ARCHITECT Anti-HBe

REF 6C34-25
REF 6C34-20
REF 6C34-35

en

Anti-HBe
6C34
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B6C340

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-HBe

INTENDED USE

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

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis B e antigen (HBeAg) and its antibody (anti-HBe) are found in association with hepatitis B viral infection.[1] HBeAg is first detectable in the early phase of hepatitis B viral infection, after the appearance of hepatitis B surface antigen (HBsAg).[2] The titers of both antigens rise rapidly during the period of viral replication in acute infection. Seroconversion from HBeAg to anti-HBe during acute hepatitis B infection is usually indicative of resolution of infection and a reduced level of infectivity. A negative HBeAg result may indicate (1) early acute infection before the peak of viral replication or (2) early convalescence when HBeAg has declined below detectable levels. The presence of anti-HBe serves to distinguish between these two phases.[3] A subset of chronic hepatitis B patients have no detectable HBeAg in serum, but are positive for anti-HBe; these patients may also be positive for serum hepatitis B virus DNA.[4]

Additionally HBe antigen/antibody seroconversion is used as an indicator of virological response when treating patients with chronic hepatitis B.[5]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

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

1. Sample, neutralizing reagent, and anti-HBe (mouse, monoclonal) coated paramagnetic microparticles are combined. The anti-HBe present in the sample binds to the recombinant HBeAg present in the neutralizing reagent. Unbound recombinant HBeAg is available to bind to the anti-HBe coated microparticles.
2. After washing, acridinium-labeled anti-HBe conjugate is added to create a reaction mixture.
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 an inverse relationship between the amount of anti-HBe in the sample and the RLUs detected by the ARCHITECT iSystem optics.

The presence or absence of anti-HBe 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 of the reaction is greater than the cutoff signal, then the sample is considered nonreactive for anti-HBe.

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

REAGENTS

Kit Contents

ARCHITECT Anti-HBe 6C34

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

REF	6C34-25	6C34-20	6C34-35
Σ	100	400	500
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL
NEUTRALIZING REAGENT	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 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 Acridinium-labeled antibody to Hepatitis B e Antigen (mouse, monoclonal) conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.08 µg/mL. Preservative: ProClin 300.

NEUTRALIZING REAGENT Hepatitis B e Antigen (recombinant DNA) in TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 6.7 PEI U/mL. Preservatives: Antimicrobial Agents.

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.[6-9]

The following warnings and precautions apply to: MICROPARTICLES / CONJUGATE	
	
WARNING	Contain 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 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.

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-HBe 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.

NOTE: For details on configuring the ARCHITECT iSystem 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.

Alternate Result Units

The default result unit for the ARCHITECT Anti-HBe assay is S/CO (Sample to Cutoff ratio). An alternate result unit, %Inh (Percent Inhibition), may be selected for reporting results by editing assay parameter “Result concentration units”, to %Inh. For information on editing the Result concentration units, refer to the ARCHITECT System Operations Manual, Section 2.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Validated specimen types to be used with this assay:

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

- Other specimen collection tube types have not been validated with this assay.
- Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum and plasma.

- 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.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed
  - obvious microbial contamination
- 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.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
- 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.
- 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).

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- 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 red blood cells, clots, or particulate matter,
  - they require repeat testing, or
  - they were frozen and thawed.

  Transfer clarified specimens 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.
- 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	≤ 7 days

Specimens may be stored on or off the clot or red blood cells for up to 7 days at 2-8˚C or off the clot or red blood cells for 3 days at 15-30˚C.

Plasma specimens that have been stored at 2-8˚C more than three days without removal from red blood cells should be re-centrifuged before analysis, to avoid erroneous results.

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).

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.

