Anti-HBs

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

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.

---

Key to symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>List Number</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td></td>
<td>Expiration Date</td>
</tr>
<tr>
<td></td>
<td>Store at 2-8°C</td>
</tr>
<tr>
<td></td>
<td>Caution</td>
</tr>
<tr>
<td></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
</tr>
<tr>
<td>REAGENT LOT</td>
<td>Reagent Lot</td>
</tr>
<tr>
<td>CONTROL NO.</td>
<td>Control Number</td>
</tr>
<tr>
<td>REACTION VESSELS</td>
<td>Reaction Vessels</td>
</tr>
<tr>
<td>SAMPLE CUPS</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>SEPTUM</td>
<td>Septum</td>
</tr>
<tr>
<td>REPLACEMENT CAPS</td>
<td>Replacement Caps</td>
</tr>
<tr>
<td>CONTAINS: AZIDE</td>
<td>Contains Sodium Azide. Contact with acids liberates very toxic gas.</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
have demonstrated the effectiveness of the Hepatitis B vaccine to stimulate
ARCHITECT Anti-HBs Reagent Kit (7C18)
•
•
ARCHITECT
NOTE:
Reagent Kit, 100/500 Tests
the specimen is considered reactive for anti-HBs. If the
previously generated ARCHITECT Anti-HBs calibration curve. If the
between the amount of anti-HBs in the sample and the RLUs detected by
is measured as relative light units (RLUs). A direct relationship exists
sample binds to the rHBsAg coated microparticles. After washing,
acidinium-labeled rHBsAg conjugate is added in the second step.
Following another wash cycle, Pre-Trigger and Trigger Solutions are
added to the reaction mixture. The resulting chemiluminescent reaction
exists between the amount of anti-HBs in the sample and the RLUs detected by
ARCHITECT i* System optics.
The concentration of anti-HBs in the specimen is determined using a
previously generated ARCHITECT Anti-HBs calibration curve. If the
calibration curve. If the concentration of the specimen is greater than or equal to 10.0 mIU/mL,
the specimen is considered reactive for anti-HBs.
For additional information on system and assay technology, refer to the
* i = immunoassay
REAGENTS
Reagent Kit, 100/500 Tests
NOTE: Some kit sizes are not available in all countries or for use on all
ARCHITECT / Systems. Please contact your local distributor.
ARCHITECT Anti-HBs Reagent Kit (7C18)
• MICROPARTICLES 1 or 4 Bottle(s) (4.56 mL per 100 test bottle/
16.80 mL per 500 test bottle) Hepatitis B Surface (E. coli,
Recombinant) Antigen (Subtypes ad and ay) Coated Paramagnetic Microparticles
• CONJUGATE 1 or 4 Bottle(s) (5.9 mL per 100 test bottle/28.3 mL per
500 test bottle) Conjugate: Hepatitis B Surface (E. coli, Recombinant)
Antigen (Subtypes ad and ay) Acidinium-Labeled Conjugate in MES buffer with protein stabilizers
Minimum concentration: 0.10 µg/mL. Preservatives: sodium azide and antimicrobial agents;
Assay Diluent
ARCHITECT / Multi-Assay Manual Diluent (7D82-50)
• MULTI-ASSAY MANUAL DILUENT 1 Bottle (100 mL) ARCHITECT
Other Reagents
ARCHITECT / Pre-Trigger Solution
• PRE-TRIGGER SOLUTION Pre-Trigger Solution containing 1.32% (w/v)
hydrogen peroxide.
ARCHITECT / Trigger Solution
• TRIGGER SOLUTION Trigger Solution containing 0.35 N sodium hydroxide.
ARCHITECT / Wash Buffer
• WASH BUFFER Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.
WARNINGS AND PRECAUTIONS
• IVD
For In Vitro Diagnostic Use
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.
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.7
Biosafety Level 28 or other appropriate biosafety practices7,8 should
be used for materials that contain or are suspected of containing
infectious agents.
• This product contains sodium azide; for a specific listing, refer to the
REAGENTS section. Contact with acids liberates very toxic gas. This
material and its container must be disposed of in a safe way.
• For information on the safe disposal of sodium azide and a detailed
discussion of safety precautions during system operation, refer to the
The human plasma used in the conjugate is nonreactive for HBsAg,
HIV-1 RNA or HIV-1 Ag, anti-HCV, anti-HIV-1/HIV-2, and anti-HBs.
Handling Precautions
• Do not use reagent kits beyond the expiration date.
• Do not pool reagents within a reagent kit or between reagent kits.
• Prior to loading the ARCHITECT Anti-HBs Reagent Kit on the
system for the first time, the microparticle bottle requires mixing to
resuspend microparticles that may have settled during shipment. For
microparticle mixing instructions, refer to the PROCEDURE, Assay
Procedure section of this package insert.
• Septums MUST be used to prevent reagent evaporation and
contamination, and to ensure reagent integrity. Reliability of assay
results cannot be guaranteed if septums are not used according to the
instructions in this package insert.
• To avoid contamination, wear clean gloves when placing a septum
on an uncapped reagent bottle.
• Once a septum has been placed on an open reagent bottle, do
not invert the bottle as this will result in reagent leakage and may
compromise assay results.
• Over time, residual liquids may dry on the septum surface. These are
typically dried salts and have no effect on assay efficacy.
• For a detailed discussion of handling precautions during system
operation, refer to the ARCHITECT System Operations Manual,
Section 7.
Storage Instructions

