January 14, 2020

DNA Genotek Inc.
Austin Udocor
Senior Regulatory Affairs Manager
3000 - 500 Palladium Drive
Ottawa, Ontario K2V 1C2 Canada

Re: K192920
Trade/Device Name: Oragene®•Dx
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: OYJ
Dated: October 11, 2019
Received: October 16, 2019

Dear Austin Udocor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Division Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k192920

Device Name
Oragene®•Dx

Indications for Use *(Describe)*
Oragene®•Dx is intended for use in the non-invasive collection of saliva samples for in vitro diagnostic testing of human DNA. Saliva may be collected by spitting directly into the Oragene®•Dx container or may be transferred into the Oragene®•Dx container using a sponge. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using Oragene®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using Oragene®•Dx can be transported and/or stored long term at ambient conditions

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DNA genotek

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92.

Date:	14 January 2020
510(k) Number	k192920
Submitter:	DNA Genotek Inc. 3000 – 500 Palladium Drive, Ottawa, Ontario K2V 1C2 Canada
Contact:	Austin Udocor, Senior Regulatory Affairs Manager Tel: (613) 723-5757 Ext. 2245, Fax: (613) 368-4628 Email: austin.udocor@dnagenotek.com
Device Proprietary Name Device models	Oragene®•Dx OGD-500, OGD-510, OGD-575, OGD-600, OGD-610, OGD-675
Common names	Kit for collection of human DNA, Saliva kit, Sample collection kit for over-the-counter (direct-to-consumer) genetic testing use
Proposed Device Regulatory Classification	Regulation: 21CFR 862.1675 Blood specimen collection device Panel: Chemistry (75) Classification: Class II Product Code: OYJ DNA Specimen Collection, Saliva
Predicate Device	Oragene®•Dx (k110701) Regulation: 21CFR 862.1675 Blood specimen collection device Panel: Chemistry (75) Classification: Class II Product Code: OYJ DNA Specimen Collection, Saliva
Additional Predicate Devices	Oragene®•Dx (k141410, k152556) Regulation: 21CFR 862.1675 Blood specimen collection device Panel: Chemistry (75) Classification: Class II Product Code: OYJ DNA Specimen Collection, Saliva

Intended use

Oragene®•Dx is intended for use in the non-invasive collection of saliva samples for *in vitro* diagnostic testing of human DNA. Saliva may be collected by spitting directly into the Oragene®•Dx container or may be transferred into the Oragene®•Dx container using a sponge. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using Oragene®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using Oragene®•Dx can be transported and/or stored long term at ambient conditions.

Indications for use

See Intended Use, above.

Special conditions for use statement

- Oragene®•Dx saliva samples can be self-collected or collected with assistance.
- Oragene®•Dx devices are intended for use in prescription and over-the-counter (direct-to-consumer) downstream diagnostic testing applications.
- Test manufacturers must validate the use of Oragene®•Dx for their specific indications for use.

DEVICE DESCRIPTION

Oragene®•Dx family of collection devices offers reliable collection, stabilization, transportation and long-term ambient temperature storage of human DNA from saliva. Oragene®•Dx devices are a non-invasive alternative for collecting high quality and quantity DNA for use with prescription and over-the-counter (direct-to-consumer) diagnostic testing applications.

Oragene®•Dx devices consist of a collection tube with a funnel lid attached (containing a stabilizing liquid). Saliva is delivered directly by spitting into the collection tube or may be transferred into the Oragene®•Dx container using a sponge. Saliva collection can take place at home, in a laboratory setting, physician's office, or in the field. Untrained (naïve) or professional users can carry out saliva collection.

After saliva is collected, the stabilizing liquid is mixed with the sample. A small cap is provided to close the tube for transport and storage (funnel with lid is removed and discarded). Upon contacting saliva cells, the stabilizing liquid lyses cellular and nuclear membranes to release and stabilize nucleic acids (DNA). Samples can be immediately processed, transported or stored for future use. Samples can be shipped at ambient temperature to the laboratory for processing. Oragene®•Dx samples are stable at room temperature for up to 12 months. Device and sample integrity are preserved during typical ambient transport and storage conditions.

