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| /Volumes/dsm/UPH/Creative Services/Graphic Design/Logos/UnityPoint Health/UnityPoint Health/png/1 UP Health 2c H.pngMETHODIST | Page 1 of 15 | Section: UPM CHEMC | Policy #: 01.017 |
|  | CHEMISTRY, CENTAUR | Approved by: see signature block at end of document | Date: 3/20/18Review by: 3/20/20 |
|  | LABORATORY | Policy Created: 7/30/15 Supersedes: 7/30/15, 3/16/18  |
|  |  | Primary Responsible Parties: Ray GrossSecondary Responsible Parties: Amy Gibbs |
|  |  | CAP Standard: NA |
| SUBJECT: | HEPATITIS B SURFACE ANTIGEN CONFIRMATION ASSAY  |

**TEST CODE:HBsAg**

1. **PRINCIPLE**

The ADVIA Centaur HBsAgII Confirmatory assay is based on the principle of specific

antibody neutralization. The sample is incubated with polyclonal (human) antibody to

HBsAg. The antibody will bind to HBsAg present in the sample, thereby neutralizing the

antigen. The neutralized HBsAg is blocked from binding to the antibodies in the assay.

Blocking of the HBsAg by the assay antibodies results in a reduction in signal when

compared to a second aliquot of sample that has been incubated with a non-neutralizing

control reagent. The non-neutralizing control reagent serves as a control for the

neutralization as well as the 0 percent baseline for calculation of the amount of reduction

in signal as percent neutralization. A sample is considered positive for HBsAg if the

percent neutralization is 50% or greater after treatment with the antibody (neutralizing

reagent).

The sample is pretreated and tested in parallel; one sample aliquot is dispensed and

incubated with a neutralizing reagent containing high titers of anti-HBs (Reagent A); the

second sample aliquot is incubated with a non-neutralizing control reagent (Reagent B).

HBsAg in the patient sample is bound by the anti-HBs in Reagent A and not allowed to

react in the ADVIA Centaur HBsAg II assay. When both aliquots are run in the ADVIA

Centaur HBsAg II assay, the inhibition of the RLU signal in the aliquot with Reagent A is compared to the RLU signal in the aliquot with Reagent B. The relative percent

neutralization is calculated and an interpretation of the sample is generated.

Percent neutralization is calculated by comparing the RLU values obtained with Reagent

A to those obtained with the control reagent, Reagent B. If the RLU value with Reagent

B is below the cutoff, the assay is invalid. Refer to Interpretation of Results for a

description of the assay interpretations and the calculation for percent neutralization.

1. **CLINICAL SIGNIFICANCE**

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. Common modes of transmission include blood transfusion, needle puncture, direct contact with open wounds, sexual contact, and mother-neonate contact during birth.

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.

Hepatitis B surface antigen (HBsAg) is a distinctive serological marker of acute or chronic hepatitis B infection. HBsAg is the first antigen to appear following infection with hepatitis B virus and is generally detected 1 to 10 weeks before the onset of clinical symptoms. HBsAg assays are routinely used to diagnose suspected HBV infection and to monitor the status of infected individuals to determine whether the infection has resolved or the patient has become a chronic carrier of the virus. In patients who recover from HBV infection, HBsAg levels disappear 3 to 5 months after the onset of the infection. In patients with chronic HBV infection, HBsAg levels may remain detectable for life. Prenatal HBsAg screening has been recommended so that newborns from HBV carrier mothers may obtain prophylactic treatment.

1. **POLICY SCOPE**

The scope of this policy applies to all Laboratory staff that prepares or performs testing on laboratory specimens at UnityPoint Methodist.

1. **SPECIMEN**

This assay requires a minimum of 200 ul 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.

No patient preparation is required.

Serum is the sample of choice for this assay. EDTA plasma may also be used. Sodium and lithium heparinized plasma are acceptable, however these samples have been shown to lower the Index Value in some samples near the assay cut off for the ADVIA Centaur HBsAgII assay.

Do not use specimens with obvious microbial contamination. The performance of the

ADVIA Centaur HBsAgII assay has not been established with cord blood, neonatal

specimens, 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 general recommendations for handling and storing blood samples are

furnished by the National Committee for Clinical Laboratory Standards (NCCLS) H

18-A2,6 and augmented with additional sample handling studies using the ADVIA Centaur HBsAg II assay:

1. Handle all samples as if capable of transmitting disease.

B. 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. When testing ten serum samples where the centrifugation step was varied by up to 24 hours post draw, no clinically significant differences were observed. Time to centrifugation was established for serum only.

