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Revised March 2013

HBsAg Qualitative II Calibrators

INTENDED USE

The ARCHITECT HBsAg Qualitative II Calibrators are for the calibration of the ARCHITECT *i* System when used for qualitative detection and 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 (4.0 mL each) of ARCHITECT HBsAg Qualitative II Calibrators. Calibrator 1 (**CAL1**) contains inactivated purified human HBsAg (subtype *ad*) in phosphate buffer with human plasma and protein (bovine serum albumin) stabilizers. Preservatives: ProClin 300 and ProClin 950. Calibrator 2 (**CAL2**) contains recalified human plasma. Preservatives: ProClin 950 and sodium azide.

The ARCHITECT HBsAg Qualitative II and HBsAg Qualitative II Confirmatory assays use Calibrator 1 and Calibrator 2 to assess calibration validity and to calculate the assay cutoff. The ARCHITECT HBsAg Qualitative II Confirmatory assay uses Calibrator 2 to calculate the % Neutralization.

STANDARDIZATION

The ARCHITECT HBsAg Qualitative II Calibrator 1 is referenced to the World Health Organization (WHO) Second International Standard for HBsAg (subtype *adw2*, genotype A, NIBSC Code 00/588).

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.
- Calibrator 1 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.
- Calibrator 2 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.
- 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 Calibrators:



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.abbottdiagnostics.com or contact your local representative.

STORAGE

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



PREPARATION FOR USE

- The ARCHITECT HBsAg Qualitative II Calibrators are liquid ready-to-use.
- ARCHITECT HBsAg Qualitative II Calibrators must be mixed by gentle inversion before use.
- To perform a calibration, test the calibrators in replicates of 3. The calibrators should be priority loaded.
- For information on ordering calibrations and for the recommended volume requirements for the calibrators for each assay, refer to the ARCHITECT HBsAg Qualitative II and ARCHITECT HBsAg Qualitative II Confirmatory package inserts.
- After each use, tightly close the caps and return the calibrators to 2-8°C storage.

QUALITY CONTROL PROCEDURE

A single sample of each control level must be tested to evaluate the assay calibration. For information on ordering controls, refer to the ARCHITECT System Operations Manual, Section 5.

- Ensure that assay control values are within the ranges specified in the control package insert.

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. *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