



For Release

Mar 23, 2020

15 Minute COVID-19 Rapid Test Kit

National Bio Green Sciences LLC Announces Availability of Product

NBGS Novel Coronavirus (2019-nCoV) IgM / IgG Antibody Rapid Test Kit

Branchburg, NJ— Mar 23, 2020 — National Bio Green Sciences LLC, announces that it has been greenlit by the FDA to market and sell *NBGS' Novel Coronavirus (2019-nCoV) IgM / IgG Antibody Rapid Test Kits*. The Rapid Test Kits are for whole blood, serum and or plasma; require no special equipment thus allowing flexibility of location use and deliver results in 15 minutes.

Novel Coronavirus (2019-nCoV) IgM / IgG Antibody Rapid Test Kit are:

- Deliver results in 15 minutes
- 95% accurate (after one week from infection)
- No special facilities needed; test can be used anywhere.
- Results are easy and clear to read.
- Can detect “silent infections” before symptoms appear.
- No specialized training required to operate.

IgM antibodies provides the first line of defense during viral infections, followed by the generation of adaptive, high affinity IgG antibody responses for long term immunity and immunological memory. Therefore, testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection.



Thus, this combined antibody test could also provide information on the stage of infection. NBGS rapid test kits provide ease of use for professionals at remote or dedicated point of care sites.

The test is ideally suited for hospitals, clinics, medi-merge / urgent care and any point of care facilities. The test can also be effectively deployed in businesses, airports, schools, seaports, train stations, universities and are ideal for triage pop up facilities.

National Bio Green Sciences LLC (NBGS) is located in Central Jersey, the Pharma Capital of the world. NBGS is an FDA registered medical device specifications developer, initial importer and manufacturer of HandSan (Organic hand cleanser) and are a contract manufacturer of N95 and NIOSH masks and protective gear as well as other medical products and devices.

Note:

On March 19, National Bio Green Sciences LLC, received its submittal confirmation from the FDA (PEUA200124). Under the announced FDA policy, upon filing its submittal, NBGS was authorized to market and distribute “NBGS Novel Coronavirus COVID-19 IgM / IgG Rapid Test Kits to any licensed healthcare practitioner in the United States for diagnostic use while it awaits a final decision on its FDA EUA application. While the policy does not apply to at-home testing, the policy does allow testing in laboratories or by healthcare workers at the point-of-care.

This test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43 or 229E.



NBGS has partnered with Gulf Coast Pharmaceuticals PLUS (GCPP) for exclusive distribution.

For sales please contact:

Gulf Coast Pharmaceuticals Plus
888-517-3701
Testkits@gulfcoastpharmaceuticalsplus.com



Acknowledgment Letter

3/12/2020

Nikolaos Renieris, CEO
National Bio Green Sciences LLC
NBGS PHARMA
6-B Culnen Drive
Branchburg, NJ 08876
UNITED STATES

Dear Nikolaos Renieris:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200063
Received: 3/12/2020
Applicant: National Bio Green Sciences LLC
Device: NBGS PHARMA Novel Coronavirus (2019-nCoV) Igm / IgG Antibody
Rapid Test Kit

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

Product Classification

[FDA Home](#) [Medical Devices](#) [Databases](#)



[New Search](#)

[Back to Search Results](#)

Device	Reagents, 2019-Novel Coronavirus Nucleic Acid
Definition	Nucleic acid-based in vitro diagnostic devices for the detection of 2019-novel coronavirus (2019-nCoV) and/or diagnosis of 2019-nCoV infection in human clinical specimens.
Physical State	In Vitro Diagnostic Primers, Probes and/or capture oligos.
Technical Method	Nucleic acid amplification and/or detection.
Target Area	The device is an in-vitro diagnostic device; none of the body parts will utilize the device or are intended to be affected by the device.
Review Panel	Microbiology
Product Code	QJR
Premarket Review	Division of Microbiology Devices (DMD) Division of Microbiology Devices (DMD)
Not Classified Reason	EUA - Emergency Use Authorization
Submission Type	EUA - Emergency Use Authorization
Device Class	Not Classified
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Page Last Updated: 03/09/2020

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#)

[Help \(./help/index.html\)](#)[DRLM Home \(mainMenu.htm\)](#) > [Change Registration Information for a Facility](#)

✓ Facility

✓ Products Listing

Update Registration Successful

Facility: NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY , Branchburg ,
New Jersey, UNITED STATES

Registration/FEI Number: 3015176291/3015176291

The Owner/Operator Number for this Registration is: 10058677.

Facility Information

Registration Number:

3015176291

Initial Importer:

Y

Facility Name:

NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

Address:6 Culnen Dr Ste B,
Branchburg, New Jersey, 08876, UNITED STATES**DUNS Number:****Foreign Trade Zone:**

N

Facility URL:**Other Business Trade Name(s):**

Owner/Operator Information

Owner/Operator Number:

10058677

Contact Name:

Nikolaos Renieris

Company:

NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

Address:6 Culnen Dr Ste B
Branchburg, NEW JERSEY, 08876, UNITED STATES**Telephone:**

1 - 917 - 8591114

Fax:

-

E-mail:

nik@nbgsusa.com

DUNS Number:

Official Correspondent Information

Contact Name:

Nikolaos Renieris

Company:

NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

Address:

6 Culnen Dr Ste B
Branchburg, NEW JERSEY, 08876, UNITED STATES

Telephone:

1 - 917 - 8591114

Fax:

-

E-mail:

nik@nbgsusa.com

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D353439	K170077	FRO	Dressing, wound, drug	Specification Developer
D340847	Exempt	MDA	Elastomer, silicone, for scar management	Specification Developer
D340848	Exempt	PFP	Silicone hydrogel for scar management	Specification Developer

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
		MDA	Elastomer, silicone, for scar management	
		PFP	Silicone hydrogel for scar management	

		QJR	Reagents, 2019-novel coronavirus nucleic acid	
--	--	-----	--	--

Date of Initial Registration: 2018-10-19 11:42:02.0
