ARCHITECT HBeAg

REF 6C32-27
REF 6C32-37

en
HBeAg
6C32
G65476R03
B6C3X0

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 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.

The ARCHITECT HBeAg assay can also be used for the quantitative determination of HBeAg. Refer to ARCHITECT HBeAg Quantitative Calibrators package insert (7P24-01) for instructions and further information.

SUMMARY AND EXPLANATION OF THE 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.

1. 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.
2. After washing, acridinium-labeled anti-HBe 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 HBeAg in the sample and the RLUs detected by the ARCHITECT iSystem optics.

The presence or absence of HBeAg 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 less than the cutoff signal, then the specimen is considered nonreactive for HBeAg.

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

REAGENTS

Kit Contents

ARCHITECT HBeAg 6C32

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

REF	6C32-27	6C32-37
Σ	100	500
MICROPARTICLES	1 x 6.6 mL	1 x 27.0 mL
CONJUGATE	1 x 5.9 mL	1 x 26.3 mL
ASSAY DILUENT	1 x 3.9 mL	1 x 16.1 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: 0.04 µg/mL. Preservative: ProClin 300.

ASSAY DILUENT Phosphate buffer with recalcified human plasma and protein (bovine) stabilizer. Preservatives: ProClin 300 and a second antimicrobial agent.

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 contains human-sourced 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, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[3-6]

The human plasma used in the Assay Diluent is nonreactive for HBeAg, HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.

The following warnings and precautions apply to: MICROPARTICLES / CONJUGATE / ASSAY DILUENT	
	
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 HBeAg assay file must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.

The assay file number for ARCHITECT HBeAg Qualitative Assay is 305 (HBeAgQual).

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.

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 anticoagulants have not been validated for use with the ARCHITECT HBeAg assay.
- 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.
- Performance has not been established using cadaver specimens or body fluids other than human serum or 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

- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed
  - obvious microbial 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.
- For accurate results, serum and plasma specimens must be free of fibrin, red blood cells, or other particulate matter.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. 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.
- 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,
  - they require repeat testing, or
  - they were frozen and thawed.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.
- **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.
- 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	2-8°C	≤ 7 days
	-20°C or colder	--

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

Remove serum or plasma from the clot, serum separator, or red blood cells if stored longer than the maximum 2-8°C storage time and store frozen (-20°C or colder).

No qualitative performance 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.

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).

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

6C32 ARCHITECT HBeAg Reagent Kit

Materials Required but not Provided

- ARCHITECT HBeAg Assay file (Assay file number 305) obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 6C32-01 ARCHITECT HBeAg Calibrators
- 6C32-10 ARCHITECT HBeAg 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: 80 µL

    Sample volume for each additional test from same sample cup: 30 µL
  - ≤ 3 hours on board:

    Sample volume for first test: 150 µL

    Sample volume for each additional test from same sample cup: 30 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 HBeAg Calibrators 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: 4 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 HBeAg assay.

Calibration

- Test Calibrators 1 and 2 in replicates of three. Calibrators should be priority loaded.

  A single sample of each qualitative 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.

  Refer to ARCHITECT HBeAg Calibrators package insert (6C32-01) and ARCHITECT HBeAg Controls package insert (6C32-10).
- Once an ARCHITECT HBeAg 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 HBeAg assay is that a single sample of both controls 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 HBeAg Control values must be within the acceptable ranges specified in the control package insert (6C32-10). 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 iSystem 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.

Calculation

The ARCHITECT iSystem 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

Initial Results

S/CO values	Instrument Flag	Instrument Interpretation	Retest Procedure
< 1.000	NONREACTIVE	Nonreactive	No retest required.
≥ 1.000	REACTIVE	Reactive	Retest in duplicate.

Duplicate Retest Results

Instrument Interpretation	Specimen Classification
Both results nonreactive	Specimen considered nonreactive for HBeAg.
One or both results reactive	Specimen considered repeatedly reactive 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.

For details on configuring the ARCHITECT iSystem 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

- For diagnostic or monitoring purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis or monitoring of acute or chronic infection.
- In the presence of anti-HBe, immune complex formation might occur which can lead to lower HBeAg results.
- If the HBeAg results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- 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 such as ARCHITECT HBeAg that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.[7, 8]

  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. 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.[9]

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[10] using a mixed analysis of variance model.[11] 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.

Assay Comparison

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).

BIBLIOGRAPHY

1. Koff RS. Viral Hepatitis. In: Schiff L, Schiff ER, editors. *Diseases of the Liver*. 7th ed. Philadelphia: JB Lippincott, 1993:492-577.
2. Bonino F, Rosina F, Rizzetto M, et al. Chronic hepatitis in HBsAg carriers with serum HBV-DNA and anti-HBe. *Gastroenterology* 1986;90:1268-1273.
3. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
4. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
5. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
6. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition.* CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
7. Primus FJ, Kelley EA, Hansen HJ, et al. "Sandwich"-type immunoassay of carcinoembryonic antigen in patients receiving murine monoclonal antibodies for diagnosis and therapy. *Clin Chem* 1988;34(2):261-264.
8. Schroff RW, Foon KA, Beatty SM, et al. Human anti-murine immunoglobulin responses in patients receiving monoclonal antibody therapy. *Cancer Res* 1985;45(2):879-885.
9. Boscato LM, Stuart MC. Heterophilic antibodies: a problem for all immunoassays. *Clin Chem* 1988;34(1):27-33.
10. Box GEP, Hunter WG, Hunter JS. *Statistics for experimenters; an introduction to design, data analysis, and model building.* New York, NY: John Wiley & Sons, Inc, 1978:510-539, 571–583.
11. SAS Institute, Inc. SAS Technical Report P-229, *SAS/STAT Software: Changes and enhancements,* Release 6.07. Cary, NC: SAS Institute Inc, 1992:289–366.

Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
ASSAY DILUENT	Assay Diluent
CONJUGATE	Conjugate
CONTROL NO.	Control Number
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
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

Revised July 2019.

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