ARCHITECT SYSTEM

en

HBeAg

IVD REF 6C32

34-9992/R4

B6C320

Read Highlighted Changes
Revised April, 2008

HBeAg

Customer Service

For additional product information, please contact your local customer service organization.

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

Key to symbols used

REF	List Number	CALIBRATORS	Calibrator Kit
IVD	*In Vitro* Diagnostic Medical Device	CONTROLS	Control Kit
LOT	Lot Number	ASSAY CD-ROM	Assay CD-ROM
	Expiration Date	CONTROL NO.	Control Number
2°C 8°C	Store at 2-8°C	REAGENT LOT	Reagent Lot
	CAUTION: Consult accompanying documents	REACTION VESSELS	Reaction Vessels
SN	Serial Number	SAMPLE CUPS	Sample Cups
		SEPTUM	Septum
	Manufacturer	REPLACEMENT CAPS	Replacement Caps

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

ABBOTT
Diagnostics Division

NAME

ARCHITECT HBeAg

INTENDED USE

The ARCHITECT HBeAg assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of hepatitis B e antigen (HBeAg) in human serum and plasma and is indicated for use as an aid in the diagnosis and monitoring of hepatitis B viral infection.

SUMMARY AND EXPLANATION OF TEST

HBeAg determinations can be used to monitor the progress of hepatitis B viral infection. HBeAg is first detectable in the early phase of hepatitis B viral infection, after the appearance of hepatitis B surface antigen (HBsAg).[1] The titers of both antigens rise rapidly during the period of viral replication in acute infection. The presence of HBeAg correlates with increased numbers of infectious virus (Dane particles), the occurrence of core particles in the nucleus of the hepatocyte, and the presence of hepatitis B virus specific DNA and DNA polymerase in serum.[1] HBeAg may persist together with HBsAg in chronic hepatitis B viral infection. However, a subset of chronic hepatitis B patients have no detectable HBeAg in serum, but are positive for antibody to HBeAg (anti-HBe); these patients may also be positive for serum hepatitis B virus DNA.[2]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

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

In the first step, sample, assay diluent, and anti-HBe (mouse, monoclonal) coated paramagnetic microparticles are combined. HBeAg present in the sample binds to the anti-HBe coated microparticles. After washing, acridinium-labeled anti-HBe conjugate is added in the second step. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of HBeAg in the sample and the RLUs detected by the ARCHITECT *i** System optics.

The presence or absence of HBeAg in the sample is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an ARCHITECT HBeAg calibration. If the chemiluminescent signal of the reaction is less than the cutoff signal, then the sample is considered nonreactive for HBeAg.

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

* *i* = immunoassay

REAGENTS

Reagent Kit, 100 Tests

ARCHITECT HBeAg Reagent Kit (6C32)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL) Microparticles: antibody to hepatitis B e antigen (mouse, monoclonal) coated microparticles in phosphate buffer with protein (bovine) stabilizer. Minimum concentration: 0.08% solids. Preservatives: ProClin 300 and other antimicrobial agents.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL) Conjugate: acridinium-labeled antibody to hepatitis B e antigen (mouse, monoclonal) conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.04 µg/mL. Preservative: ProClin 300.
- **ASSAY DILUENT** 1 or 4 Bottle(s) (3.9 mL) Assay Diluent: phosphate buffer with recalcified human plasma, nonreactive for HBsAg, HIV-1 Ag or HIV-1 RNA, anti-HCV, anti-HIV-1/HIV-2 and HBeAg, and protein (bovine) stabilizer. Preservatives: ProClin 300 and a second antimicrobial agent.

Other Reagents

ARCHITECT *i* Pre-Trigger Solution

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

ARCHITECT *i* Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35 N sodium hydroxide.

