

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Hepatitis B Surface Antigen
Hepatitis B Surface Antigen Confirmatory
Hepatitis B Surface Antigen Positive and Negative Control
Materials

Device Trade Name: ADVIA Centaur[®] HBsAgII for use on the ADVIA Centaur[®] and
ADVIA Centaur[®] XP
ADVIA Centaur[®] HBsAg Confirmatory
ADVIA Centaur[®] HBsAg Quality Control Material

Device Procode: LOM

Applicant's Name and Address:
Siemens Healthcare Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

Dates of Panel Recommendation: Not applicable

Premarket Approval Application (PMA) Number: P110041

Date of FDA Notice of Approval: May 16, 2014

Expedited: Not Applicable

II. INDICATIONS FOR USE

1. ADVIA Centaur HBsAgII

The ADVIA Centaur HBsAgII (HBsII) assay is an *in vitro* immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human adult, adolescent, and pediatric serum and plasma (EDTA, lithium-heparin, or sodium-heparin), and neonatal samples using the ADVIA Centaur and ADVIA Centaur XP systems. The assay may be used in conjunction with other serological and clinical information to diagnose individuals with acute or chronic hepatitis B infection. The assay may also be used to screen for hepatitis B infection in pregnant women to identify neonates who are at risk of acquiring hepatitis B during the perinatal period.

2. ADVIA Centaur HBsAg Confirmatory

The ADVIA Centaur HBsAg Confirmatory assay is an *in vitro* immunoassay for the confirmation of hepatitis B surface antigen (HBsAg) in human serum and plasma (potassium EDTA, lithium-heparin, or sodium-heparin), and neonatal samples using the ADVIA Centaur and ADVIA Centaur XP systems. The assay is intended to be used to confirm the presence of HBsAg in samples that are repeatedly reactive using the ADVIA Centaur HBsAgII assay.

3. ADVIA Centaur HBsAg Quality Control Material

For monitoring the performance of the HBsAg, HBsAgII and HBsAg Confirmatory assays on the ADVIA Centaur systems. The performance of the HBsAg quality control material has not been established with any other HBsAg or HBsAg Confirmatory assays.

III. **CONTRAINDICATIONS**

None.

IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the ADVIA Centaur HBsAgII, the ADVIA Centaur HBsAg Confirmatory, and the ADVIA Centaur HBsAg Quality Control Material labeling.

V. **DEVICE DESCRIPTION**

Kit Configurations and Components

The ADVIA Centaur HBsAgII kit is comprised of the following components:

ADVIA Centaur HBsAgII ReadyPack primary reagent pack:

- Solid Phase - 21.0 mL/ reagent pack. Streptavidin-coated magnetic latex particles (60 mg/dL) in buffer with bovine serum albumin, bovine gamma globulin, goat serum, surfactant, sodium azide (< 0.1%) and preservatives
- Lite Reagent - 8.0 mL/ reagent pack. Acridinium ester-labeled monoclonal mouse anti-HBsAg (~0.6 µg/mL) in buffer with bovine serum albumin, bovine gamma globulin, goat serum, mouse IgG, surfactant, sodium azide (< 0.1%) and preservatives

ADVIA Centaur HBsAgII ReadyPack ancillary reagent pack;

- Ancillary Pack Reagent - 25.0 mL/ reagent pack. Biotinylated monoclonal mouse anti-HBsAg antibodies (~2.0 µg/mL) and acridinium ester-labeled monoclonal mouse anti-HBsAg (~0.3 µg/mL) in buffer with bovine serum

ADVIA Centaur or ADVIA Centaur XP systems the probable benefits outweigh the probable risks and the device adds no additional risks to the risks of existing devices approved for testing HBsAg.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the instructions for use. The submitted clinical studies have shown that the ADVIA Centaur HBsAgII and the ADVIA Centaur HBsAg Confirmatory assays, when compared to reference clinical laboratory procedures, have a similar ability to detect the presence of HBsAg in human adult and pediatric serum and plasma (EDTA, lithium-heparin, or sodium-heparin), and neonatal samples. The rates of false positivity and false negativity are within acceptable limits compared to the reference assay. It has been shown that the device has no demonstrable cross-reactivity with the majority of viruses or organisms that may cause clinical hepatitis. Therefore, this device should benefit the physician in the diagnosis and management of HBV.

XIII. CDRH DECISION

CDRH issued an approval order on May 16, 2014. The final conditions of approval can be found in the approval order.

The applicant's manufacturing facilities were inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.