DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 26, 2016

DNA GENOTEK INC
DAN FULLERTON
2 BEAVERBROOK ROAD
OTTAWA, ONTARIO K2K 1L1
CANADA

Re: k152464
Trade/Device Name: ORAcollect•Dx OCD-100, ORAcollect•Dx OCD-100A
Regulation Number: 21 CFR §862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: OYJ
Dated: April 18, 2016
Received: April 19, 2016

Dear Mr. Fullerton:

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. 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 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152464

Device Name
ORAcollect•Dx OCD-100; ORAcollect•Dx OCD-100A

Indications for Use *(Describe)*
ORAcollect•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 samples collected using ORAcollect•Dx are stabilized and 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.

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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:	18 April 2016
Submitter:	DNA Genotek Inc. 3000 – 500 Palladium Drive, Ottawa, Ontario K2V 1C2 Canada
Contact:	Dan Fullerton Vice President Operations, Quality & Regulatory Affairs Tel: (613) 723-5757 Ext. 213, Fax: (613) 368-4628 Email: dan.fullerton@dnagenotek.com
Device Proprietary Name	ORAcollect®•Dx Formats: OCD-100; OCD-100A
Common names	Kit for collection of human DNA, Saliva kit, Sample collection kit for use in genetic testing; Swab for collection of human DNA
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 OGD-500 (k110701) Regulation: 21CFR 862.1675 Blood specimen collection device Panel: Chemistry (75) Classification: Class II Product Code: OYJ DNA Specimen Collection, Saliva

INTENDED USE

Intended use

ORAcollect·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 samples collected using ORAcollect·Dx are stabilized and can be transported and/or stored long term at ambient conditions.

Indications for use

See Intended Use, above.

Special conditions for use statement

For Professional use.

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DEVICE DESCRIPTION

The ORAcollect·Dx family of collection devices offers reliable collection, stabilization, transportation and long-term ambient temperature storage of human DNA from saliva. ORAcollect·Dx is a non-invasive alternative for collecting high quality and quantity human DNA and is suitable for use in molecular diagnostic applications.

ORAcollect·Dx consists of a collection tube containing a stabilizing liquid and a double ended cap with an integrated sponge used to collect a saliva sample. After receiving instruction from a professional, saliva collection can take place in a laboratory setting, physician's office, at home, or in the field. Untrained (naïve) or professional users can carry out saliva collection.

Using the provided instructions for use, the donor uses the integrated sponge on the device to collect a saliva sample from the mouth. After saliva is collected, the cap is removed from the tube, inverted to place the sponge into the collection tube with the stabilizing liquid, and re-capped with the sponge remaining inside the tube. 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.

ORAcollect·Dx device pre-collection shelf life is 24 months at room temperature (15°C to 25°C) from the date of manufacture. Post collection, ORAcollect·Dx samples are stable at room temperature for up to 60 days. ORAcollect·Dx device and sample integrity are preserved during typical ambient transport and storage conditions.

SUBSTANTIAL EQUIVALENCE INFORMATION

The following table outlines the similarities and differences between Oragene·Dx and ORAcollect·Dx.

Principle, Materials and Technology	Predicate devices Oragene·Dx: OGD-500, OGD-575, OYD-500, OXD-500 (k110701)	Subject devices ORAcollect·Dx: OCD-100, OCD-100A (K152556)	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	ORAcollect·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 samples collected using ORAcollect·Dx are stabilized and can be transported and/or stored long term at ambient conditions.	X	

Principle, Materials and Technology	Predicate devices Oragene·Dx: OGD-500, OGD-575, OYD-500, OXD-500 (k110701)	Subject devices ORAcollect·Dx: OCD-100, OCD-100A (K152556)	Similar	Different
	stabilized and can be transported and/or stored long term at ambient conditions.			
Special conditions for use	Prescription	Prescription	X	
Device physical design	Consists of a collection tube, a DNA stabilizing liquid and optional sponges for assisted collection.	Consists of a tube cap with an attached integrated sponge and a collection tube containing a DNA stabilizing liquid.		X
Sample source	Human saliva	Human saliva	X	
Analyte	Human DNA	Human 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	Multiple	Multiple	X	
Tube material	Plastic	Plastic	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 24 months Post-collection Oragene·Dx samples can be stored at room temperature for up to 12	Pre-collection ORAcollect·Dx kits can be transported at temperatures ranging from -20°C to 50°C Post-collection ORAcollect·Dx samples can be transported at temperatures ranging from -20°C to 50°C Pre-collection ORAcollect·Dx kits can be stored at room temperature for up to 24 months Post-collection ORAcollect·Dx samples can be stored at	X	