C. Test samples as soon as possible after collecting. Samples may be stored at room temperature for up to 8 hours**. If testing is not completed within 8 hours,**

**separated samples may be stored at 2 to 8°C for up to 14 days.**

D. Store primary tube samples at 2 to 8°C up to 3 days (up to 12 hours for lithium

heparin). Keep samples stoppered and upright at all times. Primary tube

include serum stored on the clot, plasma stored on packed red cells, and samples processed and stored in gel barrier blood collection tubes. When 10 samples in these primary tubes were tested up to 3 days, no clinically significant differences were observed.

E. Freeze samples, devoid of red blood cells, at or below -20°C for longer storage. Do not store in a frost-free freezer. When 10 samples were subject to 6 freeze/thaw cycles, no clinically significant differences were observed.

F. Package and label samples for shipment in compliance with applicable federal and international regulations covering the transport of clinical samples and etiological agents. Samples maintained at room temperature up to 8 hours or refrigerated up to 14 days demonstrated no qualitative differences. Store samples stoppered and upright at 2 to 8°C upon arrival. If shipment is expected to exceed 14 days, ship specimens frozen.

Before placing samples on the system, ensure the following:

* Samples are free of fibrin or other particulate matter. Remove particulates by centrifugation. (example: 1500 x g for 10 minutes; follow tube manufacturer’s recommendations).
* Samples are free of bubbles or foam.
1. **REAGENTS**

**Preparing Reagents**

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 re-suspended. For detailed information

about preparing the reagents for use, see the system operator’s guide.

**Storage and Stability**

* Store reagent packs upright at 2° to 8°C away from heat and light sources.
* Discard reagent packs at the end of the 60-day onboard stability interval. Do not use reagents beyond the expiration date.

**Reagents used in the assay:**

1. ADVIA Centaur Conf **RGT A** ReadyPack ancillary reagent pack:

* Neutralizing Reagent
* 5.0 ml human plasma positive for antibodies to HBsAg with preservatives.
* Stable at 2-8C until the expiration date on the pack label or 41 consecutive days after accessing the ancillary reagent pack.

2. ADVIA Centaur Conf **RGT B** ReadyPack ancillary reagent pack:

* Non-Neutralizing Control Reagent
* 5.0 ml human plasma negative for HBsAg and antibodies to HBsAg with preservatives.
* Stable at 2-8C until the expiration date on the pack label or 41 consecutive days after accessing the ancillary reagent pack.

3. ADVIA Centaur **M-DIL 2** ReadyPack ancillary reagent pack:

* Multi-Diluent 2
* 10.0 ml goat serum with sodium azide (0.1%) and preservatives.
* Stable at 2-8C until the expiration date on the pack label or 28 consecutive days after accessing the ancillary reagent pack.

4. ADVIA Centaur **APW 1** ReadyPack ancillary reagent pack

* Probe Wash
* 25 ml 0.4 N sodium hydroxide.
* Stable at 2 - 8°C until the expiration date on

 the pack label or 14 consecutive days after accessing the ancillary reagent pack.

5. ADVIA Centaur **HBsAgII ReadyPack** primary reagent pack:

* Solid Phase
* 21.0 ml streptavidin-coated magnetic latex particles in buffer with bovine

serum albumin, goat serum, surfactant, sodium azide (< 0.1%) and

preservatives.

* Stable at 2 - 8°C until the expiration date on the pack label or

60 days on board.

6. ADVIA Centaur HBsAg **LR** ReadyPack ancillary reagent pack

* Lite Reagent
* 8.0 ml/reagent pack;acridinium ester-labeled monoclonal mouse anti- HBsAg (approx. 0.6 ug/ml) in buffer with bovine serum albumin, bovine gamma globulin, goat serum, mouse IgG, surfactant, sodium azide (<0.1%) and preservatives.
* Stable at 2- 8°C until the expiration date on the pack label or 60 days on board.

7. ADVIA Centaur Wash 1

* 2500 mL phosphate buffered saline with sodium azide (< 0.1%) and surfactant.
* Stable at 2 - 25°C until the expiration date on the vial or 1 month on board.

