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NAME

Alinity i HBsAg Qualitative II Calibrators (also referred to as HBsAg Qual Cals)

INTENDED USE

The Alinity i HBsAg Qualitative II Calibrators are for the calibration of the Alinity i analyzer when used for qualitative detection and confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma using the Alinity i HBsAg Qualitative II and HBsAg Qualitative II Confirmatory Reagent Kits.

For additional information, refer to the Alinity i HBsAg Qualitative II and Alinity i HBsAg Qualitative II Confirmatory reagent package inserts and the Alinity ci-series Operations Manual.

CONTENTS

CAL 1 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.

CAL 2 contains recalcified human plasma. Preservatives: ProClin 950 and sodium azide.

The Alinity i 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 Alinity i HBsAg Qualitative II Confirmatory assay uses Calibrator 2 to calculate the % Neutralization.

The calibrators are at the following concentrations:

Calibrator	Quantity	HBsAg CONC (IU/mL)
CAL 1	1 x 3.0 mL	0.5244
CAL 2	1 x 3.0 mL	0

MATERIALS REQUIRED BUT NOT PROVIDED

- 04R1001 Alinity ci-series Calibrator/Control Replacement Caps

STANDARDIZATION

The Alinity i 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

Safety Precautions

-  **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

- Calibrator 1 contains purified HBsAg (inactivated) and human plasma. The human plasma is nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, anti-HIV-1/HIV-2, anti-HCV, and anti-HBs.
- The human-sourced material used in Calibrator 2 is nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, anti-HIV-1/HIV-2, anti-HCV, and anti-HBs.

The following warnings and precautions apply to: CAL 1	
	
WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
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.

The following warnings and precautions apply to: CAL 2	
	
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 Alinity ci-series Operations Manual, Section 8.

PREPARATION FOR USE

- This product is liquid ready-to-use.
- This product may be used immediately after removal from 2 to 8°C storage.
- Prior to each use, mix by gentle inversion.

STORAGE

- Do not use past expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	
Opened	2 to 8°C	Until expiration date	Store tightly capped with new replacement cap. Return to refrigerated storage after use.

The analyzer will track In-use Stability, which is the time the calibrator is outside of refrigerated storage while on the analyzer. The analyzer will not allow the use of the calibrator if the In-use Stability has been exceeded. Maximum In-use Stability can be found in the Assay Parameter Report. For additional information on calibrator In-use Stability, refer to the Alinity ci-series Operations Manual, Section 5.

For additional information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

INSTRUMENT PROCEDURE

- Calibrator lots may be configured using the bar code label on the calibrator carton.
- For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 2.
- For instructions on ordering and loading calibrators on the instrument, refer to the Alinity ci-series Operations Manual, Section 5.

QUALITY CONTROL PROCEDURES

A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.

For information on ordering controls, refer to the Alinity ci-series Operations Manual, Section 5.

Once a calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

- A reagent kit with a new lot number is used.
- Daily quality control results are outside of statistically-based quality control limits used to monitor and control system performance, as described in the Quality Control Procedures section of the associated reagent package insert.
- If statistically-based quality control limits are not available then the calibration should not exceed a 30-day limit for recalibration frequency.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

For additional information, refer to the assay reagent package insert and the Alinity ci-series Operations Manual.

INDICATIONS OF INSTABILITY OR DETERIORATION

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, if calibration does not meet the appropriate package insert and/or Alinity ci-series Operations Manual criteria, or if controls do not meet the appropriate criteria.

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—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
	Calibrator (1, 2)
	Control Number
	Concentration
	Contains Sodium Azide. Contact with acids liberates very toxic gas.
	In Vitro Diagnostic Medical Device
	Lot Number
	Product of Ireland
	List Number
	Serial Number

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