ARCHITECT *i* Wash Buffer

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

WARNINGS AND PRECAUTIONS

- **For *In Vitro* Diagnostic Use.**

Safety Precautions

- **CAUTION:** This product contains human sourced infectious and/or potentially infectious components. Refer to the **REAGENTS** 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, it is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.
- All of the components of this kit contain a mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1), which is a component of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases:

R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S35 This material and its container must be disposed of in a safe way.
S37 Wear suitable gloves.
S46 If swallowed, seek medical advice immediately and show this container or label.

- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Handling Precautions

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a reagent kit or between reagent kits.**
- Prior to loading the ARCHITECT HBeAg 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.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions

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The ARCHITECT HBeAg Reagent Kit must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- When stored and handled as directed, reagents are stable until the expiration date.
- The ARCHITECT HBeAg Reagent Kit may be stored on board the ARCHITECT *i* System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

- Reagents may be stored on or off the ARCHITECT *i* System. 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 they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with the septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** After reagents are removed from the system, initiate a scan to update the onboard stability timer.

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 HBeAg assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM prior to performing the assay. For detailed information on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

  NOTE: For details on configuring the ARCHITECT *i* System to use grayzone interpretations, 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

- Human serum (including serum collected in serum separator tubes) or plasma collected in potassium EDTA, sodium citrate, sodium heparin, ACD-B, CPDA-1, CPD, and potassium oxalate may be used in the ARCHITECT HBeAg assay. Other anticoagulants have not been validated for use with the ARCHITECT HBeAg assay. Follow the manufacturer's processing instructions for serum or plasma collection tubes.
- The ARCHITECT *i* System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify the correct specimen types are used in the ARCHITECT HBeAg assay.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- This assay was designed and validated for use with human serum or plasma from individual patient and donor specimens. Pooled specimens must not be used since the accuracy of their test results has not been validated.
- Do not use heat-inactivated specimens.
- Do not use grossly hemolyzed specimens.
- Specimens with obvious microbial contamination should not be used.
- Performance has not been established using cadaver specimens or body fluids other than human serum or plasma.
- For optimal results, inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results or aspiration errors.
- Specimens from heparinized patients may be partially coagulated and erroneous results could occur due to the presence of fibrin. To prevent this phenomenon, draw the specimen prior to heparin therapy.
- For accurate results, serum and plasma specimens must be free of fibrin, red blood cells, or other particulate matter.
- Gravity separation is not sufficient for specimen preparation. Specimens must be separated from clots or red blood cells using the centrifugation instructions recommended by the collection tube manufacturer.
- After specimens have been processed according to the collection tube manufacturer's instructions, they must be transferred to a centrifuge tube and centrifuged at ≥ 10,000 RCF (Relative Centrifugal Force) for 10 minutes if:
  - They contain red blood cells, clots, or particulate matter.
  - They require repeat testing.
  - They were frozen and thawed.

  Transfer clarified specimen to a sample cup or secondary tube for testing.
- **Mix thawed specimens by inverting 180 degrees from upright and return, for a total of 10 inversion cycles. Visually inspect the specimens for the absence of stratification. If layering or stratification is observed, repeat until specimens are visibly homogeneous.**

  Centrifuge at ≥ 10,000 RCF for 10 minutes to remove particulate matter and to ensure consistency in the results.
- No qualitative differences were observed between experimental controls and the 23 nonreactive or spiked reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.
- 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.
- Specimens may be stored on or off the clot or red blood cells for up to 7 days at 2-8°C. If testing will be delayed more than 7 days, remove serum or plasma from the clot, serum separator, or red blood cells and store frozen (-20°C or colder).
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances. Specimens may be shipped at 2-8°C (wet ice), or -20°C or colder (dry ice). Do not exceed the storage time limitations listed above. Prior to shipment, it is recommended that specimens be removed from the clot, serum separator, or red blood cells.
- No qualitative performance differences were observed between experimental controls and the 22 nonreactive or the 22 spiked reactive specimens tested with elevated levels of hemoglobin (≤ 500 mg/dL) or triglycerides (≤ 3,000 mg/dL).
- No qualitative performance differences were observed between experimental controls and the 23 nonreactive or the 23 spiked reactive specimens tested with elevated levels of bilirubin (≤ 20 mg/dL).
- No qualitative performance differences were observed between experimental controls and the 25 nonreactive or the 25 spiked reactive specimens tested with elevated levels of protein (≤ 12 g/dL), or red blood cells (≤ 0.4% v/v).

