# Innova Medical Group, Inc. MARCS-CMS 614819 — June 10, 2021



**Delivery Method:**
VIA Electronic Mail

**Product:**
Medical Devices

**Recipient:**
Daniel J. Elliot

Chief Executive Officer

Innova Medical Group, Inc.

800 E. Colorado Blvd., Suite 288 Pasadena, CA 91101 United States

Daniel.elliott@innovamedgroup.com

**Issuing Office:**
Center for Devices and Radiological Health

United States

**WARNING LETTER**

CMS # 614819

June 10, 2021

Dear Mr. Elliot:

The United States Food and Drug Administration (FDA) conducted an inspection of your firm's medical device operations, Innova Medical Group, Inc., located at 800 E. Colorado Blvd., Suite 288, Pasadena, CA from March 15 through April 9, 2021. In addition, your other manufacturing facilities at 495 N. Berry Street, Brea, CA, and MPS Medical, Inc. at 785 Challenger Street, Brea, CA, were also inspected from March 15 through April 8, 2021. During these inspections, the FDA investigators determined that your firm is a medical device manufacturer and initial distributor/importer of the SARS-CoV-2 Antigen Rapid Qualitative Test (also distributed under the names INNOVA COVID-19 Self-Test Kit (3T Configuration), INNOVA SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and INNOVA SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration)). Based on our review, your SARS-CoV-2 Antigen Rapid Qualitative Test is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19[1] in people, and thus, it is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h).

Our inspection revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test has been distributed in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the product is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g), for the device as described and marketed. The product is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded.

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.[3] Therefore, FDA is taking urgent measures to protect consumers from certain products that, without

approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described herein, you have distributed a product that is intended for use in mitigation, prevention, treatment, diagnosis, or cure COVID-19 in people. We request that you take immediate action to cease the sale and distribution of such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices. In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)"[4] provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency.

Our inspections also revealed that the 25T Configuration and 7T Configuration of the SARS-CoV-2 Antigen Rapid Qualitative Test are misbranded within the meaning of section 502(a) of the Act, 21 U.S.C. § 352(a), in that the devices' respective labeling was false or misleading. More specifically, the labeling distributed for your 25T Configuration devices included a "Clinical Performance" section, which claimed a Relative Sensitivity of 96% (88.75-99.17% CI); a Relative Specificity of 100% (98.34-100% CI); and an Accuracy of 98.98% (97.06-99.79% CI). This level of clinical performance for the 25T Configuration devices appears unsupported by any clinical data including both clinical performance data submitted to FDA in your Emergency Use Authorization (EUA) request for the SARS-CoV-2 Antigen Rapid Qualitative Test and in published reports of clinical studies of the SARS-CoV-2 Antigen Rapid Qualitative Test.[5] Similarly, the labeling distributed for your 7T Configuration devices included a "Performance of Prospective Clinical Study" section based on a prospective clinical study conducted by "third-party investigators in UK in September and October 2020" which claimed a Positive Percent Agreement of 81.4% (74.3-88.4% CI). This PPA for the 7T Configuration devices does not appear to align with the PPA observed in the phase 3b prospective clinical study conducted in the United Kingdom.[6] Accordingly, the clinical performance estimates reported in the labeling of the 25T Configuration and 7T Configurations devices are false or misleading as they do not accurately reflect the performance estimates observed during the clinical studies of your devices.

Separate and apart from the foregoing issues, FDA further notes that the clinical study data you submitted in your EUA request for the SARS-CoV-2 Antigen Rapid Qualitative Test was identical to data previously provided by other manufacturers in their separate EUA requests. The data reliability and accuracy issues noted herein raise significant concerns that the performance of the SARS-CoV-2 Antigen Rapid Qualitative Test has not been adequately established, and that the products distributed by Innova without FDA approval, clearance, or authorization could present a serious risk to the public health.

The inspections also revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test is adulterated with the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, is manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received your response dated April 30, 2021, from Eric Grubel, Chief Operating Officer, and the following update dated May 28, 2021, from Janet L. Michener Whipple, Interim Vice President of Quality, which responded to the Form FDA 483, List of Inspectional Observations issued to your firm on April 9, 2021. We address your responses below. These violations include, but are not limited to, the following:

**1. Failure to establish procedures for control and distribution of finished devices, as required by 21 CFR § 820.160(a).**

Specifically, your firm has not established and maintained procedures for the control and distribution of your SARS-CoV-2 Antigen Rapid Qualitative Test system to ensure only devices approved for release are distributed, and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. For example:

Our investigators observed your firm has executed contractual agreements with at least **(b)(4)** distributors for the commercial promotion and sale of the SARS-CoV-2 Antigen Rapid Qualitative Tests in the United States and has distributed more than **(b)(4)** test kits to US customers. According to your firm, these Tests have been shipped to several customers to Indiana, New York, Vermont, and Oregon during January and February of 2021. No records were maintained to demonstrate that these devices were approved for release.