Oragene®•Dx saliva collection devices are suitable for use with prescription and over-the-counter (direct-to-consumer) downstream diagnostic testing applications, systems or platforms. Test or assay manufacturers must validate the use of Oragene®•Dx for their specific indications for use.

Using DNA obtained from an Oragene®•Dx sample, laboratory testing is performed on genotyping systems or platforms in a CLIA (Clinical Laboratory Improvement Amendments) certified laboratory. The resulting genetic information may be used to generate a personalized health report related to detected mutations and may be used by medical and health practitioners as an aid in patient management.

To date, Oragene®•Dx collection device performance has been established with the following FDA cleared test systems:

eSensor® Warfarin Sensitivity Saliva Test (k110786)

The eSensor® Warfarin Sensitivity Saliva Test is an in vitro diagnostic test for the detection and genotyping of the *2 and *3 alleles of the cytochrome P450 (CYP450) 2C9 gene locus and the Vitamin K epoxide reductase C1 (VKORC1) gene promoter polymorphism (-1639G>A) from genomic DNA of human saliva samples collected using the Oragene®•Dx Device, as an aid in the identification of patients at risk for increased warfarin sensitivity. For Prescription use only.

23andMe PGS (DEN140044, DEN160026)

The 23andMe PGS Carrier Screening Test for Bloom Syndrome is indicated for the detection of the BLMAsh variant in the BLM gene from saliva collected using an FDA cleared collection device (Oragene®•Dx model OGD-500.001). This test can be used to determine carrier status for Bloom syndrome in adults of reproductive age, but cannot determine if a person has two copies of the BLMAsh variant. The test is most relevant for people of Ashkenazi Jewish descent.

The 23andMe Personal Genome Service (PGS) Test uses qualitative genotyping to detect clinically relevant variants in genomic DNA isolated from human saliva collected from individuals ≥18 years with the Oragene®•Dx model OGD-500.001 for the purpose of reporting and interpreting Genetic Health Risks (GHR). For over-the-counter use.

Akonni TruDiagnosis® System (k183530)

The TruDiagnosis® System is an in vitro diagnostic device intended for processing and genotyping multiple genetic variants in a DNA sample utilizing on-slide PCR gel-drop microarray technology. The TruDiagnosis® System consists of the TruDx® 2000 Imager, the TruArray® Warfarin Sensitivity Test Kit, and the ProFlex™ PCR System using the ProFlex™ 2x Flat Sample Block. The TruDx® 2000 Imager is an instrument intended for processing and genotyping multiple genetic variants in a DNA sample utilizing on-slide PCR gel-drop microarray technology. The TruArray® Warfarin Sensitivity Test Kit is an in vitro diagnostic test for the detection and genotyping of the 2C9*2, 2C9*3 alleles of the cytochrome P450 (CYP450) 2C9 gene locus and Vitamin K epoxide reductase Cl, VKORCl, gene promoter polymorphism (-1639) from genomic DNA of human saliva samples collected using the Oragene® Dx Device (OGD-500) as an aid in the identification of patients at risk for increased warfarin sensitivity. The TruArray® Warfarin Sensitivity Test Kit is a qualitative assay for use in clinical laboratories upon prescription by the attending physician. For Prescription use.

SUBSTANTIAL EQUIVALENCE INFORMATION

The following table outlines the similarities and differences between the predicate and proposed device.

