Version 1.0
Update: 2021.12.16

# SARS-CoV-2 Neutralizing Antibody Calibrator

## Instruction for Use

# Ref: A02087

For *In Vitro* Diagnostic Use Only

For FDA Emergency Use Authorization Only

For Use with the cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit (L00847)

For Prescription Use Only

# Contents

## I. PRODUCT NAME

SARS-CoV-2 Neutralizing Antibody Calibrator

## II. PACKING SPECIFICATION

Calibrator Stock 20 μl /bottle (1,000,000 U/mL)

## III. INTENDED USE

The SARS-CoV-2 Neutralizing Antibody Calibrator is intended to be used to calibrate the GenScript cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit for the qualitative and semi-quantitative direct detection of total neutralizing antibodies to SARS-CoV-2 in human serum and K2-EDTA plasma.

## IV. PRINCIPLE

The calibration of a semi-quantitative determination is a process of testing a sample with a known analyte concentration (for example, a measured calibrator) as in a patient sample to calculate its response value. The mathematical relationship between the measured response value and the known analyte concentration can be used to establish a calibration curve. This mathematical relationship, or calibration curve, is used to convert the measured value of the OD (Optical Density value) of the patient sample into a specific semi-quantitative or quantitative analyte concentration.

## V. CALIBRATOR CONTENTS

| Component | content |
|---|---|
| SARS-CoV-2 Neutralizing Antibody Calibrator | 1 vial (20 µl), containing SARS-CoV-2 neutralizing monoclonal antibody, Phosphate buffer with 2% BSA, 0.1% Proclin-300. Concentration is 1,000,000 U/ml. |

## VI. MATERIALS REQUIRED BUT NOT PROVIDED

- cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit (L00847)
- 10µL, 200µL and 1000µL precision pipettes
- 10µL, 200µL and 1000µL pipette tips

## VII. STORAGE CONDITION AND EXPIRE DATE

The unopened calibrator is stable if stored at -20°C, until expiration date and the opened kit is stable for up to 1 month from the date of opening at 2 to 8°C.

## VIII. Calibrator Preparation

1. **Calibrator Handling** The Calibrator must be taken out from -20°C and returned to room temperature before use (20 to 25°C). Store all reagents in refrigerator promptly after use.
2. The Calibrator should be vortexed before use.
3. For calibration curve generation and results calculation refer to the IFU of cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit.

### ■ Calibrator Dilution

**Stock SARS-CoV-2 Neutralizing Antibody Calibrator**: The SARS-CoV-2 Neutralizing Antibody (NAb) Calibrator is supplied in a **Stock** solution at a concentration of $1\times10^6$ Units (U) per mL (U/mL) (Figure 1). Produce a **Diluted Stock** solution of 6000U/mL by mixing 6µL of the **Stock** with

994µL of the kit supplied Sample Dilution Buffer. Each 30µL of the **Diluted Stock** is enough to run the NAb dilution series in duplicate on each plate. Store the **Diluted Stock** of NAb in aliquots frozen at -20°C.

**SARS-CoV-2 Neutralizing Antibody Calibrator Working Solution:** Dilute the 6000 U/mL **Diluted Stock** (see Step 4 in Reagent Preparation section of the cPass SARS-CoV-2 Neutralization Antibody Detection Kit IFU) by a factor of 1:10 to a 600U/mL **Working Solution** by adding 30µL of the **Diluted Stock** solution to 270µL of Sample Dilution Buffer (Figure 1). Calibrator dilutions should be tested in duplicate.

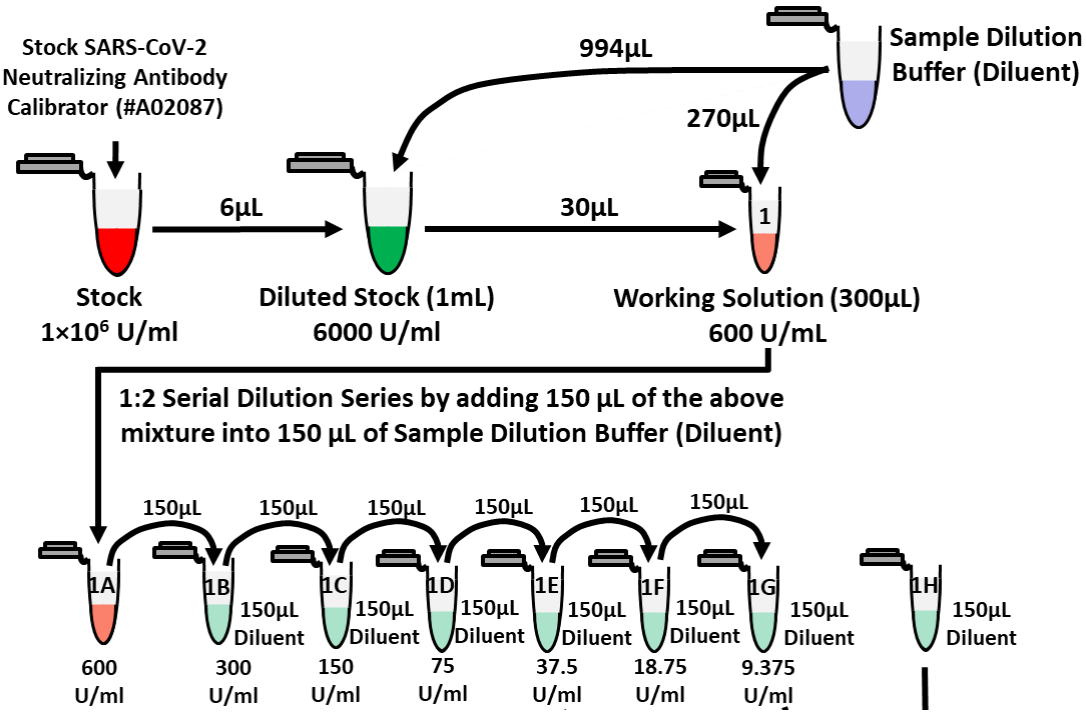
**SARS-CoV-2 Neutralizing Antibody Calibration Curve Preparation (see Figure 1)**

