ARCHITECT Anti-HBc II

REF 8L44-25
REF 8L44-35
REF 8L44-30

en

Anti-HBc II
8L44
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Read Highlighted Changes: Revised July 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

ARCHITECT Anti-HBc II

INTENDED USE

The ARCHITECT Anti-HBc II assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of antibody to hepatitis B core antigen (anti-HBc) in human serum and plasma, including specimens collected post-mortem (non-heart-beating). The ARCHITECT Anti-HBc II assay is intended to be used as an aid in the diagnosis of hepatitis B infection and as a screening test to prevent transmission of hepatitis B virus (HBV) to recipients of blood, blood components, cells, tissue and organs.

SUMMARY AND EXPLANATION OF THE TEST

The ARCHITECT Anti-HBc II assay utilizes microparticles coated with recombinant hepatitis B virus core antigen (rHBcAg) for the detection of anti-HBc. Anti-HBc determinations can be used as an indicator of current or past HBV infection. Anti-HBc is found in serum shortly after the appearance of hepatitis B surface antigen (HBsAg) in acute HBV infections. It will persist after the disappearance of HBsAg and before the appearance of detectable antibody to HBsAg (anti-HBs).[1-7] In the absence of information about any other HBV markers, it must be considered that an individual with detectable levels of anti-HBc may be actively infected with HBV or that the infection may have resolved, leaving the person immune.[8] Anti-HBc may be the only serological marker of HBV infection and potentially infectious blood.[9-15]

The presence of anti-HBc does not differentiate between acute or chronic hepatitis B infection.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Anti-HBc II assay is a two-step immunoassay for the qualitative determination of anti-HBc in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample, assay diluent, specimen diluent, and rHBcAg coated paramagnetic microparticles are combined. Anti-HBc present in the sample binds to the rHBcAg coated microparticles.
2. The reaction mixture is washed and anti-human acridinium-labeled conjugate is added.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of anti-HBc in the sample and the RLUs detected by the ARCHITECT iSystem optics.

The presence or absence of anti-HBc in the specimen is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an active calibration. If the chemiluminescent signal in the reaction is greater than or equal to the cutoff signal, the specimen is considered reactive for anti-HBc.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT Anti-HBc II 8L44

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	8L44-25	8L44-35	8L44-30
Σ	100	500	2000
MICROPARTICLES	1 x 6.6 mL	1 x 27.0 mL	4 x 27.0 mL
CONJUGATE	1 x 11.0 mL	1 x 28.8 mL	4 x 28.8 mL
ASSAY DILUENT	1 x 5.36 mL	1 x 23.72 mL	4 x 23.72 mL
SPECIMEN DILUENT	1 x 5.36 mL	1 x 23.72 mL	4 x 23.72 mL

MICROPARTICLES Hepatitis B core (*E. coli*, recombinant) antigen coated microparticles in TRIS buffer. Minimum concentration: 0.08% solids. Preservatives: ProClin 950 and sodium azide.

CONJUGATE Murine acridinium-labeled anti-human conjugate in MES buffer with protein stabilizers. Minimum concentration: 0.04 µg/mL. Preservatives: sodium alkyl paraben and sodium azide.

ASSAY DILUENT Assay diluent containing murine protein stabilizers in MOPSO buffer. Preservatives: ProClin 950 and sodium azide.

SPECIMEN DILUENT Specimen diluent containing reductant in MOPSO buffer.

Other Reagents

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and 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.[16-19]

The following warnings and precautions apply to: **MICROPARTICLES**	
	
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.

The following warnings and precautions apply to: **ASSAY DILUENT**	
	
DANGER	Contains polyethylene glycol octylphenyl ether (Triton X-405), methylisothiazolone and sodium azide.
H318	Causes serious eye damage.
H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
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.
P273	Avoid release to the environment.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor / physician.
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: **CONJUGATE**	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
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.

