

Anti-HBs2 (aHBs2)

Assay for the Detection of Antibodies to Hepatitis B Surface Antigen

Current revision and date^a	Rev. M, 2021-04	
Product Name	ADVIA Centaur® anti-HBs2 assay (200 tests/kit)	REF 04670661
	ADVIA Centaur anti-HBs2 assay (200 tests/kit)	REF 10698706
Systems	ADVIA Centaur XP system ADVIA Centaur XPT system	
Materials Required but Not Provided	ADVIA Centaur Wash 1 (2 x 1500 mL)	REF 01137199 (112351)
	ADVIA Centaur Wash 1 (2 x 2500 mL)	REF 03773025
Specimen Types	Serum, plasma (EDTA, lithium-heparinized, or sodium-heparinized)	
Assay Range	3.1–1000 mIU/mL	
Reagent Storage	2–8°C	
Reagent On-System Stability	90 days	

^a In Rev. B or later, a vertical bar in the margin indicates a technical update to the previous version.

Intended Use

The ADVIA Centaur anti-HBs2 assay is an *in vitro* diagnostic immunoassay for the qualitative and quantitative determination of total antibodies to hepatitis B surface antigen in human adult, adolescent, and pediatric serum or plasma (EDTA, lithium-heparinized, or sodium-heparinized) and neonatal samples using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems. The assay results may be used as an aid in the determination of susceptibility to hepatitis B virus (HBV) infection in individuals prior to or following HBV vaccination or where vaccination status is unknown. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. A reactive assay result will allow a differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.

This assay has not been FDA-cleared or approved for the screening of blood or plasma donors.

Summary and Explanation

The ADVIA Centaur Anti-HBs2 assay is an antibody-capture microparticle direct chemiluminometric immunoassay used to measure the amount of antibody to hepatitis B surface antigen in human serum and plasma.

Hepatitis B virus (HBV) is endemic throughout the world and is the major cause of liver disease. HBV is transmitted sexually and through direct contact with blood and body fluids.^{1,2}

The average incubation period for HBV infection is 6 to 8 weeks (range 1 to 6 months). Common clinical symptoms include malaise, fever, gastroenteritis, and icterus. HBV infection can result in typical icteric hepatitis, subclinical anicteric hepatitis, fulminant hepatitis, or chronic or persistent hepatitis. In adults, 90 to 95% of patients with HBV infection completely recover from acute illness and clear the virus. Approximately 5 to 10% of patients with HBV become chronic carriers. In HBV infected neonates, approximately 90% develop chronic hepatitis B infection. It is estimated that over 300 million people worldwide are chronic carriers of the virus. HBV infection, particularly in cases of chronic infection, is clearly associated with the development of hepatocellular carcinoma.¹⁻³





The presence of antibody to hepatitis B surface antigen (anti-HBs) is used to determine immune status to HBV or disease progression in individuals infected with HBV. An increase in anti-HBs levels, together with a loss of detectable circulating hepatitis B surface antigen (HBsAg), denotes convalescence in hepatitis B infections. Furthermore, anti-HBs levels can be measured to determine if vaccination is needed or, following a vaccination regimen, to determine if protective immunity has been achieved.^{4,5}

Principles of the Procedure

The ADVIA Centaur Anti-HBs2 assay is a sandwich immunoassay using direct, chemiluminometric technology. HBsAg (ad and ay) is coupled to magnetic latex particles in the Solid Phase. In the Lite Reagent, the HBsAg (ad and ay) is labeled with acridinium ester. Non-magnetic latex particles are added from the ancillary well.

The sample is incubated simultaneously with Lite Reagent, Solid Phase, and Ancillary Reagent. Antibody-antigen complexes will form if anti-HBs is present in the sample.

Reagents

Reagent	Description	Storage	Reagent Stability
ADVIA Centaur aHBs2 ReadyPack® primary reagent pack; Lite Reagent	11.0 mL/reagent pack inactivated human hepatitis B surface antigen (ad and ay) (~1 µg/mL) labeled with acridinium ester in protein buffer with bovine serum, albumin, surfactant, and preservatives	2–8°C	Unopened: Stable until the expiration date on the carton On-system: 90 days
ADVIA Centaur aHBs2 ReadyPack primary reagent pack; Solid Phase Reagent	26.0 mL/reagent pack recombinant hepatitis B surface antigen (ad and ay) (~3 µg/mL) coupled to magnetic latex particles in protein buffer with bovine serum albumin, surfactant, and preservatives	2–8°C	Unopened: Stable until the expiration date on the carton On-system: 90 days
ADVIA Centaur aHBs2 ReadyPack primary reagent pack; Ancillary Reagent	5.0 mL/reagent pack non-magnetic latex particles in tris buffer with surfactant and preservatives	2–8°C	Unopened: Stable until the expiration date on the carton On-system: 90 days
ADVIA Centaur aHBs2 Calibrator	2.0 mL/vial processed human plasma positive for antibodies to HBsAg with preservatives	2–8°C	Unopened: Stable until the expiration date on the vial On-system: 8 hours
ADVIA Centaur Wash 1 ^a 	1500 mL/pack phosphate-buffered saline with sodium azide (< 0.1%) and surfactant	2–25°C	Unopened: Stable until the expiration date on the pack On-system: 1 month
ADVIA Centaur Wash 1 ^a 	2500 mL/pack phosphate-buffered saline with sodium azide (< 0.1%) and surfactant	2–25°C	Unopened: Stable until the expiration date on the pack On-system: 1 month
ADVIA Centaur aHBs2 Quality Control Material ^b	10.0 mL/vial processed human plasma negative and positive for antibodies to HBsAg with preservatives	2–8°C	Unopened: Stable until the expiration date on the vial On-system: 8 hours
ADVIA Centaur ReadyPack ancillary reagent pack; Multi-Diluent 11 ^b 	5.0 mL/pack tris buffer and goat serum with protein stabilizers and preservatives	2–8°C	Unopened: Stable until the expiration date on the pack On-system: 28 consecutive days after accessing the ancillary reagent pack
ADVIA Centaur Multi-Diluent 11 ^b 	10.0 mL/vial tris buffer and goat serum with protein stabilizers and preservatives	2–8°C	Unopened: Stable until the expiration date on the vial

^a See *Materials Required but Not Provided*

^b See *Optional Materials*

Warnings and Precautions

Safety data sheets (MSDS/SDS) available on siemens.com/healthcare.