Specimen Shipping

- Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

6C34 ARCHITECT Anti-HBe Reagent Kit

Materials Required but not Provided

- ARCHITECT Anti-HBe Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 6C34-01 ARCHITECT Anti-HBe Calibrator
- 6C34-10 ARCHITECT Anti-HBe 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, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Carefully snap the septum onto the top of the bottle.
- 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: 150 µL

    Sample volume for each additional test from same sample cup: 100 µL
  - ≤ 3 hours on board:

    Sample volume for first test: 150 µL

    Sample volume for each additional test from same sample cup: 100 µL
  - > 3 hours on board: Additional sample volume 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 ARCHITECT Anti-HBe Calibrator and Controls.
  - Mix calibrator(s) and controls by gentle inversion (5-10 times) before use.
  - Hold bottles **vertically** and dispense recommended volumes into each respective sample cup.
  - Recommended volumes:

    for each calibrator: 10 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-HBe assay.

Calibration

- Test Calibrator 1 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-HBe 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 minimum control requirement for the ARCHITECT Anti-HBe assay is that a single sample of both the 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 Anti-HBe 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-HBe assay belongs to method group 5.

RESULTS

The ARCHITECT iSystem calculates the ARCHITECT Anti-HBe Calibrator 1 mean chemiluminescent signal (RLU) from 3 replicates and stores the result.

Calculation

The ARCHITECT iSystem calculates an ARCHITECT Anti-HBe result based on the ratio of the sample RLU to the cutoff RLU (S/CO) for each specimen and control.

- Cutoff RLU = Calibrator 1 mean RLU x 0.5
- The cutoff RLU is stored for each reagent lot calibration.
- S/CO = Sample RLU/Cutoff RLU

Example:

If the Sample RLU = 15000 and the

Cutoff RLU = 30000, then

15000/30000 = 0.50

S/CO = 0.50

The ARCHITECT iSystem calculates the percent inhibition (%Inh) of the sample RLU relative to the Calibrator 1 mean RLU.

$$\% \text{ Inhibition} = \frac{\text{Calibrator 1 Mean RLU} - \text{Sample RLU}}{\text{Calibrator 1 Mean RLU}} \times 100$$

Example:

If the Sample RLU = 15000 and the

Calibrator 1 Mean RLU = 60000, then

$$\frac{60000-15000}{60000} \times 100 = 75$$

% Inhibition = 75

Interpretation of Results

- Specimens with S/CO values > 1.00 are considered nonreactive by the ARCHITECT Anti-HBe assay and need not be tested further.
- Specimens with S/CO values ≤ 1.00 are considered reactive by the ARCHITECT Anti-HBe assay.
- Specimens with %Inh < 50* are considered nonreactive by the ARCHITECT Anti-HBe assay.
- Specimens with %Inh ≥ 50* are considered reactive by the ARCHITECT Anti-HBe assay.
- Samples with S/CO values > 3.0 or %Inh < -50 may be reactive for HBeAg and should be tested for HBeAg.
- 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 anti-HBe. If either of the retest values is reactive, the specimen must be considered repeat reactive for anti-HBe by the criteria of ARCHITECT Anti-HBe.
- For details on configuring the ARCHITECT iSystem to use grayzone interpretations, refer to the ARCHITECT System Operations Manual, Section 2.

* **NOTE:** Due to mathematical rounding a sample result of, for example, 49.8%Inh equals 50%Inh and is considered reactive by the ARCHITECT Anti-HBe assay.

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-HBe 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.
- 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.[10, 11] ARCHITECT Anti-HBe 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. 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.[12]

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The precision of the ARCHITECT Anti-HBe assay across the control range (0.21 - 2.70 S/CO) is ≤ 10%. A study was performed using a panel consisting of one nonreactive member, four diluted anti-HBe reactive members, controls, and the calibrator. Two external sites tested two different lots of the controls and the calibrator across two reagent lots (every combination), and an internal site tested three different lots of controls and calibrator 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[13] using a mixed analysis of variance model[14]. The data from this study are summarized in Table 1.