Reagent Handling

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between kits.**
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
  - To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
  - Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
- When handling conjugate vials, change gloves that have contacted human serum or plasma, since introduction of human IgG or IgM will result in a neutralized conjugate.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

When stored and handled as directed, reagents are stable until the expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/ Opened*	2-8˚C	Until expiration date	May be used immediately after removal from 2-8˚C storage. Store in upright position.
On board	System temperature	30 days	Discard after 30 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

* Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8˚C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The ARCHITECT Anti-HBc II assay file must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Verified specimen types to be used with this assay:

Specimen Types	Collection Tubes
Human serum	Serum
	Serum separator tubes
Human plasma	Sodium heparin
	Lithium heparin (PST)
	Potassium-EDTA
	Sodium citrate
	Potassium oxalate
	CPD
	CPDA-1
	ACD

- ACD tubes may show a positive bias up to 20 % relative to serum.
- Other specimen collection tube types have not been tested with this assay.
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.
- Performance has been established for the use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating), for details refer to section **Testing of Cadaveric Blood Specimens**.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed (> 500 mg/dL hemoglobin)
  - obvious microbial contamination
  - body fluids other than human serum and plasma
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
- Patient specimens should be tested within 3 hours of being placed on board the ARCHITECT iSystem.
- No interference was observed between experimental controls and nonreactive or reactive specimens tested with elevated levels of bilirubin (20 mg/dL), triglycerides (3000 mg/dL), protein (4.5 - 12 g/dL), red blood cells (0.4% v/v), or hemoglobin (500 mg/dL).

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at ≥ 10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if
  - they contain fibrin, red blood cells, or other particulate matter or
  - they were frozen and thawed.

  Transfer clarified specimen to a sample cup or secondary tube for testing.
- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Specimen Storage

Specimen Type	Storage Temperature	Maximum Storage Time
Serum/Plasma	15-30˚C	≤ 3 days
	2-8˚C	≤ 14 days
	-20˚C or colder	--

Specimens may be stored on or off the clot, red blood cells, or separator gel.

Remove serum or plasma from the clot, red blood cells, or separator gel if stored longer than the maximum 15-30˚C or 2-8˚C storage time and store frozen at -20˚C or colder.

No qualitative performance differences were observed between experimental controls and nonreactive or spiked reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

Specimen Shipping

- Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- It is recommended that specimens be removed from the clot, red blood cells, or separator gel.
- Ship on wet ice or dry ice.
- Do not exceed the storage time limitations listed above.

Testing of Cadaveric Blood Specimens

- Performance has been established for the use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating) that have been collected up to 17.5 hours after death. Performance was established using 50 spiked and 50 non-spiked cadaveric blood specimens. [23]
- Testing of cadaveric blood specimens from patients with plasma dilution due to transfusions of > 2000 mL of blood or colloids within 48 hours, or > 2000 mL of crystalloids within 1 hour (or any combination thereof) prior to collection of the specimens have not been validated.
- Follow general standards and/or regulations for collection, storage and handling.

- Follow the tube manufacturer's processing instructions for serum or plasma collection tubes. After initial centrifugation, transfer the supernatant to a centrifuge tube and centrifuge at 10,000 RCF (Relative Centrifugal Force) for 10 minutes. If specimens are not processed directly after initial centrifugation, it is recommended to remove the supernatant from the clot, red blood cells or separator gel until further processing.
- Cadaveric blood specimens can be stored for up to 7 days at 2-8°C or up to 3 days at 15-30°C following collection.
- No qualitative differences were observed for cadaveric blood specimens (nonreactive or spiked reactive) when subjected to up to 3 freeze/thaw cycles. However, multiple freeze/thaw cycles should be avoided.

