

DIABETOMICS®

CovAb™ Control Kit



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2039, 2x 0.5mL



xxxx



YYYY-MM-DD

For Emergency Use Authorization (EUA) only | For prescription use only | For in vitro diagnostic use only

INTENDED USE

CovAb™ Control Kit (negative and positive) is a stable, ready-to-use liquid, bi-level control for use as assayed quality control samples to monitor the performance of the CovAb™ SARS-CoV-2 Ab Test.

CovAb™ Control Kit is for In Vitro Diagnostic use only.

SUMMARY AND PRINCIPLE

Good laboratory practices require that control samples with known performance with the CovAb™ SARS-CoV-2 Ab Test be used to effectively monitor that the run is valid in order to minimize the risks of reporting false results.

REAGENTS

CovAb™ Control Kit is prepared using heat-inactivated human serum (0.05%) to achieve the desired concentration levels. These are serum based, liquid-stable controls that contain ProClin 300 as preservative. The Negative Control is a protein based buffer spiked with heat inactivated normal human serum, and the Positive Control is a protein based buffer spiked with heat inactivated SARS-CoV-2 antibody-positive serum at a level that consistently produces a low-medium intensity color Test Line when assayed in the CovAb™ SARS-CoV-2 Ab Test. The final concentration of serum in the control materials is less than or equal to 0.05%. CovAb™ Control Kit is a ready to use liquid product manufactured according to standard quality control procedures. The manufacturer guarantees stability and consistency of this product.

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use only. For prescription use only. For use under Emergency Use Authorization 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 total antibodies to SARS-CoV2, 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.

CovAb™ Control Kit is intended solely for in vitro diagnostic use for the purpose described on the instructions for use. Diabetomics, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

CovAb™ Control Kit is stored at 2-8°C and will remain stable in the unopened vial until the expiration date.

After opening, the contents should be used according to the instructions for use included in the Control Kit IFU and immediately returned to 2-8°C.

The CovAb™ Control Kit has an open vial stability of up to 30 days under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use. To avoid evaporation, do not leave the vial uncapped. Controls should not be used beyond their expiration date.

MATERIALS PROVIDED

1. CovAb™ Control Kit, 2 x 0.5 mL
2. Positive control 0.5mL
3. Negative control 0.5mL

MATERIALS NOT PROVIDED

1. Timer
2. Tube rack

INSTRUCTIONS FOR USE

To run the controls follow the instructions provided below

1. Use a cartridge for the positive control and another for the negative control.
2. Remove a vial from the package and mix by gentle inversion. Do not shake. Do not mix mechanically. Do not dilute the controls.
3. Add five drops (~150 µL) of each control (either negative control or positive control) to the respective test cassette with the transfer pipette and read results at 15 minutes.
4. After use, return the controls to 2-8°C.
5. The vial should remain stored at 2-8°C at all times. If additional testing is necessary, the time outside of 2-8°C storage should be minimized.

Controls should be run in the following scenarios

A new operator uses the kit;

1. A new lot of test kits is used;
2. A new shipment of kits is used;
3. The temperature used during storage of the kit falls outside of 2-30°C;
4. The temperature of the test area falls outside of 15-30°C;
5. To verify a higher than expected frequency of positive or negative results;
6. To investigate the cause of repeated invalid results

EXPECTED VALUES

The performance for each sample is described in the table below. Refer to instructions for use for details on test interpretation. If controls do not provide expected results, stop testing and contact customer support.

Control	CovAb™ SARS-CoV-2 Ab Test Result
REF 3043 Negative	Negative
REF 3044 Positive	Positive

LIMITATIONS OF THE PROCEDURE

1. If the liquid in the vial becomes frozen, discard and use another vial, as the results will not be valid.
2. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

ORDERING INFORMATION

Product number	Product description	Product packaging
2039	CovAb™ Control Kit	2 x 0.5 mL

GLOSSARY OF SYMBOLS



Manufacturer



Component number



Storage temperature



Batch code, lot number



For in vitro diagnostic use



Date of manufacture



Consult instructions for use



Use by date



Caution