Table 1. Comparison between Primary Predicate and Proposed devices

Principle, Materials and Technology	Oragene®•Dx (*predicate – k110701*)	Oragene®•Dx *(proposed devices – K192920)*	Similar	Different
Intended Use	Oragene®•Dx is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. Saliva may be collected by spitting directly into the Oragene®•Dx container or may be transferred into the Oragene®•Dx container using a sponge. Saliva samples collected using Oragene®•Dx are stabilized and can be transported and/or stored long term at ambient conditions	Oragene®•Dx is intended for use in the non-invasive collection of saliva samples for *in vitro* diagnostic testing of human DNA. Saliva may be collected by spitting directly into the Oragene®•Dx container or may be transferred into the Oragene®•Dx container using a sponge. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using Oragene®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using Oragene®•Dx can be transported and/or stored long term at ambient conditions		X
Special conditions for use	Prescription use only	Prescription and Over-the-counter use		X
Analyte	DNA	DNA	X	
Sample collection	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	X	
Formats/Models	Multiple: OGD-500, OGD-575	Multiple: OGD-500, OGD-510, OGD-575, OGD-600, OGD-610, OGD-675	X	

Principle, Materials and Technology	Oragene®•Dx (*predicate – k110701*)	Oragene®•Dx *(proposed devices – K192920)*	Similar	Different
Tube material	Plastic	Plastic	X	
Sample source	Human saliva	Human saliva	X	
Additive	Nucleic acid stabilization solution	Nucleic acid stabilization solution	X	
Transport and Stability	Pre-collection Oragene®•Dx kits can be transported at temperatures ranging from -20°C to 50°C Post-collection Oragene®•Dx samples can be transported at temperatures ranging from -20°C to 50°C Pre-collection Oragene®•Dx kits can be stored at room temperature for up to 30 months Post-collection Oragene®•Dx samples can be stored at room temperature for up to 12 months (OGD-500, OGD-575, OYD-500) and 3 months for OXD-525	Pre-collection Oragene®•Dx kits can be transported at temperatures ranging from -20°C to 50°C Post-collection Oragene®•Dx samples can be transported at temperatures ranging from -20°C to 50°C Pre-collection Oragene®•Dx kits can be stored at room temperature for up to 30 months Post-collection Oragene®•Dx samples can be stored at room temperature for up to 12 months	X	
Performance and suitability for use with molecular diagnostic applications	Stabilized DNA can be used in molecular diagnostic testing; e.g., • Performance has been established with the eSensor® Warfarin Sensitivity Saliva Test.	Performance of stabilized DNA used in molecular diagnostic testing has been established in k110701, k141410, k152556 Suitability of standard Oragene®•Dx instructions for use in a typical over-the-counter (direct-to-consumer) setting has been established (k192920)	X	

The similarities in intended use, materials, technological characteristics show that Oragene®•Dx (*k192920*) are substantially equivalent to the primary predicate Oragene®•Dx devices (k110701). The differences tabulated above do not affect the safety and performance of Oragene®•Dx devices.

Table 2. Comparison between Additional Predicate and Proposed devices

Principle, Materials and Technology	Oragene®•Dx *(additional predicate: k141410, k152556*)	Oragene®•Dx *(proposed devices - k192920)*	Similar	Different
Intended Uses	**Prescription (k152556):** Oragene®•Dx is intended for use in the non-invasive collection of saliva samples. Human DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. Saliva may be collected by spitting directly into the Oragene®•Dx container or may be transferred into the Oragene®•Dx container using a sponge. Saliva samples collected using Oragene®•Dx are stabilized and can be transported and/or stored long term at ambient conditions **Over-the-counter (k141410):** Oragene®•Dx OGD-500.001 is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for over-the-counter use with FDA cleared, approved, or legally marketed exempt DNA carrier screening genotyping tests. Saliva samples collected using Oragene•Dx OGD-500.001 are stabilized and can be transported and/or stored long term at ambient conditions.	Oragene®•Dx is intended for use in the non-invasive collection of saliva samples for *in vitro* diagnostic testing of human DNA. Saliva may be collected by spitting directly into the Oragene®•Dx container or may be transferred into the Oragene®•Dx container using a sponge. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using Oragene®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using Oragene®•Dx can be transported and/or stored long term at ambient conditions	X	