PROCEDURE

Materials Provided

8L44 ARCHITECT Anti-HBc II Reagent Kit

Materials Required but not Provided

- ARCHITECT Anti-HBc II Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 8L44-01 ARCHITECT Anti-HBc II Calibrator
- 8L44-10 ARCHITECT Anti-HBc II Controls
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Reaction Vessels
- ARCHITECT Sample Cups
- ARCHITECT Septum
- ARCHITECT Replacement Caps
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
  - Once the microparticles have been resuspended, discard the cap and place a septum on the bottle. For instructions on placing septums on bottles refer to the **Reagent Handling** section of this package insert.
- Load the reagent kit on the ARCHITECT iSystem.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- Minimum sample cup volume is calculated by the system and printed on the Orderlist report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

  Maximum number of replicates sampled from the same sample cup: 10
  - Priority:

    Sample volume for first test: 75 µL

    Sample volume for each additional test from same sample cup: 25 µL
  - ≤ 3 hours on board:

    Sample volume for first test: 150 µL

    Sample volume for each additional test from same sample cup: 25 µL
  - > 3 hours on board: Replace with a fresh sample (patient specimens, controls, and calibrators).
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare ARCHITECT Anti-HBc II Calibrator and Controls.
  - Mix calibrator(s) and controls by gentle inversion before use.
  - Hold bottles **vertically** and dispense recommended volumes into each respective sample cup.
  - Recommended volumes:

    for each calibrator: 5 drops

    for each control: 4 drops
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Specimen Dilution Procedures

Specimens cannot be diluted for the ARCHITECT Anti-HBc II assay.

Calibration

- Test calibrator in replicates of three. The calibrator should be priority loaded.

  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.
- Once an ARCHITECT Anti-HBc II 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 or
  - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Quality Control Procedures

The recommended control requirement for the ARCHITECT Anti-HBc II assay is that a single sample of each control level be tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures.

The ARCHITECT Anti-HBc II control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and samples must be retested. Recalibration may be indicated.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

The ARCHITECT Anti-HBc II assay belongs to method group 5, except functional sensitivity.

RESULTS

Calculation

- The ARCHITECT iSystem calculates the cutoff RLU from the mean RLU of three replicates of Calibrator 1 and stores the result. The cutoff RLU is determined by multiplying the Anti-HBc II Calibrator 1 mean RLU by 1.0.
  Cutoff RLU = Calibrator 1 Mean RLU x 1.0
- The ARCHITECT iSystem calculates the S/CO result for each specimen and control as follows.
  S/CO = Sample RLU/Cutoff RLU

Interpretation of Results

Initial ARCHITECT Anti-HBc II Results

Initial Result (S/CO)	Instrument Flag	Interpretation	Retest Procedure
< 1.00	NONREACTIVE	Nonreactive	No retest required.
≥ 1.00	REACTIVE	Reactive	Retest in duplicate.

Final ARCHITECT Anti-HBc II Interpretation

Initial Interpretation	Results with Retest	Final Interpretation
Nonreactive	No retest required.	**Nonreactive**
Reactive	If two of the three results are < 1.00 S/CO	**Nonreactive**
Reactive	If two of the three results are ≥ 1.00 S/CO	**Reactive**

For details on configuring the ARCHITECT iSystem to use grayzone interpretations, refer to the ARCHITECT System Operations Manual, Section 2.

The grayzone interpretation from the ARCHITECT interpretations screen is not used by the ARCHITECT iSystem unless a grayzone is configured.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- If the anti-HBc results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.[20]
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values when tested with assay kits that employ mouse monoclonal antibodies.[21, 22]

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Anti-HBc II assay is designed to have an imprecision of ≤10% total** CV for specimens at 1.20 S/CO and for the Positive Control. The study was performed at one internal and two external evaluation sites each using one instrument. A panel consisting of three different control lots and two human plasma specimens was tested in replicates of four across three reagent lots and three calibrator lots per site. Each combination of instruments, panel members, and reagent lots was tested in four runs. Data from this study are summarized in Table 1*.

Table 1: ARCHITECT Anti-HBc II Precision

		Mean	Within Run		Total**	
Panel member	n	(S/CO)	SD	%CV	SD	%CV
Negative Control	432	0.22	0.01	6.52	0.02	7.57
Positive Control	431	2.97	0.08	2.63	0.09	2.87
Human Plasma Panel 1	144	0.81	0.02	2.73	0.03	3.24
Human Plasma Panel 2	144	1.18	0.03	2.52	0.03	2.87

* Representative data; results in individual laboratories may vary from these data.

