

HBsAg Next Qualitative Calibrators

Created January 2019.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

Alinity i HBsAg Next Qualitative Calibrators (also referred to as HBsAgNx Cals)

INTENDED USE

The HBsAg Next Qualitative Calibrators are for the calibration of the Alinity i system when used for qualitative detection and confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma.

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

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The **CAL 1** contains recombinant HBsAg (subtype ad) in phosphate buffer with protein (bovine) stabilizer.

The **CAL 2** contains phosphate buffer with a protein (bovine) stabilizer.

Preservatives: ProClin 300 and ProClin 950.

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

The calibrators are at the following target concentrations:

Calibrator	Quantity	HBsAg CONC (IU/mL)
CAL 1	1 x 3.0 mL	0.1
CAL 2	1 x 3.0 mL	0.0

MATERIALS REQUIRED BUT NOT PROVIDED

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

STANDARDIZATION

The Alinity i HBsAg Next Qualitative 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

The following warnings and precautions apply to: **CAL 1** and **CAL 2**

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.

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 system will track In-use Stability, which is the time the calibrator is outside of refrigerated storage while on the system. The system 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

- For the Alinity i HBsAg Next Qualitative assay, a single sample of each control level must be tested to evaluate the assay calibration.
- For the Alinity i HBsAg Next Confirmatory assay, a single sample of the positive control **only** 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.

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

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number
Other Symbols	
CAL 1	Calibrator 1
CAL 2	Calibrator 2
CN	Control Number
CONC	Concentration
PRODUCT OF IRELAND	Product of Ireland

Alinity is a trademark of Abbott Laboratories in various jurisdictions. All other trademarks are property of their respective owners.



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Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

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