, anti-HCV and HIV-1 RNA or HIV-1 Ag.
- The human plasma used in the Positive Control is reactive for anti-HBc, and nonreactive for HBsAg, anti-HIV-1/HIV-2, anti-HCV and HIV-1 RNA or HIV-1 Ag.

The following warnings and precautions apply to: CONTROL - / CONTROL +	
WARNING	Contain methylisothiazolone and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
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 may be used immediately after removal from 2-8°C storage. Prior to each use, mix by gentle inversion. After each use, tightly close the caps and return the controls to 2-8°C storage.

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
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
WARNING: SENSITIZER	Warning: May cause an allergic reaction.

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