PROCEDURE

Materials Provided

- 6C32 ARCHITECT HBeAg Reagent Kit

Materials Required but not Provided

- ARCHITECT *i* System
- ARCHITECT *i* **ASSAY CD-ROM**
- 6C32-01 ARCHITECT HBeAg **CALIBRATORS**
- 6C32-10 ARCHITECT HBeAg **CONTROLS**
- ARCHITECT *i* **PRE-TRIGGER SOLUTION**
- ARCHITECT *i* **TRIGGER SOLUTION**
- ARCHITECT *i* **WASH BUFFER**
- ARCHITECT *i* **REACTION VESSELS**
- ARCHITECT *i* **SAMPLE CUPS**
- ARCHITECT *i* **SEPTUM**
- ARCHITECT *i* **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 ARCHITECT HBeAg Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment.
  - 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 Abbott representative.**
  - Once the microparticles have been resuspended, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Carefully snap the septum onto the top of the bottle.
- 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.
- Load the ARCHITECT HBeAg Reagent Kit on the ARCHITECT *i* System.
  - Verify that all necessary assay reagents are present. Ensure that septums are present on all reagent bottles.
- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
  - Priority: 80 µL for the first ARCHITECT HBeAg test plus 30 µL for each additional ARCHITECT HBeAg test from the same sample cup.
  - ≤ 3 hours on board: 150 µL for the first ARCHITECT HBeAg test plus 30 µL for each additional ARCHITECT HBeAg test from the sample cup.
  - > 3 hours on board: additional sample volume is required. For information on sample evaporation and volumes, refer to the ARCHITECT System Operations Manual, Section 5.
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare calibrators and controls.
  - ARCHITECT HBeAg Calibrators and Controls should be mixed by gentle inversion (5 - 10 times) prior to use.
  - To obtain the recommended volume requirements for the ARCHITECT HBeAg Calibrators and Controls, hold the bottles **vertically** and dispense 4 drops of each calibrator or 4 drops of each control into each respective sample cup.
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN. The ARCHITECT *i* System performs the following functions:
  - Moves the sample carrier to the aspiration point.
  - Loads a reaction vessel (RV) into the process path.
  - Aspirates and transfers sample into the RV.
  - Advances the RV one position and transfers microparticles and assay diluent into the RV.
  - Mixes, incubates and washes the reaction mixture.
  - Adds conjugate to the RV.
  - Mixes, incubates, and washes the reaction mixture.
  - Adds Pre-Trigger and Trigger Solutions.
  - Measures chemiluminescent emission to detect the presence of HBeAg in the sample.
  - Aspirates contents of RV to liquid waste and unloads RV to solid waste.
  - Calculates the result.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the ARCHITECT System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures

Specimens cannot be diluted for the ARCHITECT HBeAg assay.

Calibration

- To perform an ARCHITECT HBeAg calibration, test Calibrators 1 and 2 in replicates of three. A single sample of both ARCHITECT HBeAg Controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the control package insert. Calibrators should be priority loaded.
- Once an ARCHITECT HBeAg calibration is accepted and stored, all subsequent samples may be tested without further calibration unless one or both of the following occur:
  - A reagent kit with a new lot number is used.
  - 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 minimum control requirement for the ARCHITECT HBeAg assay is that a single sample of both controls be tested once every 24 hours each day of use for each reagent lot. 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 HBeAg 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 HBeAg assay belongs to method group 5.

RESULTS

The ARCHITECT *i* System calculates the ARCHITECT HBeAg Calibrator 1 (Cal 1) and Calibrator 2 (Cal 2) mean chemiluminescent signals (RLUs) from three replicates of each calibrator and stores the results.

