SIEMENS

ADVIA Centaur®

QC

HIV Ag/Ab Combo (CHIV) Quality Control

Contents

REF	Contents
10697214	1 vial of CHIV Negative Control CONTROL –
	1 vial of CHIV Positive anti-HIV-1 Control CONTROL Ab-1 +
	1 vial of CHIV Positive anti-HIV-2 Control CONTROL Ab-2 +
	1 vial of CHIV Positive anti-HIV-1 group O Control CONTROL Ab-3 +
	1 vial of CHIV Positive HIV-1 p24 antigen Control CONTROL Ag +
	Expected Values card and barcode labels

Intended Use

For *in vitro* diagnostic use to monitor the performance of the ADVIA Centaur® HIV Ag/Ab Combo (CHIV) assay on the ADVIA Centaur systems. The performance of the CHIV quality control material has not been established with any other HIV assay.

Control Description

Volume	Ingredients	Storage	Stability
14 mL/vial	Processed human plasma nonreactive for HIV, reactive for HIV-1, reactive for HIV-2, reactive for HIV-1 group O, and reactive for HIV-1 p24 antigen with sodium azide (< 0.1%) and preservatives.	2–8°C	**Unopened:** Stable until the expiration date on product **On-system:** 8 hours

Warnings and Precautions

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

CAUTION! POTENTIAL BIOHAZARD

Contains 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.[1–3]

The negative control has been assayed by FDA-approved methods and found to be nonreactive for hepatitis B virus, antibody to HCV, and antibody to HIV-1/2. The positive controls, low calibrator and high calibrator have been assayed by FDA-approved methods and found to be nonreactive for hepatitis B virus and antibody to HCV. The positive controls, low calibrator, and high calibrator contain human plasma that is reactive for antibody to HIV. The units were treated with a BPL-UV inactivation procedure,[4] however, all products manufactured using human source material should be handled as potentially infectious.

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.

H317 **P280, P272, P302 + P352, P333 + P313, P501**	**Warning!** May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing should not be allowed out of the workplace. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** Proclin 300; ADVIA Centaur CHIV QC

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

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 the Quality Control Material

Gently swirl and invert the vials to ensure homogeneity.

Performing Quality Control

Follow government regulations or accreditation requirements for quality control frequency.

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, quality control samples should be assayed at least once every 24 hours. Quality control samples should also be assayed when performing a two-point calibration. Treat all quality control samples the same as patient samples.

The 5 controls: a Negative Control and four Positive Controls (anti-HIV-1, anti-HIV-2, anti-HIV-1 group O, HIV-1 p24 antigen) supplied in the CHIV Control kit should be assayed at least once every 24 hours. Control values must be within the index ranges specified in the quality control package insert. If any control result is outside of its specified Index range, all test results generated since the last acceptable control results must be evaluated for possible adverse effects. If it is determined that any test result is adversely affected, the affected sample, or a new sample from that patient, must be retested.

Perform the quality control procedure, using the following steps:

1. Ensure that the quality control definitions are defined, and that the quality control values are entered on the system using the lot-specific *Expected Values* card provided.
2. Ensure that the required reagents are loaded for the assay.
3. Schedule the quality control samples to the worklist.
4. Label five sample cups with quality control barcode labels: one cup for each positive control, and another cup for the negative control.

Note Place the barcode label on the sample cup with the readable characters oriented vertically.

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

5. Gently mix the quality control materials and dispense at least 10–12 drops into the appropriate sample cups. Avoid bubbles.

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

6. Load the samples according to the system operating instructions.

CAUTION

Discard 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.

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

Reviewing, Editing, and Printing Results

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

Expected Results

Refer to the *Expected Values* card for the assigned values specific to the lot number of the CHIV quality control material.

Control values should fall within the range specified in *Expected Values*.

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. Determine and correct the cause of the unacceptable control results:
   a. Verify that the materials are not expired.
   b. Verify that required maintenance was performed.
   c. Verify that the assay was performed according to the instructions for use.
   d. Rerun the assay with fresh quality control samples, and confirm that quality control results are within acceptable limits before running patient samples.
   e. If the quality control results are not within acceptable limits, recalibrate the assay, and repeat step d.
   f. If necessary, contact your local technical support provider or distributor for assistance.
2. Repeat testing of patient samples before reporting results.

Perform corrective actions in accordance with your established laboratory protocol.

Limitations

The ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay kit controls are quality control reagents for use only with the ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay. Assay values have not been established for assays other than the ADVIA Centaur CHIV assay.

Technical Assistance

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

www.siemens.com/diagnostics

References

1. 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; 37:377–382, 387–388.
2. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition.* Wayne, PA: Clinical and Laboratory Standards Institute. 2014; CLSI Document M29-A4.
3. Federal Occupational Safety and Health Administration, Bloodborne Pathogens Standard, 29 CFR 1910.1030.
4. Yoshizawa H, Itoh Y, et al. Beta-propiolactone for the inactivation of non-A/non-B type 1 hepatitis virus capable of inducing cytoplasmic tubular ultrastructures in chimpanzees. *Vox Sang.* 1984, 46:86–91.

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
0°C	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 use only

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