**Precautions**

1. Sodium azide can react with copper and lead plumbing to form explosive metal

azides. On disposal, flush reagents with a large volume of water to prevent the

buildup of azides.

2. Potential biohazard, human and/or other biological source material. Handle as if potentially infectious, according to established good laboratory practices and

universal precautions.

3. The human source components in the ADVIA Centaur HBsAg Confirmatory kit 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.

4. Do not use kit components beyond expiration date.

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

 **Loading Reagents**

1. Ensure that the system has sufficient primary and ancillary reagent packs.

2.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 re-suspended.

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

4 To perform the ADVIA Centaur HBsAg Confirmatory assay, load the

ADVIA Centaur HBsAgII 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. Load the ADVIA Centaur HBsAg Lite Reagent,

ADVIA Centaur HBsAg Confirmatory Reagent A and Reagent B, ADVIA Centaur

Multi-Diluent 2, and ADVIA Centaur Ancillary Probe Wash 1 ReadyPack ancillary

reagent packs in the ancillary reagent entry.

5.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.

6.The Lite Reagent in the ancillary reagent pack provided in this kit is

matched to the Solid Phase and Ancillary Reagent in the primary reagent pack.

Do not mix Lite Reagent lots with different lots of Solid Phase and Ancillary

reagent.

 **Onboard stability:**

1. The ADVIA Centaur HBsAgII assay has an onboard stability of 60 days. The ADVIA Centaur HBsAG Confirmatory Reagent A and Reagent B are stable onboard for 41 days.
2. Discard the primary and ancillary reagent packs at the end of the onboard

 stability interval.

1. Do not use reagents beyond the expiration date.
2. **INSTRUMENTATION**

The ADVIA CENTAUR XPT system is an automated, immunoassay analyzer that offersoptimal productivity and efficiency. No-pause reloading of reagents, samples, and

supplies means that the system is always ready to process samples. All assays use direct

chemiluminescent technology. Chemiluminescence is a chemical reaction that emits

energy in the form of light. When used in combination with immunoassay technology, the light produced by the reaction indicates the amount of analyte in the sample. Direct

chemiluminescent reactions directly measure the light energy without the use of added

steps or amplifying molecules. The ADVIA Centaur assays use acridinium ester as the

chemiluminescent label, since it does not require the addition of a catalyst or substrate.

When the sample start key is pressed, the barcode labels on the sample cups are read,

sample is aspirated, reagent is dispensed, and the assay process begins. Particles are

magnetically separated in the cuvette incubation ring. The addition of hydroxyl groups to complete the flash reaction is accomplished by the addition of Reagent 1 & 2; Acid and Base. The chemiluminescent reaction occurs in the luminometer. The photomultiplier tube measures the chemical light reaction that takes place.

There is one (1) main system operation key on the ACS:CENTAUR, the “**Sample Start**

**button**”. Pressing this key performs the following actions:

1. Homes the subsystems.

2. The system starts specimen sampling.

3. If the start button is pressed while the instrument is running, it stops sampling

additional specimens, however it continues to process the specimens in the

incubation ring.

**Additional Equipment and Supplies**

Reagent Water

Sample cups / tubes

Cuvettes

Sample tips

Reagent 1 (0.5% H2O2; 0.1N HNO3)

Reagent 2 (less than 0.25N. Sodium Hydroxide and surfactant)

ACS:CENTAUR Cleaning Solution

ACS:CENTAUR primary and ancillary reagents.

**VI. CALIBRATION**

The ADVIA Centaur system uses a Master Curve and a two-point operator initiated

calibration to calibrate assays. The Master Curve is established as part of the

manufacturing process for each assay lot number.

The ADVIA Centaur HBsAg Confirmatory assay requires a valid ADVIA Centaur HBsAg II assay calibration on the ADVIA Centaur System prior to performing the assay. Insure that both the ADVIA Centaur HBsAgII and HBsAg Confirmatory calibrations have been completed. The ADVIA Centaur HBsAgII Confirmatory Master Curve Card is included in the ADVIA Centaur HBsAgII kit. Refer to Calibration in the ADVIA Centaur HBsAgII instructions for use.

A two-point calibration must be performed at regular, assay specific intervals. Replicates

for two calibrators of known value are processed. If the calibrators meet defined validity

criteria, the system is adjusted. Refer to the Centaur Operating Procedures for

calibration procedure.

For calibration of the ADVIA Centaur HBsAgII assay, use ADVIA Centaur HBsAgII

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.