Principle, Materials and Technology	Predicate devices Oragene·Dx: OGD-500, OGD-575, OYD-500, OXD-500 (k110701)	Subject devices ORAcollect·Dx: OCD-100, OCD-100A (K152556)	Similar	Different
	months (OGD-500, OGD-575, OYD-500) and 3 months for OXD-525	room temperature for up to 60 days.		
Performance	Performance has been established with the eSensor® Warfarin Sensitivity Saliva Test	Performance has been established with the eSensor® Warfarin Sensitivity Saliva Test	X	

The similarities in intended use, materials, technological characteristics show that ORAcollect·Dx is *substantially equivalent* to Oragene·Dx (k110701). The differences tabulated above do not affect the safety and performance of ORAcollect·Dx. Performance of both Oragene·Dx and ORAcollect·Dx devices have been validated using GenMark Diagnostics' FDA cleared eSensor Warfarin Sensitivity Saliva Test.

PERFORMANCE CHARACTERISTICS

REPRODUCIBILITY/PRECISION

Reproducibility of the performance of the ORAcollect·Dx device was evaluated to establish multi-center (site-to-site), lot-to-lot, sample-to-sample, day-to-day extraction and operator-to-operator reproducibility.

Sample-to-sample, Lot-to-Lot, day-to-day and operator-to-operator reproducibility

Donors were selected based on their naivety to the ORAcollect·Dx device; none of the donors had used the device previously. A diverse CYP2C9 and VKORC1 genotype distribution was targeted during donor selection.

Ten (10) donors collected nine (9) saliva samples each over multiple days using three multiple lots of ORAcollect·Dx devices. To evaluate operator-to-operator reproducibility the same sample was split to generate three (3) replicate samples for each donor. Sample replicates were divided equally among three (3) Operators who processed the samples across multiple days. Sample processing consisted of extraction of the DNA using the QIAamp DNA Mini Kit (QIAGEN), followed by the determination of DNA concentration, DNA yield and A260/A280 ratios. Purified DNA was tested using the eSensor Warfarin Sensitivity Saliva Test and results were compared to bi-directional sequencing.

All samples met the study acceptance criteria of DNA concentration of at least 2 ng/µl; total DNA yield of at least 0.01 µg; A260/A80 ratio between 1.2 and 2.3. In first-pass results, there was 100% agreement of the eSensor Warfarin Sensitivity Test results with bidirectional sequencing. There were no DNA Contamination Monitor (DCM) failures and no no-call results. No re-testing of any samples was required. All operators had all samples meet the DNA concentration, yield and A260/A280 ratio acceptance criteria. There was 100% agreement between eSensor Warfarin Sensitivity Test results and bidirectional sequencing.

Multi-centre reproducibility

Thirty (30) donors collected multiple saliva samples each from 3 sites; 2 of the 3 sites were in a professional setting and had supervised collections compared to unsupervised collections at the third site. The 30 donors were selected to encompass a diverse genotype distribution for CYP2C9 and VKORC1 genotype distribution. After sample collection, one sample from each donor was transported at ambient temperatures to three (3) independent sites. Each site had one operator for a study total of 3 operators. Following sample extraction, all purified genomic DNA samples were tested for DNA concentration and A260/A280 at the sites where they were extracted. All purified genomic DNA samples were transported to Site 1 for testing on the eSensor Warfarin Sensitivity Saliva Test (k152612, GenMark Diagnostics) where 1 extracted DNA aliquot from each sample from each site was tested on the Warfarin assay, excluding a single sample that did not meet assay input criteria.

When data from all 3 sites are combined, only one (1) sample did not meet the eSensor Warfarin Sensitivity Saliva Test input requirements. After final pass there was 100% agreement (89/89) with bidirectional sequencing.

Overall, the conducted reproducibility studies demonstrates that ORAcollect·Dx device performance is reproducible from site-to-site, lot-to-lot, sample-to-sample, day-to-day extraction and operator-to-operator when compared to the predicate device (Oragene·Dx k110701).