Calculations

The ARCHITECT *i* System calculates an ARCHITECT HBeAg result based on the ratio of the sample RLU to the cutoff RLU (S/CO) for each specimen and control.

- Cutoff RLU = [(Cal 2 mean RLU - Cal 1 mean RLU) x 0.1] + Cal 1 mean RLU
- The cutoff RLU is stored for each reagent lot calibration.
- S/CO = Sample RLU/Cutoff RLU

Example: If the Sample RLU = 1800 and the Cutoff RLU = 1000, then 1800/1000 = 1.800 S/CO = 1.800

Interpretation of Results

- Specimens with S/CO values < 1.000 are considered nonreactive by the ARCHITECT HBeAg assay and need not be tested further.
- Specimens with S/CO values ≥1.000 are considered reactive by the ARCHITECT HBeAg assay.
- All initially reactive specimens should be transferred to a centrifuge tube, recentrifuged at ≥ 10,000 RCF for 10 minutes and retested in duplicate. If both retest values are nonreactive, the specimen must be considered nonreactive for HBeAg. If either of the retest values is reactive, the specimen must be considered repeat reactive for HBeAg by the criteria of ARCHITECT HBeAg.
- For details on configuring the ARCHITECT *i* System regarding grayzone and high reactive interpretations, refer to the ARCHITECT System Operations Manual, Section 2. The grayzone and high reactive result interpretation is an editable parameter, and should be utilized per end user requirements.

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 HBeAg results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute or chronic infection.
- Specimens that have been frozen and thawed and specimens containing red blood cells, clots, or particulate matter must be centrifuged prior to running the assay.
- Performance has not been established using cadaver specimens or body fluids other than human serum or plasma.
- Do not use heat-inactivated specimens.
- Do not use grossly hemolyzed specimens.
- Specimens with obvious microbial contamination should not be used.
- Specimens from heparinized patients may be partially coagulated and erroneous results could occur due to the presence of fibrin. To prevent this phenomenon, draw the specimen prior to heparin therapy.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits that employ mouse monoclonal antibodies.[3,4] ARCHITECT HBeAg reagents contain a component that reduces the effect of HAMA reactive specimens. Additional clinical or diagnostic information may be required to determine patient status.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.[5] 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The precision of the ARCHITECT HBeAg assay for reactive specimens (S/CO ≥ 1.000) is ≤ 10%. A study was performed using a panel consisting of one nonreactive member, four diluted HBeAg reactive members, controls, and calibrators. Two external sites tested two different lots of the controls and calibrators across two reagent lots (every combination), and an internal site tested three different lots of controls and calibrators across three reagent lots (every combination). All panel members were tested in replicates of three per run. The intra-run and inter-run standard deviations (SD) and percent coefficient of variation (%CV) were analyzed with a variance components analysis[6] using a mixed analysis of variance model.[7] The data from this study are summarized in Table 1.

Table 1
ARCHITECT HBeAg Precision*

Panel Member	Total n	Mean S/CO	Intra-run SD	Intra-run %CV	Inter-run** SD	Inter-run** %CV
Calibrator 1	516	0.309	0.042	13.61	0.043	13.92
Calibrator 2	516	7.223	0.281	3.88	0.321	4.44
Negative Control	516	0.368	0.046	12.40	0.049	13.36
Positive Control	516	3.889	0.120	3.09	0.172	4.43
Panel 1	204	0.389	0.088	22.63	0.090	22.99
Panel 2	204	1.164	0.049	4.19	0.057	4.86
Panel 3	204	4.375	0.148	3.38	0.171	3.91
Panel 4	204	169.903	4.110	2.42	6.367	3.75
Panel 5	204	1191.234	24.793	2.08	39.426	3.31

* Representative performance data are shown. Results obtained in individual laboratories may vary.

