SIEMENS

ADVIA Centaur®
Immunoassay Systems

SARS-CoV-2 IgG Master Curve Material (sCOVG MCM)

Current Revision and Date[a]	Rev. 01, 2021-06
Product Name	ADVIA Centaur SARS-CoV-2 IgG Master Curve Material (sCOVG MCM)
Abbreviated Product Name	ADVIA Centaur sCOVG MCM
	4 x 1.0 mL levels of master curve material MCM 1 – 4 REF 11207586 Master curve material assigned value sheet
Systems	ADVIA Centaur systems

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For Prescription Use Only.

Intended Use

The ADVIA Centaur® SARS-CoV-2 IgG Master Curve Material (sCOVG MCM) is for *in vitro* diagnostic use in the verification of calibration and measuring interval of the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay.

Material Description

Material Description	Storage	Stability
ADVIA Centaur sCOVG MCM[a, b] **MCM: 1:** 1.0 mL/vial Processed* human plasma nonreactive for SARS-CoV-2 antibodies; sodium azide (< 0.1%) **Processed plasma is defibrinated and filtered plasma.*	Unopened at 2–8°C Opened at 2–8°C At room temperature	Until expiration date on product 60 days 8 hours
ADVIA Centaur sCOVG MCM[a, b] **MCM 2–4:** 1.0 mL/vial Horse serum spiked with human monoclonal IgG antibodies to SARS-CoV-2; sodium azide (< 0.1%)	Unopened at 2–8°C Opened at 2–8°C At room temperature	Until expiration date on product 60 days 8 hours

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

Warnings and Precautions

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product is for use with a test authorized only for detecting the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

CAUTION

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

Safety data sheets (SDS) available on siemens-healthineers.com.

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]

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.

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.

Storage and Stability

Do not use products beyond the expiration date printed on the product labeling. For information about product storage and stability, refer to *Material Description*.

Preparing the Master Curve Material

Master curve materials are liquid and ready to use. Allow the master curve material to come to room temperature. Gently mix and invert the vials to ensure homogeneity of the material.

Master curve materials greater than the assay's measuring interval may be diluted with Atellica IM sCOVG MCM level 1 to within the measuring interval of the assay.

Note Use master curve materials within the stability limits specified in *Material Description* and discard any remaining material.

Scheduling the Master Curve Material

Schedule the master curve material using the following steps:

1. Ensure that a valid calibration is available for the assay on the system.
2. Schedule the master curve material for three replicates, in order of increasing concentration:
   - Add Level 1 to the work list.
   - Add Level 2 to the work list.
   - Continue until all levels are scheduled.
3. Label sample containers to identify each MCM level.
4. Gently mix each vial of master curve material and dispense an adequate volume into each sample container.
5. Place the master curve material on the system from the lowest concentration to the highest concentration.
6. Start the system, if required.

Note Dispose of any master curve material that remains in the sample container after 8 hours. Do not refill or reuse sample containers. Do not return any master curve material back into the original container.

Evaluating the Results

Refer to the ADVIA Centaur sCOVG MCM assigned value sheet for the assigned values. The assigned values represent the acceptable results for master curve material tested in triplicate as unknown samples. Each level is expected to be within its assigned interval. When evaluating results that are outside of the acceptable interval, use the same criteria used when evaluating patient and quality control results.

Master curve material is not intended for use as routine quality control material or as calibration material.

The results obtained depend on several factors. Erroneous results can occur from causes such as improper storage, inadequate mixing, reconstitution errors, or sample handling errors.

Technical Assistance

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

siemens-healthineers.com

References

1. Centers for Disease Control. Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. *MMWR*. 1988;37(24):377–382, 387–388.
2. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
3. 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.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	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 XXXX	CE Mark with notified body ID number Notified body ID number can vary.
	Consult instructions for use		Biological risks Potential biological risks are associated with the medical device.
	Do not freeze		Temperature limit
	Lower limit of temperature		Upper limit of temperature
	Keep away from sunlight Prevent exposure to sunlight and heat.		Up Store in an upright position.
	Use-by date Use by the designated date.	Σ (n)	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
LOT	Batch code		Shake the reagent pack vigorously. Refer to *Preparing Reagents* in the assay-specific ADVIA Centaur product instructions for detailed information.
YYYY-MM-DD	Date format (year-month-day)	Rev.	Revision
MC DEF	Master Curve Definition	CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
LOT DTL	Lot Details	PRINTED WITH SOY INK	Printed with soy ink
	Recycle	RxOnly	Prescription device (US only)

Legal Information

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