- Store the ARCHITECT Anti-HBs Reagent Kit, Calibrators, and Controls 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 Anti-HBs Reagent Kit may be stored on board the ARCHITECT / 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 / System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit 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 will require retesting. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT Anti-HBs assay file must be installed on the ARCHITECT / System from the ARCHITECT / 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.
- 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.
- The default result unit for the ARCHITECT Anti-HBs assay is mIU/mL. An alternate result unit, IU/L, may be selected for reporting results by editing assay parameter "Result concentration units" to IU/L. The conversion factor used by the system is 1.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum (including serum collected in serum separator tubes) or plasma collected in potassium EDTA, sodium citrate, ACD, CPDA-1, and sodium heparin may be used in the ARCHITECT Anti-HBs assay. Liquid anticoagulants may have a dilutional effect resulting in lower concentrations for individual patient samples. Other anticoagulants have not been validated for use with the ARCHITECT Anti-HBs assay. Follow the tube manufacturer’s processing instructions for serum or plasma collection tubes.
- The ARCHITECT / System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify the correct specimen types are used in the ARCHITECT Anti-HBs assay.
- Performance has not been established using cadaver specimens or body fluids other than human serum or plasma.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- This assay was designed and validated for use with human serum or plasma from individual patient and donor specimens. Pooled specimens must not be used since the accuracy of their test results has not been validated.
- Do not use heat-inactivated specimens.
- Do not use grossly hemolyzed specimens.
- For optimal results, inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- Analytical performance differences observed between experimental controls and the 23 nonreactive or 23 spiked reactive specimens subjected to 4 freeze-thaw cycles. The quantitative performance differences observed were within normal assay variability; however, multiple freeze-thaw cycles should be avoided.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of specimens and infectious substances. Specimens may be shipped ambient, at 2-8°C (wet ice), or -20°C or colder (dry ice). Do not exceed the storage time limitations listed above. Prior to shipment, it is recommended that specimens be removed from the clot, serum separator, or red blood cells.
- Frozen specimens must be mixed THOROUGHLY after thawing by LOW speed vortexing.
- 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.
- No qualitative performance differences were observed between experimental controls and the 24 nonreactive or 23 spiked reactive specimens subjected to 4 freeze-thaw cycles. The quantitative performance differences observed were within normal assay variability; however, multiple freeze-thaw cycles should be avoided.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of specimens and infectious substances. Specimens may be shipped ambient, at 2-8°C (wet ice), or -20°C or colder (dry ice). Do not exceed the storage time limitations listed above. Prior to shipment, it is recommended that specimens be removed from the clot, serum separator, or red blood cells.
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PROCEDURE

Materials Provided
- 7C18 ARCHITECT Anti-HBs Reagent Kit

Materials Required but not Provided
- ARCHITECT i System
- 7C18-01 ARCHITECT Anti-HBs Calibrators
- 7C18-10 ARCHITECT Anti-HBs Controls
- 7D82-50 ARCHITECT i [MULTI-ASSAY MANUAL DILUENT]
- ARCHITECT i TRIGGER SOLUTION
- ARCHITECT i WASH BUFFER
- ARCHITECT i REACTION SOLUTIONS
- ARCHITECT i SAMPLE CUPS
- ARCHITECT i SEPTUM
- ARCHITECT i REPLACEMENT CAPS

Assay Procedure
Before loading the ARCHITECT Anti-HBs Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment:
- Invert the microparticle bottle 30 times.
- Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
- 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.
- If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.

