LetsGetChecked Inc. (formerly PrivaPath Diagnostics Inc.)
% Karen Walsh
Director of Manufacturing Quality and Regulatory
LetsGetChecked
Unit 1, Northern Cross Business Park, North Road
Dublin 11, IE D11 XT26

December 1. 2023

Re: DEN200070
Trade/Device Name: Simple 2 Test
Regulation Number: 21 CFR 866.3385
Regulation Name: System for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens
Regulatory Class: Class II
Product Code: QYA
Dated: November 4, 2020
Received: November 16, 2020

Dear Karen Walsh:

This letter corrects our previous classification order, dated November 15, 2023, to correct your contact address.

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 Simple 2 Test, an over-the-counter device with the following indications for use:

> The Simple 2 Test is intended for in vitro detection and identification of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) in home-collected specimens which are shipped to a clinical laboratory for testing using the Aptima Combo 2 Assay on the Panther System. This product is available over-the-counter (OTC) to consumers 18 years of age and older.
>
> The Simple 2 Test contains all the necessary components to collect urine from male patients (Simple 2 Urine Home Collection Kit (Penile)) or vaginal swabs from female patients (Simple 2 Swab Home Collection Kit (Vaginal)) in their home, or in similar environments, without supervision from a healthcare provider.
> The Simple 2 Test Collection Kits may also be used to self-collect specimens in a clinic.
>
> The testing is performed, as determined to be appropriate, based on the results of LetsGetChecked Suitability Questionnaire.

This test system is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

Testing is limited to the manufacturer, Priva Path laboratories (d.b.a. LetsGetChecked, Inc.).

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Simple 2 Test, and substantially equivalent devices of this generic type, into Class II under the generic name system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens.

FDA identifies this generic type of device as:

System for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens. This device is an in vitro diagnostic system intended for self-collecting specimens in home settings or similar environments and testing in a clinical laboratory for detection of nucleic acids from non-viral microorganism(s) causing sexually transmitted infections. The device is intended to aid in the diagnosis of sexually transmitted infections. The device is intended for prescription use or over-the-counter use.

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 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 request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. 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 announcing the classification.

On November 16, 2020, FDA received your De Novo requesting classification of the Simple 2 Test. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Simple 2 Test 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 Simple 2 Test 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:

Risks to Health	Mitigation Measures
Risk of false results	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, risk analysis strategies.
Failure to correctly interpret test results	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, risk analysis strategies.
Failure to correctly operate the device	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, risk analysis strategies.

In combination with the general controls of the FD&C Act, the system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens is subject to the following special controls:

(1) The test must use a sample collection device that is FDA-cleared, -approved, or -classified as 510(k) exempt with an indication for over-the-counter in vitro diagnostic use in molecular testing; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device in which performance data demonstrates that lay users can correctly collect specimens without health care provider (HCP) supervision.

(2) The intended use in the labeling required under 21 CFR 809.10 must include a description of the following: the analytes the device detects and identifies, the clinical indications for which the test is to be used, the specimen types tested, the specific intended population(s), the name of the testing facility or facilities, as applicable, and other conditions of use as appropriate.

(3) The intended use of the device must only include indications for testing of specimens that are appropriate for collection by lay users for which there are performance data that demonstrate lay users can correctly collect specimens without HCP supervision.

(4) Design verification and validation must include:
   (i) A detailed test description of test components including reagents, instruments, ancillary materials, control elements, and a detailed explanation of the methodology, including pre-analytical methods for processing of specimens, microorganism target(s), identification of target detection reagents (e.g., primers), internal controls, and computational path from

collected raw data to reported results (e.g., how collected raw signals are converted into a reported signal and result), as applicable to the detection method and device design.

(ii) A description of the process from acquisition of the collection kit to results reporting.

(iii) Detailed descriptions of the test procedure, the interpretation of test results for clinical specimens, and acceptance criteria for any quality control testing.

(iv) Detailed documentation and test performance results from a clinical study that includes prospective self-collected samples for each claimed specimen type. This study must be performed on a study population consistent with the intended use population and compare the device performance to results obtained using a comparator that FDA has determined is appropriate. Detailed documentation from the clinical study must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of statistical analyses.

(v) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as Failure Modes Effects Analysis and/or Hazard Analysis. This must include information that demonstrates the effectiveness of risk control measures and device robustness, including the entire testing procedure from sampling to result interpretation, based on results from the following studies, as applicable per the intended use of the test device: usability studies, user label comprehension, and flex studies.

