



ARCHITECT
Anti-HBc II Calibrator

REF 8L44-01



Anti-HBc II
8L44
G4-7702 / R04
S8L440

Read Highlighted Changes: Revised November 2014.

INTENDED USE

The ARCHITECT Anti-HBc II Calibrator 1 is for the calibration 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

1 Bottle (4.0 mL) of ARCHITECT Anti-HBc II Calibrator 1 containing recalified human plasma and dyes. The calibrator is reactive for anti-HBc. Preservatives: ProClin 950 and sodium azide.

The calibrator is at the following concentration:

Calibrator	Color	Concentration (PEI U/mL)
CAL 1	Green*	0.5

* Dyes: Acid Yellow No.23 and Acid Blue No.9

STANDARDIZATION

The ARCHITECT Anti-HBc II Calibrator 1 concentration is standardized against the Anti-HBc IgG reference standard of the Paul Ehrlich Institute, Langen, Germany.

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-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: CAL 1	
	
WARNING	Contains 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

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



PREPARATION FOR ANALYSIS

Calibrator 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 cap and return the calibrator 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
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
WARNING: SENSITIZER	Warning: May cause an allergic reaction.

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**Customer Service: Contact your local representative
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www.abbottdiagnostics.com**

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