CAUTION POTENTIAL BIOHAZARD

Some components of this product contain human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.⁶⁻⁸

The controls and calibrators have been assayed by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2. The human derived HBsAg used in the manufacture of this product was obtained from units tested by FDA-approved methods and found nonreactive for antibody to HCV and HIV-1/2. The units were inactivated and the HBsAg was purified, however, all products manufactured using human source material should be handled as potentially infectious.



CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

H412	Harmful to aquatic life with long lasting effects.
P273, P501	Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: Microprotect; ADVIA Centaur aHBs2 Calibrator	

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

For *in vitro* diagnostic use.

Preparing Reagents

All reagents are liquid and ready to use.

Mix all primary reagent packs by hand before loading them onto the system. Visually inspect the bottom of the reagent pack to ensure that all particles are dispersed and resuspended. For detailed information about preparing the reagents for use, refer to the system operating instructions.

Note

- Discard reagent packs at the end of the on-system stability interval.
- Do not use reagents beyond the expiration date.

Storing and Stability

Store the reagents upright at 2–8°C.

Protect reagent packs from all heat and light sources. Reagent packs loaded on the system are protected from light. Store unused reagent packs at 2–8°C away from heat and light sources.

All reagents are stable at 2–8°C until the expiration date on the packaging.

Specimen Collection and Handling

Serum and plasma (EDTA, lithium-heparinized, or sodium-heparinized) are the recommended sample types for this assay. Do not use specimens with obvious microbial contamination. The performance of the ADVIA Centaur anti-HBs2 assay has not been established with cadaver specimens, heat-inactivated specimens, or body fluids other than serum or plasma such as saliva, urine, amniotic, or pleural fluids.



CAUTION

Thoroughly mix and centrifuge thawed specimens before using. Centrifuge thawed specimens (10,000 x g for 2 minutes) and collect the supernatant into a clean vial.

The following recommendations for handling and storing blood samples are furnished by the Clinical and Laboratory Standards Institute (CLSI),⁹ and augmented with additional sample handling studies using the ADVIA Centaur Anti-HBs2 assay:

Collecting the Specimen

- Handle all samples as if capable of transmitting disease.
- Samples are processed by centrifugation, typically followed by physical separation of the serum or plasma from the red cells. The centrifugation step may occur up to 24 hours post draw.
- Test samples as soon as possible after collecting.

Storing the Specimen

- Store samples stoppered at all times at 2–8°C up to 7 days.
- Store primary tube samples at 2–8°C up to 7 days. Keep samples stoppered at all times. Primary tube samples include serum stored on the clot, plasma stored on packed red cells, and samples processed and stored in gel barrier blood collection tubes.
- Samples refrigerated up to 7 days demonstrated no qualitative differences. Serum and EDTA plasma samples maintained at room temperature up to 7 days and heparinized plasma samples maintained at room temperature up to 3 days demonstrated no qualitative differences.
- Store samples stoppered at 2–8°C upon arrival.
- Freeze samples, devoid of red blood cells, at or below -20°C for longer storage. Do not store in a frost-free freezer. When samples were subjected to 4 freeze/thaw cycles, no clinically significant differences were observed.¹⁰ Thoroughly mix thawed samples and centrifuge before using.

The purpose of handling and storage information is to provide guidance to users. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Transporting the Specimen

- Package and label samples for shipment in compliance with applicable federal and international regulations covering the transport of clinical samples and etiological agents.
- If during shipment, samples may be subjected to temperatures above 25°C, then ship samples frozen.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
04670661	1 ReadyPack primary reagent pack containing ADVIA Centaur anti-HBs2 Lite Reagent, Solid Phase, and Ancillary Reagent ADVIA Centaur and ADVIA Centaur CP anti-HBs2 Master Curve card 1 vial ADVIA Centaur anti-HBs2 low calibrator <input type="checkbox"/> CAL <input type="checkbox"/> L 1 vial ADVIA Centaur anti-HBs2 high calibrator <input type="checkbox"/> CAL <input type="checkbox"/> H ADVIA Centaur anti-HBs2 Calibrator Assigned Value card	200
10698706	1 ReadyPack primary reagent pack containing ADVIA Centaur anti-HBs2 Lite Reagent, Solid Phase, and Ancillary Reagent ADVIA Centaur anti-HBs2 Master Curve card 1 vial ADVIA Centaur anti-HBs2 low calibrator <input type="checkbox"/> CAL <input type="checkbox"/> L 1 vial ADVIA Centaur anti-HBs2 high calibrator <input type="checkbox"/> CAL <input type="checkbox"/> H ADVIA Centaur anti-HBs2 Calibrator Assigned Value card	200

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

Item	Description
	ADVIA Centaur, ADVIA Centaur XP, or ADVIA Centaur XPT system
REF 01137199 (112351)	ADVIA Centaur Wash 1 <input type="checkbox"/> WASH <input type="checkbox"/> 1 2 x 1500 mL/pack
REF 03773025	ADVIA Centaur Wash 1 ^a <input type="checkbox"/> WASH <input type="checkbox"/> 1 2 x 2500 mL/pack

^a for use with systems with 2500 mL capacity

Optional Materials

The following materials may be used to perform this assay, but are not provided:

Item	Description
REF 06521435	ADVIA Centaur aHBs2 quality control material 2 x 10.0 mL negative control <input type="checkbox"/> CONTROL <input type="checkbox"/> - 2 x 10.0 mL positive control <input type="checkbox"/> CONTROL <input type="checkbox"/> + Expected Value card
REF 05699280 (117228)	ADVIA Centaur Multi-Diluent 11 <input type="checkbox"/> M-DIL <input type="checkbox"/> 11 2 ReadyPack ancillary reagent packs containing 5 mL/pack
REF 03479704 (111088)	ADVIA Centaur Multi-Diluent 11 <input type="checkbox"/> M-DIL <input type="checkbox"/> 11 10 mL/vial
REF 04800387	ADVIA Centaur aHBs2 Master Curve Material 5 x 1.0 mL

Assay Procedure

For detailed instructions on performing the procedure, refer to the system operating instructions.