SHELF LIFE AND STABILITY

Pre-collection shelf-life

Shelf life conditions were evaluated by using unused ORAcollect·Dx devices stored in real-world storage conditions (i.e. ambient, indoor temperature) and simulated transport conditions.

ORAcollect·Dx devices stored for at least 24 months at ambient, real-world storage conditions were evaluated. 100% of the ORAcollect·Dx devices met the acceptance criteria for all chemistry endpoints. These results demonstrate there is no degradation in the chemical reagents within the device over time when stored at room temperature.

After a minimum of 24 months storage at ambient temperature, ORAcollect·Dx devices used to collect samples generated DNA that met all DNA endpoints acceptance criteria. These results demonstrate that storing ORAcollect·Dx devices at ambient, room temperature for up to 25 months prior to collecting samples has no significant impact on the DNA concentration, yield or A260/A280 ratio of the DNA extracted from the sample.

ORAcollect·Dx devices exposed to simulated transport conditions (multiple freeze-thaw cycles between -20°C and 50°C) were evaluated. 100% of devices met the acceptance criteria for all chemistry endpoints. These results demonstrate there is no degradation in the chemical reagents when devices are exposed to transport conditions. In addition, 100% of devices met acceptance criteria for evaporation demonstrating no effect of simulated transport conditions on chemistry loss from the device. These results demonstrate there is no degradation in the chemical reagents within the device after transient exposure to temperatures between -20°C and 50°C.

After exposure to simulated transport conditions, all ORAcollect·Dx devices used to collect samples provided DNA that met all DNA endpoints acceptance criteria. These results demonstrate that

ORAcollect·Dx devices can withstand conditions expected to be experienced during typical shipping with no significant impact on the DNA concentration, yield or A260/A280 ratio of the DNA extracted from the sample.

The above supports that ORAcollect·Dx devices can be stored for 24 months at ambient, room temperature conditions or exposed to typical transport conditions, with no significant impact on performance.

Post-collection sample stability

This study evaluated post collection stability of ORAcollect·Dx samples stored at room temperature and stability during simulated transport conditions.

Thirty (30) donors provided samples for evaluation of room temperature storage conditions and simulated transport. A total of 120 DNA samples were analyzed for DNA concentration, yield, A260/A280 ratio and microbial content. A subset of samples comprising of samples across all time-points from 10 donors were tested on the eSensor Warfarin Sensitivity Saliva Test (n=40 total tests).

Each time point met the acceptance criteria for DNA concentration, yield and A260/A280 ratio, as 100% of samples in each group had a minimum DNA concentration ≥ 2 ng/µL, a minimum DNA yield ≥ 0.01 µg, an A260/A280 ratio between 1.2 and 2.3 and no significant difference in mean percent microbial content from baseline.

Overall, all samples met the acceptance criteria for DNA concentration, total DNA yield, A260/A280 ratio and microbial content. All samples met performance acceptance criteria on the eSensor Warfarin Sensitivity Saliva Test.

This data supports a post-collection sample stability of 60 days at room temperature and stability upon exposure to conditions expected during typical transport (i.e. transient exposure to temperatures between -20°C and 50°C).

DETECTION LIMIT

User Study

This study evaluated the effect of sampling variability due to user collection error. Specifically, the study evaluated the effects of incorrect collection methods and the effect of collection from an incorrect site.

Multiple samples were collected from each of ten (10) donors, with each donor using one of the pre-identified collection methods for each sample collection. Additionally, multiple samples were collected from each of ten (10) donors, with each donor using one of the pre-identified collection sites for each sample collection. DNA was extracted from each sample using the QIAamp DNA Mini kit (QIAGEN) and performance was evaluated by measuring DNA concentration, total sample DNA yield, A260/A280 ratio and agreement between genotyping results on the eSensor Warfarin Sensitivity Saliva Test (GenMark Diagnostics) and bidirectional sequencing. Study success was evaluated against pre-defined acceptance criteria and performance claims determined based on study data.

Robustness of the ORAcollect·Dx collection device was demonstrated with all samples collected using the varied collected methods meeting the acceptance criteria of DNA concentration ≥ 2 ng/µl ; total

DNA yield ≥ 0.01 µg and A260/A280 ratio between 1.2 – 2.3. Robustness of the ORAcollect·Dx collection device was also demonstrated with samples collected from an incorrect site in the mouth meeting acceptance criteria of DNA concentration ≥ 2 ng/µl; total DNA yield ≥ 0.01 µg and A260/A280 ratio between 1.2 – 2.3, except in the case of an atypical collection site (cheek), where only 90% of samples had a DNA concentration ≥ 2ng/µl., After final pass there was 100% agreement irrespective of using alternative, incorrect collection methods or incorrect collection site.