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

* Every 21 days.
* When changing lot numbers of primary reagent packs
* When replacing system components
* When quality control results are repeatedly out of range

 **Master Curve Calibration**

The ADVIA Centaur HBsAgII assay requires a Master Curve calibration when using a new lot number of Solid Phase, Ancillary Reagent, and Lite Reagent. For each new lot number of Solid Phase, Ancillary Reagent, and Lite Reagent, use the bar-code 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 or to the online help system.

**Using Bar-code Labels**

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

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

**Calibration Procedure**

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

Perform the calibration procedure using the following steps:

**Note :** This procedure uses calibrator volumes sufficient to measure each calibrator in duplicate.

1. Schedule the calibrators to the worklist.

2. Label 2 sample cups with calibrator bar-code labels: 1 for the low and another for the high.

**Note:** Each drop from the calibrator vial is approximately 50 μL.

3. Gently mix the Low and High Calibrators and dispense at least 6 to 7 drops into the appropriate sample cups.

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.

**VII. QUALITY CONTROL**

Virotrol 1, unassayed, Bio-Rad Laboratories, Inc., Hercules, CA.

Virotrol 1 is designed to be reactive/pos when analyzed in the same manner as unknown

specimens.

Run QC on day of patient testing

**A. Preparation/handling**

1. Store HBsAg QC material at 2 to 8°C. To prevent leakage into caps, bottles

should be stored upright. Cap bottles tightly while in storage. No preparation is

required.

2. Mix by gentle inversion prior to dispensing.

3. Avoid microbial contamination when opening and dispensing aliquots from

bottles.

4. Virotrol 1 has a 18 month shelf life at 2-8º C and a 60 day open-vial stability at 2-

8ºC.

5.Do not use controls beyond the expiration date.

**B. Frequency**

The HBsAg Positive Control should be run ( once daily) when a HBsAg confirmation

is needed (specimen in “repeat range” on HBsAg assay) and also following a

calibration for HBsAg confirmation.

**C. Acceptability Criteria**

For the run to be valid, the percent neutralization for the Positive Control must be

greater than or equal to 50%, and a result of confirmed must be obtained.

**D. 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:

• Consider the sample results invalid and repeat testing.

• 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.

**VIII. PROCEDURE**

A. The HBsAg Confirmatory assay is utilized to confirm repeatedly reactive ( 2 of 3 /or 3

of 3 results) in the retest zone (1 – 50 Index Value) for Hep Bs Ag assay results.

Good practice would indicate obtaining the original specimen, if possible, for testing,

rather than use the pour-off aliquot.

B. Prepare the sample container for each sample, ensuring that a barcode label is

affixed.

C. Samples can be loaded on the Aptio in the appropriate lane or if front loaded, use the appropriately coded sample racks for the type of sample tube to be used:

1. Position A – cup atop tube

2. Position 2 – primary sample tube

D. Load each sample tube into a rack, ensuring that the barcode is visible through the

slot in the rack.

E. Place the rack(s) in the entry queue.

F. Press ’START’ **only** if the system is not currently ‘In Process’. The analyzer will read

the barcode label and run the appropriate tests via the Cerner interface.

G. For the HBsAg Confirmatory assay, the system automatically performs the following

steps for sample pretreatment:

1. dispenses 100 uL of sample into each of two cuvettes

2. dispenses 50 uL of Reagent A in the first cuvette

3. dispenses 50 uL of Reagent B in the second cuvette

4. incubates for 29 minutes at 37C

5. on the second pass, the pretreated samples are tested following the ADVIA

Centaur HBsAg protocol:

a. dispenses 100 uL of sample into a cuvett

b. dispenses 120 uL of Lite Reagent and incubates for 5 minutes at 37°C

c. dispenses 105 uL of Solid Phase and 25 uL of Ancillary Reagent and

Iincubates the mixture for 18 minutes at 37°C

d. separates the Solid Phase from the mixture and aspirates the unbound

reagent

e. washes the cuvette with Wash 1

f. dispenses 300 uL each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction

NOTE:Percent neutralization is calculated by comparing the RLU values obtained with Reagent A to those obtained with the control reagent, Reagent B. If the RLU value with Reagent B is below the cutoff, the assay is invalid. Refer to Interpretation of Results for a description of the assay interpretations and the calculation for percent neutralization.