The ADVIA Centaur, the ADVIA Centaur XP, and the ADVIA Centaur XPT systems automatically perform the following actions:

- Dispenses 100 µL of sample into a cuvette.
- Dispenses 50 µL of Lite Reagent and 20 µL of Ancillary reagent and incubates for 2.75 minutes at 37°C.
- Dispenses 125 µL of Solid Phase and incubates the mixture for 5.5 minutes at 37°C.
- Separates the Solid Phase from the mixture and aspirates the unbound reagent.
- Washes the cuvette with Wash 1.
- Dispenses 300 µL each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction.
- Reports results according to the selected option, as described in the system operating instructions.

A direct relationship exists between the amount of anti-HBs activity present in the patient sample and the amount of relative light units (RLUs) detected by the system. Refer to *Interpretation of Results* for a description of the Cutoff Value calculation.

Preparing the System

Ensure that the system has sufficient primary reagent. For detailed information about preparing the system, refer to the system operating instructions.

Load the ReadyPack primary reagent packs in the primary reagent compartment using the arrows on the packs as a placement guide. The system automatically mixes the primary reagent packs to maintain homogeneous suspension of the reagents. For detailed information about loading reagents, refer to the system operating instructions.

Preparing the Samples

This assay requires 100 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For detailed information about determining the minimum required volume, see the system operating instructions.

Note The sample volume required to perform on-system dilution differs from the sample volume required to perform a single determination. For detailed information, refer to *Dilutions*.

Before placing samples on the system, ensure that samples have the following characteristics:

- Samples are free of fibrin or other particulate matter. Remove particulates by centrifugation. (example: 1500 x g for 10 minutes; follow tube manufacturer's recommendations⁹)
- Samples are free of bubbles or foam. Remove any visual lipid layer.

On-System Stability

The ADVIA Centaur anti-HBs2 assay reagents are stable unopened until the expiration date on the carton or onboard the system for 90 days.

Performing Calibration

For calibration of the ADVIA Centaur Anti-HBs2 assay, use ADVIA Centaur Anti-HBs2 Calibrators provided with each kit. The calibrators provided in this kit are matched to the ReadyPack primary reagent pack.

Note The Low and High Calibrators provided in this kit are matched to the ReadyPack primary reagent pack. Do not mix calibrator lots with different lots of reagent packs.

Each lot of calibrators contains a Calibrator Assigned Value card to facilitate entering the calibration values on the system. Enter the values using the barcode scanner or the keyboard. For detailed information about entering calibrator values, refer to the system operating instructions.

Perform the calibration procedure using the following steps:

Note This procedure uses calibrator volumes sufficient to measure each calibrator in triplicate.

1. Schedule the calibrators to the worklist.
2. Label two sample cups with calibrator barcode labels: one for the low and another for the high.
3. Gently mix the Low and High Calibrators and dispense at least 12–14 drops into the appropriate sample cups.

Note Each drop from the calibrator vial is approximately 35–40 μL .

4. Load the sample cups in a rack.
5. Place the rack in the sample entry queue.
6. Ensure that the assay reagents are loaded.
7. Start the entry queue, if required.

Note Dispose of any calibrator remaining in the sample cups after 8 hours. Do not refill sample cups when the contents are depleted; if required, dispense fresh calibrators.

Calibration Frequency

Calibrate the assay at the end of the 42-day calibration interval.

Additionally, the ADVIA Centaur Anti-HBs2 assay requires a two-point calibration:

- When changing lot numbers of primary reagent packs
- When replacing system components
- When quality control results are repeatedly out of range

Using Barcode Labels

Note Calibrator barcode labels are lot-number specific. Do not use barcode labels from one lot of calibrators with any other lot of calibrators.

Use the ADVIA Centaur Anti-HBs2 Calibrator barcode labels to identify the Low and High Calibrator sample cups when performing the ADVIA Centaur Anti-HBs2 assay. Place the barcode label on the sample cup so that the readable characters on the side of the label are vertical on the sample cup.

Performing Master Curve Calibration

The ADVIA Centaur Anti-HBs2 assay requires a Master Curve calibration when using a new lot number of Lite Reagent, Solid Phase, and Ancillary Reagent. For each new lot number of Lite Reagent, Solid Phase, and Ancillary Reagent, use the barcode reader or keyboard to enter the Master Curve values on the system. The Master Curve card contains the Master Curve values. For detailed information about entering calibration values, refer to the system operating instructions.

Performing Quality Control

Follow government regulations or accreditation requirements for quality control frequency.

For quality control of the ADVIA Centaur Anti-HBs2 assay, use of ADVIA Centaur Anti-HBs2 quality control material is recommended. Refer to the Expected Value card for the suggested expected values specific for the lot number of the positive and negative controls. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

Note The recommended quality control material is intended to monitor substantial reagent failure. If additional controls are desired, it is recommended to run a negative control and positive control close to the clinically relevant decision point (10 mIU/mL). Further, the recommended quality control is in a serum matrix. It may not adequately control the assay for plasma specimens. The user should provide alternate control material for plasma.

For detailed information about entering quality control values, refer to the system operating instructions.

To monitor system performance and chart trends, as a minimum requirement, assay quality control material on each workshift that samples are analyzed. Assay quality control samples when performing a two-point calibration. Treat all quality control samples the same as patient samples.

Perform the quality control procedure using the following steps:

Note This procedure uses control volumes sufficient to measure each control in duplicate.

1. Schedule the quality control samples to the worklist.
2. Label two sample cups with quality control barcode labels: one for the positive, and another for the negative.
3. Gently mix the quality control materials and dispense at least 8–10 drops into the appropriate sample cups.

Note Each drop from the control vial is approximately 35–40 μ L.

4. Load the sample cups in a rack.
5. Place the rack in the sample entry queue.
6. Ensure that the assay reagents are loaded.
7. Start the entry queue, if required.

Note Dispose of any quality control materials remaining in the sample cups after 8 hours. Do not refill sample cups when the contents are depleted; if required, dispense fresh quality control materials.

Using Barcode Labels

Note Control barcode labels are lot-number specific. Do not use barcode labels from one lot of controls with any other lot of controls.

Use the ADVIA Centaur Anti-HBs2 quality control barcode labels to identify the positive and negative sample cups when performing the ADVIA Centaur Anti-HBs2 assay. Place the barcode label on the sample cup so that the readable characters on the side of the label are vertical on the sample cup.