Principle, Materials and Technology	Oragene®•Dx *(additional predicate: k141410, k152556)*	Oragene®•Dx *(proposed devices - k192920)*	Similar	Different
Special conditions for use	Over-the-counter and prescription use	Prescription or Over-the-counter use	X	
Analyte	DNA	DNA	X	
Sample collection	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	X	
Formats/Models	Multiple: OGD-500.001, OGD-510, OGD-600, OGD-610, OGD-675	Multiple: OGD-500, OGD 510, OGD-575, OGD 600, OGD 610, OGD-675	X	
Tube material	Plastic	Plastic	X	
Sample source	Human saliva	Human saliva	X	
Additive	Nucleic acid stabilization solution	Nucleic acid stabilization solution	X	
Transport and Stability	Pre-collection Oragene®•Dx kits can be transported at temperatures ranging from -20°C to 50°C Post-collection Oragene®•Dx samples can be transported at temperatures ranging from -20°C to 50°C Pre-collection Oragene®•Dx kits can be stored at room temperature for up to 30 months Post-collection Oragene®•Dx samples can be stored at room temperature for up to 12 months (OGD-500, OGD-575, OYD-500) and 3 months for OXD-525	Pre-collection Oragene®•Dx kits can be transported at temperatures ranging from -20°C to 50°C Post-collection Oragene®•Dx samples can be transported at temperatures ranging from -20°C to 50°C Pre-collection Oragene®•Dx kits can be stored at room temperature for up to 30 months Post-collection Oragene®•Dx samples can be stored at room temperature for up to 12 months	X	

Principle, Materials and Technology	Oragene®•Dx *(additional predicate: k141410, k152556*)	Oragene®•Dx *(proposed devices - k192920)*	Similar	Different
Performance and suitability for use with molecular diagnostic applications	Stabilized DNA can be used in molecular diagnostic testing; e.g., • Performance has been established with the eSensor® Warfarin Sensitivity Saliva Test. • Performance has been established with the 23andMe Personal Genome Service	Performance of stabilized DNA used in molecular diagnostic testing has been established in k110701, k141410, k152556 Suitability of standard Oragene®•Dx instructions for use in a typical over-the-counter (direct-to-consumer) setting has been established (k192920)	X	

The similarities in intended use, materials, technological characteristics show that Oragene®•Dx (*k192920)* are substantially equivalent to the additional predicate Oragene®•Dx devices (k141410, k152556). The differences tabulated above do not affect the safety and performance of Oragene®•Dx devices.

PERFORMANCE CHARACTERISTICS

Reproducibility/Precision

The reproducibility of the Oragene®•Dx (*device models: OGD-500, OGD-510, OGD-600, OGD-610*) collection device has been evaluated (**see k110701, k152556)**. In addition, analytical precision of Oragene®•Dx collection device has been further demonstrated with the following FDA cleared test systems eSensor® Warfarin Sensitivity Saliva Test (k110786), 23andMe PGS (DEN140044, DEN160026) and Akonni TruDiagnosis® System (k183530).

Stability

Pre-collection shelf-life

Shelf-life stability testing of the Oragene®•Dx device has been demonstrated (**see k110701, k152556**). The Oragene®•Dx (*device models: OGD-500, OGD-510, OGD-575, OGD-600, OGD-610, OGD-675)* formats are FDA cleared and have of the same physical and chemical components including their instructions for use. Studies in k110701 and k152556 support the following shelf-life performance claims:

- 30 months at room temperature
- 12 months at -20±5°C and 6±4°C

Post-collection sample stability

Post-collection sample stability of the Oragene®•Dx (*device model: OGD-500*) has been demonstrated in studies evaluating DNA yield, DNA concentration, A260/A280 ratio and microbial content (**see k110701**). The Oragene®•Dx format is comprised of the same physical and chemical components as the FDA cleared Oragene®•Dx OGD-500 format; therefore, studies in k110701, k152556 support the following sample stability performance claims:

- 12 months at room temperature, -20±5°C or 6±4°C
- 3 months at 50±5°C

Sample Volume Tolerance

The effect of overfilling or underfilling the Oragene®•Dx device has been evaluated **(see k110701)**. Oragene®•Dx device models are comprised of the same physical and chemical components as the FDA cleared Oragene®•Dx OGD-500 format. As demonstrated, underfilling the Oragene®•Dx device (OGD-500) by 25% or 50% of target volume, or overfilling by 50% of target volume did not impact performance. Collected samples ranged from as low as 0.58mL saliva to as much as 3.64 mL saliva. As expected, the DNA yield was dependent on collected volume, but downstream performance was not affected by over or under spitting.

In addition, sample volume tolerance of the Oragene®•Dx collection device has been further demonstrated with the following FDA cleared test systems eSensor® Warfarin Sensitivity Saliva Test (k110786), 23andMe PGS (DEN140044, DEN160026) and Akonni TruDiagnosis® System (k183530).

Interfering Substances

Endogenous Substances

The effect of potentially interfering endogenous substances on performance of saliva samples collected with the Oragene®•Dx device has been successfully demonstrated with the following FDA cleared test systems eSensor® Warfarin Sensitivity Saliva Test (k110786), 23andMe PGS (DEN140044, DEN160026), and Akonni TruDiagnosis® System (k183530). There was no observable effect to performance of any of the potentially interfering endogenous substances.

Exogenous Substances

The effect of potentially interfering exogenous substances on the performance of saliva samples collected with the Oragene®•Dx devices have been demonstrated with the following FDA cleared test systems eSensor® Warfarin Sensitivity Saliva Test (k110786), 23andMe PGS (DEN140044, DEN160026), and Akonni TruDiagnosis® System (k183530).There was no observable effect to performance of any of the potentially interfering exogenous substances.

Over-the-Counter (Direct-to-Consumer) Use

Performance of saliva samples collected with custom Oragene®•Dx (*device model OGD-500.001)* when used in an over-the-counter (direct-to-consumer) setting was previously evaluated with 23andMe PGS (k141410, DEN140044). In addition, a user comprehension study using standard Oragene®•Dx devices (k192920) when used in a simulated over-the-counter (direct-to-consumer) setting was completed. This usability study evaluated user comprehension and compliance to the standard Oragene®·Dx device Instructions for Use (IFU). The objective of the study was to demonstrate that customers comprehend the instructions for use provided with the Oragene®·Dx device and can successfully collect saliva samples acceptable for use in over-the-counter (direct-to-consumer) setting.

Specifically,

- To evaluate if study participants can correctly perform the sample collection through management of physical sample parameters, including the volume of sample, compliance of the sample with collection instructions, the concentration of extracted DNA, and test performance (call rate).
- To evaluate user comprehension of the IFU through survey parameters that include customer demographics, opinion on the ease of device usage, and user comprehension of the collection and shipping instructions.

Potential users enrolled in usability studies collected saliva samples at home using standard Oragene®•Dx devices instructions and mailed them to a testing laboratory as is typical in a direct-to-consumer setting. Upon receipt at a certified CLIA testing laboratory, each study sample was assessed for compliance to collection instructions and sample volume, DNA concentration. The results of the user comprehension survey and the physical characteristics of the participant samples met the acceptance criteria for the study and demonstrated that the Oragene®•Dx collection device can be used successfully in the direct-to-consumer setting.

CONCLUSION

The submitted information in this premarket notification is complete and supports the safety and effectiveness of the Oragene®•Dx devices for prescription and over-the-counter (direct-to-consumer) use with FDA cleared and legally marketed molecular diagnostics applications.