** Total is an accumulation of within run, between run and between day.

Specificity

The ARCHITECT Anti-HBc II assay is designed to have an overall specificity of ≥ 99.5% on a blood donor population and ≥ 98.0% on a hospitalized/diagnostic population. A study was performed at one internal and two external evaluation sites. A total of 5141 serum and plasma specimens collected from five blood-donation centers and 260 hospitalized/diagnostic specimens were evaluated to assess specificity.

From the blood donor population a total of 26 specimens were classified as reactive. Two additional specimens were excluded from specificity calculation as final specimen disposition could not be determined. From the hospitalized/diagnostic specimens a total of 28 specimens were classified as reactive. One additional specimen was excluded from specificity calculation as final specimen disposition could not be determined. Data from this study are summarized in Table 2*.

Table 2: ARCHITECT Anti-HBc II Specificity

Category	N	IR [%]	RR [%]	Clinical Specificity	95% Confidence Interval
Overall Blood Donors	5141	44 [0.86]	41 [0.80]	99.71% (5098/5113)	99.52 - 99.84%
Blood Donor Serum	3584	25 [0.70]	22 [0.61]	99.75% (3561/3570)	99.52 - 99.88%
Blood Donor Plasma	1557	19 [1.22]	19 [1.22]	99.61% (1537/1543)	99.16 - 99.86%
Hospitalized/ Diagnostic Specimens	260	28 [10.77]	28 [10.77]	100% (231/231)	98.42 - 100%

* Representative data; results in individual laboratories may vary from these data.

Sensitivity

A total of 406 anti-HBc positive specimens from patients with acute, chronic and recovered HBV infection and signs and symptoms of HBV infection were tested, resulting in a sensitivity of 100% (406/406), 95% confidence interval: 99.10% - 100%. (Representative data; results in individual laboratories may vary from these data).

Analytical Sensitivity

The ARCHITECT Anti-HBc II assay is designed to show an analytical sensitivity of less than 1.0 PEI U/mL. The sensitivity of the ARCHITECT Anti-HBc II assay was evaluated with a four-member panel that was standardized against reference serum from the Paul-Ehrlich-Institute (PEI). The panel was tested with three reagent lots. The ARCHITECT Anti-HBc II assay sensitivity ranged from 0.4 to 0.5 PEI U/mL. (Representative data; results in individual laboratories may vary from these data).

Interference

Additional studies were performed to evaluate other potential interfering disease states on the ARCHITECT Anti-HBc II assay. A total of 104 specimens were tested from the following categories: antinuclear antibodies (ANA), Epstein-Barr virus (anti-EBV positive), hepatitis A virus (anti-HAV IgM positive), hepatitis C virus (anti-HCV positive), human immunodeficiency virus (anti-HIV-1 positive), human anti-mouse antibodies (HAMA) positive, influenza vaccine recipients, non-viral liver disease, rheumatoid factor positive, syphilis, systemic lupus erythematosus (SLE), toxoplasmosis IgG positive, varicella zoster (anti-VZV positive), anti-*E. coli* positive and yeast infection. With these specimens, ARCHITECT Anti-HBc II showed the same qualitative results as the comparator method.

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Key to Symbols

	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
ASSAY DILUENT	Assay Diluent
CONJUGATE	Conjugate
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL NO.	Control Number
ECO HAZARD	Ecological hazard
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCT OF GERMANY	Product of Germany
REACTION VESSELS	Reaction Vessels
REAGENT LOT	Reagent Lot
REF	List Number
REPLACEMENT CAPS	Replacement Caps
SAMPLE CUPS	Sample Cups
SEPTUM	Septum
SN	Serial number
SPECIMEN DILUENT	Specimen Diluent
TRIGGER SOLUTION	Trigger Solution
WARNING: SENSITIZER	Warning: May cause an allergic reaction.
WASH BUFFER	Wash Buffer


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

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