Taking Corrective Action

If the quality control results do not fall within the Expected Values or within the laboratory's established values, do not report results. Take the following actions:

1. Investigate and determine the cause of the unacceptable control results:
 - Verify that the materials are not expired.
 - Verify that required maintenance was performed.
 - Verify that the assay was performed according to the instructions for use.
 - Rerun the assay with fresh quality control samples.
 - If necessary, contact your local technical support provider or distributor for assistance.
2. When the condition is corrected, retest the controls, and confirm that results are within acceptable limits.
3. Repeat testing of patient samples before reporting results.

Perform corrective actions in accordance with your established laboratory protocol.

Results

Calculation of Results

For detailed information about how the system calculates results, refer to the system operating instructions.

The system reports anti-HBs antibody results in mIU/mL, and as reactive (positive), nonreactive (negative), or needing retest.

Dilutions

The sample volume required to perform on-system dilution differs from the sample volume required to perform a single determination. Refer to the following information for the sample volume required to perform on-system dilutions:

Dilution	Sample Volume (μ L)
1:2	100
1:5	40
1:10	20

The following information pertains to dilutions:

- Samples with anti-HBs levels greater than 1000 mIU/mL may be diluted and retested.
- Patient samples can be automatically diluted by the system or prepared manually.
- For automatic dilutions, ensure that ADVIA Centaur Multi-Diluent 11 is loaded and set the system parameters as follows:
 - Dilution point: \leq 1000 mIU/mL
 - Dilution factor: 2, 5, 10
 For detailed information about automatic dilutions, refer to the system operating instructions.
- Manually dilute the patient samples when patient results exceed the linearity of the assay using automatic dilution, or when laboratory protocol requires manual dilution.
- Use Multi-Diluent 11 to manually dilute patient samples, and then load the diluted sample in the sample rack, replacing the undiluted sample.

Ensure that results are mathematically corrected for dilution. If a dilution factor is entered when scheduling the test, the system automatically calculates the result.

Interpretation of Results

Results should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

The ADVIA Centaur Anti-HBs2 assay is traceable to the World Health Organization (WHO) Hepatitis B Immunoglobulin 1st International Reference Preparation (1977). Samples with a calculated value of 10 mIU/mL or greater are considered reactive (protective) in accordance with the CDC guidelines.⁵ The accepted criteria for immunity to HBV is anti-HBs activity \geq 10 mIU/mL, as defined by the WHO International Reference Preparation.

- Nonreactive: Samples with an initial value $<$ 8 mIU/mL. Anti-HBs is below 10 mIU/mL and the patient is considered not to have protective immunity to HBV infection.
- Reactive: Samples with an initial value \geq 12 mIU/mL. Anti-HBs is detected at \geq 10 mIU/mL and the patient is considered to have protective immunity to HBV infection.
- Retest Zone: Samples with an initial value \geq 8 and $<$ 12 mIU/mL. If results are within the retest zone after initial testing, samples must be retested in duplicate. After retesting, if 3 results are available and 2 results are \geq 10 mIU/mL, then the sample is considered to be reactive. If 3 results are available and 2 results are $<$ 10 mIU/mL, then the sample is considered to be nonreactive.

Sample results are invalid and must be repeated if the controls are out of range.

Limitations

The following information pertains to limitations of the assay:

- United States federal law restricts this device to sale by or on the order of a physician.
- The ADVIA Centaur Anti-HBs2 assay is limited to the detection of antibodies to HBsAg in human serum and plasma (EDTA, sodium-heparinized, or lithium-heparinized).
- Assay performance characteristics have not been established when the ADVIA Centaur Anti-HBs2 assay is used in conjunction with other manufacturers' assays for specific HBV serological markers; and therefore, users are responsible for establishing their own performance characteristics.
- Assay performance characteristics have not been established in pregnant women, or in populations of immunocompromised or immunosuppressed patients; and therefore, users are responsible for establishing their own performance characteristics in these populations.
- This assay does not differentiate between a vaccine-induced immune response and an immune response induced by infection with HBV. To determine if the anti-HBs response is due to vaccine or HBV infection, a total anti-HBc assay may be performed.
- This assay is not intended for use in screening blood or plasma donors.
- The performance of the ADVIA Centaur Anti-HBs2 assay has not been established with cadaver specimens, heat-inactivated specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids.
- Do not use specimens with obvious microbial contamination.
- Results obtained with ADVIA Centaur Anti-HBs2 assay may not be used interchangeably with values obtained with different manufacturer assay methods.
- Individuals that have received blood component therapies, for example, whole blood, plasma, immunoglobulin administered during the previous 3–6 months may have a false reactive anti-HBs result due to passive transfer of anti-HBs.
- The prevalence of the analyte in the population tested will affect the assay's predictive value.

- A positive anti-HBs result does not exclude co-infection by another hepatitis virus.
- High-Dose Hook Effect: In the ADVIA Centaur Anti-HBs2 assay, patient samples with levels of antibodies to HBsAg as high as 200,000 mIU/mL do not demonstrate a decrease in the RLU (high-dose hook effect¹⁰). Specimens having anti-HBs activity greater than 200,000 mIU/mL are extremely rare.

Expected Values

The prospective study population for the ADVIA Centaur Anti-HBs2 assay consisted of 2030 patients. Of these 2030 patients, 1098 patients (54.09%) were from the high risk population, 828 patients (40.79%) were from the signs and symptoms population, 83 patients (4.09%) were from the dialysis population, and 21 patients (1.03%) were transplant recipients. The prospective study population was 60.15% Black, 19.80% Caucasian, 17.04% Hispanic, 1.77% Asian, 0.39% American Indian or Alaskan Native, and 0.84% from unknown or other ethnicity. The majority of patients were male (64.43% male and 35.57% female). The mean age was 46.0 years (range of 13 to 91 years). Patients in the prospective study population were from the following geographic regions: Florida (55.67%), District of Columbia (23.94%), Texas (11.18%), California (5.32%), Maryland (3.15%) and other states (0.74%).

The ADVIA Centaur Anti-HBs2 results for the prospective population for all sites combined by age group and gender are summarized in the following table:

Distribution of High Risk, Signs and Symptoms, Dialysis, and Transplant Recipient Population by Age Group and Gender (All Testing Sites)

Age (Years)	Gender	Reactive (N)	Nonreactive (N)	Total (N)
0–9	Male	0	0	0
	Female	0	0	0
10–19	Male	8	4	12
	Female	8	3	11
20–29	Male	74	48	122
	Female	43	31	74
30–39	Male	61	105	166
	Female	35	59	94
40–49	Male	216	235	451
	Female	125	131	256
50–59	Male	216	232	448
	Female	88	130	218
60–69	Male	32	58	90
	Female	24	28	52
≥ 70	Male	4	15	19
	Female	4	13	17
All	Male	611	697	1308
	Female	327	395	722
Total		938	1092	2030

Performance Characteristics

Analytical Measuring Range

The ADVIA Centaur anti-HBs2 assay measures concentrations of total antibodies to hepatitis B surface antigen from 3.1–1000 mIU/mL.

