



ARCHITECT
SYSTEM

en

HBsAg Qualitative

REF 1P97

48-5882/R2

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Read Highlighted Changes
Revised August, 2009

HBsAg Qualitative

Customer Service

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

This package insert must be read carefully before product 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	ASSAY CD-ROM	Assay CD-ROM
IVD	<i>In Vitro</i> Diagnostic Medical Device	SN	Serial Number
LOT	Lot Number	CONTROL NO.	Control Number
	Expiration Date	CAL 1	Calibrator 1, 2
	Store at 2-8°C	REAGENT LOT	Reagent Lot
	Caution	REACTION VESSELS	Reaction Vessels
	Consult instructions for use	SAMPLE CUPS	Sample Cups
	Manufacturer	SEPTUM	Septum
		REPLACEMENT CAPS	Replacement Caps

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

NAME

ARCHITECT HBsAg Qualitative

INTENDED USE

The ARCHITECT HBsAg Qualitative assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma.

SUMMARY AND EXPLANATION OF TEST

The causative agent of serum hepatitis is hepatitis B virus (HBV) which is an enveloped DNA virus. During infection, HBV produces an excess of hepatitis B surface antigen (HBsAg), also known as Australia antigen, which can be detected in the blood of infected individuals. It is responsible for binding the virus to the liver cell and is the target structure of neutralizing antibodies^{1,2}. HBsAg is the first serological marker after infection with HBV appearing one to ten weeks after exposure and two to eight weeks before the onset of clinical symptoms^{3,4}. HBsAg persists during this acute phase and clears late in the convalescence period. Failure to clear HBsAg within six months indicates a chronic HBsAg carrier state.

HBsAg assays are used to identify persons infected with HBV and to prevent transmission of the virus by blood and blood products as well as to monitor the status of infected individuals in combination with other hepatitis B serological markers⁵. In most countries, testing for HBsAg is part of the antenatal screening program to identify HBV infected mothers and to prevent perinatal HBV infection by subsequent immunization⁶.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT HBsAg Qualitative assay is a one-step immunoassay for the qualitative detection of HBsAg in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex. (Note: Ancillary wash buffer is added in a second incubation step, so the assay file performs a two-step assay protocol).

Sample, anti-HBs coated paramagnetic microparticles, and anti-HBs acridinium-labeled conjugate are combined to create a reaction mixture. HBsAg present in the sample binds to the anti-HBs coated microparticles and to the anti-HBs acridinium-labeled conjugate. After washing, ancillary wash buffer is added to the reaction mixture. 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 HBsAg in the sample and the RLUs detected by the ARCHITECT *i* System optics.

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

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

REAGENTS

Reagent Kit, 100 Tests / 500 Tests / 4 x 500 Tests

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

ARCHITECT HBsAg Qualitative Reagent Kit (1P97)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL per 100-test bottle/27.0 mL per 500-test bottle) anti-HBs (mouse, monoclonal, IgM, IgG) coated microparticles in MES buffer with protein stabilizers. Minimum concentration: 0.12% solids. Preservatives: ProClin 300 and ProClin 950.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL per 100-test bottle/26.3 mL per 500-test bottle) anti-HBs (goat, IgG) acridinium-labeled conjugate in MES buffer with protein stabilizers (bovine and human plasma; nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2 and anti-HCV). Minimum concentration: 0.25 µg/mL. Preservative: ProClin 300.
- **ANCILLARY WASH BUFFER** 1 or 4 Bottle(s) (5.9 mL per 100-test bottle/26.3 mL per 500-test bottle) ancillary wash buffer containing MES buffer. Preservative: ProClin 300.

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

- **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 and handled with appropriate biosafety practices.
- All of the components of this kit contain methylisothiazolones, which are components of ProClin. These components 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 kit or between reagent kits.**
- Before loading the ARCHITECT HBsAg Qualitative Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that 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 the 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, which 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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- 2-8°C The ARCHITECT HBsAg Qualitative 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 HBsAg Qualitative 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 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 HBsAg Qualitative assay file (assay number 149) must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM before performing the assay.

- For detailed information on the assay file installation and on 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

The specimen collection tubes listed below were verified to be used with the ARCHITECT HBsAg Qualitative assay. Other specimen collection tubes have not been tested with this assay.