The calibrators can be diluted into a 96-well PCR plate containing the diluted samples, controls and calibrators to streamline the pipetting and minimize the time for the downstream steps. The calibration curve from the **neutralizing antibody calibrator working solution** (described above) is prepared according to the steps below as depicted in Figure 1:

1. The 300µL, **SARS-CoV-2 Neutralizing Antibody calibrator Working Solution** (see above) represents a final concentration of 600U/mL. Label this tube "1A". Vortex and lightly centrifuge to assure proper mixing.
2. Serially dilute the 600U/mL **Working Solution** (Tube 1A) by a factor of 1:2 for six dilutions in Sample Dilution Buffer according to Figure 1 as follows:
    a. Prepare six, 1.5ml Eppendorf tubes labelled alphanumerically from "1B" to "1G" consecutively and one additional tube labelled 1H for Background.

b. Pipette 150µL of **Sample Dilution Buffer (Diluent)** into each of tubes 1B through 1H using a calibrated P200 pipette.

c. Transfer 150µL from Tube 1A to Tube 1B using a calibrated P200 pipette then vortex and lightly centrifuge. Transfer 150µL from Tube 1B to Tube 1C and vortex/centrifuge. Continue the serial 1:2 dilution series by transferring 150µL from Tube 1C to Tube 1D with vortex/centrifugation. Complete the serial dilutions from Tube 1D to Tube 1E, Tube 1E to Tube 1F and Tube 1F to Tube 1G always with vortexing and centrifugation between each transfer to assure adequate and uniform mixing.



## IX. LIMITATIONS OF THE PROCEDURE

1. The user of this kit is advised to carefully read and understand the package insert.
2. If there are signs of microbial contamination or significant turbidity in the reagent, it should be discarded.
3. To only be used with the cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit (L00847) under FDA Emergency Use Authorization.

## X. Warnings

1. For Prescription and *In Vitro* Diagnostic Use only
2. For Use under an Emergency Use Authorization Only;
3. 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;
4. This product is for use with a test authorized only for detecting the presence of total neutralizing antibodies to SARS-CoV-2, not for any other viruses or pathogens; and
5. 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

## XI. PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Only to be use with the cPass SARS-CoV-2 Neutralization Antibody Detection Kit.
3. Do not use the calibrator if there is any visible damage or deviation in physical appearances of component.
4. Do not mix components from different SARS-CoV-2 Neutralizing Antibody Calibrator lots.
5. Do not use calibrator beyond the stated expiration date.
6. The Calibrator must be at room temperature (20 to 25°C) before running assay.

7. Remove only the volume of calibrator that is needed. Do not pour calibrator back into vials as calibrator contamination may occur.
8. Before opening the calibrator, tap the vial or quick spin to ensure that all liquid is at the bottom of the vial.
9. Avoid bubble formation.
10. Decontaminate and dispose of potentially contaminated materials in accordance with local, state, and federal regulations.

## XII. REFERENCES


1. XUE Xiongyan, ZHU Changlin, HUANG Shaozhen, (2020) Inactivation of 2019 new coronary virus before antibodies detection by different methods. Journal of Southern Medical University.
2. SHI Heshui, HAN Xiaoyu, FAN Yanqing. Radiologic Features of Patients with 2019-n Co V Infection (2020) Journal of Clinical Radiology.
3. NCCLS. 1991. National Committee for Clinical Laboratory Standard. Internal Quality
4. Testing of Reagent Water in the Clinical Laboratory. NCCLS Publication C3-A3.
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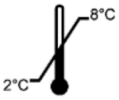
## XIII. INSTRUCTION APPROVAL AND REVISION DATE

Approval Date: 2021.12.16
Revision Date: N/A
Date of Issue: 2021.12.16

## XIV. INDEX OF CE SYMBOLS

| | | | |
|---|---|---|---|
| IVD | The product is used *in vitro*, please don't swallow it. | | Please don't reuse it |
| | Validity | | Please read the instruction book carefully before using |
| | Warning, please refer to the instruction in the annex | LOT | Batch number |

| | | | |
|---|---|---|---|
|  | Date of manufacture |  | Manufacturer |
| EC REP | European union authorization representative |  | Biological risks |
|   | Temperature scope within which the product is reserved | CE | The product meets the basic requirements of European *in vitro* diagnostic medical devices directive 98/79/EC |

## XV. TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

**GenScript USA Inc.**

860 Centennial Ave.
Piscataway, NJ 08854
Technical Support +1 732-885-9188

In case of technical problems, you can obtain assistance via contacting the manufacturer below. This product is manufactured by:

**Nanjing GenScript Diagnostics Technology Co., Ltd.**
Address: 2nd Floor, Unit D, Building 5, Ruihong Zhihui Park, No. 2289 Tianyuan East Road (Jiangning High-tech Park, .Jiangning District, Nanjing City, Jiangsu Province, China
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