Load the ARCHITECT Anti-HBs Reagent Kit on the ARCHITECT 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 specimen evaporation and volumes:
- Order calibration, if necessary.
- Order tests.
- For information on ordering patient specimens, calibrators, and controls, and general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.

Load the ARCHITECT Anti-HBs Reagent Kit on the ARCHITECT i System. Verify that all necessary reagents are present. Ensure that septums are present on all reagent bottles.

The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The concentration reported by the ARCHITECT System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures
Specimens with an anti-HBs value exceeding 1,000 mIU/mL are flagged with the code “>1000.00 mIU/mL” and may be diluted with either the: 1) Automated Dilution Protocol or 2) Manual Dilution Procedure.

1) Automated Dilution Protocol (for concentrations up to 15,000 mIU/mL)
- The system performs a 1:15 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result.

2) Manual Dilution Procedure (for concentrations up to 100,000 mIU/mL)
- The suggested manual dilution for Anti-HBs is 1:100. It is recommended dilutions not exceed 1:100.
- For a 1:100 dilution, add 10 μL of the patient specimen to 990 μL of ARCHITECT i Multi-Assay Manual Diluent (7D82).
- The operator must enter the dilution factor in the Patient or Control order screen. All assays selected for that order will be diluted. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The concentration reported by the ARCHITECT i System MUST be greater than 10.0 mIU/mL. If the reported concentration is less than 10.0 mIU/mL, make a smaller dilution.

Specimens with an anti-HBs value reported as greater than 15,000 mIU/mL may be diluted using either the: 1) Automated Dilution Protocol and the Manual Dilution Procedure or 2) Manual Dilution Procedure.

1) Automated Dilution Protocol and the Manual Dilution Procedure (for concentrations up to 1,500,000 mIU/mL)
- The suggested manual dilution for Anti-HBs is 1:100. It is recommended dilutions not exceed 1:100.
- For a 1:100 dilution, add 10 μL of the patient specimen to 990 μL of ARCHITECT i Multi-Assay Manual Diluent (7D82).
- Order the Automated Dilution Protocol using the manually diluted 1:100 sample.
- The concentration reported by the ARCHITECT System MUST be greater than 10.0 mIU/mL. Multiply the result (from the Automated Dilution Protocol) by the manual dilution factor (e.g. 100) to obtain the final sample concentration. If the concentration reported by the ARCHITECT System is less than 10.0 mIU/mL, make a smaller dilution.
2) **Manual Dilution Procedure** (for concentrations up to 100,000 mIU/mL)

- The suggested manual dilution for Anti-HBs is 1:100. It is recommended dilutions not exceed 1:100.
- For a 1:100 dilution, add 10 μL of the patient specimen to 990 μL of ARCHITECT i Multi-Assay Manual Diluent (7D82).
- The operator must enter the dilution factor in the Patient or Control order screen. All assays selected for that order will be diluted. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The concentration reported by the ARCHITECT i System MUST be greater than 10.0 mIU/mL. If the reported concentration is less than 10.0 mIU/mL, make a smaller dilution.
- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

**Calibration**

- To perform an ARCHITECT Anti-HBs calibration, test Calibrators 1 and 2 in duplicate. A single sample of all levels of Anti-HBs controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the Control package insert. Calibrators should be priority loaded.
  - Calibrator Range: 0 - 1000 mIU/mL.
  - Once an ARCHITECT Anti-HBs 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**

**NOTE:** It is recommended that the ARCHITECT Anti-HBs Positive Control 1, Anti-HBs Positive Control 2, and Negative Control be run in order to verify the calibration.

The recommended control requirement for the ARCHITECT Anti-HBs assay is a single sample of each control 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. Ensure that assay Control values are within the concentration ranges specified in the Control package insert.