Sensitivity

A study was conducted based on guidance from CLSI EP17-A producing a Limit of Blank (LoB) of 1.7 mIU/mL and a Limit of Detection (LoD) of 3.1 mIU/mL.¹¹

Prospective Study

The HBV disease classification for each patient in the high risk, signs and symptoms, dialysis, and transplant populations (2030 patients total) was determined by serological assessment using resultant hepatitis marker profiles obtained from results of commercially available, FDA-approved reference assays. The serological assessment included the following 4 HBV markers: HBsAg, total antibody to hepatitis B virus core antigen (Anti-HBc Total), IgM antibody to hepatitis B virus core antigen (Anti-HBc IgM), and total antibody to hepatitis B virus surface antigen (anti-HBs) (quantitative). Testing of these specimens occurred at diagnostic laboratories located in Miami, FL (34.3%), Dallas, TX (36.2%), and Tarrytown, NY (29.5%). The individual ADVIA Centaur HBV assay result was compared to the reference HBV assay result and to the patient classification. No patients were excluded from the complete study set due to incomplete reference HBV serological results.

Each patient's HBV infection was classified based on the reactive (+)/nonreactive (-) patterns of the 4 reference HBV serological markers. Disease classification for each patient was based only on the HBV serological marker results, and was not affected by additional laboratory or clinical information. There were 14 unique reference marker patterns. These patterns are presented in the following table:

Classification by HBV Reference Markers (All Testing Sites)

HBV Classification	HBV Reference Markers			
	HBsAg	IgM Anti-HBc	Total Anti-HBc	Anti-HBs
Early Acute	+	-	-	-
Acute	+	+	+	-
Late Acute	+	+	+	+
Chronic	+	-	+	+
Chronic	+	-	+	-
Chronic	+	-	-	+
Early Recovery	-	+	+	+
Early Recovery	-	Equivocal	+	+
Early Recovery	-	+	+	-
Early Recovery	-	+	-	+
Immune due to hepatitis vaccination	-	-	-	+
Immune natural infection	-	-	+	+
Recovered	-	-	+	-
Not Previously Infected	-	-	-	-

+ = Reactive

- = Nonreactive

Comparison of Results

Following the assignment of specimen classification, the HBV results obtained using the ADVIA Centaur Anti-HBs2 assay were compared with results obtained using the reference anti-HBs assay for each result category (reactive and nonreactive). Specimens with an anti-HBs2 value and/or an anti-HBs value within the retest zone were retested and interpreted as described under *Interpretation of Results*.

The method comparison for all testing sites combined is presented in the following table:

Comparison of Results in High Risk, Signs and Symptoms, Dialysis, and Transplant Recipient Populations by HBV Classification

ADVIA Centaur Anti-HBs2 Assay versus Reference Anti-HBs Assay (All Testing Sites)^a

HBV Classification	Reference Anti-HBs Assay Nonreactive		Reference Anti-HBs Assay Reactive		Total (N)
	ADVIA Centaur Anti-HBs2 Assay		ADVIA Centaur Anti-HBs2 Assay		
	Reactive (N)	Nonreactive (N)	Reactive (N)	Nonreactive (N)	
Early Acute	0	8	0	0	8
Acute	0	10	0	0	10
Late Acute	0	0	0	2	2
Chronic	0	112	6	1	119
Early Recovery	0	2	20	0	22
Immune due to hepatitis vaccination	1	2	362	6	371
Immune due to natural infection	0	8	522	9	539
Recovered	13	207	3	2	225
Not Previously Infected	11	723	0	0	734
Total	25	1072	913	20	2030

^a In this study, 73 of 2030 specimens (3.6%) fell within the aHBs2 retest zone. Thirty-four of these specimens (46.6%) were determined to be reactive after retesting.

The percent agreement between the ADVIA Centaur Anti-HBs2 assay (including the upper and lower 95% confidence intervals) and the reference anti-HBs assay for each specimen classification was performed. The positive, negative, and overall percent agreements were calculated as follows:

Positive percent agreement =

$$\frac{\text{Number of ADVIA Centaur Anti-HBs2 reactive results in agreement with reference anti-HBs}}{\text{Total number of reference anti-HBs reactive results}} \times 100$$

Negative percent agreement =

$$\frac{\text{Number of ADVIA Centaur Anti-HBs2 nonreactive results in agreement with reference anti-HBs}}{\text{Total number of reference anti-HBs nonreactive results}} \times 100$$

Overall percent agreement =

$$\frac{\text{Number of ADVIA Centaur Anti-HBs2 results in agreement with reference anti-HBs}}{\text{Total number of reference anti-HBs reactive and nonreactive results}} \times 100$$

The percent agreement between the ADVIA Centaur Anti-HBs2 assay and the reference anti-HBs assay for the high risk, signs and symptoms, and dialysis populations across all testing sites is summarized in the following table:

**Percent Agreement and Confidence Intervals by HBV Classification in High Risk, Signs and Symptoms, Dialysis, and Transplant Recipient Populations
ADVIA Centaur Anti-HBs2 Assay versus Reference Anti-HBs Assay (All Testing Sites)**

HBV Classification	Positive Percent Agreement % (x/n)	95% Exact Confidence Interval	Negative Percent Agreement % (x/n)	95% Exact Confidence Interval
Early Acute			100 (8/8)	68.8–100
Acute			100 (10/10)	74.1–100
Late Acute	0 (0/2)	0–77.6		
Chronic	85.7 (6/7)	42.1–99.6	100 (112/112)	97.4–100
Early Recovery	100 (20/20)	86.1–100	100 (2/2)	22.4–100
Immune due to Hepatitis B vaccination	98.4 (362/368)	96.5–99.4	66.7 (2/3)	9.4–99.2
Immune due to natural infection	98.3 (522/531)	96.8–99.2	100 (8/8)	68.8–100
Recovered	60 (3/5)	14.7–94.7	94.1 (207/220)	90.1–96.8
Not Previously Infected			98.5 (723/734)	97.3–99.3
Total	97.9 (913/933)	96.7–98.7	97.7 (1072/1097)	96.7–98.5

ADVIA Centaur XPT System versus ADVIA Centaur XP System

The percent agreement between the ADVIA Centaur XPT and the ADVIA Centaur XP systems was evaluated by testing 344 samples on 2 sets of 2 instruments each of 2 ADVIA Centaur XPT systems and 1 ADVIA Centaur XP system, at 1 clinical testing site, using 1 lot each of the ADVIA Centaur aHBs2 reagents, calibrators, and controls.