**IX. INTERPRETATION OF RESULTS**

Indicator tests are generated by the Centralink software, which indicates the instrument test result, the test sequence, and the individual test result. Whenever an instrument test result requires a retest, the system automatically generates an associated indicator test. The Aptio will receive an order from Centalink, and deliver the sample to the Centaur for additional testing. The Aptio holds the sample in the “Infectious Disease Park” lane until the hepatitis testing is complete.

Interpretive tests are generated by the Centralink software to show the interpretive value of the instrument test result as recommended by the assay-specific instructions for use. Each interpretive test is designated by the suffix\_INTR appended to the test name. The possible results for interpretive tests are:

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

operating instructions or to the online help system.

The system calculates the cutoff and percent neutralization automatically based on the

calibration of the ADVIA Centaur HBsAgII Confirmatory assay and the values obtained for the sample run with Reagent A and Reagent B.

NOTE: The cutoff is based on RLU values of the calibrators and not on the ADVIA Centaur HBsAg Index Value (Index Value = 1.0). This is so that the cutoff can be

adjusted to allow for dilution of the sample with Reagent A and Reagent B.

The system reports ADVIA Centaur HBsAg Confirmatory results as Invalid, Redilute,

Not Confirmed, or Confirmed. The Confirmatory test results are always held in Review in the CentraLink system. Manual validation is required.

The CentrLink software displays the % neutralization value uploaded from the ADVIA Centaur system.

The user determines the correct action based on the interpretive value displayed on the ADVIA Centaur system.

**A. Invalid**

Samples are reported as “Invalid” if the sample run with Reagent B is below the cutoff

value of the ADVIA Centaur HBsAg Confirmatory assay. The assay is invalid and

should be repeated. The CentraLink system reflexes the sample to the “Infectious Disease Park “ lane so the tube can be located easily.

 If the interpretation is Invalid after repeat testing, it means a valid

result cannot be obtained with this sample and a new sample should be obtained.

**B. Redilute**

Samples reported as Redilute require further dilution for confirmation. Redilute is the

reported result when the sample run with Reagent B is above the cutoff value and

the sample run with Reagent A is above the cutoff value but <50% neutralization.

Schedule a 1:50 dilution for the sample and repeat. If the reported result is still

‘Redilute’, schedule a 1:2500 dilution. If the reported result is still ‘Redilute’,consult

with the clinical chemist or pathologist. The CentraLink system reflexes the sample to the “Infectious Disease Park “ lane so the tube can be located easily.

**C. Not Confirmed**

Samples reported as Not Confirmed are HBsAg negative. “Not Confirmed” is the

reported result when the sample run with Reagent B is above the cutoff value and

the sample run with Reagent A is below the cutoff value. The CentraLink system reflexes the sample to the “Infectious Disease Park “ lane so the tube can be located easily. Once the testing is completed, the Aptio will store the sample in the Refrigerated Storage Module.

**D. Confirmed**

Samples reported as “Confirmed” are HBsAg positive. Confirmed is the reported result

when the sample run with Reagent B is above the cutoff value and the sample run

with Reagent A is above the cutoff value with > 50 % neutralization. The CentraLink system reflexes the sample to the “Infectious Disease Park “ lane so the tube can be located easily. Once the testing is completed, the Aptio will store the sample in the Refrigerated Storage Module.

**NOTE:** Heterophilic antibodies in human serum can react with reagent

immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed

to animals or to animal serum products can be prone to this interference and

anomalous values may be observed. Additional information may be required for

diagnosis. Samples containing heterophilic antibodies should not neutralize using

the ADVIA Centaur HBsAg Confirmatory assay.

For diagnostic purposes and to differentiate between acute and chronic HBV

infection, the detection of HBsAg should be correlated with patient clinical

information and other HBV serological markers. It is recognized that current

methods for detection of hepatitis B surface antigen may not detect all potentially

infected individuals. A false reactive HBsAg test result or invalid Confirmatory result

does not exclude the possibility of exposure to or infection with hepatitis B.

**CAUTION:** It has been reported that certain assays will not detect all HBV mutants.

If acute or chronic HBV infection is suspected and the HBsAg result is nonreactive it

is recommended that other HBV serological markers be tested to confirm the HBsAg

nonreactivity.