Table 1: ARCHITECT Anti-HBe Precision*

Panel member	Total n	Mean S/CO	Intra-run SD	Intra-run %CV	Inter-run** SD	Inter-run** %CV
Calibrator 1	516	2.00	0.096	4.79	0.097	4.83
Negative Control	516	1.97	0.086	4.38	0.095	4.80
Positive Control	516	0.51	0.027	5.29	0.029	5.68
Panel 1	204	0.11	0.006	5.64	0.007	6.55
Panel 2	204	0.23	0.008	3.72	0.010	4.48
Panel 3	204	0.47	0.018	3.76	0.022	4.66
Panel 4	204	0.93	0.044	4.75	0.047	5.04
Panel 5	204	1.70	0.080	4.69	0.084	4.93

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

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

Specificity

The ARCHITECT Anti-HBe assay specificity for random blood donor specimens is ≥ 99.5%.

A study on a total of 1310 random blood (serum and plasma) donor specimens was performed at two clinical sites. Six specimens were reactive by ARCHITECT Anti-HBe and were also reactive for anti-HBc. The remaining 1304 specimens were nonreactive by ARCHITECT Anti-HBe. The data from this study are summarized in Table 2.

The ARCHITECT Anti-HBe 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. Sixty-three specimens were reactive by ARCHITECT Anti-HBe and were also reactive for anti-HBc. The remaining 435 specimens were nonreactive by ARCHITECT Anti-HBe. The data from this study are summarized in Table 2.

Table 2: ARCHITECT Anti-HBe Specificity Results Using Specimens from Random Blood Donors and Hospitalized Patients*

Population	Number of Specimens Tested	Initial Reactive	Repeat Reactive	Number of Reactives by Supplemental Testing**
Random Blood Donors	1310	6	6	6
Hospitalized Patients	498	64	63	63
Total	1808	70	69	69

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

** Supplemental testing on anti-HBe repeat reactives was performed with an anti-HBc 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 Anti-HBe. Seven specimens were reactive by ARCHITECT Anti-HBe and were also reactive for anti-HBc. 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 Anti-HBe. Fifteen specimens were reactive by ARCHITECT Anti-HBe and were also reactive for anti-HBc. The data from this study are summarized in Table 3.

Table 3: ARCHITECT Anti-HBe Specificity Results Using Potentially Interfering Substances and High Risk Specimens*

Population	Number of Specimens Tested	Initial Reactive	Repeat Reactive	Number of Reactives by Supplemental Testing**
Potentially Interfering Substances	155	7	7	7
High Risk of Blood Transmissible Infections	75	15	15	15

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

** Supplemental testing on anti-HBe repeat reactives was performed with an anti-HBc assay.

Sensitivity

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

Table 4: ARCHITECT Anti-HBe Sensitivity Results Using Specimens Pre-characterized Reactive for Anti-HBe*

Population	Number of Specimens Tested	Reactive
Pre-characterized Anti-HBe Reactives	206	206

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

The ARCHITECT Anti-HBe assay sensitivity at the cut-off is ≤ 0.45 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 Anti-HBe. Seventeen out of 36 acute specimens were reactive and 19 were nonreactive. Out of 57 chronic specimens, 36 were reactive and 21 were nonreactive.

Assay Comparison

A total of 2605 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 Anti-HBe and AxSYM Anti-HBe 2.0. The agreement between the two methods was 99.19% (2584/2605).

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Key to Symbols

	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
CONJUGATE	Conjugate
CONTROL NO.	Control Number
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
NEUTRALIZING REAGENT	Neutralizing Reagent
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
TRIGGER SOLUTION	Trigger Solution
WARNING: SENSITIZER	Warning: May cause an allergic reaction.
WASH BUFFER	Wash Buffer

The following US Patents are relevant to the ARCHITECT iSystem or its components. There are other such patents and patent applications in the United States and worldwide.

5 468 646	5 543 524	5 545 739
5 565 570	5 669 819	5 783 699

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