**NOTE:** For special instructions on how to run controls with a value of 0 mIU/mL (ARCHITECT Anti-HBs Negative Control) refer to the ARCHITECT Anti-HBs Control package insert.

**Verification of Assay Claims**

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT Anti-HBs assay belongs to method group 4.

**RESULTS**

The ARCHITECT Anti-HBs assay utilizes a 4 Parameter Logistic Curve Fit data reduction method (4PLC, X-weighted) to generate a calibration curve.

**Interpretation of Results**

- Specimens with concentration values < 10.00 mIU/mL are considered nonreactive by the criteria of ARCHITECT Anti-HBs.
- Specimens with concentration values ≥ 10.00 mIU/mL are considered reactive by the criteria of ARCHITECT Anti-HBs.

**NOTE:** For details on configuring the ARCHITECT i System regarding grayzone and high reactive interpretations, refer to the ARCHITECT System Operations Manual, Section 2. The grayzone and high reactive interpretation is an editable parameter, and should be utilized per end user requirements.

**Flags**

- Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

**LIMITATIONS OF THE PROCEDURE**

- If the Anti-HBs 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, chronic, or recovered infection.
- Samples containing particulate matter or red blood cells must be centrifuged prior to running the assay.
- Performance has not been established using cadaver specimens or body fluids other than human serum or plasma.
- Do not use heat-inactivated specimens.
- 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.
- Quantitative values obtained using alternative assays (i.e. MEIA, EIA or RIA) may not be equivalent and cannot be used interchangeably. A new baseline, using the ARCHITECT Anti-HBs assay, should be established when monitoring vaccines.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Precision**

The precision of ARCHITECT Anti-HBs was determined during clinical studies using three reagent lots. A panel composed of five unique members was tested in replicates of four with each reagent lot once daily for five days at three sites. Each daily run included the ARCHITECT Positive Controls each tested in duplicate at the beginning and end of the run. The intra-assay and inter-assay standard deviation (SD) and percent coefficient of variation (%CV) were determined with a variance component analysis for a random effects model (Table I).

### TABLE I

<table>
<thead>
<tr>
<th>Panel Members</th>
<th>Total No. Replicates</th>
<th>Grand Mean mIU/mL</th>
<th>Intra-assay SD</th>
<th>Inter-assay SD</th>
<th>Total SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>180</td>
<td>4.67</td>
<td>0.302</td>
<td>6.5</td>
<td>0.403</td>
<td>8.6</td>
</tr>
<tr>
<td>2</td>
<td>180</td>
<td>14.60</td>
<td>0.434</td>
<td>3.0</td>
<td>0.708</td>
<td>4.9</td>
</tr>
<tr>
<td>3</td>
<td>180</td>
<td>79.75</td>
<td>3.082</td>
<td>3.9</td>
<td>4.130</td>
<td>5.2</td>
</tr>
<tr>
<td>4</td>
<td>180</td>
<td>255.04</td>
<td>4.752</td>
<td>1.9</td>
<td>7.565</td>
<td>3.0</td>
</tr>
<tr>
<td>5</td>
<td>180</td>
<td>489.20</td>
<td>14.474</td>
<td>3.0</td>
<td>19.225</td>
<td>3.9</td>
</tr>
</tbody>
</table>

**a** Inter-assay variability contains intra-assay variability.

**b** Total assay variability contains intra-assay, inter-assay, inter-lot, inter-site variability.

**Sensitivity**

A total of 389 specimens from 248 HBV vaccine recipients, 41 individuals recovered from HBV infection, and 100 individuals at risk for HBV infection were tested. Of the 389 specimens, 340 (87.40%) were repeatedly reactive and positive by supplemental testing (Table II).