Overall, study data supports the robustness of ORAcollect·Dx, even in the hands of naive users and/or when instructions for use are not followed properly.

Dry Mouth Study

This study evaluated the effect of dry mouth on the samples collected using the ORAcollect·Dx device and the subsequent effect on eSensor Warfarin Sensitivity Saliva Test as compared to bidirectional sequencing.

Dry mouth refers to the subjective sensation of oral dryness (xerostomia) or hyposalivation, or both[1]. Study participants were selected using a questionnaire to allocate study patients to a xerostomia group[2].

Suitable donors identified as experiencing dry mouth were selected, with each donor collecting one (1) sample each using ORAcollect·Dx devices according to the instructions for use.

DNA was extracted from each sample using the QIAamp DNA Mini kit (QIAGEN). Performance was evaluated by measuring DNA concentration and total sample DNA yield using fluorescence and A260/A280 ratio using absorbance. Samples meeting assay input criteria were tested on the eSensor Warfarin Sensitivity Saliva Test, following the procedure in the product insert (PI0200). Performance of ORAcollect Dx device samples on the eSensor Warfarin Sensitivity Saliva Test was evaluated by comparing genotyping results to genotypes determined by bidirectional sequencing and calculating first and final pass percent agreement. Study success was evaluated against pre-defined acceptance criteria (see next section) and performance claims determined based on study data.

Overall, 12 of 13 of samples met acceptance criteria for the eSensor Warfarin Sensitivity Saliva Testing. After Final pass there was 100% agreement with bidirectional sequencing.

Human Factors

This study evaluated compliance to collection instructions and its impact on sample performance, as well as to identify areas of difficulty in the collection procedure. The study evaluated (1) if users can correctly perform the ORAcollect·Dx collection procedure core tasks and evaluate collection performance using DNA concentration, yield and A260/A280 as the endpoint (2) areas of user difficulty or confusion (3) the effects of variable collection instructions procedures on sample quality and device performance.

The user compliance to collection instructions and its impact on sample performance was evaluated by task observation, post-collection follow-up survey, DNA concentration, yield and A260/A280 ratio.

[1] Borgnakke WS et al., (Delta Dental Plans Association) (2011). Oral and General Health – Exploring the Connection; Dry mouth (xerostomia): Diagnosis, causes, complications and treatment. Research Review 2011.

[2] Agha-Hosseini F et al. (2009). Serum and stimulated whole saliva parathyroid hormone in menopausal women with oral dry feeling. *Oral Surg Oral Med Oral Pathol Oral Radiol Endo.* 107: 806-810.

Naïve donors were recruited for the study. Study staff provided oral instructions from the package insert and the donor was handed an ORAcollect·Dx collection kit. In addition, donors were asked to complete the sample collection following the instructions for use on the collection kit and the oral instructions provided by the study staff, including intentionally varied collection instructions for the critical tasks. Study staff observed the collections and asked pre-determined post-collection follow-up questions to each donor to provide the subject the opportunity to explain any core tasks that they completed incorrectly. The results from the observations were tallied for each donor. All samples were analyzed for DNA concentration and yield to assess the impact of instruction compliance on collection performance.

Overall, all samples met the acceptance criteria for the identified critical tasks; Success rate ≥ 80% overall (all tasks combined) and ≥70% of each task. 100% of samples met acceptance criteria for total DNA yield ≥0.01 µg and A260/A280 ratio between 1.2-2.3. At least 99% of samples tested had DNA concentration ≥ 2ng/µL. This demonstrates that even in cases when donors deviated from core tasks or when they did not follow instructions, >99% of all samples tested still met acceptance criteria. Further, study data shows that minor observed deviations from the collection instructions had no negative impact on device performance.

INTERFERING SUBSTANCES

Endogenous Substances

This study evaluated the effect of analytical specificity of the ORAcollect·Dx device by examining the effects of potential interfering endogenous substances on performance.

