ARCHITECT®
SYSTEM

E

HAVAb-IgG

REF 6C29

B6C290

36-6800/R1

HAVAb-IgG

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. 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	CAL 1	Calibrator 1
IVD	For *In Vitro* Diagnostic Use	CONTROL –	Negative Control
2°C 8°C	Store at 2-8°C	CONTROL +	Positive Control
	CAUTION: Handle human sourced materials as potentially infectious. Consult instructions for use. (Infection Risk)	ASSAY CD-ROM	Assay CD-ROM
		SN	Serial Number
LOT	Lot Number	CONTROL NO.	Control Number
	Expiration Date	REAGENT LOT	Reagent Lot
	Consult instructions for use.	REACTION VESSELS	Reaction Vessels
		SAMPLE CUPS	Sample Cups
CE ABBOTT Max-Planck-Ring 2 65205 Wiesbaden Germany +49-6122-580	Legal Manufacturer	SEPTUM	Septum
		REPLACEMENT CAPS	Replacement Caps

CE ABBOTT
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

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

ABBOTT
Diagnostics Division

NAME

ARCHITECT® HAVAb-IgG

INTENDED USE

The ARCHITECT HAVAb-IgG assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human serum and plasma. The ARCHITECT HAVAb-IgG assay is indicated as an aid in the diagnosis of hepatitis A viral infection or detection of IgG anti-HAV.

SUMMARY AND EXPLANATION OF TEST

The ARCHITECT HAVAb-IgG assay determines the presence of IgG anti-HAV in human serum and plasma. The presence of IgG anti-HAV, with a nonreactive IgM anti-HAV test result, implies past infection with hepatitis A virus (HAV) or vaccination against HAV.[1]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT HAVAb-IgG assay is a two-step immunoassay for the qualitative detection of IgG anti-HAV in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®. In the first step, sample, assay diluent, and hepatitis A virus (human) coated paramagnetic microparticles are combined. IgG anti-HAV present in the sample binds to the hepatitis A virus (human) coated microparticles. After washing, the anti-human IgG acridinium-labeled conjugate that is added in the second step binds to IgG anti-HAV. 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 IgG anti-HAV in the sample and the RLUs detected by the ARCHITECT *i** System optics. The presence or absence of IgG anti-HAV in the sample is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an ARCHITECT HAVAb-IgG calibration. Specimens with signal to cutoff (S/CO) values ≥ 1.00 are considered reactive for IgG anti-HAV. Specimens with S/CO values < 1.00 are considered nonreactive.

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 HAVAb-IgG Reagent Kit (6C29)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL) Microparticles: Hepatitis A virus (human) coated microparticles in TRIS buffer. Minimum concentration: 0.08% solids. Preservatives: ProClin® 300 and other Antimicrobial Agents.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL) Conjugate: Anti-human IgG (mouse monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.01 µg/mL. Preservatives: Antimicrobial Agents.
- **ASSAY DILUENT** 1 or 4 Bottle(s) (10.0 mL) Assay Diluent: HAVAb-IgG Assay Diluent containing protein (goat) stabilizer in TRIS buffer. Preservatives: ProClin 300 and other Antimicrobial Agents.

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 0.35M sodium hydroxide.

ARCHITECT *i* Wash Buffer

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservative: Antimicrobial Agents.

WARNINGS AND PRECAUTIONS

- **IVD** **For *In Vitro* Diagnostic Use.**
- Package instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

- **CAUTION: This product contains human sourced and/or potentially infectious components. For a specific listing, 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.[2] Biosafety Level 2[3] or other appropriate biosafety practices[4,5] should be used for materials that contain or are suspected of containing infectious agents. These precautions include, but are not limited to, the following:**
  - Wear gloves when handling specimens or reagents.
  - Do not pipette by mouth.
  - Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
  - Clean and disinfect all spills of specimens or reagents using a tuberculocidal disinfectant such as 0.5% sodium hypochlorite, or other suitable disinfectant.[6,7]
  - Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[8,9]
- Microparticles and Assay Diluent 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 is 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.