** Inter-run variability contains intra-run variability.

Specificity

The ARCHITECT HBeAg assay specificity for random blood donor specimens is ≥ 99.5%. A study on a total of 1309 random blood (serum and plasma) donor specimens was performed at two clinical sites. All 1309 were nonreactive by ARCHITECT HBeAg. The data from this study are summarized in Table 2.

The ARCHITECT HBeAg assay specificity for hospitalized patient specimens is > 99.0%. A study on a total of 498 hospitalized patient specimens was performed at one clinical site. Seven were reactive by ARCHITECT HBeAg and were also positive for HBsAg. The remaining 491 specimens were nonreactive by ARCHITECT HBeAg. The data from this study are summarized in Table 2.

Table 2
ARCHITECT HBeAg Specificity Results Using Specimens from Random Blood Donors and Hospitalized Patients*

Population	Number of specimens Tested	Initially Reactive	Repeatedly Reactive	Number of Positives by Supplemental Testing**
Random Blood Donors	1309	0	0	0
Hospitalized Patients	498	7	7	7
Total	1807	7	7	7

* Representative performance data are shown. Results obtained in individual laboratories and with different populations may vary.

** Supplemental testing on HBeAg repeatedly reactives was performed with an HBsAg assay.

A study was performed in which a total of 155 specimens from individuals with potentially interfering substances and disease states other than HBV (CMV, EBV, anti-HAV, anti-HCV, anti-HIV-1, HSV, rubella, HBV vaccine recipients, syphilis, urinary tract infections, rheumatoid factor, anti-nuclear autoantibodies [ANA], toxoplasmosis, alcoholic cirrhosis, pregnant females, multiple myeloma, multiparous females, dialysis patients, human anti-mouse antibodies [HAMA]) were tested by ARCHITECT HBeAg. The data from this study are summarized in Table 3.

A study was performed in which 75 specimens from individuals with high risk of blood transmissible infections (intravenous drug users [IVDU], men who have sex with men [MSM], hemophiliacs) were tested by ARCHITECT HBeAg. Four specimens were reactive by ARCHITECT HBeAg and were also positive for HBsAg. The data from this study are summarized in Table 3.

Table 3
ARCHITECT HBeAg Specificity Results Using Potentially Interfering and High Risk Specimens*

Population	Number of Specimens Tested	Initially Reactive	Repeatedly Reactive	Number of Positives by Supplemental Testing**
Potentially Interfering Substances	155	0	0	0
High Risk of Blood Transmissible Infections	75	4	4	4

* Representative performance data are shown. Results obtained in individual laboratories and with different populations may vary.

** Supplemental testing on HBeAg repeatedly reactives was performed with an HBsAg assay.

Sensitivity

The ARCHITECT HBeAg assay sensitivity is ≥ 99.5%. A study was performed in which a total of 206 specimens, which were pre-characterized reactive for HBeAg and HBsAg, were all reactive by ARCHITECT HBeAg. The data from this study are summarized in Table 4.

Table 4
ARCHITECT HBeAg Sensitivity Results Using Specimens Pre-characterized Reactive for HBeAg*

Population	Number of Specimens Tested	Reactive
Pre-characterized HBeAg Reactives	206	206

* Representative performance data are shown. Results obtained in individual laboratories and with different populations may vary.

The ARCHITECT HBeAg assay sensitivity at the cutoff is < 0.5 PEI U/mL.

A study was performed in which a total of 93 specimens from individuals clinically or serologically classified with different stages of HBV infection were tested by ARCHITECT HBeAg. Twenty-seven out of 36 acute specimens were reactive and 9 were nonreactive. Out of 57 chronic specimens, 18 were reactive and 39 were nonreactive.

Comparison to a Commercially Available HBeAg Assay

A total of 2702 specimens (random blood donors, hospitalized patients, potentially interfering substances, high risk of blood transmissible infections, acute HBV infection, chronic HBV infection, other HBV positives, and seroconversion panels) were tested by ARCHITECT HBeAg and AxSYM HBe 2.0. The agreement between the two methods was 99.30% (2683/2702).

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