We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge you have opened CAPA #2021-002 and created new standard operating procedures to address Purchase Management and Control and Distribution of your products, in addition to completing personnel training on the new procedures and processes. You did not provide evidence of implementation of your new SOPs, or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response.

**2. Failure to establish procedures for acceptance activities, as required by 21 CFR § 820.80(a).**

Specifically, your firm has not established procedures for incoming product and finished device acceptance activities. There are no acceptance records of your SARS-CoV-2 Antigen Rapid Qualitative Test system to ensure that specified requirements for your devices are met and meets the acceptance criteria. For example,

Your firm distributed SARS-CoV-2 Antigen Rapid Qualitative Tests. These test kits were not inspected, tested, or otherwise verified after receiving it from your contract manufacturer in China or prior to shipment to the end users. Consequently, the 7T and 3T boxes were shipped to customers with the incorrect Instructions for Use (IFU).

We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge you opened CAPA #2021-003 and created a new acceptance activity work instruction for incoming and finished devices, and completed personnel training on the new procedures and work instructions. You did not provide evidence of implementation of your new work instruction and evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. We also acknowledge that your firm initiated a voluntary recall of certain lots of 3T and 7T test kits distributed for non-investigational use only. It is unclear how you plan to address incorrectly labeled products distributed for investigational use. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response.

**3. Failure to establish procedures to control product that does not conform to specified requirements, as required by 21 CFR § 820.90(a).**

Specifically, your firm has not established and maintained procedures to ensure that nonconforming product is identified, documented, evaluated, segregated, and dispositioned. During the inspection, the investigators observed 13 cartons of SARS-CoV-2 Antigen Rapid Qualitative Tests co-mingled in a storage room with multiple cartons of returned nonconforming test kits, samples used for product evaluation, and damaged controls, all of which was slated for destruction. The 13 cartons of test kits were not identified as nonconforming and no records were maintained to demonstrate if an investigation was needed or the disposition of nonconforming products.

We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge that you opened CAPA #2021-004, and created an SOP 9.0, Control of Nonconformances, and completed personnel training on the new procedures. You did not provide adequate evidence of implementation of your new procedure or evidence demonstrating the CAPA is effective in preventing the noted violations from recurring. For example, in your May 28 response you provided the Nonconforming Incident Report, NCR #2021-002, for **(b)(4)** tests that were destroyed during the inspection. According to your incident report, an investigation to determine the root cause of the nonconforming product was not required because the "root cause is known as identified during FDA inspection" while your SOP 9.0 requires all product nonconformances to be investigated unless otherwise justified and documented. It is not clear how an FDA inspection justifies not investigating the root cause of the **(b)(4)** nonconforming tests. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response.

**4. Failure to establish procedures for corrective and preventative action, as required by 21 CFR § 820.100(a).**

Specifically, Your firm has not established procedures for implementing and documenting corrective and preventive action, including requirements for: analyzing quality data sources; investigating the cause of nonconformities; identifying the action(s) needed to correct and prevent occurrence or recurrence of nonconformities; verifying or validating the CAPA to ensure the actions implemented are effective; documenting the changes in methods and procedures; disseminating information related to quality problems to appropriate individuals; and submitting relevant information on quality problems for management review.

We reviewed your firm's response and conclude the adequacy cannot be determined at this time. We acknowledge your firm has created SOP 10.0, Corrective and Preventive Action, and opened CAPA #2021-001 in accordance with your new procedure, and completed training personnel on the new procedures. However, you did not provide evidence of the effectiveness of your new CAPA procedure as the corrective actions remain in progress, and therefore we are unable to fully assess the adequacy of your response.

**5. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR § 820.198(a).**

Specifically, your firm has not established procedures for complaint handling to ensure that complaints are processed in a uniform and timely manner, oral complaints are documented upon receipt, and complaints are evaluated to determine if the reported event is required to be submitted to the FDA as a Medical Device Report.

We reviewed your firm's response and conclude the adequacy cannot be determined at this time. We acknowledge that you opened CAPA #2021-006 and created SOP 14.0, Complaint Handling and Failure Investigation, and completed personnel training on the new procedures. However, your response does not indicate whether your firm will conduct a retrospective review of any complaints your firm previously received. While your response states your firm "has not received any complaints regarding its SARVS-CoV-2 Antigen Rapid Qualitative Test", our investigators noted your storage room was holding damaged product returned from your customers, which appears to fall under section 5.6 of your new complaint procedure. You did not provide evidence of implementation of your new procedure or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response.