- ARCHITECT *i* Trigger Solution contains sodium hydroxide (NaOH) and is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases:

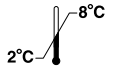
R41	Risk of serious damage to eyes.
S25	Avoid contact with eyes.
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S35	This material and its container must be disposed of in a safe way.
S36/39	Wear suitable protective clothing and eye/face protection.
S46	If swallowed, seek medical advice immediately and show this container or label.

- **Information for European customers: For product not classified as dangerous per European Directive 1999/45/EC - 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.**
- Prior to loading the ARCHITECT HAVAb-IgG 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.**
- When handling conjugate vials, change gloves that have contacted human serum or plasma, since introduction of human IgG will result in a neutralized conjugate.
- Prior to placing the septum on an uncapped reagent bottle, squeeze the septum in half to confirm that the slits are open. If the slits appear sealed, continue to gently squeeze the septum to open the slits.
- 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, 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

- 

The ARCHITECT HAVAb-IgG 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 HAVAb-IgG 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 reagents must be discarded.** After reagents are removed from the system, you must 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 HAVAb-IgG 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.
- 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, CPDA-1, and CPD may be used in the ARCHITECT HAVAb-IgG assay. Other anticoagulants have not been validated for use with the ARCHITECT HAVAb-IgG assay. Follow the manufacturer's instructions for processing 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 that the correct specimen types are used in the ARCHITECT HAVAb-IgG 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 have 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 specimens for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each specimen 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 should 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 centrifugation, as recommended by the 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 $\geq$ 10,000 RCF (Relative Centrifugal Force) for 10 minutes if one or more of the following has occurred:
  - they contain red blood cells, clots, or particulate matter
  - they require repeat testing

  Transfer clarified specimens to a sample cup or secondary tube for testing.
- Multiple freeze/thaw cycles of specimens should be avoided.
  Mix thawed specimens by inverting 10 times. Visually inspect the specimens for the absence of stratification. If layering or stratification is observed repeat until specimens are visibly homogeneous.
  Centrifuge at $\geq$ 10,000 RCF for 10 minutes to remove particulate matter and 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.
- Specimens may be stored on or off the clot or red blood cells for up to 14 days at 2-8°C. If testing will be delayed more than 14 days, remove serum or plasma from the clot, serum separator, or red blood cells and store frozen at -10°C or colder.
- No qualitative performance differences were observed between experimental controls and 21 nonreactive or 21 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 19 nonreactive or 19 spiked reactive specimens tested with elevated levels of bilirubin (≤ 20 mg/dL), triglycerides (≤ 3,000 mg/dL), protein (≤ 12 g/dL), or hemoglobin (≤ 500 mg/dL).
- No qualitative performance differences were observed between experimental controls and 21 nonreactive or 21 spiked reactive specimens tested with elevated levels of red blood cells (≤ 0.4% v/v).
- Before shipping specimens, it is recommended that specimens be removed from the clot, serum separator, or red blood cells. 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 at -10°C or colder (dry ice). Do not exceed the storage time limitations identified in this section of the package insert.

PROCEDURE

Materials Provided:

- 6C29 ARCHITECT HAVAb-IgG Reagent Kit

Materials Required but not Provided:

- ARCHITECT *i* System
- ARCHITECT *i* **ASSAY CD-ROM**
- 6C29-01 ARCHITECT HAVAb-IgG Calibrator
- 6C29-10 ARCHITECT HAVAb-IgG 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 HAVAb-IgG Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment:
  - **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 Laboratories representative.**
  - Once the microparticles have been resuspended, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Squeeze the septum in half to confirm that the slits are open. 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 general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- Load the ARCHITECT HAVAb-IgG Reagent Kit on the ARCHITECT *i* System.
  - Verify that all necessary 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: 75 µL for the first ARCHITECT HAVAb-IgG test plus 25 µL for each additional ARCHITECT HAVAb-IgG test from the same sample cup.
  - ≤ 3 hours on board: 150 µL for the first ARCHITECT HAVAb-IgG test plus 25 µL for each additional ARCHITECT HAVAb-IgG test from the sample cup.
  - > 3 hours on board: additional sample volume is required. For additional 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 sample volume is present.
- Prepare calibrator and controls.
  - ARCHITECT HAVAb-IgG Calibrator 1 and Controls should be mixed by gentle inversion 5-10 times prior to use.
  - To obtain the recommended volume requirements for the ARCHITECT HAVAb-IgG Calibrator 1 and Controls, hold the bottles **vertically** and dispense 4 drops of 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 to the aspiration point.
  - Loads a reaction vessel (RV) into the process path.
  - Aspirates and transfers an aliquot of sample into the RV.
  - Moves RV one position.
  - Aspirates and transfers aliquots of assay diluent and microparticles to the RV containing sample.
  - 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 IgG anti-HAV in the sample.
  - Aspirates contents of RV to liquid waste and unloads RV to solid waste.
  - Calculates the result.
- For optimal performance of the ARCHITECT *i* System , 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 HAVAb-IgG assay.

Calibration

- To perform an ARCHITECT HAVAb-IgG calibration, test Calibrator 1 in replicates of three by ordering a Calibration for the ARCHITECT HAVAb-IgG assay from the Orders menu. A single sample of each ARCHITECT HAVAb-IgG Control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrator 1 should be priority loaded.
- Once an ARCHITECT HAVAb-IgG 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 recommended control requirement for the ARCHITECT HAVAb-IgG assay is that a single sample of each control 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 HAVAb-IgG 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 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 HAVAb-IgG assay belongs to method group 5.

RESULTS

Calculation

The ARCHITECT *i* System calculates cutoff RLU (CO) from the mean RLU value of three Calibrator 1 replicates and stores the result.

- Cutoff RLU = Calibrator 1 mean RLU Value x 0.29
- The cutoff RLU is stored for each reagent lot calibration.

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

- Example If the sample RLU = 4730 and the Cutoff RLU = 1920
  4730/1920 = 2.46
  S/CO = 2.46

Interpretation of Results

ARCHITECT HAVAb-IgG Results

Results (S/CO)	Interpretation
< 1.00	Nonreactive (NR)
≥ 1.00	Reactive (R)

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 IgG anti-HAV 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 must be centrifuged prior to running the assay if one or more of the following has occurred:
  - they contain red blood cells, clots, or particulate matter
  - they require repeat testing
- 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.
- 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.[10,11] ARCHITECT HAVAb-IgG 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.[12] 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 ARCHITECT HAVAb-IgG assay demonstrated imprecision of ≤ 10% for Calibrator 1 and Positive Control in a study where a panel, consisting of one diluted IgG anti-HAV reactive specimen, three control lots, and three calibrator lots, was tested. The study was performed at one external site, running one ARCHITECT *i* System (and only one lot of negative control), and one internal site, running two ARCHITECT *i* Systems. Both sites tested all panel members with three reagent lots and evaluated them with each calibrator lot. Each combination of instruments, control lots, calibrator lots, and reagent lots was tested in four runs. The controls and calibrator were tested in replicates of three on each run. The diluted IgG anti-HAV reactive specimen was tested in replicates of four on each run. The intra-run and inter-run standard deviation (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 HAVAb-IgG Precision

Panel Member	n	Mean	Intra-assay SD	Intra-assay %CV	Inter-assay[a] SD	Inter-assay[a] %CV
Calibrator 1 (RLUs)	324	7758	478.5	6.2	488.6	6.3
Negative Control (S/CO)	756	0.13	0.020	16.12	0.020	16.12
Positive Control (S/CO)	972	2.32	0.141	6.08	0.164	7.05
Diluted Specimen (S/CO)	432	1.72	0.101	5.87	0.107	6.23

[a] Inter-assay variability contains intra-assay variability.

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

Specificity

- The ARCHITECT HAVAb-IgG assay demonstrated a specificity of ≥ 99.17%* in a study testing serum and plasma specimens from the following populations:
  - Randomly selected blood donors (BD)
  - Randomly selected hospitalized patients (HP)

  The testing was performed at one clinical site and one internal site.