The sample panels were developed from leftover patient samples and banked samples from suppliers. The contrived samples were prepared by spiking positive samples into individual negative samples to achieve the levels required. Samples included in this study spanned the range of the assay.

Results from the method comparison study on the 2 ADVIA Centaur XPT systems were found to be similar. Comparison results between the ADVIA Centaur XPT and ADVIA Centaur XP systems are shown in the table below.

Combined ADVIA Centaur XPT Systems	ADVIA Centaur XP			
	Reactive	Retest	Nonreactive	Total
Reactive	339	3	0	342
Retest	5	41	5	51
Nonreactive	0	0	295	295
Total	344	44	300	688

% Positive Agreement = 98.55% (339/344)
95% Confidence Interval: 96.64–99.53%

% Negative Agreement = 98.33% (295/300)
95% Confidence Interval: 96.15–99.46%

% Retest Zone Agreement = 93.18% (41/44)
95% Confidence Interval = 81.34–98.57%

Pediatric / Adolescent Comparison

One hundred and ten (110) pediatric / adolescent retrospective serum samples (age range from 1 to 17 years) were evaluated using the ADVIA Centaur anti-HBs2 assay and another commercially available assay. Interpretive results for reactive or nonreactive samples were compared between the two assays. The following results were obtained:

Pediatric Population (age range from 1 to 11 years)

		Reference anti-HBs Assay		
		Reactive	Nonreactive	Total
ADVIA Centaur anti-HBs2 Assay	Reactive	29	0	29
	Nonreactive	1	28	29
	Total	30	28	58

% Overall Agreement = 98.28% (57/58)

95% Confidence Interval: 90.76–99.96%

Adolescent Population (age range from 12 to 17 years)

		Reference anti-HBs Assay		
		Reactive	Nonreactive	Total
ADVIA Centaur anti-HBs2 Assay	Reactive	30	2	32
	Nonreactive	2	18	20
	Total	32	20	52

% Overall Agreement = 92.31% (48/52)

95% Confidence Interval: 81.46–97.86%

Neonate Comparison

Twenty (20) retrospectively collected neonate samples were evaluated using the ADVIA Centaur aHBs2 assay and another commercially available assay. Interpretive results for reactive or nonreactive samples were compared between the two assays. The following results were obtained.

		Reference anti-HBs Assay		
		Reactive	Nonreactive	Total
ADVIA Centaur anti-HBs2 Assay	Reactive	9	0	9
	Nonreactive	0	11	11
	Total	9	11	20

% Overall Agreement = 100.00% (20/20)

95% Confidence Interval: 86.10–100.00%

HBV Vaccine Panel Study

A study was conducted using 52 well-characterized, commercially available serum samples from 26 individuals before and after vaccination. Testing of these specimens occurred at diagnostic laboratories located in Miami, FL (34.6%), Dallas, TX (34.6%), and Tarrytown, NY (30.8%). Samples were tested using the ADVIA Centaur Anti-HBs2 assay and the reference anti-HBs assay, and the results were compared. The percent agreement between the ADVIA Centaur Anti-HBs2 assay and the reference anti-HBs assay for the vaccination panel population is summarized in the following table:

Comparison of ADVIA Centaur Anti-HBs2 and Reference Anti-HBs Results in Pre- and Post-Vaccinated Populations^a

ADVIA Centaur Anti-HBs2 Results	Reference Anti-HBs Results		
	Nonreactive (N)	Reactive (N)	Total (N)
Pre-vaccination			
Nonreactive, N (%)	26 (100%)	0	26 (100%)
Reactive, N (%)	0	0	0
Percent agreement: 100%			
95% confidence interval: 89.1–100			
Post-vaccination			
Nonreactive, N (%)	0	0	0
Reactive, N (%)	0	26 (100%)	26 (100%)
Percent agreement: 100%			
95% confidence interval: 89.1–100			

a For the vaccinee panel (samples from 26 patients), the percent agreement between ADVIA Centaur Anti-HBs2 results and reference results was determined for pre-vaccination and for post-vaccination.

Precision

Precision Estimates for All Testing Sites and Reagent Lots

The ADVIA Centaur Anti-HBs2 precision and reproducibility study was performed on the ADVIA Centaur system at 3 external sites using 2 reagent lots per site. An 8-member serum panel was assayed in replicates of 4 in 2 runs per day over at least 5 days for each lot. The study was completed with a single calibration of the assay (one calibration interval).

The data from all 3 sites and from all 3 reagent lots were combined to obtain SD and percent CV for within run, between run, between testing site, between lot, and total. The precision estimates were derived from variance component analysis.

The reproducibility results are presented in the following table:

Precision Estimates for All Testing Sites and Reagent Lots

Panel Member	Mean Concentration ^a	Within Run ^b		Between Run ^c		Between Days ^d		Between Lot ^e		Within Site ^f		Between Site ^g		Total ^h		Number of Observations
	(mIU/mL)	SD ⁱ	CV (%)	SD ⁱ	CV (%)	SD ^{i,j}	CV (%)	SD ⁱ	CV (%)	SD ⁱ	CV (%)	SD ⁱ	CV (%)	SD ⁱ	CV (%)	
1	3.1	0.22	7.0	0.11	3.4	0.10	3.2	0.20	6.6	0.33	10.7	0.37	12.0	0.49	16.1	248
2	6.3	0.27	4.4	0.17	2.7	0.07	1.1	0.25	4.0	0.42	6.6	0.49	7.8	0.64	10.2	248
3	13.1	0.39	2.9	0.31	2.4	0.00	0.0	0.37	2.8	0.62	4.7	0.73	5.6	0.96	7.3	248
4	20.7	0.56	2.7	0.43	2.1	0.00	0.0	0.58	2.8	0.92	4.4	1.05	5.1	1.39	6.7	248
5	133.7	2.86	2.1	2.60	1.9	0.00	0.0	4.23	3.2	5.73	4.3	5.45	4.1	7.91	5.9	248
6	401.8	8.14	2.0	7.51	1.9	0.00	0.0	13.77	3.4	17.67	4.4	14.16	3.5	22.65	5.6	248
7	638.7	15.01	2.4	15.86	2.5	2.55	0.4	24.46	3.8	32.89	5.1	23.34	3.7	40.33	6.3	248
8	906.8	17.65	1.9	16.10	1.8	0.00	0.0	23.04	2.5	33.19	3.7	31.56	3.5	45.80	5.1	234
Positive Control	115.9	2.72	2.4	3.29	2.8	0.00	0.0	1.45	1.2	4.51	3.9	6.03	5.2	7.53	6.5	164

