



November 29, 2017

DxNA, LLC  
% Fran White  
President  
MDC Associates, LLC  
180 Cabot Street  
Beverly, Massachusetts 01915

Re: DEN170041

Trade/Device Name: GeneSTAT.MDx *Coccidioides* Assay

Regulation Number: 21 CFR 866.3376

Regulation Name: Device to detect and identify fungal nucleic acids directly in respiratory specimens

Regulatory Class: Class II

Product Code: QAA

Dated: July 28, 2017

Received: August 1, 2017

Dear Fran White:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the GeneSTAT.MDx *Coccidioides* Assay, a prescription device with the following indications for use:

The GeneSTAT.MDx *Coccidioides* Assay is a qualitative real-time polymerase chain reaction (PCR) in vitro diagnostic test for the detection of nucleic acids from *Coccidioides immitis* and *Coccidioides posadasii*. The assay does not differentiate between these two species. The assay is performed on bronchial alveolar lavage (BAL) or bronchial wash (BW) specimens from patients presenting with respiratory signs and symptoms consistent with coccidioidomycosis. The GeneSTAT.MDx *Coccidioides* Assay is intended to be used along with clinical findings and other laboratory results as an aid in the diagnosis of coccidioidomycosis in patients with possible or probable exposure to *Coccidioides immitis* or *Coccidioides posadasii*.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the GeneSTAT.MDx *Coccidioides* Assay, and substantially equivalent devices of this generic type, into Class II under the generic name "Device to detect and identify fungal nucleic acids directly in respiratory specimens."

FDA identifies this generic type of device as: **Device to detect and identify fungal nucleic acids directly in respiratory specimens.**

A device to detect and identify fungal nucleic acids directly in respiratory specimens is an in vitro diagnostic device intended for the detection and identification of fungal pathogens in respiratory

specimens collected from patients with signs or symptoms and suspicion of fungal infection. The device is intended to aid in the diagnosis of fungal disease in conjunction with clinical signs and symptoms and other laboratory findings.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On August 1, 2017, FDA received your De Novo requesting classification of the GeneSTAT.MDx *Coccidioides* Assay. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the GeneSTAT.MDx *Coccidioides* Assay into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the GeneSTAT.MDx *Coccidioides* Assay can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

**Table 1 – Identified Risks to Health and Mitigation Measures**

| <b>Identified Risk</b>   | <b>Mitigation Measures</b>   |
|--|--|
| Incorrect identification or lack of identification of a pathogenic microorganism by the device can lead to improper patient management | General Controls and Special Controls (1), (2)(i), (2)(ii), (2)(iii), (2)(iv), (2)(v), (3)(i), (3)(ii), and (3)(iii) |
| Failure to correctly interpret test results  | General Controls and Special Controls (1), (2)(iii), (2)(iv), and (2)(v)   |
| Failure to correctly operate the instrument  | General Controls and Special Controls (1), (2)(i), (3)(ii), and (3)(iii)   |

In combination with the general controls of the FD&C Act, the Device to detect and identify fungal nucleic acids directly in respiratory specimens is subject to the following special controls:

- 1) The intended use for the 21 CFR 809.10 compliant labeling must include a detailed description of what the device detects, the type of results provided to the user, the clinical indications appropriate for test use, and the specific population(s) and testing location(s) for which the device is intended.
- 2) The 21 CFR 809.10 compliant labeling must include:

- (i) A detailed device description, including the device components, instrument requirements, ancillary reagents required but not provided, and a detailed explanation of the methodology including all pre-analytical methods for processing of specimens.
  - (ii) Performance characteristics from analytical studies, including but not limited to analytical sensitivity (Limit of Detection), inclusivity, reproducibility, interference, cross reactivity, interfering substances, carryover/cross contamination, and specimen stability.
  - (iii) A statement that the device is intended to be used in conjunction with clinical history, signs and symptoms and the results of other diagnostic tests.
  - (iv) A detailed explanation of the interpretation of test results and acceptance criteria for any quality control testing.
  - (v) A limiting statement that negative results do not preclude the possibility of infection, and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.
- 3) The compliant design controls must include:
- (i) Performance characteristics from clinical studies that include prospective (sequential) samples and, if appropriate, additional characterized samples. The study must be performed on a study population consistent with the intended use population and compare the device performance to results obtained from well-accepted comparator methods. Documentation from the clinical studies must include the clinical study protocol (including predefined statistical analysis plan), clinical study report, and results of all statistical analyses.
  - (ii) A detailed device description of the following:
    - (A) Overall device design including all device components and all control elements incorporated into the testing procedure
    - (B) Thorough description of the methodology including, but not limited to, primer/probe sequences, primer/probe design and rationale for target sequence selection
    - (C) Computational path from collected raw data to reported result (e.g., how collected raw signals are converted into a reported signal and result), as applicable
  - (iii) A detailed documentation for device software, including, but not limited to, software applications and hardware-based devices that incorporate software.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Device to detect and identify fungal nucleic acids directly in respiratory specimens they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Noel Gerald at 301-796-4695.

Sincerely,

for

Uwe Scherf, Ph.D.  
Director  
Division of Microbiology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health