**Reporting Results**

A specimen which is repeatedly reactive by the ADVIA Centaur HBsAg test and

confirmed by neutralization with the ADVIA Centaur HBsAg Confirmatory assay is

reported positive for HBsAg. Samples are considered Positive for confirmation when the sample run with Reagent B is about the cutoff value and the sample run with Reagent A

is about the cutoff value with >50% neutralization.

Report the Hep Bs Ag as Reactive and footnote ‘confirmed by neutralization’ as a footnote to the HBsAg result.

If the centaur printout reports “Not confirmed” , the HBsAg is negative..“Not confirmed” is when the sample with Reagent B is above the cutoff value and the sample run with Reagent A is below the cutoff value. (<50%).

The Hep Bs Ag is reported out as Non-Reactive.

**X. LIMITATIONS OF THE PROCEDURE/ PROCEDURAL NOTES**

A.The ADVIA Centaur HBsAg Confirmatory assay is limited to the confirmation of

HBsAg in human serum or plasma (potassium EDTA plasma, lithium or sodium

heparinized plasma) in samples repeatedly reactive using the ADVIA Centaur

HBsAg assay.

B. The performance of the ADVIA Centaur HBsAg Confirmatory assay has not been

established with cord blood, neonatal specimens, cadaver specimens, heat inactivated

specimens, or body fluids other than serum or plasma, such as saliva,

urine, amniotic fluid, or pleural fluid.

C. The performance of the assay has not been established for populations of

immunocompromised or immunosuppressed patients. Results from these individuals

must be interpreted with caution.

For interfering substances and cross-reactivity results refer to the ADVIA Centaur

HBsAgII Procedurre.

D. Potential Interfering Substances

**Serum specimens that are . . . Demonstrate ≤ 10% 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

cholesterol 400 mg/dL of cholesterol

proteinemic (high) 12 g/dL of total protein

proteinemic (low) 4 g/dL of total proteina

hyper IgG 6 g/L of immunoglobulin G

biotin-spiked 10 ng/mL of biotin

 E. Course of action if system is inoperable:

 Short term: STAT specimens will be sent to OSF St. Francis Laboratory

 Long term: all specimens other than STAT will be sent to ARUP Reference Lab

**XIII. REFERENCES**

1. Bayer HealthCare ADVIA Centaur HBsAg Confirmatory (Conf) product insert,

 Revision A.

2. Bayer Diagnostics ADVIA Centaur Reference Manual, Revision D.

3. Bayer Diagnostics ADVIA Centaur Assay Manual, Revision AT.

4. National Committee for Clinical Laboratory Standards (NCCLS). Clinical

 Laboratory Procedure Manuals¾Fourth Edition (GP2-A4), 2002.

5.Siemens Centaur, Centaur XP IFU: Document 10629870 EN Rev. R, 2014-08.

6.Siemens Healthcare ADVIA Centaur HBsAgII assay product insert, Rev.E, 2015-01.

7.ADVIA Centaur XP Operator’s Guide Rev A, 2007-10.

MMCI Laboratory is a CAP accredited facility, as of 7/1/11 the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

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| ***POLICY CREATION :*** |  |
| ***Author: Donna Roth, CLS*** | ***July 14, 2016*** |
| ***Medical Director: Devendra Trivedi, M.D.***  | ***July 25, 2016*** |

|  |
| --- |
| ***MEDICAL DIRECTOR*** |
| DATE | NAME | SIGNATURE |
| March 4, 2017 | Elizabeth A. Bauer-Marsh, M.D. |  |
| ***SECTION MEDICAL DIRECTOR*** |
| July 20, 2016 | Lori Racsa, DO |  |
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| --- |
| **REVISION HISTORY (began tracking 2011)** |
| **Rev** | **Description of Change** | **Author** | **Effective Date** |
| 0 | Initial Release | D. Roth | 7/14/16 |
| 1 | Updated from XP to XPT, Added CentraLink rules for interpretation of results | 1. Gibbs
 | 02/13/17 |
| 2 | Added Non-Reactive in the Reporting Section | A.Gibbs | 05/21/18 |

**Reviewed by**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Lead** | **Date** | **Coordinator/Manager** | **Date** | Medical Director | **Date** |
| Donna Roth | 7/14/16 |  | 7/18/16 |  | 7/20/16 |
| Ray Gross | 2/16/17 |  | 2/13/172/13/17 |  | 2/24/173/5/17 |
| Ray Gross | 5/24/18 |  | 5/21/18 |  | 5/29/18 |
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