- Human serum (including serum collected in serum separator tubes and tubes containing kaolin)
- Human plasma collected in:
 - plasma separator tubes (lithium heparin)
 - potassium EDTA
 - sodium citrate
 - lithium heparin
 - sodium heparin
 - potassium oxalate
 - CPDA-1
 - ACD
 - CPD
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The ARCHITECT *i* System 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 ARCHITECT HBsAg Qualitative assay.

Specimen Conditions

- Do not use specimens with the following conditions:
 - heat-inactivated
 - pooled
 - grossly hemolyzed (> 500 mg/dL)
 - obvious microbial contamination
 - cadaver specimens or any other body fluids
- 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.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- As specimens from heparinized patients may be partially coagulated and erroneous results could occur due to the presence of fibrin, draw the specimen prior to heparin therapy.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal 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.
- No qualitative performance differences were observed between experimental controls and nonreactive or spiked reactive specimens tested with elevated levels of bilirubin (20 mg/dL), triglycerides (3000 mg/dL), protein (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 serum and plasma 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 ≥ 10000 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.
- 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.

Storage

- Specimens may be stored on or off the clot, red blood cells, or separator gel for up to 14 days refrigerated at 2-8°C, or for up to 3 days at 15-30°C.
- If testing will be delayed more than the recommended storage time, remove serum or plasma from the clot, or red blood cells, and store frozen (-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.

Shipping

- Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel.
- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Specimens may be shipped ambient. Do not exceed the storage time limitations listed above.

PROCEDURE

Materials Provided

- 1P97 ARCHITECT HBsAg Qualitative Reagent Kit

Materials Required but not Provided

- ARCHITECT *i* System
- ARCHITECT *i* System **ASSAY CD-ROM**
- 1P97-01 ARCHITECT HBsAg Qualitative Calibrators
- 1P97-10 ARCHITECT HBsAg Qualitative 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)

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

Assay Procedure

- Before loading the ARCHITECT HBsAg Qualitative Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that 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 remain adhered to the bottle, continue inverting 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, place a septum on the bottle. For instructions on placing septums on bottles refer to the **WARNINGS AND PRECAUTIONS, Handling Precautions** section of this package insert.
- Load the ARCHITECT HBsAg Qualitative Reagent Kit on an ARCHITECT *i* System.
- Verify that all necessary assay 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.
 - If using ARCHITECT system software version 5.0 or higher, refer to the ARCHITECT System Operations Manual, Section 5, for information on ordering patient specimens and controls, and for general operating procedures.
 - If using an ARCHITECT system software version lower than 5.0, use the following instructions to order patient specimens and controls:

For information on ordering patient specimens and the positive control and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.

- Use the following instructions to order a negative control:
 - Order a negative control as a patient specimen, not as a Control.
 - Manually verify the validity of the negative control every time it is run. Because the control is run as a patient specimen, a result will not be flagged by the ARCHITECT *i* System if it is outside the acceptable control range.
To troubleshoot control values that fall outside the control range, refer to the ARCHITECT System Operations Manual, Section 10.

- 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 before running the test.
 - Priority: 125 μ L for the first ARCHITECT HBsAg Qualitative test plus 75 μ L for each additional ARCHITECT HBsAg Qualitative test from the same sample cup.
 - \leq 3 hours on board: 150 μ L for the first ARCHITECT HBsAg Qualitative test plus 75 μ L for each additional ARCHITECT HBsAg Qualitative test from the same 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.
 - Mix ARCHITECT HBsAg Qualitative Calibrators and Controls by gentle inversion before use.
 - To obtain the recommended volume requirements for the ARCHITECT HBsAg Qualitative Calibrators and Controls, hold the bottles **vertically** and dispense 11 drops of each calibrator or 6 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.
- For additional information on principles of operation, refer to the ARCHITECT 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 HBsAg Qualitative assay.

Calibration

- To perform an ARCHITECT HBsAg Qualitative calibration, test calibrators 1 and 2 in replicates of three. A single sample of each HBsAg Qualitative control level 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 HBsAg Qualitative 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.
 - 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 HBsAg Qualitative assay is that a single sample of each control be tested once every 24 hours each day of use. If your laboratory quality control procedures require more frequent use of controls to verify test results, follow those procedures.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT HBsAg Qualitative assay belongs to method group 5, except functional sensitivity.

RESULTS

Calculation

The ARCHITECT *i* System calculates an ARCHITECT HBsAg Qualitative 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 0.083 + Calibrator 2 mean RLU x 0.6 + 69
- S/CO = Sample RLU/Cutoff RLU

Example: If the Sample RLU = 1800 and the
Cutoff RLU = 500, then
1800/500 = 3.60
S/CO = 3.60

Interpretation of Results

Initial Result

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

NOTE: Prepare specimens for retest according to the directions in the **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** section of this package insert.