(vi) Detailed documentation of analytical studies, including the limit of detection (LoD), inclusivity, cross-reactivity, microbial interference, interfering substances, competitive inhibition, carryover/cross contamination, specimen stability, within-lab precision, and reproducibility, as applicable.

(vii) Validation data to support specimen integrity during handling and shipping.

(viii) Detailed documentation of reagent stability studies.

(ix) For devices with associated software or instrumentation, documentation including a detailed description of device software, including software applications and hardware-based devices that incorporate software. The detailed description must include documentation of verification, validation, and hazard analysis and risk assessment activities.

(5) The labeling required under 21 CFR 809.10(b) must include the following:

(i) Clear information written in appropriate language for the intended user that includes: instructions for sample collection and sample packaging for shipping and transport to the testing site, an explanation of test results and results interpretation including instructions on what actions to take based on the test results, and information for technical assistance with the collection kit.

(ii) A Frequently Asked Questions (FAQ) section that provides technical and educational information (e.g., information about notifying sexual partners, how to prevent future infections, what to do if symptoms persist after treatment, and directions to resources for further information on the disease and epidemiology).

(iii) Warning and limitation statements including the following:

(A) A negative test result does not preclude the possibility of infection with other pathogens;

(B) The test system is not a substitute for visits to a healthcare provider. The information provided by the product should not be used to start, stop, or change any course of treatment unless advised by their healthcare provider;

(C) Anyone with recent sexual contact with a person known to have a sexually transmitted infection, should visit a healthcare provider for treatment and evaluation as soon as possible (refer to professional guidelines);

(D) Contact a healthcare provider prior to collecting the sample if the user has a condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results);
(E) Accurate results are dependent on adequate product storage and adherence to the specimen collection and testing procedures;
(F) Failure to follow test procedures can lead to incorrect results; and
(G) The home collection kit must not be used beyond the expiration date. Use of expired kits can lead to incorrect results.

(iv) Accessioning criteria for acceptability of samples received by the laboratory (e.g., time from sample collection, transport media leakage, integrity of the sample).

(6) The device's labeling must include a prominent hyperlink to the manufacturer's public website where the manufacturer must make the information, identified in this section, publicly and prominently available. The information must include, written in language appropriate for the intended user:
(i) A brief summary of the purpose of the test.
(ii) Detailed instructions for proper sample collection and shipping procedures, and interpretation of results.
(iii) Required warnings and limitation statements.
(iv) Contact information for technical assistance with the collection kit (e.g., help-line contact information).
(v) For tests intended for over-the-counter use, information on who should and who should not use this test, and directions for further information for a user who might not be appropriate for testing using this device.
(vi) For tests intended for over-the-counter use, information for users on any follow-up actions (e.g., a link for in-person consultation or telehealth visit with an HCP).
(vii) The performance characteristics established in required studies.
(viii) If appropriate (e.g., recommended by Centers for Disease Control and Prevention, by current well-accepted clinical guidelines, or by published peer reviewed research, as determined by FDA), information that the clinical performance is inferior in a specific clinical subpopulation or for a specific claimed specimen type.
(ix) If the device is intended to detect antimicrobial resistance markers, limiting statements, as appropriate, indicating that:
(A) Negative results for claimed resistance markers do not indicate susceptibility of detected microorganisms, as resistance markers not measured by the assay or other potential mechanisms of antibiotic resistance may be present;
(B) Detection of resistance markers cannot be definitively linked to specific microorganisms and the source of a detected resistance marker may be an organism not detected by the assay, including colonizing flora;
(C) Detection of antibiotic resistance markers may not correlate with phenotypic gene expression; and
(D) Therapeutic failure or success cannot be determined based on the assay results, since nucleic acids may persist following appropriate antimicrobial therapy.

(7) The outer box label required under 21 CFR 809.10(a) must include the following:
(i) A description of who may use the home collection kit and age of the intended users.
(ii) A list of the components included.

(iii) A list of the components required, but not provided (including e.g., software applications needed to complete the process).
(iv) A statement that this is a home sample collection kit which requires shipping of the sample to a laboratory within the specified timeframe to receive results.
(v) A statement that anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to professional guidelines).

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected 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 Part 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (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 Anna Mielech at 301-796-2479.

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health