^a Arithmetic mean of all results

^b Variability of the assay performance within run

^c Variability of the assay performance between runs

^d Variability of the assay performance between days

^e Variability of the assay performance between reagent lots

^f Variability of the assay performance within site

^g Variability of the assay performance between testing sites

^h Variability of the assay performance incorporating all days and runs

ⁱ SD of mean concentration (mIU/mL)

^j If the variation of the day means is less than that which is expected from the within-run and between-run effects, then the between-day SD is set to zero since there is no variation attributable to days.

Note 4 replicates per panel in 2 runs per day for at least 5 days

Precision was evaluated on the ADVIA Centaur XPT system according to the Clinical and Laboratory Standards Institute protocol EP5-A2.¹² A 5-member sample panel and controls were assayed in 2 runs with 2 instruments, in 2 replicates, 2 times a day, for 12 days. The following results were obtained:

Sample	Instrument number	Day	Run	Rep	Mean	Within Run		Between Run		Between Days		Total	
					(mIU/mL)	SD ^g	CV (%)	SD ^g	CV (%)	SD ^g	CV (%)	SD ^g	CV (%)
Positive Control	1	12	24	48	105.81	3.70	3.5	0.00	0.0	2.29	2.2	4.36	4.1
1	1	12	24	48	5.10	0.39	7.7	0.00	0.0	0.30	5.9	0.49	9.7
2	1	12	24	48	16.41	0.52	3.2	0.54	3.3	0.35	2.1	0.83	5.1
3	1	12	24	48	226.97	5.29	2.3	6.28	2.8	4.30	1.9	9.27	4.1
4	1	12	24	48	596.92	8.86	1.5	20.59	3.4	0.00	0.0	22.42	3.8
5 ^a	1	12	24	48	9.92	0.27	2.7	0.10	1.0	0.17	1.8	0.34	3.4
Positive Control ^a	1	12	24	48	117.52	2.38	2.0	1.08	0.9	1.23	1.0	2.89	2.5

^a Value comes from another run/instrument

Precision Estimates in Serum, EDTA, Lithium Heparin and Sodium Heparin Matrices

The ADVIA Centaur aHBs2 precision and reproducibility in various sample matrices was examined in a 20-day precision protocol¹² (CLSI EP5-A2) using 2 lots of reagents. Thirty-two specimens in four matrices were prepared to measure the precision of the assay at different dose levels. In addition to serum matrix, the anticoagulants tested were potassium EDTA, sodium heparin, and lithium heparin. The specimens were assayed in duplicate twice per day for 20 time points (n = 80 for each sample). A single instrument was used in this study over the course of 30 days with one recalibration.

The matrix reproducibility results from a representative lot of reagents are presented in the following table. The precision estimates were derived from variance component analysis. Calculations for within run, between run, between day, and total precision were performed as recommended by the guidance protocol.¹²

Matrix - Sample	Mean Concentration ^a	Within Run ^b		Between Run ^c		Between Days ^d		Total ^e	
	(mIU/mL)	SD ^f	CV (%)	SD ^f	CV (%)	SD ^f	CV (%)	SD ^f	CV (%)
EDTA plasma 2	3.9	0.24	6.1	0.14	3.7	0.15	3.9	0.32	8.1
EDTA plasma 3	9.2	0.27	2.9	0.35	3.8	0.12	1.4	0.46	5.0
EDTA plasma 4	14.2	0.40	2.8	0.58	4.1	0.00	0.0	0.71	4.9
EDTA plasma 5	96.4	1.95	2.0	3.35	3.5	1.44	1.5	4.14	4.3
EDTA plasma 6	242.2	4.89	2.0	8.40	3.5	0.96	0.4	9.76	4.0
EDTA plasma 7	498.9	9.51	1.9	14.80	3.0	4.52	0.9	18.16	3.6
EDTA plasma 8	585.7	12.39	2.1	16.16	2.8	13.78	2.4	24.59	4.2
EDTA plasma 9	790.8	16.88	2.1	17.85	2.3	21.20	2.7	32.45	4.1
Lithium-heparin 2	4.8	0.22	4.7	0.20	4.1	0.20	4.1	0.36	7.5
Lithium-heparin 3	10.6	0.29	2.7	0.31	2.9	0.43	4.1	0.60	5.7
Lithium-heparin 4	17.4	0.35	2.0	0.50	2.9	0.48	2.7	0.78	4.5
Lithium-heparin 5	176.5	3.78	2.1	3.32	1.9	5.64	3.2	7.56	4.3
Lithium-heparin 6	309.2	5.86	1.9	6.22	2.0	9.39	3.0	12.70	4.1
Lithium-heparin 7	513.0	10.59	2.1	8.26	1.6	15.08	2.9	20.19	3.9
Lithium-heparin 8	599.4	13.67	2.3	26.13	4.4	18.47	3.1	34.79	5.8
Lithium-heparin 9	850.4	15.61	1.8	20.82	2.4	25.40	3.0	36.36	4.3
Sodium-heparin 2	3.9	0.21	5.4	0.16	4.1	0.20	5.2	0.33	8.6
Sodium-heparin 3	8.8	0.24	2.7	0.94	10.8	0.28	3.2	1.01	11.5
Sodium-heparin 4	15.1	0.31	2.0	0.57	3.8	0.24	1.6	0.69	4.6
Sodium-heparin 5	55.8	1.33	2.4	2.09	3.7	0.68	1.2	2.56	4.6
Sodium-heparin 6	206.5	3.82	1.9	6.48	3.1	3.27	1.6	8.21	4.0
Sodium-heparin 7	362.3	8.01	2.2	10.89	3.0	2.03	0.6	13.67	3.8
Sodium-heparin 8	617.5	13.19	2.1	16.29	2.6	9.61	1.6	23.06	3.7
Sodium-heparin 9	863.7	16.88	2.0	22.14	2.6	8.82	1.0	29.21	3.4
Serum 2	3.1	0.16	5.1	0.15	4.9	0.18	5.8	0.28	9.2
Serum 3	6.2	0.23	3.7	0.25	4.0	0.26	4.2	0.43	6.9
Serum 4	12.7	0.30	2.3	0.33	2.6	0.49	3.8	0.66	5.2
Serum 5	20.0	0.54	2.7	0.68	3.4	0.49	2.5	1.00	5.0
Serum 6	128.3	3.16	2.5	3.76	2.9	3.80	3.0	6.21	4.8
Serum 7	382.7	7.07	1.8	10.12	2.6	8.14	2.1	14.79	3.9
Serum 8	606.6	14.86	2.4	12.27	2.0	13.76	2.3	23.68	3.9
Serum 9	870.1	17.37	2.0	24.81	2.9	16.27	1.9	34.38	4.0