Duplicate Retest Results

Instrument Interpretation	Specimen Classification
Both results nonreactive	Specimen considered nonreactive for HBsAg
One or both results reactive	Specimen considered repeatedly reactive for HBsAg - Confirm by a neutralizing assay*

* ARCHITECT HBsAg Qualitative Confirmatory is recommended

For details on configuring the ARCHITECT *i* System to use gray zone interpretations, refer to the ARCHITECT System Operations Manual, Section 2. The grayzone interpretations are editable parameters, 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 ARCHITECT HBsAg Qualitative 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.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.⁷ 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.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA).^{8,9} Specimens containing HAMA may produce anomalous values when tested with assay kits (such as ARCHITECT HBsAg Qualitative) that employ mouse monoclonal antibodies.⁸
- If you run ARCHITECT HBsAg Qualitative on the same module as the ARCHITECT B12 assay, refer to labeling of the B12 assay for additional information and instructions regarding accumulation of protein in the sample probe.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The assay is designed to have an imprecision of ≤ 10% total* CV for specimens within the range of 1.00 to 2.50 S/CO.

Assay precision was assessed at one internal and two external evaluation sites.

20-day internal precision study

A 20-day precision study was performed for the ARCHITECT HBsAg Qualitative assay based on guidance from the CLSI (Clinical and Laboratory Standards Institute, formerly National Committee for Clinical Laboratory Standards) document EP5-A2.¹⁰

Testing was conducted using 3 ARCHITECT HBsAg Qualitative reagent lots, three calibrator lots and two instruments. One control lot was used to validate the calibration.

The panel for assessment of precision consisted of three control lots (negative and positive control) and one human plasma specimen. The panel was assayed in replicates of two at two separate times of the day for 20 different days. Data from this study are summarized in the following table**.

Member	N	Mean S/CO	Within Run		Total *	
			SD	%CV	SD	%CV
NC	1440	0.29	0.041	13.8	0.042	14.3
PC	1440	3.74	0.071	1.9	0.098	2.6
Human Plasma	480	1.77	0.053	3.0	0.068	3.8

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

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

5-day external precision study

A 5-day precision study was performed for the ARCHITECT HBsAg Qualitative assay based on guidance from the CLSI document EP15-A2.¹¹

Testing was conducted using 3 ARCHITECT HBsAg Qualitative reagent lots, one calibrator lot and one instrument per site. One control lot per site was used to validate the calibration.

The panel for assessment of precision consisted of three control lots (negative and positive control) and one human plasma specimen. The panel was assayed in replicates of three for 5 different days. Data from this study are summarized in the following table**.

Member	N	Mean S/CO	Within Run		Total *	
			SD	%CV	SD	%CV
NC	270	0.35	0.072	20.8	0.080	22.9
PC	270	3.85	0.090	2.3	0.109	2.8
Human Plasma	90	1.89	0.047	2.5	0.074	3.9

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

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

Resolved Specificity

The ARCHITECT HBsAg Qualitative assay is designed to have a resolved specificity of > 99.5% on a blood donor population and to show performance within the 95% confidence interval of a commercially available HBsAg assay on a diagnostic population.

A study was performed at two external sites and one internal site on a total of 5895 serum and plasma specimens collected from five blood-donation centers. For 2 specimens which were tested as initial and repeat reactive on ARCHITECT HBsAg Qualitative, presence of HBsAg was confirmed by specific neutralization with anti-HBs. The specificity on the remaining 5893 blood donors was assessed to be 99.97% (5891/ 5893). The resolved initial reactive rate was 0.17% (10/5893).

In this study, the specificity of 619 hospitalized/diagnostic specimens was assessed to be 100% (619/619).

Data from these studies are summarized in the following table*.

Category	N	IR** [%]	RR** [%]	Resolved Specificity	95% Confidence Interval [%]
Overall Blood Donors	5895	12 [0.20]	4 [0.07]	99.97% [5891/5893]	99.88 - 100
Blood Donor Plasma	3110	9 [0.29]	3 [0.10]	99.97% [3107/3108]	99.82 - 100
Blood Donor Serum	2785	3 [0.11]	1 [0.04]	99.96% [2784/2785]	99.80 - 100
Hospitalized/ Diagnostics	619	3 [0.48]	0	100% [619/619]	99.41 - 100

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

** IR = Initially Reactive, RR = Repeatedly Reactive

Resolved Sensitivity

The ARCHITECT HBsAg Qualitative is designed to show a resolved sensitivity equivalent to or better than a commercially available HBsAg assay.