  Of 1855 specimens initially tested, 879 specimens were reactive by both ARCHITECT HAVAb-IgG and AxSYM HAVAB 2.0. In addition, 8 other specimens were found to be reactive by supplemental testing. Therefore, these 887 specimens were considered true IgG anti-HAV reactives and were excluded from the specificity calculation. The data from the remaining 968 specimens from this study are summarized in Table 2.*

Table 2
ARCHITECT HAVAb-IgG Specificity Results

Population	n	False Reactives	Specificity (%)	Specificity 95% CI[a]
BD	474	3	99.37	98.16 - 99.87
HP	494	5	98.99	97.65 - 99.67
Total	968	8	99.17	98.38 - 99.64

[a] CI = Confidence Interval

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

- Of 210 specimens initially tested from populations of interfering substances (IS) and patients at increased risk for HAV infection (HR), 118 specimens were reactive by both ARCHITECT HAVAb-IgG and AxSYM HAVAB 2.0. These 118 specimens were considered true IgG anti-HAV reactives and were excluded from the study. The data from the remaining 92 specimens from this study are summarized in Table 3.*

Table 3
ARCHITECT HAVAb-IgG
Potentially Interfering Substances and High Risk Specimens

Population	n	Initial Reactives	Repeat Reactives
IS[b]	48	4	4[c]
HR[d]	44	3	3[e]

[b] Specimens containing the following potentially interfering substances were evaluated for cross-reactivity by ARCHITECT HAVAb-IgG:

- CMV-IgG
- CMV-IgM
- Chronic HBV
- HCV
- Recovered HBV
- HIV-1
- HSV
- Flu vaccines
- Alcoholic cirrhosis
- Antinuclear antibodies (ANA)
- Elevated IgM
- Rheumatoid factor
- Elevated IgG
- HAMA

[c] The repeat reactives in the IS population were from 1 HIV-1 specimen, 1 HAMA specimen, and 2 rheumatoid factor specimens.

[d] The HR population included specimens from hemophilia patients, intravenous drug users, and men who have had sex with men.

[e] The repeat reactives in the HR population were from 1 intravenous drug user specimen and 2 hemophiliac specimens.

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

Sensitivity

- The ARCHITECT HAVAb-IgG assay demonstrated a sensitivity of ≥ 98% in a study testing serum and plasma specimens drawn from individuals vaccinated against HAV and patients who had recovered from acute HAV infection. The data from this study are summarized in Table 4.*

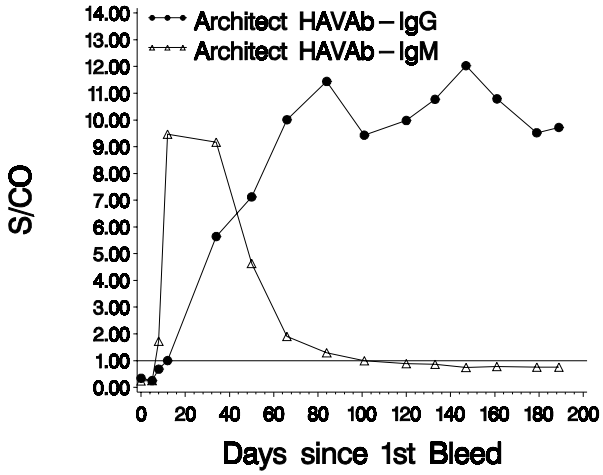
Table 4
ARCHITECT HAVAb-IgG Sensitivity Results

Population	n	Reactive	Nonreactive
Vaccinated	101	101	0
Recovered from HAV Infection	45	45	0

- Testing by ARCHITECT HAVAb-IgG and ARCHITECT HAVAb-IgM was performed on serial bleed panels. The reactive ARCHITECT HAVAb-IgG result is indicative of seroconversion from IgM anti-HAV to IgG anti-HAV.

* Representative data for one of the panels is provided in Figure 1.*

Figure 1



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

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The following U.S. 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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