Donors provided four (4) ORAcollect·Dx samples each which were each spiked with one of the four interfering substances: amylase, hemoglobin, IgA and total protein (composed of IgA, amylase and albumin). Three extractions were performed on each sample using the QIAamp DNA Mini DNA kit (QIAGEN) and performance was evaluated by measuring DNA concentration, total sample DNA yield, A260/A280 ratio and agreement between genotyping results on the eSensor Warfarin Sensitivity Saliva Test and bidirectional sequencing. Study success was evaluated against pre-defined acceptance criteria and performance claims determined based on study data.

When results were stratified by test substance, there was 100% agreement for all test substances between the eSensor Warfarin Sensitivity Saliva Test results and DNA sequencing.

Exogenous Substances

This study evaluated the effect of analytical specificity of the ORAcollect·Dx device by examining the effects of potential interfering exogenous substances on performance.

For each exogenous substance test group (eating, drinking, gum chewing, smoking, mouthwash, brushing teeth), each donor provided three samples including up to 30 minutes post-activity. Each sample was extracted in triplicate, all DNA samples which were analyzed for DNA concentration, DNA yield and A260/A280 ratio. One extraction replicate per sample was tested on the eSensor Warfarin Sensitivity Saliva Test, for a total of 129 genotyping tests.

Overall, when results were stratified by test substance, there was 100% first-pass agreement of the eSensor Warfarin Sensitivity Saliva Test to bidirectional sequencing. The eSensor Warfarin Sensitivity Saliva Test results support that Eating, Drinking, Chewing Gum, Smoking, Mouthwash, and Brushing

teeth 30 minutes prior to collection of samples with ORAcollect·Dx does not have any negative impact on assay performance.

COMPARISON STUDIES

Matrix Comparison

ORAcollect·Dx device is available in two equivalent and identical formats; OCD-100 and OCD-100A. The OCD-100A format includes a molded plastic insert inside the collection tube. The insert is intended to facilitate or enable a more efficient physical handling of the sample in the laboratory but has no impact on sample collection. This study evaluated the analytical performance of samples collected using the OCD-100A device when compared to the performance of samples collected using OCD-100.

Forty-five (45) donors provided 1 sample each using OCD-100A format and following typical instructions. All donors were naïve to collecting samples using OCD-100A. DNA was extracted from each sample using the QIAamp DNA Mini kit (QIAGEN). Performance was evaluated by measuring DNA concentration, DNA yield and A260/A280 ratio. Performance of samples on the eSensor Warfarin Sensitivity Saliva Test was evaluated by comparing genotyping results to genotypes determined by bidirectional sequencing and calculating first and final pass percent agreement.

Study results showed that 100% of samples collected using OCD-100A format met acceptance criteria for DNA concentration ≥ 2ng/µl, total DNA yield ≥ 0.01µg, and A260/A280 ratio between 1.2 - 2.3. There was 100% (45/45) final-pass agreement between bi-directional sequencing and the eSensor Warfarin Sensitivity Saliva Test results.

When compared to results obtained with samples collected by the same donors using the OCD-100 format, study data indicates that the insert present in the OCD-100A format does not impact the performance of the device and eSensor Warfarin Sensitivity Saliva Test results. Both OCD-100 and OCD-100A formats met acceptance criteria for DNA concentration ≥ 2ng/µl, total DNA yield ≥ 0.01µg, and A260/A280 ratio between 1.2 - 2.3.

Method Comparison

This study evaluated the overall analytical performance of ORAcollect·Dx samples on the eSensor® Warfarin Sensitivity Saliva Test. Genotyping results on the eSensor Warfarin Sensitivity Saliva Test were compared to results from the 'gold standard' bidirectional sequencing in order to assess performance.

Overall, 100% of samples met acceptance criteria for DNA concentration ≥ 2ng/µl, total DNA yield ≥ 0.01µg, A260/A280 ratio between 1.2 - 2.3 and performance on the eSensor Warfarin Sensitivity Saliva Test. The final pass results indicated that the genotyping calls by the eSensor Warfarin Sensitivity Saliva Test method were 99.4% concordant with genotypes determined by bidirectional sequencing for all polymorphisms.

See GenMark Diagnostic's eSensor Warfarin Sensitivity Saliva Test submission (K152612).

CONCLUSION

The submitted information in this premarket notification is complete and supports the safety and effectiveness of the ORAcollect·Dx device family and that the ORAcollect·Dx collection device is substantially equivalent to the predicate device (Oragene·Dx k110701).