A total of 461 HBsAg positive samples from patients with unknown disease status and 45 HBsAg positive samples from patients with a chronic HBV infection were tested, resulting in a sensitivity of 99.80% (505/506), 95% confidence interval 98.90 - 99.99% - the same results were observed for the method of comparison (representative data; results in individual laboratories may vary from these data).

Analytical Sensitivity

The ARCHITECT HBsAg Qualitative assay is designed as per CTS¹² to have an analytical sensitivity of ≤ 0.130 IU/mL.

Analytical Sensitivity was assessed across three different reagent lots by testing panel NIBSC code: 03/262, traceable to the Second International Standard for HBsAg, subtype adw2, genotype A, NIBSC code: 00/588. Analytical sensitivity results calculated by linear regression have ranged from 0.041 IU/mL to 0.049 IU/mL (representative data; results in individual laboratories may vary from these data).

Seroconversion Sensitivity

The ARCHITECT HBsAg Qualitative is designed to show seroconversion sensitivity equivalent to or better than a commercially available HBsAg assay.

For the assessment of seroconversion sensitivity, 33 commercially available seroconversion panels were tested. Data from 2 panels are shown in the following table*.

Panel	Days since first bleed	ARCHITECT HBsAg Qualitative S/CO	Method of comparison HBsAg IU/mL
		Reactive \geq 1.00 S/CO	Reactive \geq 0.05 IU/mL
BCP 6271	0	0.36	0.01
	3	0.60	0.02
	7	1.50	0.05
	12	8.27	0.34
	18	63.03	2.38
BCP 6275	0	0.42	0.01
	2	0.45	0.01
	7	0.84	0.03
	9	1.00	0.03
	22	7.41	0.29
	27	19.21	0.73
	29	29.15	1.19

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

HBsAg Mutant Detection

HBsAg mutant susceptibility was evaluated with the ARCHITECT HBsAg assay. A panel consisting of 9 different recombinant HBsAg mutant samples was tested. The mutant panel consisted of following mutations Thr 126 to Ser, Gln 129 to His, Met 133 to Leu, Asp 144 to Ala, Gly 145 to Arg, Thr 126 to Ser + Gly 145 to Arg, Pro 142 to Leu + Gly 145 to Arg, Pro 142 to Ser + Gly 145 to Arg, Asp 144 to Ala + Gly 145 to Arg.

All 9 samples were tested reactive across three different ARCHITECT HBsAg Qualitative reagent lots.

Potentially Interfering Substances

Additional studies were performed to evaluate other potential interfering disease states on the ARCHITECT HBsAg Qualitative assay. A total of 261 unspiked specimens and a total of 258 specimens spiked with HBsAg positive material were tested from following categories: Viral infection (HTLV-I, HSV, CMV, HCV, EBV, HIV-1, HIV-2); fungal/yeast/protozoal/bacterial infection (*T. pallidum*, *T. gondii*, *N. gonorrhoeae*, *C. trachomatis*); autoimmune (rheumatoid factor [RF], antinuclear antibodies [ANA]), other conditions (pregnant females all trimesters, multiparous females, immunoglobulin from monoclonal and polyclonal gammopathy for IgG and IgM or multiple myeloma, influenza vaccine recipients, hemodialysis patients, hemophiliacs, multiple transfusion recipients, human anti-mouse antibody (HAMA)). Two specimens (one ANA and one flu vaccine recipient) of the 261 unspiked specimens tested as initial and repeat reactive on the ARCHITECT HBsAg Qualitative and on the ARCHITECT HBsAg Qualitative Confirmatory could also be detected by PRISM HBsAg and confirmed by PRISM HBsAg Confirmatory. The resolved specificity on the remaining 259 unspiked samples was assessed to be 100% (259/259), 95% confidence interval 98.59-100%. The resolved sensitivity on the 258 spiked positive specimens and the 2 naturally reactive samples was estimated to be 100% (260/260), 95% confidence interval 98.59-100%. (Representative data; results in individual laboratories may vary from these data).

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The following US Patents are relevant to the ARCHITECT *i* System 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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