SIEMENS

QC

CE 0197

# Anti-HBs2 (aHBs2) Quality Control

## Contents

| REF | Contents | |
|---|---|---|
| 06521435 | 2 vials of Negative Control | CONTROL – |
| | 2 vials of Positive Control | CONTROL + |
| | Expected Values Card and barcode labels | |

## Intended Use

The ADVIA Centaur® anti-HBs2 Quality Control is for *in vitro* diagnostic use in monitoring the performance of the ADVIA Centaur anti-HBs2 assay using the ADVIA Centaur® systems. The performance of the anti-HBs2 quality control material has not been established with any other anti-HBs assays.

## Control Description

| Volume | Ingredients | Storage | Stability |
|---|---|---|---|
| 10.0 mL/vial | Processed human plasma negative and positive for antibodies to HBsAg with preservatives | 2–8°C | Until the expiration date on the vial label or onboard–8 hours |

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

**CAUTION! POTENTIAL BIOHAZARD:** The controls contain human source material. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. All products manufactured using human source material should be handled as potentially infectious. Handle this product according to established good laboratory practices and universal precautions.[1–3] Use eye protection and gloves when handling this product; wash hands after handling.

The controls 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.

For *in vitro* diagnostic use.

## Preparing the Quality Control Material

Gently swirl and invert the vials to ensure homogeneity.

## Using the 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 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.

## Performing Quality Control

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

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

**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.

**NOTE:** Each drop from the control vial is approximately 35–40 µL.

3. Gently mix the quality control materials and dispense at least 8–10 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 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.

## Reviewing, Editing, and Printing Results

For detailed information about reviewing, editing, and printing quality control results, refer to the system operating instructions or to the online help system.

## Expected Results

Refer to the *Expected Values* card for the assigned values specific for the lot number of the anti-HBs2 quality control material. The expected values are traceable to the standardization of the anti-HBs2 assay. For additional information, refer to the reagent instructions for use.

The expected values should be used only as a guide in evaluating performance. Because performance is subject to the design and condition of each instrument or reagent system, it is recommended that each laboratory establish its own expected values and acceptable limits. The mean values established should fall within the range specified in *Expected Values*. Individual results may fall outside the range.

## 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:

- 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.

## Limitations

The results obtained using the anti-HBs2 quality control material depend on several factors. Erroneous results can occur from improper storage, inadequate mixing, or sample handling errors associated with system or assay procedures.

- Do not return any quality control materials back into the vials after testing because evaporation and contamination can occur, which may affect results.
- Dispose of any quality control material 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.

## Disposal

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 all federal, state, and local requirements.

## Technical Assistance

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

www.siemens.com/diagnostics

## References


1. Clinical and Laboratory Standards Institute (formerly NCCLS). *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline - Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document H18-A3.
2. Centers for Disease Control. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. MMWR: 1988; 37:377-82, 387-8.
3. Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition.* Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3.



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## Definition of Symbols

The following symbols may appear on the product labeling:

| Symbol | Definition |
|---|---|
| IVD | *In vitro* diagnostic medical device |
| REF | Catalog number |
| | Legal manufacturer |
| EC REP | Authorized Representative in the European Community |
| CE | CE Mark |
| CE 0088 | CE Mark with identification number of notified body |
| | Consult instructions for use |
| | Biological risk |
| | Temperature limitation |
| | Upper limit of temperature |
| | Lower limit of temperature |
| | Do not freeze (> 0°C) |
| | Keep away from sunlight and heat |
| | Up |
| | Use by |
| Σ (n) | Contains sufficient for (n) tests |
| LOT | Batch code |
| **YYYY-MM-DD** | Date format (year-month-day) |
| **Rev.** | Revision |
| DER GRÜNE PUNKT | Green dot |
| | Recycle |
| PRINTED WITH SOY INK | Printed with soy ink |
| **RxOnly** | Prescription device (US only) |

**Suomi**

**VAROITUS! MAHDOLLINEN TARTUNTAVAARA:** Sisältää ihmiskudoksista peräisin olevaa materiaalia. Kaikki tämän tuotteen valmistuksessa käytetyt ihmisseerumi- tai veriplasmayksiköt on testattu FDA-säännösten mukaisin menetelmin. Testeissä todettiin, että yksiköt eivät sisältäneet hepatiitti B -pinta-antigeeniä (HBsAg) tai hepatiitti C (HCV)- tai HIV-1/2-viruksen vasta-aineita. Tästä huolimatta on huomioitava, että kaikkia ihmismateriaaleista valmistettuja tuotteita on käsiteltävä mahdollisesti tartuttavina aineina. Koska yhdelläkään testausmenetelmällä ei voida tunnistaa hepatiitti B-, hepatiitti C- ja HIV-virusta tai muita taudinaiheuttajia täysin varmasti, näitä tuotteita on käsiteltävä hyvien laboratoriotyöskentelytapojen mukaisesti.[1–3] Käytä silmäsuojaimia ja suojakäsineitä käsitellessäsi tuotetta, pese kädet käsittelyn jälkeen.

Kontrollit on analysoitu FDA:n hyväksymillä menetelmillä ja havaittu ei-reaktiivisiksi hepatitis B pinta-antigeenille (HBsAg), hepatitis C vasta-aineelle (HCV), HIV-1/2 vasta-aineelle.

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