





HBsAg Qualitative II Controls



INTENDED USE

The ARCHITECT HBsAg Qualitative II Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the qualitative detection and for the confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma using the ARCHITECT HBsAg Qualitative II and HBsAg Qualitative II Confirmatory Reagent Kits. Refer to the ARCHITECT HBsAg Qualitative II and ARCHITECT HBsAg Qualitative II Confirmatory Reagent package inserts and the ARCHITECT System Operations Manual for additional information.

CONTENTS


2 Bottles (8.0 mL each) of ARCHITECT HBsAg Qualitative II Controls. The Negative Control (**CONTROL** ) contains recalcified human plasma. Preservatives: ProClin 950 and sodium azide. The Positive Control (**CONTROL** ) contains inactivated purified human HBsAg (subtype *ad/ay*) in phosphate buffer with human plasma and protein (bovine serum albumin) stabilizers. Preservatives: ProClin 300 and ProClin 950. The controls are at the following ranges:

For the ARCHITECT HBsAg Qualitative II assay:

Control	Color	S/CO	
		Target TARGET	Range RANGE
CONTROL 	Natural	N/A	≤ 0.85
CONTROL 	Blue*	3.50	1.75 - 5.25

* Dye: Acid Blue No. 9


For the ARCHITECT HBsAg Qualitative II Confirmatory assay:

Control	Color	Target	Range	HBsAgQ2 C2 S/CO**
				% Neutralization NEUTRALIZATION
CONTROL 	Blue*	3.31	1.65 - 4.96	≥ 50%

* Dye: Acid Blue No. 9

** A target and a range are not defined for HBsAgQ2 C1 S/CO.

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 Pathogens¹. Biosafety Level 2² or other appropriate biosafety practices^{3,4} should be used for materials that contain or are suspected of containing infectious agents.
- Negative Control contains human plasma that is nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, anti-HIV-1/HIV-2, anti-HCV, and anti-HBs.
- Positive Control contains purified HBsAg (inactivated). The human plasma used is nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, anti-HIV-1/HIV-2, anti-HCV, and anti-HBs.
- WARNING: SENSITIZER** Warning: May cause an allergic reaction.
- CONTAINS: AZIDE** Contains Sodium Azide. Contact with acids liberates very toxic gas.
- This material and its container must be disposed of in a safe way.

- The following warnings and precautions apply to the Controls:



WARNING: Contains methylisothiazolones.
H317 May cause an allergic skin reaction.

Prevention

P261 Avoid breathing mist / vapours / 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.
P363 Wash contaminated clothing before reuse.

This material and its container must be disposed of in a safe way.

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

STORAGE

- ARCHITECT HBsAg Qualitative II Controls are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- ARCHITECT HBsAg Qualitative II Controls must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.

2°C  8°C

QUALITY CONTROL PROCEDURE

Refer to the ARCHITECT HBsAg Qualitative II and ARCHITECT HBsAg Qualitative II Confirmatory Reagent package inserts for information on ordering controls and for the recommended volume requirements for the controls for each assay.

PREPARATION FOR USE

- The ARCHITECT HBsAg Qualitative II Controls are liquid ready-to-use.
- ARCHITECT HBsAg Qualitative II Controls must be mixed by gentle inversion before use.
- After each use, tightly close the caps and return the controls to 2-8°C storage.

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. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline-Third Edition*. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

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Key to symbols used

GTIN	Global Trade Item Number
PRODUCT OF IRELAND	Product of Ireland