Establishment Registration & Device Listing

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Establishment:
GENBODY INC.
3-18, Eopseong 2-Gil, Cheonan-Si
Chungnam , KR 31077
Status: Active; Awaiting Assignment Of Registration Number
Date Of Registration Status: 2020

Owner/Operator:
GenBody Inc.
3-18, Eopseong 2-Gil, Cheonan-Si
Cheonan-Si, Chungcheongnamdo KR 31077
Owner/Operator Number: 10067610

Official Correspondent:
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Email: Cuppmeghan@Ndapartners.Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Establishment Registration & Device Listing

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Classification Name:	REAGENT, CORONAVIRUS SEROLOGICAL
Product Code:	QKO
Device Class:	Not Classified
Registered Establishment Name:	GENBODY INC.
Owner/Operator:	GenBody Inc.
Owner/Operator Number:	10067610
Establishment Operations:	Manufacturer

FAQs on Diagnostic Testing for SARS-CoV-2

Industry Hotline: Coronavirus COVID-19 Diagnostic Tests and Shortages

- For Industry Questions: COVID-19 Diagnostic Tests, and COVID-19 device shortages, including all Personal Protective Equipment for masks and respirators
- Contact our toll-free line 24 hours a day: 1-888-INFO-FDA, choose option *

Or Email:

- Shortages: deviceshortages@fda.hhs.gov
- Diagnostic Tests: COVID19DX@FDA.HHS.GOV

COVID-19 Resources

- FDA's Role: Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions
- Coronavirus Disease (COVID-19) Emergency Use Authorization (EUA) Information
- Coronavirus Disease (COVID-2019) updates from FDA

Reporting Problems to the FDA

The sale of fraudulent COVID-19 products is a threat to the public health. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program or the Office of Criminal Investigations. You can also email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov.

If you think you had a problem with your diagnostic test, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Manufacturers that have notified FDA that they have validated and are offering serology tests as set forth in Section IV.D:

Where the Authorization Status is "FDA Authorized," the FDA reviewed and issued an EUA for the test after notification was given. Where the Authorization Status is shown as "Not FDA Authorized," the FDA has not yet reviewed the manufacturer's validation and issued an EUA for the manufacturer's test, and the test is included in this list to provide transparency regarding the notifications submitted to FDA. The "Setting for Use" designation of "H" refers to a laboratory certified under CLIA to perform high-complexity testing.

Search: genbody

Manufacturer and Test	Authorization Status	Settings for Use[2]
GenBody Inc. GenBody COVID-19 IgM/IgG	Not FDA Authorized	H

Showing 1 to 1 of 1 entries (filtered from 144 total entries)

[2] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.