**6. Failure to establish procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR § 820.50.**

Specifically, your firm has not established procedures for the evaluation of suppliers, including the quality requirements that must be met by suppliers, to ensure that received products and services conform to specified requirements. You did not evaluate your only contract manufacturer of the SARS-CoV-2 Antigen Rapid Qualitative Test system based on their ability to meet specified requirements, including quality requirements.

We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge your firm opened CAPA #2021-005 and created new standard operating procedures for purchase management and supplier controls, and completed personnel training on the new procedures. You did not provide evidence of the implementation of your new SOPs, or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response.

Our inspection also revealed that your SARS-CoV-2 Antigen Rapid Qualitative Test is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 – Medical Device Reporting. Violation include, but is not limited to:

**7. Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17.**

Specifically, your firm has not established procedures for timely and effective identification, communication, and evaluation of reportable events; a standardized review process for determining when an event meets reportability criteria; timely submission of MDRs to the FDA; or for compliance with the applicable documentation and recordkeeping requirements.

We reviewed your firm's response and conclude that your firm's response dated April 30, 2021 is not adequate. In the response, your firm noted that it developed a written MDR procedure, scheduled staff training and planned to assess the effectiveness of corrective actions by July 1. Your response included a copy of your firm's MDR procedure titled "Medical Device Reporting (MDR and eMDR)", Document Number: 7.0, Revision 1.0, Effective Date: 4/29/2021. After reviewing your firm's MDR procedure, we noted that the procedure does not reference a process for identifying and evaluating events involving similar devices to those marketed in the United States (U.S.) as potentially reportable to FDA. Specifically, the procedure notes under the Scope section that it "applies to devices marketed in the United States". If an event involves a similar device to one legally marketed in the U.S., it may be reportable under the MDR regulation. By not considering events involving similar legally marketed devices, potentially reportable MDRs may not be identified and evaluated for MDR decision making and submission to FDA as required by 21 CFR 803.50 and 21 CFR 803.53.

Additionally, your firm did not provide documentation or evidence of implementation of a systematic corrective action to include a retrospective review of its adverse events in accordance with its MDR procedure.

Your firm should take prompt action to address the violations cited in this letter. Also, federal agencies may be advised of the issuance of Warning Letters about devices and may take your compliance with Act and its implementing regulations into account when considering the award of contracts. Additionally, should FDA determine that you have Quality System regulation violations that are reasonably related to premarket approval applications for Class III devices such devices will not be approved until the violations have been corrected. Also, should FDA determine that your devices do not meet the requirements of the Act, requests for Certificates to Foreign Governments (CFG) may not be granted. More information on processes for persons denied a CFG can be found at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices.

Note, there are two response time frames specified. You should take immediate action to address the violations relating to your firm's sale or distribution of the SARS-CoV-2 Antigen Rapid Qualitative Test. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so.

FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulentcoronavirus-disease-2019-covid-19-products. Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

Please also notify FDA in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted Quality Systems and MDR reporting violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic

problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

This response should be sent to: US Food and Drug Administration, Division 3/West, Office of Medical Device and Radiological Health Operations at oradevices3firmresponse@fda.hhs.gov. Please identify your response with CMS Case #614819.

If you have questions about the contents of this letter, please contact Compliance Officers, Charles J. Chacko at 214-253-4939, or via email at charles.chacko@fda.hhs.gov or Jamie M. Bumpas at 214-253-5336, or via email at Jamie.bumpas@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, please provide us with your reasoning and any supporting information for our consideration. It is your firm's responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. Failure to adequately address any violations may result in legal action, including without limitation, seizure and injunction. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of any violations and take prompt actions to correct the violations and bring your products into compliance.

Sincerely,
/S/

Timothy T. Stenzel, M.D., Ph.D.
Director
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

/S/

Shari J. Shambaugh
Program Division Director
Office of Medical Device and Radiological Health
Division 3

Cc:

Mr. Eric E. Grubel, COO
800 E. Colorado Blvd., Suite 288
Pasadena, CA 91101
Eric.grubel@innovamedgroup.com

---

***1*** As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

***2*** Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

***3*** Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

***4*** Accessible at https://www.fda.gov/media/135659/download.

***5*** See "Preliminary report from the Joint PHE Porton Down & University of Oxford SARS-CoV-2 test development and validation cell: Rapid evaluation of Lateral Flow Viral Antigen detection devices (LFDs) for mass community testing:" published November 8, 2020 available at https://www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20University%20of%20Oxford_final.pdf.

***6*** Id.

### Content current as of:

06/10/2021

- ### Regulated Product(s)

  Medical Devices