^a Arithmetic mean of all results

^b Variability of the assay performance within run

^c Variability of the assay performance between runs

^d Variability of the assay performance between days

^e Variability of the assay performance incorporating all days and runs.

^f SD of mean concentration (mIU/mL)

Interferences

Serum specimens that are or that contain . . .	Demonstrate \leq 15% change in results up to . . .
hemolyzed	500 mg/dL of hemoglobin
lipemic	1000 mg/dL of triglycerides
icteric	40 mg/dL of conjugated bilirubin
icteric	40 mg/dL of unconjugated bilirubin
proteinemic (high)	12 g/dL of total protein
proteinemic (low)	3 g/dL of total protein ^a
hyper IgG	6 g/dL of immunoglobulin G
biotin	3521 ng/mL of biotin

^a Demonstrates \leq 15% change in results with protein as low as 3 g/dL.

Interference testing was determined according to CLSI Document EP7-A2.¹³

Cross-Reactivity

The ADVIA Centaur Anti-HBs2 assay was evaluated for potential cross-reactivity with viral antibodies and disease state specimens. The nonreactive anti-HBs status of each specimen was verified using a commercially available reference anti-HBs assay. The following results were obtained on the ADVIA Centaur Anti-HBs2 assay:

Clinical Category	Number Tested	ADVIA Centaur Anti-HBs2 Results	
		Nonreactive	Reactive
Hepatitis A Infection (HAV)	17	17	0
Hepatitis B Infection (HBsAg+)	12	12	0
Hepatitis C Infection (HCV)	24	24	0
Non-Viral Liver Disease	8	8	0
Rheumatoid Arthritis	8	8	0
Autoimmune Disease (Systemic Lupus & ANA)	15	15	0
Influenza Vaccination	6	6	0
Syphilis Infection	9	9	0
Cytomegalovirus (CMV)	13	13	0
Herpes Simplex Virus I/II (HSV)	22	22	0
<i>Toxoplasma gondii</i> Infection	12	12	0
Human Immunodeficiency Virus (HIV)	9	9	0
Rubella IgG	34	34	0
Varicella-Zoster Virus (VZV)	31	31	0
Epstein-Barr Virus (EBV)	54	54	0
Total Samples Tested	274	274	0

Alternative Sample Types

The ADVIA Centaur Anti-HBs2 assay can use plasma specimens collected using sodium-heparin, lithium-heparin, or EDTA anticoagulants. In a matched matrix study of specimens around the cutoff value (10.0 mIU/mL), drawn in four tube types including serum, EDTA, sodium-heparin and lithium-heparin vacutainer tubes, the recovery of the heparinized samples was comparable to that of the serum control.

Matrix Bias Study of Samples Near the Cutoff

N = 11 samples: (3 samples > 10.0 mIU/mL, 8 samples < 10.0 mIU/mL)

Range: approximately 2.5 to 24 mIU/mL

Statistic	Serum (mIU/mL)	EDTA (mIU/mL)	Lithium Heparin (mIU/mL)	Sodium Heparin (mIU/mL)
Mean	10.11	11.13	8.68	9.11
SD	7.51	8.32	7.54	7.50
Bias to Serum (mIU/mL)	NA	1.02	-1.42	-1.00
SD of Bias	NA	1.25	0.92	1.05
Bias to Serum (% recovery)	NA	10.09	-14.10	-9.87

Matched specimens from 70 individuals, drawn in serum and plasma (EDTA, lithium-heparinized, and sodium-heparinized) vacutainer tubes were analyzed by linear regression analysis. The anti-HBs activity of these specimens spanned a range of approximately 2 to 1000 mIU/mL. Slope and intercept estimates by linear regression analysis (see following regression equations):

$$(\text{EDTA}) = 1.083 (\text{Serum}) - 0.20, R^2 = 1.00; N = 70$$

$$(\text{Lithium heparin}) = 0.939 (\text{Serum}) - 0.78, R^2 = 1.00; N = 70$$

$$(\text{Sodium heparin}) = 0.943 (\text{Serum}) - 0.33, R^2 = 1.00; N = 70$$

Standardization

The ADVIA Centaur Anti-HBs2 assay is standardized against the World Health Organization (WHO) 1st International Reference Preparation (1977).

Technical Assistance

For customer support, please contact your local technical support provider or distributor.

























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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
	<i>In vitro</i> diagnostic medical device	 REF	Catalog number
	Legal manufacturer		Authorized Representative in the European Community
	CE Mark		CE Mark with identification number of notified body
	Consult instructions for use		Biological risk
	Do not freeze (> 0°C)		Temperature limitation
	Lower limit of temperature		Upper limit of temperature
	Keep away from sunlight and heat		Up
	Use by		Contains sufficient for (n) tests
	Batch code		Shake the reagent pack vigorously. Refer to <i>Preparing Reagents</i> in the assay-specific ADVIA Centaur product instructions for detailed information.
YYYY-MM-DD	Date format (year-month-day)	Rev.	Revision
	Master Curve Definition		Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Lot Details		Green dot
	Recycle		Printed with soy ink

Trademarks

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US Pats 5,609,822; 5,788,928

 Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA

Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Siemens Healthcare Headquarters

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthcare

Global Division

Siemens Healthcare
Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
USA
siemens.com/healthcare