### TABLE II

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Specimens Tested</th>
<th>Number of Repeatedly Reactive (% of total)</th>
<th>Number of Positive by Supplemental Testing (% of Repeatedly Reactive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV Vaccine Recipients</td>
<td>248</td>
<td>245 (98.79%)</td>
<td>245 (100.00%)</td>
</tr>
<tr>
<td>Recovered HBV Infection</td>
<td>41</td>
<td>39a (95.12%)</td>
<td>39 (100.00%)</td>
</tr>
<tr>
<td>Increased Risk for HBV Infection</td>
<td>100</td>
<td>56 (56.00%)</td>
<td>56 (100.00%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>389</td>
<td>340 (87.40%)</td>
<td>340 (100.00%)</td>
</tr>
</tbody>
</table>

**a** Two specimens were reactive for anti-HBc and anti-HBe but also nonreactive for anti-HBs by RIA.

**b** Category included the following: intravenous drug users (34), hemodialysis patients (33), and hemophiliacs patients (33).
HBV Vaccine Recipient Serial Bleed Panels

A total of 90 specimens comprising 15 serial bleed panels from HBV vaccine recipients were tested. The vaccine was administered in three injections over a six-month period. All specimens drawn one month following the third and final injection were reactive by the ARCHITECT Anti-HBs assay.

Correlation

ARCHITECT Anti-HBs was compared to a commercially available assay for correlation using the Passing-Bablok Regression method and Spearman Rank correlation. The comparison was made using results from 187 specimens from HBV vaccine recipients and individuals who have recovered from HBV infection. The correlation coefficient was 0.906, the slope was 1.07 and the intercept was -3.01.

Specificity

Three clinical sites tested a total of 1,716 serum and plasma specimens from the following categories: volunteer whole blood donors, matched serum and plasma pairs, random hospital patients, medical conditions unrelated to HBV infection and potentially interfering substances. A total of 259 (15.09%) of the 1,716 specimens were repeatedly reactive, and 254 (98.07%) of the 259 specimens were positive by supplemental testing (Table III).

TABLE III

Reactivity of the ARCHITECT Anti-HBs Assay in Specimens from Whole Blood Donors, Plasma Specimens from Matched Serum/Plasma Pairs, Hospital Patients, Individuals with Medical Conditions Unrelated to HBV Infection and in Specimens Containing Potentially Interfering Substances

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Specimens Tested</th>
<th>Number of Reactively Reactive (% of total)</th>
<th>Number of Positive by Supplemental Testinga (% of Reactively Reactive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volunteer Whole Blood Donors</td>
<td>1006</td>
<td>154 (15.31%)</td>
<td>151 (98.05%)</td>
</tr>
<tr>
<td>Plasma Specimens from Matched Serum/Plasma Pairs</td>
<td>50</td>
<td>8 (16.00%)</td>
<td>8 (100.00%)</td>
</tr>
<tr>
<td>Hospital Patients</td>
<td>500</td>
<td>65 (13.00%)</td>
<td>63 (96.92%)</td>
</tr>
<tr>
<td>Medical Conditions Unrelated to HBV Infection and Potentially Interfering Substancesb</td>
<td>160</td>
<td>32 (20.00%)</td>
<td>32 (100.00%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1716</td>
<td>259 (15.09%)</td>
<td>254 (98.07%)</td>
</tr>
</tbody>
</table>

a Supplemental testing for anti-HBc, HBsAg and anti-HBe was performed to support the presence of anti-HBs in an ARCHITECT Anti-HBs reactive specimen. Detection of anti-HBs by RIA was also performed. A specimen was defined as anti-HBs positive if one or more of the following HBV markers were detected: anti-HBs (detected by the comparator method or RIA), anti-HBc, HBsAg, or anti-HBe.

b Category included the following: anti-CMV positive (10), anti-EBV positive (10), anti-HSV (10), anti-HAV (10), anti-HCV (10), anti-HIV (10), rubella antibody positive (10), toxoplasma antibody positive (10), E. coli infections (10), yeast infections (10), syphilis positive (10), anti-nuclear antibody positive (10), rheumatoid factor (10), multiple myeloma (10), HBsAg positive (10) and alcoholic liver disease (10).

Overall Specificity and Sensitivity

Overall specificity and sensitivity were estimated from the results of 2,105 specimens tested with ARCHITECT Anti-HBs at five clinical sites. In order to represent unique specimens, results from the HBV vaccine recipient serial bleed panels and the serum specimens from the matched serum/plasma pairs were excluded from these calculations. The overall specificity was estimated to be 99.67% (1,491/1,496) with a 95% confidence interval of 99.22% to 99.89%. The overall sensitivity was estimated to be 97.54% (594/609) with a 95% confidence interval of 95.97% to 98.62%.

BIBLIOGRAPHY


ARCHITECT is a trademark of Abbott Laboratories in various jurisdictions.

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

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